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Document Owner: Technical Services Management

Revision History

REV.	CHANGE ID#	DESCRIPTION
А	DCO-0003828	Initial Release
в	DCO- 0004318	Removed deactivated complaints codes, C3202, C3203, C3204, C3205 and C3206. Updated complaint code C2567 description and new details for when to use. Updated complaint code C2520 description and troubleshooting. Added new complaint code C2521 with meaningful data, troubleshooting and resolution details. Updated table of contents to reflect updated/deactivated/new complaint codes. Updated Applicable Documents to add new and remove obsoleted documents. Updated formatting/grammar/clarity throughout document. Added information regarding blue CHEM8+ and CG4+ sample types where applicable for unexpected patient results. Additional troubleshooting steps added to transmission-related complaints. Added NCi configuration instructions for 2.4 / 5 GHz wireless analyzer to Appendix B. Added troubleshooting information where appropriate for 5 GHz Wireless Analyzer configuration issues (C3229, C3233, C3231, C3232, C3230, C3234, C1023), Sample-Type customization issues (C4411), Info HQ issues (C2590, C4332, C4581) and DE version 2.10 log in issues (C4411). Added table examples to Appendix A. Updated prompts for meaningful data and troubleshooting for Unacceptable Proficiency for clarity. Updated troubleshooting for transmission related complaints (C4133 and C4132). Added troubleshooting for dim backlighting to C2525. Added meaningful data prompts and troubleshooting step(s) to unacceptable method comparison and unacceptable comparison regulatory complaints. Added updated descriptions, troubleshooting, prompts for meaningful data and/or resolution scenarios to quality check codes 14, 47, 50, 55, 69, 82, 83, 84, 92, 126, 128, 130, 131, 132, 134, 135, 136, 137, 138, 145 and complaint codes C1065, C2563, C2583, C2581, C2582, C1070, C2580, C5571, C2595, C2591, C3211, C2568, C1069, C3214, C3221, C1002, C4581, C4332, C4141, C4143, C5567, C1812
с	DCO-0004246	Removed C4129 as no longer applicable. Removed references to Central Data Station (CDS). Removed C5557 as deactivated in Rocketware. Added prompts for meaningful data and troubleshooting for "Invalid Cart." message associated with CG4+ cartridges to C3223. Updated description for codes C1101, C1102 and C1219. Updated prompts for meaningful data throughout for all Unexpected Results complaint codes: removed (WB or plasma) from Patient Sample Type Tested prompt, removed "(if applicable)" and added new prompts for impact to patient information. Added prompt to C1521 and C1519 (ACT Unexpected Results) to request if patient is on low molecular weight heparin. Added troubleshooting to include needle gauge to C1502 (K Unexpected Results). Added new example for B-hCG intended use to C1066. Added Appendix G for Barcode Scanner Limitations. Added Appendix H for a list of Inquiry Codes. Added panel codes, new sample type and i-STAT 1 Analyzer results storage information to Appendix E. Reformatted Appendix E. Added size of screwdriver to use with the Ceramic Conditioning Cartridge procedure. Added information to Sensor Dependencies to explain analyte dependency on Sodium (Na) and removed notes 1 and 2 as no longer applicable to Appendix A. Added information regarding TCO2 <> results on CHEM8+ cartridge and resetting to factory default settings to C3214. Added prompts and troubleshooting for ACT specific complaints to ACT Star Outs (C1313 and C1316) and codes C1222, C1225, C1226, C1244 and C1146. Updated Applicable Documents. Updated formatting and spacing throughout document. Added troubleshooting and resolution clarification to C1002 (compromised product) regarding color in windows 3 and 4. Updated prompts for meaningful data and troubleshooting for C2055. Added troubleshooting step about not being able to revert to lower eVAS in C3221. Updated C5559 description.

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Purpose

i-STAT Support Guide REF-1151 will be used for troubleshooting and documentation of APOC product complaints.

Scope

This document applies to APOC Technical Services and global support personnel who assist customers with troubleshooting i-STAT System products.

Applicable Documents

i-STAT 1 System Manual, Section 1: Introduction	714363
i-STAT 1 System Manual, Section 2: i-STAT Analyzer	714364
i-STAT 1 System Manual, Section 3: i-STAT Cartridge	714365
i-STAT 1 System Manual, Section 5: Electronic Simulator	714367
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Quick Reference Instructions for Updating the i-STAT 1 Analyzer with Serial Downloaders and JAMMLITE, using www.pointof	care.abbott 732159
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Info HQ Manager User Guide	
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1.0 Quality Check Codes for the i-STAT 1 System

Complaint	Description		
Code 1	The battery voltage is too low for testing. Dead battery message will display when battery reaches 6.0 volts, either at		
	power on or during testing.		
Dead Batteries –	Prompts for Meaningful Data Collection		
Replace Batteries	1. What is analyzer serial number(s)?		
	2. What type of batteries are being used?		
RW Code: C2001	a. If 9-volt lithium, what is the color of the battery car	rrier (i.e. red/green)?	
	 If i-STAT rechargeable, what is the Born-on-Date (B 	SOD)?	
Synonyms: N/A	What is the battery voltage?		
	Note: It is possible for the battery to read greater than 6.0 volts	s on the Analyzer Status page and still display code 1.	
	Troubleshooting		
	A. Replace with fresh/new 9-volt lithium batteries or a fully ch	harged i-STAT rechargeable battery pack.	
	B. If using disposable batteries, verify red battery carrier is being used.		
	1. If battery carrier is suspected, try a different battery carrier		
	2. If different battery carrier resolves the code, send replacement battery carrier		
	C. If using the i-STAT rechargeable battery pack, verify the four charging contacts on the analyzer and		
	downloader/recharger are intact		
	D. Run the external electronic simulator or test a cartridge		
	Note: Verify user is using the option '2 - i-STAT cartridge' from the test menu on the analyzer to test cartridge (and is not		
	choosing option '1 - Last Result' under test menu on the analyzer)		
	Resolution		
	IF the rechargeable battery pack or 9-volt lithium batteries or	THEN the incident is resolved	
	the battery carrier are replaced and code 1 is resolved • Classification is Complaint 1		
	IF the battery carrier and/or disposable batteries have been	THEN the i-STAT analyzer should be replaced or repaired	
	replaced and code 1 persists after performing a test • Classification is Repair		
	IF the i-STAT rechargeable battery is charged or replaced AND THEN the i-STAT analyzer should be replaced or repa		
	all the charging contacts are intact AND code 1 persists after	Classification is Repair	
	performing a test		
	IF the charging contacts on the analyzer or	THEN refer to C3213	
	downloader/recharger are not intact		

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Complaint	Description		
Code 2	The i-STAT 1 Analyzer's reading of the ambient temperature exceeds the operating temperature.		
	Prompts for Meaningful Data Collection		
Temperature Out	1. What is analyzer serial number(s)?		
of Range – Check	2. What is the ambient temperature reading on the analyzer st	atus page?	
Status Page	NOTE: it may take up to 90 minutes for the i-STAT 1 Analyzer to a	acclimate to ambient temperature.	
	3. Was the analyzer in the downloader/recharger when code o	ccurred?	
RW Code: C2002	4. Is the analyzer stored or used in a hot or cold area where the temperature is outside of the operating temperature?		
	Troubleshooting		
Synonyms: N/A	A. Move the analyzer to an area where the ambient temperature is within 16-30°C (61-86°F) and allow the analyzer to		
	come to the new room temperature. Check the analyzer's temperature reading on the status page.		
	B. Remove the analyzer from the downloader/recharger and check the temperature on the analyzer status page		
	Resolution		
	IF the analyzer status page temperature is between 16-30°C	THEN the incident is resolved	
	(61-86°F) after the analyzer has been moved or removed	Classification is Complaint 1	
	from downloader recharger AND code 2 is resolved		
	IF the code 2 persists and the analyzer status page	THEN the i-STAT analyzer should be replaced or repaired	
	temperature is not matching the ambient temperature after	Classification is Repair	
	analyzer has been moved to adjust to ambient temperature		
	OR removed from the downloader		

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Complaint	Description		
Code 3	The software version changed since the last power down of an	alyzer.	
	Prompts for Meaningful Data Collection		
New Software	1. What is analyzer serial number(s)?		
Installed – Use	2. What is the battery voltage?		
Electronic	3. Is code 3 present after updating or downloading a new cus	istomization profile?	
Simulator	Troubleshooting		
	A. Verify battery voltage is acceptable for testing; replace or charge the batteries if the voltage is low		
RW Code: C2003	B. Perform the external electronic simulator test		
	C. If applicable, re-install the CLEW and JAMS software		
Synonyms: N/A	Resolution		
	IF the external electronic simulator test is completed AND T	THEN the incident is resolved	
	code 3 is not present	Classification is Complaint 1	
	IF the CLEW and JAMS software has been re-installed AND T	THEN the incident is resolved	
	code 3 is not present	Classification is Complaint 1	

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Complaint	Description		
Code 4	At the start of the test cycle, the i-STAT 1 Analyzer detects that the last test cycle was not completed, and therefore, the		
	cartridge inserted must be a used cartridge.		
Analyzer	Prompts for Meaningful Data Collection		
Interrupted –	 What is analyzer serial number(s)? 		
Use Another	2. What type of batteries are being used?		
Cartridge	a. If 9-volt lithium, what is the color of the batter	ry carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-Da	ite (BOD)?	
RW Code: C2004	What is the battery voltage?		
	Troubleshooting		
Synonyms: N/A	A. Remind the customer not to remove the batteries or ba	ttery pack while the display is still on	
	B. If the voltage on the analyzer status page is low		
	1. If 9-volt lithium, replace batteries verifying correct battery carrier (red) is being used		
	2. If rechargeable, replace or recharge the battery pack		
	C. If using rechargeable battery pack, verify the charging contacts on the analyzer and the downloader/recharger are		
	intact		
	D. Run the external electronic simulator or test a cartridge		
	Resolution		
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the incident is resolved	
	carrier resolves code 4	Classification is Complaint 1	
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the i-STAT analyzer should be replaced or repaired	
	carrier does not resolve code 4	Classification is Repair	
	IF replacing or recharging the rechargeable battery pack	THEN the incident is resolved	
	resolves code 4	Classification is Complaint 1	
	IF the i-STAT rechargeable battery is charged or replaced	THEN the i-STAT analyzer should be replaced or repaired	
	AND all the charging contacts are intact AND code 4	Classification is Repair	
	persists after attempting to test the simulator or cartridge		
	IF the charging contacts on the analyzer or	THEN refer to C3213	
	downloader/recharger are not intact		

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Complaint	Description		
	When attempting to refrech the screen, the i STAT 1 Analyzer detects "nothing" in memory to refresh		
Code 5	when attempting to refresh the screen, the I-STATI Analyzer detects nothing in memory to refresh.		
Amahanan	Prompts for Meaningful Data Collection		
Analyzer	1. What is analyzer serial number(s)?		
Interrupted –	2. What type of batteries are being used?		
Ready for Use	a. If 9-volt lithium, what is the color of the batter	ry carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-Da	ite (BOD)?	
RW Code: C2005	3. What is the battery voltage?		
	Troubleshooting		
Synonyms: N/A	A. Remind the customer not to remove the batteries or ba	ttery pack while the display is still on	
	B. If the voltage on the analyzer status page is low		
	1. If 9-volt lithium, replace batteries verifying con	rrect battery carrier (red) is being used	
	2. If rechargeable, replace or recharge the batter	ry pack	
	C. If using rechargeable battery pack, verify the charging contacts on the analyzer and the downloader/recharger are		
	intact		
	D. Run the external electronic simulator or test a cartridge		
	Resolution		
	IF replacing the 9-volt lithium batteries and/or the battery THEN the incident is resolved		
	carrier resolves code 5	Classification is Complaint 1	
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the i-STAT analyzer should be replaced or repaired	
	carrier does not resolve code 5	Classification is Repair	
	IF replacing or recharging the rechargeable battery pack	THEN the incident is resolved	
	resolves code 5		
	IF the i-STAT rechargeable battery is charged or replaced	THEN the i-STAT analyzer should be replaced or repaired	
	AND all the charging contacts are intact AND code 5	Classification is Repair	
	persists after attempting to test the simulator or cartridge		
	IF the charging contacts on the analyzer or	THEN refer to C3213	
	downloader/recharger are not intact		
	dominouaci/recildiger dre not intdet		

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Complaint	Description		
Code 6	When attempting to refresh the screen, the i-STAT 1 Analyzer detects "nothing" in the memory to refresh. A defective		
	internal Lithium battery could also cause this code.		
Analyzer	Prompts for Meaningful Data Collection		
Interrupted – Use	 What is analyzer serial number(s)? 		
Another Cartridge	2. What type of batteries are being used?		
	 If 9-volt lithium, what is the color of the batter 	ry carrier (i.e. red/green)?	
RW Code: C2006	b. If i-STAT rechargeable, what is the Born-on-Da	te (BOD)?	
	3. What is the battery voltage?		
Synonyms: N/A	Troubleshooting		
	A. Remind the customer not to remove the batteries or bat	ttery pack while the display is still on	
	B. If the voltage on the analyzer status page is low		
	1. If 9-volt lithium, replace batteries verifying correct battery carrier (red) is being used		
	2. If rechargeable, replace or recharge the battery pack		
	C. If using rechargeable battery pack, verify the charging contacts on the analyzer and the downloader/recharger are		
	Intact D. Bue the externel electronic simulator or test a contrider		
	D. Run the external electronic simulator or test a cartridge		
	Resolution		
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the incident is resolved	
	carrier resolves code 6	Classification is Complaint 1	
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the i-STAT analyzer should be replaced or repaired	
	carrier does not resolve code 6	Classification is Repair	
	IF replacing or recharging the rechargeable battery pack	THEN the incident is resolved	
	resolves code 6	Classification is Complaint 1	
	IF the i-STAT rechargeable battery is charged or replaced	THEN the i-STAT analyzer should be replaced or repaired	
	AND all the charging contacts are intact AND code 6	Classification is Repair	
	persists after attempting to test the simulator or cartridge		
	IF the charging contacts on the analyzer or	THEN refer to C3213	
	downloader/recharger are not intact		

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Complaint	Description		
Code 8	The i-STAT 1 Analyzer's internal hardware mechanism did not reset after the last cartridge run.		
	Prompts for Meaningful Data Collection		
Analyzer	1. What is analyzer serial number(s)?		
Interrupted – Use	2. What type of batteries are being used?		
Another Cartridge	a. If 9-volt lithium, what is the color of the battery	/ carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-Dat	e (BOD)?	
RW Code: C2008	3. What is the battery voltage?		
	Troubleshooting		
Synonyms: N/A	A. Remind the customer not to remove the batteries or battery pack while the display is still on		
	B. If the voltage on the analyzer status page is low		
	1. If 9-volt lithium, replace batteries verifying correct battery carrier (red) is being used		
	2. If rechargeable, replace or recharge the battery pack		
	C. If using rechargeable battery pack, verify the charging contacts on the analyzer and the downloader/recharger are		
	intact		
	D. Run the external electronic simulator or test a cartridge		
	Resolution		
	IF replacing the 9-volt lithium batteries and/or the battery THEN the incident is resolved		
	carrier resolves code 8	Classification is Complaint 1	
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the i-STAT analyzer should be replaced or repaired	
	carrier does not resolve code 8	Classification is Repair	
	IF replacing or recharging the rechargeable battery pack	THEN the incident is resolved	
	resolves code 8	Classification is Complaint 1	
	IF the i-STAT rechargeable battery is charged or replaced	THEN the i-STAT analyzer should be replaced or repaired	
	AND all the charging contacts are intact AND code 8 persists	• Classification is Repair	
	after attempting to test the simulator or cartridge	·	
	IF the charging contacts on the analyzer or	THEN refer to C3213	
	downloader/recharger are not intact		

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Complaint	Description		
Code 9	When attempting to refresh the screen, the i-STAT 1 Analyzer's internal hardware mechanism did not fully reset into		
	position.		
Analyzer	Prompts for Meaningful Data Collection		
Interrupted –	 What is analyzer serial number(s)? 		
Ready for Use	2. What type of batteries are being used?		
	a. If 9-volt lithium, what is the color of the batter	y carrier (i.e. red/green)?	
RW Code: C2009	b. If i-STAT rechargeable, what is the Born-on-Da	te (BOD)?	
	3. What is the battery voltage?		
Synonyms: N/A	Troubleshooting		
	A. Remind the customer not to remove the batteries or bat	tery pack while the display is still on	
	B. If the voltage on the analyzer status page is low		
	1. If 9-volt lithium, replace batteries verifying correct battery carrier (red) is being used		
	2. If rechargeable, replace or recharge the battery pack		
	C. If using rechargeable battery pack, verify the charging contacts on the analyzer and the downloader/recharger are		
	intact		
	D. Run the external electronic simulator or test a cartridge		
	Resolution		
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the incident is resolved	
	carrier resolves code 9	Classification is Complaint 1	
	IF replacing the 9-volt lithium batteries and/or the battery	THEN the i-STAT analyzer should be replaced or repaired	
	carrier does not resolve code	Classification is Repair	
	IF replacing or recharging the rechargeable battery pack	THEN the incident is resolved	
	resolves code 9	Classification is Complaint 1	
	IF the i-STAT rechargeable battery is charged or replaced	THEN the i-STAT analyzer should be replaced or repaired	
	AND all the charging contacts are intact AND code 9	Classification is Repair	
	persists after attempting to test the simulator or cartridge		
	IF the charging contacts on the analyzer or	THEN refer to C3213	
	downloader/recharger are not intact		

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Complaint	Description		
Code 11	The date in the i-STAT 1 Analyzer is set before the release date stored in the JAMS Software or the clock is out of		
	specification.		
Date Invalid –	Prompts for Meaningful Data Collection		
Check on Status	1. What is analyzer serial number(s)?		
Page	2. What is date and time on the analyzer(s)?		
	3. If the date and time is correct, did code occur during co	agulation (ACT-C, ACT-K, PT/INR, PT ^{plus}) cartridge testing?	
RW Code: C2011	Troubleshooting		
	A. Verify the cartridge type testedB. If the date on the analyzer is incorrect, have customer correct the date		
Synonyms: N/A			
	C. Run the external electronic simulator and verify the analyzer date is maintained		
	Resolution		
	IF code 11 occurs during coagulation cartridge testing	THEN the i-STAT analyzer should be replaced or repaired	
		Classification is Repair	
	IF the date cannot be maintained after running the	THEN the i-STAT analyzer should be replaced or repaired	
	external simulator or cartridge	Classification is Repair	
	IF the date on the analyzer was corrected AND code 11 is	THEN the incident is resolved	
	resolved after testing an external simulator	Classification is Complaint 1	

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Complaint	Description		
Code 12	The i-STAT 1 Analyzer CLEW/JAMS software has expired.		
	The analyzer date is set after the expiration date of the CLEW/JAMS software.		
Expired Software,	Prompts for Meaningful Data Collection		
Update Required	1. What is analyzer serial number(s)?		
– See Manual	2. What is the CLEW/JAMS version displayed on analyzer sta	atus page?	
	3. What is the analyzer date?		
RW Code: C2012	Troubleshooting		
	A. If the CLEW/JAMS software has expired, perform the CLEW and JAMS software update		
Synonyms: N/A	B. If the date on the analyzer is incorrect, correct the date on the analyzer		
	C. Once the date on the analyzer is correct, run the external electronic simulator and verify the analyzer date is		
	correctly maintained		
	Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using www.pointofcare.abbott Art: 731335		
	Technical Bulletin: Network Options for Updating the i-STAT 1 Handheld using www.pointofcare.abbott Art: 731336		
	Resolution		
	IF the software update was performed AND code 12 is	THEN the incident resolved	
	resolved	Classification is Complaint 1	
	IF the date on the i-STAT 1 Analyzer was corrected AND	THEN the incident is resolved	
	code 12 is resolved	Classification is Complaint 1	
	IF the software update was performed AND code 12 persists	THEN the i-STAT analyzer should be replaced or repaired	
		Classification is Repair	
	IF the date cannot be maintained after running the external	THEN the i-STAT analyzer should be replaced or repaired	
	electronic simulator	Classification is Repair	

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Complaint	Description		
Code 13	The i-STAT 1 Analyzer CLEW is incompatible with the installed JAMS software		
	Prompts for Meaningful Data Collection		
Invalid CLEW,	1. What is analyzer serial number(s)?		
Update Required	2. What is the CLEW and JAMS version displayed on analyzer status page?		
– See Manual	Troubleshooting		
	A. Perform the CLEW and JAMS software update if the CLEW or JAMS version is incompatible on the analyzer		
RW Code: C2013	B. If Code 13 persists after the software update, reseat the disposable batteries or the i-STAT rechargeable battery pack		
Synonyms: N/A	Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using www.pointofcare.abbott Art: 731335 Technical Bulletin: Network Options for Updating the i-STAT 1 Handheld using www.pointofcare.abbott Art: 731336		
	Resolution		
	IF the CLEW and JAMS software was updated AND code 13 is	THEN the incident is resolved	
	resolved	Classification is Complaint 1	
	IF the battery was reinstalled AND code 13 is resolved	THEN the incident is resolved	
		Classification is Complaint 1	
	IF code 13 persists after above troubleshooting	THEN the i-STAT analyzer should be replaced or repaired	
		Classification is Repair	

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Complaint	Description		
Code 14	Customization profile in the analyzer is corrupt or invalid		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. Is the impacted i-STAT analyzer used with a data management system?		
	a. What data management system is being used?		
RW Code: C2014	b. Is the impacted i-STAT analyzer successfully communicating with the data management software?		
	c. Is the operator list feature being utilized on the data management software?		
Synonyms: N/A	Troubleshooting		
	A. Verify that the analyzer is successfully communicating with the data management system (DMS); place the i-STAT		
	analyzer in a downloader to confirm communication in progress appears on screen		
	B. If using DE, verify institution and location in customization workspace is correct for analyzer serial number		
	C. Reset the analyzer to factory settings and place it in the downloader; check if Code 14 persists after communication		
	and if not, verify that the customization profile updated after communication		
	D. Access the customization workspace to verify Operator List customization		
	 Code 14 can occur if the "Action" box for "Invalid Operator" is checked in ID Entry customization and "Use Operator List" is not checked 		
	Operator List" is not checked		
	2. Code 14 call occur is use Operator List is checked and there is no operator list to send to analyzer		
	check to see if there are certified operators in the data manager		
	Check to see if there are certified operators in the data manager.		
	F. If there are no certified operators in the data manager, the data manager will not send the list.		
	certified Have the customer certify at least one operator		
	H If there is no DMS in use and the analyzer shows code 14 restore to factory settings to resolve the code 14		
	Resolution		
	IF placing the analyzer in a downloader and successfully THEN the issue is resolved		
	communicating with the data manager resolves the code 14 • Classification is Complaint 1		
	IF resetting the analyzer to factory settings and placing in the THEN the issue is resolved		
	downloader resolves the code 14 after successful • Classification is Complaint 1		
	communication		

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IF enabling the operator list feature in the customization	THEN the issue is resolved
workspace resolves the code 14 after successful	 Classification is Complaint 1
communication	
IF the operator list was found to not be correct in the DE	THEN the issue is resolved
System Page and working with the data management vendor	 Classification is Complaint 1
resolved that issue AND placing the analyzer in the	
downloader resolves the code 14 after successful	
communication	

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Complaint	Description		
Code 15	The scanned i-STAT cartridge barcode does not match the inserted i-STAT cartridge		
	Prompts for Meaningful Data Collection		
Barcode Does	1. What cartridge lot number(s)/box number(s) has code 15 or	ccurred?	
Not Match	2. How many code 15 have occurred?		
Cartridge Type	3. Which barcode is being scanned?		
	4. What is analyzer serial number(s)?		
RW Code: C2115	Troubleshooting		
	A. Run a new cartridge to verify the cartridge barcode being so	canned is from the pouch of the cartridge being tested in	
Synonyms: N/A	the analyzer		
	B. Determine and document code rate as appropriate		
	C. Clean IR window on analyzer		
	Resolution		
	IF the code 15 is due to improper cartridge testing or dirty IR	THEN the incident is resolved	
	window	Classification is Complaint 1	
	IF the code 15 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND other	Classification is Complaint 2	
	cartridge lot(s) run without issue on the same i-STAT analyzers		
		Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	
	IF the code 15 is persistent on a specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		

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Complaint	Description	
Code 17	No clot was detected during PT ^{plus} /aPTT cartridge test cycle	
	Prompts for Meaningful Data Collection	
No Clot Detected	1. What cartridge lot number(s)/box number(s) has the code 17 occurred?	
See Manual	2. How many code 17 have occurred?	
	3. What is analyzer serial number(s)?	
RW Code: C1101	4. What was tested on the cartridge – QC material or patient sample?	
	5. If code 17 occurred while testing QC material	
Answer pRE	a. How is the QC material being handled?	
Questions!	b. What is lot number of QC material?	
a	6. If code 17 occurred while testing patient sample	
Synonyms: N/A	a. Is only one patient sample giving the code or mu	Iltiple patients?
	b. How is sample collected (i.e. skin puncture, veni	puncture)?
	i. If venous draw, what is the collection of	device used? What anticoagulant?
	II. If fingerstick, how is the sample loaded	into the cartridge?
	C. What is the time from sample collection to testin	ig.
	A Verify that the nationt cample is being collected and hand	led correctly:
	A. Verify that the patient sample is being collected and hand	agulant) plastic collection device
	2 Fingerstick or venous blood samples must be tes	agulant), plastic collection device
	3 Transfer device is plastic and contains no antico:	agulant
	B. If the code 17 occurred on one patient only, test a new car	rtridge with fresh sample to rule out sample related issue
	C. If code occurred while testing OC material:	
	a. Verify QC material handling and testing procedure	
	b. Test a new cartridge with fresh QC material	
	D. If persistent code 17 errors, determine and document code rate as appropriate	
	Resolution	
	IF no code 17 occurs after correcting any sample collection or	THEN the incident is resolved
	handling issues	Classification is Complaint 1
	IF the code 17 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot should be investigated
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2
	other cartridge lot(s) run without issue on the same i-STAT	
	analyzer(s)	Ask customer if cartridges are available to be returned
		for investigation and document request(s)
	IF the code 17 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot and QC material lot should
	troubleshooting but only on specific cartridge lot AND	be investigated
	specific QC material lot AND other cartridge lots and other	Classification is Complaint 2
	QC material lot(s) run without issue on the same i-STAT	
	analyzer(s)	Ask customer if cartridges and QC material are available
	IF the code 17 is persistent on specific i STAT apply as AND	THEN the i STAT analyzer should be replaced or repoined
	those same cartridge lot(s) run without issue on the other i-	Classification is Densir
	STAT analyzer(s)	

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Complaint	Description	
Code 18	No clot was detected during PT ^{plus} /aPTT cartridge test cycle	
	Prompts for Meaningful Data Collection	
No Clot Detected	1. What cartridge lot number(s)/box number(s) has the code	18 occurred?
See Manual	2. How many code 18 have occurred?	
	3. What is analyzer serial number(s)?	
RW Code: C1102	4. What was tested on the cartridge – QC material or patient sample?	
	5. If code 18 occurred while testing QC material	
Answer pRE	a. How is the QC material being handled?	
Questions!	b. What is lot number of QC material?	
	6. If code 18 occurred while testing patient sample	
	 Is only one patient sample giving the code or mu 	Iltiple patients?
Synonyms: N/A	b. How is sample collected (i.e. skin puncture, veni	puncture)?
	i. If venous draw, what is the collection of	device used? What anticoagulant?
	ii. If fingerstick, how is the sample loaded	d into the cartridge?
	c. What is the time from sample collection to testir	ng?
	Troubleshooting	
	A. Verify that the patient sample is being collected and handl	led correctly:
	1. Venous samples are collected in plain (no antico	agulant), plastic collection device
	 Fingerstick or venous blood samples must be tes Transfan device in plantic and contained and contained	sted immediately
	3. Transfer device is plastic and contains no anticoa	
	B. If the code 18 occurred on one patient only, test a new cartridge with fresh sample to rule out sample related issue	
	C. If code occurred while testing QC material:	
	vering QC material nationing and testing procedure Test a new cartridge with freeh OC material	
	2. Test a new callinge with fresh QC indicide D If persistent code 18 errors determine and document code rate as appropriate	
	D. If persistent code 18 errors, determine and document code rate as appropriate	
	IE no code 18 occurs after correcting any sample collection or	THEN the incident is resolved
	handling issues	Classification is Complaint 1
	IF the code 18 is persistent on multiple i STAT analyzers after	THEN the suspect cartridge let(s) should be investigated
	troublesbooting but only on specific cartridge lot(s) AND	Classification is Complaint 3
	other cartridge lot(s) run without issue on the same i-STAT	
	analyzer(s)	Ask customer if cartridges are available to be returned
		for investigation and document request(s)
	IF the code 18 is persistent on multiple i STAT applyzers ofter	THEN the suspect cartridge let(c) and OC material let(c)
	IF the code 18 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND	chould be investigated
	specific OC material lot(s) AND other cartridge lot(s) AND	Classification is Complaint 3
	Ω material lot(s) run without issue on the same i-STAT	
	analyzer(s)	Ask sustamor if cartridges and OC material are available
		to be returned for investigation and document request(s)
	IF the ends 19 is persistent on specific i STAT arehurse AND	THEN the is CTAT analyzer should be replaced as reprint d
	these same cartridge lot(s) run without issue on the other i	There use is start analyzer should be replaced or repaired
	STAT analyzor(c)	Classification is Repair
	STAT dildlyzer(S)	

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Complaint	Description	
Code 19	No clot was detected during PT/INR cartridge test cycle	
	Prompts for Meaningful Data Collection	
No Clot Detected	1 What cartridge lot number(s)/box number(s) has the code 19 occurred?	
See Manual	2. How many code 19 have occurred?	
	3. What is analyzer serial number(s)?	
RW Code: C1219	4. What was tested on the cartridge $-$ OC material or nationt cample?	
	5. If code 19 occurred while testing OC material:	
Synonyms: N/A	a How is the OC material being bandled?	
-,,,	h What is lot number of OC material?	
	6 If code 19 occurred while testing nations sample:	
	a Is only one nations sample giving the code or mu	Itinle natients?
	h Is nationt(s) on Couradin or warfarin?	
	c How is sample collected (i.e. skin puncture, veni	ouncture)?
	i. If yenous draw, what is the collection (levice used? What anticoagulant?
	ii If fingerstick how is the sample loader	linto the cartridge?
	d What is the time from sample collection to testi	
	a. Was the nationt tested on a different method?	ig:
	e. Was the patient tested on a different method:	ant mathed what is the INP result?
	Troublechooting	
	A Verify that the nationt cample is being collected and handl	ad correctly: oncure that finger stick or yenous blood
	A. Verify that the patient sample is being conected and hand	ed correctly, ensure that hinger stick of venous blood
	samples are tested inimediately in a plain plastic collection	agulant) plastic collection device
	Venous samples are collected in plain (no anticol Eingerstick or venous blood samples must be tes	ted immediately
	2. Fingerstick of venous blood samples must be les	
	3. Transfer device is plastic and contains no anticoagulant	
	B. If the code 19 occurred on one patient only, test a new cartridge with fresh sample to rule out sample related issue	
	 If control will be and the sting procedure (Pafer to section 14 of the inSTAT 1 System Manual) 	
	1. Verify QC material handling and testing procedure (Refer to section 14 of the I-STAT 1 System Manual)	
	2. Test a new cartridge with fresh QC material	
	D. If persistent code 19 errors determine and document code	Tate for the specific cartiloge for number of box number
	Resolution	THEN the incident is see build
	IF no code 19 occurs after correcting any sample collection or	
		Classification is Complaint 1
	IF the code 19 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2
	other cartridge lot(s) run without issue on the same I-STAT	
	analyzer(s) Ask customer if cartridges are available to be returned	
		for investigation and document request(s)
	IF the code 19 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) and QC material lot(s)
	troubleshooting but only on specific cartridge lot(s) AND	should be investigated
	specific QC material lot(s) AND Other cartridge lots and other	Classification is Complaint 2
	QC material lot(s) run without issue on the same i-STAT	
	analyzer(s)	Ask customer if cartridges and QC material are available
		to be returned for investigation and document request(s)
	IF the code 19 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair
	STAT analyzer(s)	

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Complaint	Description	
Code 20	No calibrant material detected	
	NOTE: Code 20 will <u>not</u> occur with Immunoassay (cTnI, CK-ME	3, BNP, в-hCG) or Coagulation (ACTc, ACTk, PT/INR)
Cartridge Error –	cartridges.	
Use Another	Prompts for Meaningful Data Collection	
Cartridge	1. What cartridge lot number(s) has the code 20 occurred?	
	2. How many code 20 have occurred?	
RW Code: C1220	3. What is tested on the cartridge – QC material or patient sa	ample?
	 If code is occurred while testing QC material, wh 	nat is the lot number(s)?
Synonyms: N/A	4. How are cartridges stored and handled?	
	5. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Verify cartridge storage and handling	
	B. If only one code 20 occurred, test another cartridge	
	C. If code is persistent on different analyzers, test cartridges from a different lot number on the same analyzers	
	D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot	
	number or box number	
	then run a new cartridge on the analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code	
	then run a new cartriage on the analyzer	
	Resolution	
	IF the code 20 is due to improper cartridge storage and	THEN the incident can be resolved
	handling	Classification is Complaint 1
	IF running the ceramic conditioning cartridge and new	THEN the incident can be resolved
	cartridge resolves the code 20 on a specific analyzer	Classification is Complaint 1
	IF the code 20 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2
	other cartridge lot(s) run without issue on the same i-STAT	
	analyzers	Ask customer if cartridges are available to be returned
		for investigation and document request(s)
	IF the code 20 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	using the ceramic conditioning cartridge	Classification is Repair

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Complaint	Description			
Code 21	Analyzer detected material on the sensors before it should have	Analyzer detected material on the sensors before it should have		
	Prompts for Meaningful Data Collection			
Cartridge Preburst	1. What was being tested when the code 21 occurred (cartrid	dge or external simulator)?		
– Use Another	2. How many code 21 have occurred?			
Cartridge	3. If cartridges were being tested			
	a. What cartridge lot number(s)/box number(s)?			
RW Code: C1121	b. What is tested on the cartridge – QC material or	patient sample?		
	i. If code is occurring with QC material, v	vhat is the lot number(s)?		
Synonyms: N/A	c. How are the cartridges handled?			
	i. Did user press on the calibrant pack in	the center of the cartridge?		
	II. Did the user insert and test a previous	ly used cartridge?		
	d. How are the cartridges stored?	- 2		
	I. Did the cartridges pass initial QC testin	lg;		
	II. Have the cartridges been frozen at any	/ point?		
	4. If external simulator was being tested			
	a. What is external simulator senar number:	or impeding proper insertion of the simulator?		
	5 What is analyzer serial number(s)?	or impeding proper insertion of the simulator:		
	Troubleshooting			
	A If code occurred while testing cartridges			
	1 Verify that the user is not pressing on the calibra	ant nouch of the cartridge		
	2. Verify that the cartridges have not been frozen			
	 Verify that the user is not running a previously tested cartridge 			
	4. Test a new cartridge			
	B. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot			
	number or box number			
	C. If code occurred while testing an external simulator			
	1. Ensure the blue cap is not impeding proper inser	rtion (remove cap if necessary)		
	2. Retest external simulator			
	Resolution			
	IF the code 21 is due to improper storage or handling of the	THEN the incident is resolved		
	cartridges	Classification is Complaint 1		
	IF the code 21 is resolved after re-testing the external	THEN the incident is resolved		
	simulator OR is confirmed to be due to the blue cap of the	Classification is Complaint 1		
	external simulator impeding the insertion			
	IF the code 21 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated		
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2		
	other cartridge lot(s) run without issue on the same i-STAT			
	anaiyzers	Ask customer if cartridges are available to be returned		
		for investigation and document request(s)		
	IF the code 21 is persistent on multiple i-STAT analyzers after	THEN the external simulator should be replaced		
	troubleshooting with a single external simulator	Classification is Repair		
	IF the code 21 is persistent on specific i-STAT analyzer AND	THEN the I-STAT analyzer should be replaced or repaired		
	the same cartridge lot(s) run without issue on the other i-	Classification is Repair		
	STAT analyzers			

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Complaint	Description		
Code 22	The mixing of the sample and reagent is compromised		
	Note: Code 22 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only		
Cartridge Error –	Prompts for Meaningful Data Collection		
Use Another	 What cartridge lot number(s)/box number(s) has the code 22 occurred? 		
Cartridge	2. How many code 22 have occurred?		
	3. What is analyzer serial number(s)?		
RW Code: C1222	4. What is tested on the cartridge – QC material or patient sample?		
	5. If code occurred while testing QC materials		
Answer pRE	a. What is the QC material lot number(s)?		
Questions!	b. How are the QC material materials handled?		
Synonyme: N/A	 If code occurred while testing patient sample Is only one patient sample giving the code or multiple patients? 		
Synonyms. N/A	a. Is only one patient sample giving the code of multiple patients?		
	b. What is the sample collected?		
	d What is the time from sample collection to testing?		
	7 If multiple codes occurred while testing ACT cartridge:		
	a What are the times the code occurred?		
	b. Did ACT cartridge produce a result?		
	i. If yes, what was result?		
	ii. If no, was sample tested on a different instrument? What instrument and what was result?		
	c. Was patient being administered heparin?		
	8. How is the cartridge being handled?		
	a. Was a previously tested cartridge inserted into the analyzer?		
	b. Was the cartridge closed properly?		
	Troubleshooting		
	A. If code occurred with ACT cartridge, confirm patient was administered heparin		
	1. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants		
	2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>)		
	B. If the code is with patient sample		
	1. Verify the sample type tested		
	2. Verify the sample is tested immediately after collection		
	5. Verify that a used callinge was not rested		
	5. Test a new cartridge with fresh sample		
	C If the code is with OC material		
	1. Verify the handling of the QC material material(s)		
	2. Test a new cartridge with fresh QC material		
	D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method		
	Resolution		
	IF the code 22 is due to improper cartridge or sample THEN the incident can be resolved		
	handling through troubleshooting AND additional • Classification is Complaint 1		
	cartridges are tested successfully		
	IF the code 22 is persistent on multiple i-STAT analyzers THEN the suspect cartridge lot(s) should be investigated		
	• Classification is Complaint 2		
	AND other cartridge lot number are run without issue on Ask customer if cartridges are available to be returned for		
	investigation and document request(s)		
	IF the code 22 is persistent on multiple I-STAT analyzers (the three back and QC lot(s) should be		
	arter troubleshooting but only on specific cartridge lots and		
1	AND specific QC material lot(s). Other cartridge lots and Classification is Complaint 2		

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other QC material lot(s) run without issue on the same i- STAT analyzers	Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the code 22 is persistent on specific i-STAT analyzer AND the same cartridge lot(s) run without issue on the other i-STAT analyzers	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair

Return to the TOC

Code 23 Poor contact between analyzer connector pins and cartridge pads Poor Contact Prompts for Meaningful Data Collection Poor Contact 1. Was a cartridge or external simulator being tested at the time of code 23? Detected – See 2. How many code 23 have occurred? Manual 3. What is analyzer serial number(s)? 4. If cartridge or external simulator being tested: a. What cartridge to tnumber(s) has the code 23 been occurring? 5. If simulator was being tested: a. What is external simulator serial number? b. Is the blue cap on the simulator impeding proper insertion of the simulator? Troubleshooting A. If one code 23, test a new cartridge B. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code then run a new cartridge on the analyzer C. If code 23 is occurring on multiple analyzers with a specific cartridge to number, determine and document code rate D. If code occurred while testing an external simulator 1. Ensure the blue cap is not impeding proper insertion (remove cap if necessary) 2. Retest external simulator If the code 23 is resolved after re-testing the external simulator If the code 23 is persistent on specific analyzer (s) after troubleshooting with a single external simulator Classification is Complaint 1	Complaint	Description		
Prompts for Meaningful Data Collection Poor Contact 1. Was a cartridge or external simulator being tested at the time of code 23? Detected - See Manual 3. What is analyzer serial number(s)? 4. If cartridge was being tested: a. What cartridge lot number(s) has the code 23 been occurring? 5. If simulator was being tested: a. What is external simulator serial number? 5. If simulator was being tested: a. What is external simulator serial number? 6. Is the blue cap on the simulator impeding proper insertion of the simulator? Troubleshooting A. If one code 23, test a new cartridge 8. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code then run a new cartridge on the analyzer C. If code 23 is occurred while testing an external simulator 1. Ensure the blue cap is not impeding proper insertion (remove cap if necessary) 2. Retet external simulator 1. Furnning the ceramic conditioning cartridge and new cartridge resolves the code 23 is resolved after re-testing the external simulator is resolved IF the code 23 is persistent on multiple i-STAT analyzer (s) after roubleshooting with a single external simulator THEN the incident is resolved or repaired IF the code 23 is persistent on specific I-STAT analyzer after troubleshooting THEN the i-STAT analyzer should be replaced or repaired	Code 23	Poor contact between analyzer connector pins and cartridge p	pads	
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IF the code 23 is resolved after re-testing the external simulator OR is confirmed to be due to the blue cap of the external simulator impeding the insertion THEN the incident is resolved IF the code 23 is persistent on multiple i-STAT analyzer(s) after troubleshooting with a single external simulator THEN the external simulator should be replaced IF the code 23 is persistent on multiple i-STAT analyzer(s) THEN the external simulator should be replaced IF the code 23 is persistent on specific i-STAT analyzer after troubleshooting THEN the i-STAT analyzer should be replaced or repaired		cartridge resolves the code 23	Classification is Complaint 1	
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external simulator on the code to the bloc day of the sector of the bloc day of		simulator OR is confirmed to be due to the blue can of the	Classification is Complaint 1	
IF the code 23 is persistent on multiple i-STAT analyzer(s) after troubleshooting with a single external simulatorTHEN the external simulator should be replaced • Classification is RepairIF the code 23 is persistent on specific i-STAT analyzer after troubleshootingTHEN the i-STAT analyzer should be replaced or repaired • Classification is Repair		external simulator impeding the insertion		
after troubleshooting with a single external simulatorClassification is RepairIF the code 23 is persistent on specific i-STAT analyzer after troubleshootingTHEN the i-STAT analyzer should be replaced or repaired • Classification is Repair		IF the code 23 is persistent on multiple i-STAT analyzer(s)	THEN the external simulator should be replaced	
IF the code 23 is persistent on specific i-STAT analyzer after troubleshooting THEN the i-STAT analyzer should be replaced or repaired • Classification is Repair		after troubleshooting with a single external simulator	Classification is Repair	
troubleshooting • Classification is Repair		IF the code 23 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
		troubleshooting	Classification is Repair	
IF the code 23 is persistent on multiple i-STAT analyzers THEN the suspect cartridge lot(s) should be investigated		IF the code 23 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
after troubleshooting but only on specific cartridge lot(s) • Classification is Complaint 2		after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
AND other cartridge lot(s) is verified to run without issue on Ask customer if cartridges are available to be returned		AND other cartridge lot(s) is verified to run without issue on	Ask customer if cartridges are available to be returned	
the same analyzers for investigation and document request(s)		the same analyzers	for investigation and document request(s)	

i-STAT Support Guide REF-1151C Section 1.0

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Complaint	Description		
Code 24	The electrical resistance of the calibrant material (Rcal) used to verify the electrolyte concentration is out of specification		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge lot number(s) has the code 24 been occur	ring?	
Use Another	2. Is this a new or old cartridge lot number?		
Cartridge	a. If new lot, how many code 24 have occurred on	each analyzer?	
	b. If old lot, how many code 24 have occurred?		
RW Code: C1224	3. How is the cartridge being handled?		
	a. Was center of cartridge pressed?		
Synonyms: N/A	4. How are the cartridges stored?		
	5. What is analyzer serial number(s)?		
	Troubleshooting		
	A. Verify cartridge testing procedure – ensure that the custo	omer has not pressed down on the calibrant pouch	
	B. If new cartridge lot number - 5 cartridges must be tested for each analyzer to learn the new resistance average		
	 If code is persistent (>5 times per analyzer) document number of codes for the specific cartridge lot number If old cartridge lot number shows code 24, determine and document code rate for the specific cartridge lot number 		
	Resolution		
	IF after running 5 cartridges per analyzer for the new	THEN the incident is resolved	
	cartridge lot number the code 24 is not reproducible	Classification is Complaint 1	
	IF the code 24 is determined to be due to improper cartridge	THEN the incident is resolved	
	handling through troubleshooting and the next cartridge is	Classification is Complaint 1	
	tested successfully		
	IF the code 24 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	the same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 24 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) is verified to run without issue on the		
	same analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	
i-STAT Support Guid	e REF-1151C Section 1.0	Return to the TOC	

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Code 25 The mixing of the sample and reagent is compromised Mote: Code 25 occurs with Coaguitation (ACTE, ACTE, PT/INPL cartridge only Cartridge Error- Use Another Cartridge I. What cartridge to number(s)/box number(s) has the code 25 occurred? Cartridge The maxing of the sample and reagent is compromised many code 25 have occurred? White is tested on the cartridge – QC material or patient sample? A. Wro Cod: C1225 I. Brow many code 25 have occurred? White is tested on the cartridge – QC material or patient sample? A. Maxing Of the sample and reagent is compromised many code 25 have occurred? White is testing patient sample Questions! If code occurred while testing patient sample by the code or multiple patients? Synonyms: N/A 6. How is the patient sample by tested? If multiple codes occurred while testing patient way Collection? Synonyms: N/A 7. What is the sample type tested? If multiple codes occurred while testing administered heparin? Synonyms: N/A 8. How is the patient sample going the code or multiple patients? If move as sample type tested? Synonyms: N/A 9. How is the cartridge produce are suit? If move as a multiple codes occurred? Synonyms: N/A 9. How is the cartridge produce are suit? If move as a multiple codes occurred while testing patient was administered heparin? 6. How is the cartridge produce are suit? If move asample type tested? If move asa multiple	Complaint	Description		
Det: Code 25 accurs with Coguidation (ACTs, ACTs, PT/NR) activitiges only Cartridge Tor Maningful Data Collection Cartridge Tor Maningful Data Collection Cartridge Tor Maningful Data Collection RW Code: C1225 Si if code occurred while testing CC material RW Code: C125 Asswer pRE Cuestions! Asswer pRE Cuestions! Si in code occurred while testing CC material lot number(s)? b. How is the patient sample being collected? c. What is the sample type tested? d. What are the times the code occurred? b. How is the patient sample being collected? c. What is the time between sample collection and testing? s. What are the times the code occurred? b. Did ACT cartridge fright to fill mark? c. Was patient being administered heparin? 6. How is the cartridge being handled? a. Wast accurridge tisted to fill mark? b. Was a used cartridge tested on the analyzer? c. Was patient sample a. Uriting is filled to fill mark? b. Was a used cartridge collection c. How is the cartridge tisted tor fill mark? b. Was pane type tested?	Code 25	The mixing of the sample and reagent is compromised		
Cartridge Error- Use Another Prompts for Meaningful Data Collection 1 What cartridge lot number(s)/box number(s) has the code 25 occurred? 2 How many code 25 have occurred? What is tested on the cartridge – QC material or patient sample? 3. If code occurred while testing patient sample Answer pRE 0. 4. For doe occurred while testing patient sample Cuestions! 1. 6. How is the QC material landled before testing? Answer pRE 1. Cuestions! 1. 8. How is the QC material sample 9. How is the DC material sample collection and testing? 1. How is the patient sample collection and testing? 5. If multiple codes occurred while testing apt cartridge: a. What is the time between sample collection and testing? 5. If multiple codes occurred while testing apt cartridge: a. What is the sample type tested? b. Did ACT cartridge patient sample c. Was patient being padientistered heparin? c. How is the cartridge tested on the analyzer? c. Was a used cartridge tofill mark? b. Was a		Note: Code 25 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only		
Use Another Cartridge 1. What cartridge iot number(s)/box number(s) has the code 25 occurred? 2. How many code 25 have occurred? What is tested on the cartridge – QC material or patient sample? 3. If code occurred while testing QC material RW Code: C1225 Answer pRE Cuestions! 4. If code occurred while testing patient sample (cuestions! a. Us only one patient sample being collected? b. How is the patient sample being collected? c. What is the time between sample collection and testing? 5. If multiple codes occurred while testing ACT cartridge: a. What are the times the code occurred? b. Did ACT cartridge produce a result? i. If now sample tested on a different instrument? What instrument and what was result? c. Was the cartridge being handled? a. Was the cartridge closed properly? 7. Was the cartridge closed properly? 7. Was the cartridge closed properly? 7. Was the cartridge tested mile analyzer? c. Werity the sample type tested a. Verify the sample type tested a. Verify the sample type tested b. If the code occurred while patient sample c. Was the cartridge test in mediately after collection 3. If code occurred while testing QC material <tr< th=""><th>Cartridge Error –</th><th colspan="3">Prompts for Meaningful Data Collection</th></tr<>	Cartridge Error –	Prompts for Meaningful Data Collection		
Cartridge 2. How many code 25 have occurred? What is tested on the cartridge – QC material or patient sample? RW Code: C1225 if code occurred while testing QC material lot number(s)? Answer pIE a. What is QC material lot number(s)? Cuestions! b. How is the QC material lot defore testing? Answer pIE a. Is only one patient sample being collected? Cuestions! a. What is the sample type tested? J. How is the outrie between sample collection and testing? Synonyms: N/A c. What is the time between sample collection and testing? B. How is the cartridge period are result? i. If yes, what was result? i. If yes, what was result? ii. If now is a sample tested on a different instrument? What instrument and what was result? c. Was a sued cartridge tested on the analyzer? was the cartridge being handled? a. Was the cartridge tested on film mark? was used cartridge tested on film ank? b. Was a used cartridge tested on a different instrument? What instrument and what was result? c. Was a sued cartridge tested on a diministered heparin 1. if STAT ACT test monitors heparin, not angiomax or other anticoagulants 2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add C1056) B. If the code occurred with ACT cartridge was not tested 5. Verify the sample type tested	Use Another	1. What cartridge lot number(s)/box number(s) has the code 25 occurred?		
8. if code occurred while testing QC material 9. if code occurred while testing patient sample Answer pRE 4. 0. is only one patient sample giving the code or multiple patients? 0. is only one patient sample bing collected? 2. What is the sample type tested? 0. What is the time between sample collection and testing? 5. if multiple codes occurred? while testing ACT cartridge: a. What are the times the code or multiple patients? b. How is the cartridge produce a result? i. if row as sample tested? 0. What is analyzer serial number(s)? 1. if row as sample tested on a different instrument? What instrument and what was result? 1. i. if row as cartridge tested on the analyzer? 2. Was the cartridge confirm patient was administered heparin 1. I-STAT CT test monitors heparin, not angiomax or other anticoagulants 2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add C1065) 8. If code occurred with ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add C1065) 8. If the code occurred with fest fast amaple <tr< th=""><th>Cartridge</th><th>2. How many code 25 have occurred? What is tested on the cartridge – QC material or patient sample?</th></tr<>	Cartridge	2. How many code 25 have occurred? What is tested on the cartridge – QC material or patient sample?		
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Answer pRI If code occurred while testing patient sample	RW Code: C1225	a. What is QC material lot number(s)?		
Answer pRE 4. If code occurred while testing patient sample Questions! a. Is only one patient sample being collected? Synonyms: N/A C. What is the sample type tested? d. What is the time between sample collection and testing? 5. If multiple codes occurred while testing ACT cartridge: a. What are the times the code occurred? b. Did ACT cartridge produce a result? i. If no, was sample tested on a different instrument? What instrument and what was result? c. Was patient being administered heparin? 6. How is the cartridge blied to fill mark? b. Was a used cartridge tested on a different instrument? What instrument and what was result? c. Was the cartridge closed properly? 7. What is analyzer serial number(s)? Toubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin 1. I. STAT ACT test monitors heparin, not angiomax or other anticoagulants 2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1065</u>) B. If the code occurs while testing QC material 1. Verify the sample type tested 2. Verify that a used cartridge was not tested 3. Verify the cartridge was closed 6. Test a new cartridge with fresh sample 7. Verify the cartridge w		b. How is the QC material handled before testing?		
Questions! a. Is only one patient sample giving the code or multiple patients? Synonyms: N/A b. How is the patient sample byte tested? d. What is the sample type tested? d. What is the sample testing ACT cartridge: a. What are the times the code occurred? b. How is the cartridge produce a result? i. If yes, what was result? i. If no, was sample tested on a different instrument? What instrument and what was result? c. Was patient being administered heparin? 6. How is the cartridge big handled? a. Was the cartridge tested on a different instrument? What instrument and what was result? c. Was patient being administered heparin? 6. How is the cartridge closed properly? 7. What is analyzer serial number(s)? Toubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin i. STA ACT test monitors heparin, not angiomax or other anticoagulants i. If the code occurres while patient sample i. Verify the sample type tested Verify the sample type tested Verify the sample was tosed Toutified to fill mark Verify the angle with fresh sample C. If the code occurs while patient sample C. If the code occurs while patient sample Verify the a used cartridge was not tested Verify that a used cartridge was not tested Test a new cartridge with fresh sample C. If the code occurs while testing QC material<!--</th--><th>Answer pRE</th><th>4. If code occurred while testing patient sample</th>	Answer pRE	4. If code occurred while testing patient sample		
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b. Did ACT cartridge produce a result? i. If yes, what was result? ii. If no, was sample tested on a different instrument? What instrument and what was result? c. Was patient being administered heparin? 6. How is the cartridge being handled? a. Was the cartridge tested on the analyzer? c. Was a used cartridge tested on the analyzer? c. Was the cartridge tested on the analyzer? c. Was the cartridge tested on the analyzer? c. Was the cartridge closed properly? 7. What is analyzer serial number(s)? Troubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin 1. I- ISTAT ACT test monitors heparin, not angiomax or other anticoagulants 2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add C1056) B. If the code occurs while patient sample 1. Verify the sample type tested 2. Verify the sample type tested 3. Verify the ased cartridge was not tested 5. Verify the cartridge with fresh sample C. If the code occurs while patient sample C. If the code occurs while resting QC material 1. Verify the handling of the QC material 2. Verify the aud cartridge was not tested 3. Verify the handling of the QC mater		a. What are the times the code occurred?		
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 ii. If no, was sample tested on a different instrument? What instrument and what was result? c. Was patient being administered heparin? 6. How is the cartridge filled to fill mark? b. Was a used cartridge tested on the analyzer? c. Was the cartridge closed properly? 7. What is analyzer serial number(s)? Troubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin i. iSTAT ACT test monitors heparin, not angiomax or other anticoagulants If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>) B. If the code occurrs while patient sample Verify the sample is tested immediately after collection Verify that a used cartridge was not tested Verify that a used cartridge was not tested Verify the cartridge is filled to fill mark Verify the aused cartridge was not tested Verify the aused cartridge was not tested Verify the cartridge is filled to fill mark Verify the cartridge was closed Test a new cartridge with fresh sample Verify that a used cartridge was not tested Verify the cartridge was closed Test a new cartridge with fresh Camatrial Verify the cartridge was closed Fest an ew cartridge lot number, determine and document code rate for the specific cartridge lot number or box number E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method 		i. If yes, what was result?		
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 6. How is the cartridge being handled? a. Was the cartridge filled to fill mark? b. Was a used cartridge tested on the analyzer? c. Was the cartridge closed properly? 7. What is analyzer serial number(s)? Troubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin i. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants 2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>) B. If the code occurrs while patient sample 1. Verify the sample type tested 2. Verify the sample type tested 3. Verify that a used cartridge was not tested 5. Verify that a used cartridge was not tested 6. Test a new cartridge with fresh sample C. If the code occurs while testing QC material 1. Verify the andling of the QC material 3. Verify that a used cartridge was not tested 4. Verify that a used cartridge was not tested 5. Verify that a used cartridge was not tested 6. Test a new cartridge with fresh sample C. If the code occurs while testing QC material 1. Verify that a used cartridge was not tested 4. Verify that a used cartridge was not tested 5. Test a new cartridge with fresh QC material D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number E. Wrify times of codes, whether result was produced on I-STAT cartridge or alternate testing method Resolution If the code 25 is due to improper cartridge or sample 		c. Was patient being administered heparin?		
 a. Was the cartridge filled to fill mark? b. Was a used cartridge to the analyzer? c. Was the cartridge closed properly? 7. What is analyzer serial number(s)? Troubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin i. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>) B. If the code occurs while patient sample Verify the sample type tested Verify the sample is tested immediately after collection Verify the cartridge was closed Verify that a used cartridge was not tested Verify the cartridge with fresh sample Verify the cartridge with fresh sample Verify that a used cartridge was not tested Verify the cartridge with fresh Sample If the code occurs while testing QC material Verify that a used cartridge was not tested Verify the cartridge was closed Test a new cartridge with fresh QC material D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution If the code 25 is due to improper cartridge or sample Test a new cartridge was mapped cartridge or sample If the value due to improper ca		6. How is the cartridge being handled?		
 b. Was a used cartridge tested on the analyzer? c. Was the cartridge closed properly? 7. What is analyzer serial number(s)? Troubleshooting A. If code occurred with ACT cartridge, confirm patient was administered heparin 1. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants 2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>) B. If the code occurs while patient sample 1. Verify the sample type tested 2. Verify that a used cartridge was not tested 3. Verify that a used cartridge was not tested 5. Verify the cartridge with fresh sample 6. Test a new cartridge with fresh sample 1. Verify the handling of the QC material 1. Verify the auryle silled to fill mark 3. Verify that a used cartridge was not tested 5. Verify the handling of the QC material 1. Verify the handling of the QC material 2. Verify the tartridge was closed 5. Test a new cartridge with fresh QC material D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution IF the code 25 is due to improper cartridge or sample 		a. Was the cartridge filled to fill mark?		
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 3. Verify that a used cartridge was not tested 4. Verify the cartridge was closed 5. Test a new cartridge with fresh QC material D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution IF the code 25 is due to improper cartridge or sample THEN the incident is resolved 		2. Verify cartridge is filled to fill mark		
 Verify the cartridge was closed Test a new cartridge with fresh QC material If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution IF the code 25 is due to improper cartridge or sample THEN the incident is resolved 		3. Verify that a used cartridge was not tested		
D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution IF the code 25 is due to improper cartridge or sample THEN the incident is resolved		4. Verify the cartridge was closed		
D. If persistent on a specific cartridge for humber, determine and document code rate for the specific cartridge for number or box number E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution IF the code 25 is due to improper cartridge or sample THEN the incident is resolved		5. Test a new Caltridge With Hesh QC material		
E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method Resolution IF the code 25 is due to improper cartridge or sample THEN the incident is resolved		D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
Resolution IF the code 25 is due to improper cartridge or sample THEN the incident is resolved		number of box number		
IF the code 25 is due to improper cartridge or sample THEN the incident is resolved		E. Verify times of codes, whether result was produced on FSTAT cartilidge of alternate testing method		
if the code 25 is due to improper cartridge or sample IHEM the incident is resolved		IF the code 2E is due to improper certridge or cample TUEN the incident is received		
bandling through troubleshooting and a new cartridge is Classification is Complete 4		handling through troublochooting and a new cartridge is		
tested successfully		tested successfully		
IE the code 25 is persistent on multiple i STAT analyzers after THEN the suspect cartridge let/s) should be investigated		IE the code 25 is persistent on multiple i STAT analyzers after THEN the suspect cartridge let/s) should be investigated		
troubleshooting but only on specific cartridge lot(s) AND		troubleshooting but only on specific cartridge lot(s) AND • Classification is Complaint 2		

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other cartridge lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges are available to be returned for investigation and document request(s)
IF the code 25 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND specific QC material lot(s). Other cartridge lots and other QC material lot(s) run without issue on the same i-STAT analyzers	THEN the suspect cartridge and QC lot(s) should be investigated Classification is Complaint 2 Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the code 25 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on the other i-STAT analyzers	THEN the i-STAT analyzer should be replaced or repairedClassification is Repair

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Complaint	Description	
Code 26	Internal quality checks for coagulation cartridge failed	
	Note: Code 26 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only	
Cartridge Error	Prompts for Meaningful Data Collection	
– Use Another	1. What cartridge lot number(s)/box number(s) has the code 26 occurred?	
Cartridge	2. How many code 26 have occurred?	
	3. What is tested on the cartridge – QC material or patient sample?	
RW Code:	4. If code occurred while testing QC material	
C1226	a. What is QC material lot number(s)?	
	b. How is the QC material handled before testing?	
Answer pRE	5. If code occurred while testing patient sample	
Questions!	a. Is only one patient sample giving the code or multiple patients?	
	b. What is the sample type tested?	
Synonyms: N/A	c. How is the sample collected?	
	d. What is the time between sample collection and testing?	
	If multiple codes occurred while testing ACT cartridge:	
	a. What are the times the code occurred?	
	b. Did ACT cartridge produce a result?	
	i. If yes, what was result?	
	ii. If no, was sample tested on a different instrument? What instrument and what was result?	
	c. Was patient being administered heparin?	
	7. What is analyzer serial number(s)?	
	Troubleshooting	
	A. If code occurred with ACT cartridge, confirm patient was administered heparin.	
	1. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants	
	If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>)	
	B. If the code occurs while testing patient sample	
	1. Verify the sample type tested	
	2. Verify the sample is tested immediately after collection	
	3. Test a new cartridge with fresh sample	
	C. If the code occurs while testing QC material	
	 Verify the handling of the QC material material(s) 	
	2. Test a new cartridge with fresh QC material	
	D. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number.	ber
	or box number	
	E. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method	

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Re	esolution	
IF	after correcting any sample collection or handling issues the	THEN the incident is resolved
со	ode 26 is resolved	Classification is Complaint 1
IF	the code 26 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated
tro	oubleshooting but only on specific cartridge lot(s) AND other	Classification is Complaint 2
са	artridge lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges are available to be returned
		for investigation and document request(s)
IF	the code 26 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge and QC lot(s) should be
tro	oubleshooting but only on specific cartridge lot(s) AND	investigated
sp	pecific QC material lot(s). Other cartridge lots and other QC	Classification is Complaint 2
ma	naterial lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
		to be returned for investigation and document
		request(s)
IF	the code 26 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired
the	nose same cartridge lot(s) run without issue on the other i-	Classification is Repair
ST	TAT analyzers	

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Complaint	Description		
Code 27	Error detected after calibration		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge lot number(s)/box number(s) has the co	ode 27 occurred?	
Use Another	How many code 27 have occurred?		
Cartridge	What analyzer serial number(s)?		
	4. What is being tested on the cartridge - QC material or p	patient samples?	
RW Code: C1227	5. If code occurred while testing QC material, what is the	lot number?	
	6. How are cartridges stored?		
Synonyms: N/A	How are cartridges handled?		
	Troubleshooting		
	A. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	B. If code is persistent on specific analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	Resolution		
	IF running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge resolves the code 27	Classification is Complaint 1	
	IF the code 27 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers		
	IF the code 27 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	

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Complaint	Description		
Codo 28	Beer contact between analyzer and cartridge		
Coue 28	Promote for Monain million and Alloction		
Cortridgo Error	Prompts for Meaningful Data Collection	20. a a surred 2	
	1. What cartridge lot number(s)/box number(s) has the code	28 occurred?	
- Ose Another	2. How many code 28 have occurred?		
Cartridge	3. What is analyzer serial number(s)?		
DW/ Code	4. What is being tested on the cartridge - QC material or pati	ent samples?	
RW Code:	a. If code occurred while testing QC material, what	is the QC material lot number(s)?	
C1228	5. How are cartridges filled?		
	Troubleshooting		
Synonyms: N/A	A. Verify cartridge handling and filling – ensure cartridge is fil	led to fill mark on the cartridge	
	 Repeat cartridge testing from same cartridge lot 	number and box number	
	B. If persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number		
	or box number		
	C. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code then		
	run a new cartridge on the analyzer		
	Resolution		
	IF the code 28 is due to improperly filled cartridge through	THEN the incident is resolved	
	troubleshooting and the next cartridge is tested successfully	Classification is Complaint 1	
	IF running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge resolves the code 28	Classification is Complaint 1	
	IF the code 28 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers		
	IF the code 28 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT	·	
	analyzers	Ask customer if cartridges are available to be returned for	
	· ·	investigation and document request(s)	

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Complaint	Description		
Code 29	Poor contact between analyzer and cartridge or overfilled cartridge		
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What cartridge lot number(s)/box number(s) has the code	29 been occurring?	
– Use Another	2. How many code 29 have occurred?		
Cartridge	3. What is analyzer serial number(s)?		
	4. What is being tested on the cartridge - QC material or patie	ent samples?	
RW Code:	a. If code occurred while testing QC material, whether the second s	nat is the QC material lot number(s)?	
C1229	5. How are the cartridges filled?		
	Troubleshooting		
Synonyms: N/A	A. Verify the cartridges are not being overfilled		
	1. Repeat cartridge testing from same cartridge lot	number and box number	
	B. If code is persistent on a specific cartridge lot number, det	ermine and document code rate for the specific cartridge lot	
	number or box number		
	C. If code is persistent on specific analyzer, use the ceramic c	onditioning cartridge on analyzer experiencing the code then	
	run a new cartridge on the analyzer		
	Resolution		
	IF the code 29 is due to improper cartridge filling (overfilling)	THEN the incident is resolved	
	and the next cartridge is tested successfully after	Classification is Complaint 1	
	troubleshooting		
	IF running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge resolves the code 29	Classification is Complaint 1	
	IF the code 29 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers	·	
	IF the code 29 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT	·	
	analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
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<u>turn to the TOC</u>

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Complaint	Description		
Code 30	Overfilled cartridge		
	Prompts for Meaningful Data Collection		
Sample Positioned	1. What cartridge lot number(s)/box number(s) has the coo	de 30 been occurring?	
Beyond Fill Mark –	2. How many code 30 have occurred?		
Use Another	3. What is being tested on the cartridge - QC material or pa	atient samples?	
Cartridge	a. If code occurred while testing QC material, wh	at is the QC material lot number(s)?	
	4. How are the cartridges being handled?		
RW Code: C1130	a. Is the sample filled beyond the fill mark?		
	 b. If coagulation cartridge (ACTc, ACTk, PT/INR), v 	was a used cartridge tested (additional cause)?	
Synonyms: N/A	5. What is analyzer serial number(s)?		
	Troubleshooting		
	A. Verify that a used or overfilled coagulation cartridge is not being tested		
	B. Verify that the cartridge is not being overfilled		
	1. Repeat cartridge testing from same cartridge lot number and box number		
	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF the code 30 is due to improper cartridge filling/handling	THEN the incident is resolved	
	through troubleshooting and the new cartridge is tested	Classification is Complaint 1	
	successfully		
	IF the code 30 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
	investigation and document request(s)		
	IF the code 30 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		

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Complaint	Description		
Code 31	The analyzer did not detect movement of sample across the se	ensors	
	Prompts for Meaningful Data Collection		
Unable to	1. What cartridge lot number(s) has the code 31 been occur	ring?	
Position Sample	How many code 31 have occurred?		
– Use Another	3. What is being tested on the cartridge - QC material or pat	ient samples?	
Cartridge	a. If code occurred while testing QC material, w	<pre>/hat is the QC material lot number(s)?</pre>	
	4. What is analyzer serial number(s)?		
RW Code: C1131	5. How is the cartridge being handled?		
	a. Was the cartridge closed properly?		
Synonyms: N/A	 b. Did the sample go beyond the fill mark on th 	e cartridge?	
	6. How is the patient sample being collected and handled?		
	a. Is the sample being collected by heel puncture in a neonatal unit?		
	Troubleshooting		
	A. Verify that the cartridge is properly closed and not overfilled		
	B. Verify proper patient sample collection and handling based on the specific cartridge type tested		
	1. Test a new cartridge from the same lot number		
	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	D. If code is persistent on specific analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	Resolution		
	IF the code 31 is due to improper cartridge or sample	THEN the incident is resolved	
	handling after troubleshooting and a new cartridge is tested	Classification is Complaint 1	
	successfully		
	IF running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge on the specific analyzer resolves the code 31	Classification is Complaint 1	
	IF the code 31 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 31 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	

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Complaint	Description		
Complaint			
Code 32	Error detected after calibration		
	Prompts for Meaningful Data Collection		
Cartridge Error –	 What is analyzer serial number(s)? 		
Use Another	2. What cartridge lot number(s)/box number(s) has the code	e 32 been occurring?	
Cartridge	How many code 32 have occurred?		
	4. What is being tested on the cartridge - QC material or pat	ient samples?	
RW Code: C1232	a. If code occurred while testing QC material, wha	t is the QC material lot number(s)?	
	5. How are cartridges stored?		
Synonyms: N/A	6. How are cartridges handled?		
	Troubleshooting		
	A. If persistent on a specific cartridge lot number determine and document code rate for the specific cartridge lot		
	number or box number		
	B. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	Resolution		
	IF running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge resolves the code 32	Classification is Complaint 1	
	IF the code 32 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 32 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT	Ask customer if cartridges are available to be returned for	
	analyzers	investigation and document request(s)	
		•	

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Complaint	Description		
Code 33	Cartridge Error (possible mechanism damage)		
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What cartridge lot number(s)/box number(s) has the code 33 been occurring?		
– Use Another	2. How many code 33 have occurred?		
Cartridge	3. What is being tested on the cartridge - QC material or patien	nt samples?	
	a. If code occurred while testing QC material, what is	s the QC material lot number(s)?	
RW Code:	4. What is analyzer serial number(s)?		
C1233	Troubleshooting		
	A. Run a new cartridge		
Synonyms: N/A	B. If persistent on a specific cartridge lot number determine and document code rate for the specific cartridge lot number		
	or box number		
	Resolution		
	IF after running additional cartridges the code 33 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 33 is persistent on only specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the other	Classification is Repair	
	i-STAT analyzers		
	IF the code 33 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND other	Classification is Complaint 2	
	cartridge lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	
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Complaint	Description		
Code 34	The analyzer did not detect movement of sample across the sensors.		
	Prompts for Meaningful Data Collection		
Unable to	1. What cartridge lot number(s) has the code 34 been occurring?		
Position Sample	How many code 34 have occurred?		
– Use Another	3. What is being tested on the cartridge - QC material or patie	ent samples?	
Cartridge	a. If code occurred while testing QC material, what	is the QC material lot number(s)?	
	4. What is analyzer serial number(s)?		
RW Code: C1134	5. How is the cartridge being handled?		
	a. Was the cartridge closed properly?		
Synonyms: N/A	b. Did the sample go beyond the fill mark on the ca	rtridge?	
	6. How is the patient sample being collected and handled?		
	a. Is the sample being collected by heel puncture in a neonatal unit?		
	Troubleshooting		
	A. Verify that the cartridge is properly closed and not overfilled		
	B. Verify proper patient sample collection and handling based on the specific cartridge type tested		
	1. Test a new cartridge from the same cartridge lot number		
	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	D. If code is persistent on specific analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	Resolution		
	IF the code 34 is due to improper cartridge or sample	THEN the incident is resolved	
	handling after troubleshooting and a new cartridge is tested	Classification is Complaint 1	
	successfully		
	IF running the ceramic conditioning cartridge and a new	THEN the incident is resolved	
	cartridge on the specific analyzer resolves the code 34 • Classification is Complaint 1		
	IF the code 34 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i- Classification is Repair		
	STAT analyzers		
	IF the code 34 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	

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Complaint	Description		
Code 35			
code 55	Bromats for Mooningful Data Collection		
Sample	Prompts for Meaningful Data Collection		
Positioned Short	 What callinge for humber (3) box humber (3) has the code 3 How many code 35 have occurred? 	5 been occurring:	
of Fill Mark – Use	2. Now many code 35 have occurred: 3. What is being tested on the cartridge - OC material or nation	nt complex?	
Another	3. If code occurred while testing OC material what is	the OC material lot number(s)?	
Cartridge	A How are the cartridges being handled?		
curtinge	4. Now are the cartridges being handled:	۲ _{ot}	
RW Code: C1135	 a. Is the sample reaching the fin mark on the calling b. Was an empty cartridge with no sample tested? 	5C :	
	5 What is analyzer serial number/s)?		
Svnonvms: N/A	5. What is analyzer senar humber(s)?		
-, -, -,	A Vorify a new cartridge from same let number and hey is filled to the fill mark and tested successfully		
	A. Verify a new calchage noninsame for number and box is fined to the fin mark and tested successfully		
	b. If code is persistent of a specific carchage for number, determine and document code rate for the specific carchage for number or box number		
	IF the code 35 is determined to be due to underfilled cartridge	THEN the incident is resolved	
	or improper cartridge handling through troubleshooting and	Classification is Complaint 1	
	the new cartridge is tested successfully	Classification is complaint 1	
	IF the code 35 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND other	Classification is Complaint 2	
	cartridge lot(s) run without issue on the same i-STAT analyzers	Classification is complaint 2	
		Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	
	IF the code 2F is persistent on specific i STAT and the AND	TUEN the i STAT analyzer should be replaced as rescired	
	IF the code 55 is persistent on specific I-STAT analyzer AND	Classification is Bonoin	
	those same cartriage lot(s) run without issue on the other I-	Classification is Repair	
	STAT dildiyzers		

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Description		
Underfilled cartridge		
Prompts for Meaningful Data Collection		
1. What cartridge lot number(s)/box number(s) has the code 3	6 been occurring?	
2. How many code 36 have occurred?		
3. What is being tested on the cartridge - QC material or patier	nt samples?	
a. If code occurred while testing QC material, what is	s the QC material lot number(s)?	
4. How are the cartridges being handled?		
a. Is the sample filled to the fill mark on the cartridge?		
5. What is analyzer serial number(s)?		
Troubleshooting		
A. Verify a new cartridge from same lot number and box is filled to the fill mark and tested successfully		
B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
number or box number		
Resolution		
IF the code 36 is due to underfilled cartridge through	THEN the incident is resolved	
troubleshooting and the new cartridge is tested successfully	Classification is Complaint 1	
IF the code 36 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
troubleshooting but only on specific cartridge lot(s) AND other	Classification is Complaint 2	
cartridge lot(s) run without issue on the same i-STAT analyzers		
	Ask customer if cartridges are available to be returned	
	for investigation and document request(s)	
IF the code 36 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
STAT analyzers		
	Description Underfilled cartridge Prompts for Meaningful Data Collection 1. What cartridge lot number(s)/box number(s) has the code 3 2. How many code 36 have occurred? 3. What is being tested on the cartridge - QC material or patient a. If code occurred while testing QC material, what is 4. How are the cartridges being handled? a. Is the sample filled to the fill mark on the cartridge 5. What is analyzer serial number(s)? Troubleshooting A. Verify a new cartridge from same lot number and box is fille B. If code is persistent on a specific cartridge lot number, deternumber or box number Resolution IF the code 36 is due to underfilled cartridge through troubleshooting and the new cartridge is tested successfully IF the code 36 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND other cartridge lot(s) run without issue on the same i-STAT analyzers IF the code 36 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on the other i-STAT analyzers	

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Complaint	Description		
Code 37	Overfilled cartridge		
	Prompts for Meaningful Data Collection		
Sample	1. What cartridge lot number(s)/box number(s) has the code	e 37 been occurring?	
Positioned	2. How many code 37 have occurred?		
Beyond Fill Mark	3. What is being tested on the cartridge - QC material or pat	ient samples?	
– Use Another	a. If code occurred while testing QC material, wha	t is the QC material lot number(s)?	
Cartridge	4. How are the cartridges being handled?		
	a. Is the sample filled beyond the fill mark on the cartridge?		
RW Code: C1137	5. What is analyzer serial number(s)?		
	Troubleshooting		
Synonyms: N/A	A. Verify a new cartridge from same lot number and box is filled to the fill mark and tested successfully		
	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	Resolution		
	IF the code 37 is due to overfilled cartridge through	THEN the incident is resolved	
	troubleshooting and the new cartridge is tested successfully	Classification is Complaint 1	
	IF the code 37 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers Ask customer if cartridges are available to be returned		
		investigation and document request(s)	
	IF the code 37 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
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Complaint	Description		
Code 38	Not enough sample in sample well or bubbles in sample		
	Prompts for Meaningful Data Collection		
Insufficient	1. What cartridge lot number(s)/box number(s) has the code	38 been occurring?	
Sample – Use	2. How many code 38 have occurred?		
Another Cartridge	What is analyzer serial number(s)?		
	4. What is being tested on the cartridge - QC material or pati	ent samples?	
RW Code: C1138	 a. If code occurred while testing QC material, what 	is the QC material lot number(s)?	
	5. How is the sample collected and handled?		
Synonyms: N/A	6. How are the cartridges being handled?		
	a. Is the sample reaching the fill mark on the cartrie	dge?	
	Troubleshooting		
	A. Verify proper sample collection and handling		
	B. Verify that the cartridge is being filled to the fill mark and t	tested successfully	
	C. If code is persistent on a specific cartridge lot number, det	ermine and document code rate for the specific cartridge	
	lot number or box number		
	D. If code is persistent on specific analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	Resolution		
	IF the code 38 is due to underfilled cartridge or improper	THEN the incident is resolved	
	sample handling through troubleshooting AND additional	Classification is Complaint 1	
	cartridges have been tested successfully		
	IF running the ceramic conditioning cartridge on the specific	THEN the incident is resolved	
	analyzer resolves the code 38	Classification is Complaint 1	
	IF the code 38 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 38 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	

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Complaint	Description		
Code 39	Insufficient sample in the sample well of the cartridge		
	Note: Code 39 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only		
Insufficient	Prompts for Meaningful Data Collection		
Sample – Use	 What is analyzer serial number(s)? 		
Another Cartridge	How many code 39 have occurred?		
	3. What cartridge lot number(s)/box number(s) has the code 39 been occurring?		
RW Code: C1139	4. What is being tested on the cartridge - QC material or pa	atient samples?	
	 a. If code occurred while testing QC material, wh 	at is the QC material lot number(s)?	
Synonyms: N/A	5. How are the cartridges being handled?		
	a. Is the sample reaching the fill mark on the cart	ridge?	
	b. Is the cartridge being closed properly? Troubleshooting		
	A. Verify that the cartridge is being filled to the fill mark and cartridge is closed1. Run a new cartridge from the same cartridge lot number		
	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF the code 39 is due to improper cartridge filling/closing	THEN the incident is resolved	
	through troubleshooting and a new cartridge is tested	Classification is Complaint 1	
	successfully		
	IF the code 39 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 39 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		

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Complaint	Description		
Code 40	Poor contact between analyzer and cartridge		
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What is analyzer serial number(s)?		
– Use Another	2. How many code 40 have occurred?		
Cartridge	3. What cartridge lot number(s)/box number(s) has the code	e 40 been occurring?	
	4. What is being tested on the cartridge - QC material or pat	ient samples?	
RW Code:	a. If code occurred while testing QC material, wha	t is the QC material lot number(s)?	
C1240	Troubleshooting		
	A. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
Synonyms: N/A	number or box number		
	B. If code is persistent on specific analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code then		
	run a new cartridge on the analyzer		
	Resolution		
	IF the code 40 is resolved after running the ceramic	THEN the incident is resolved	
	conditioning cartridge and a new cartridge on the analyzer	Classification is Complaint 1	
	IF the code 40 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 40 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT	Ask customer if cartridges are available to be returned for	
	analyzers	investigation and document request(s)	

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Complaint	Description		
Code 41	No calibrant material detected, calibrant material arrived too late, or poor contact between analyzer and cartridge.		
	Prompts for Meaningful Data Collection		
Cartridge Error	 What is analyzer serial number(s)? 		
– Use Another	How many code 41 have occurred?		
Cartridge	3. What cartridge lot number(s)/box number(s) has the code	41 been occurring?	
	4. What is being tested on the cartridge - QC material or patie	ent samples?	
RW Code:	a. If code occurred while testing QC material, what	is the QC material lot number(s)?	
C1241	5. How are cartridges handled?		
	Troubleshooting		
Synonyms: N/A	A. Verify cartridge handling		
	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	C. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code then		
	run a new cartridge on the analyzer		
	Resolution		
	IF the code 41 is resolved after running the ceramic THEN the incident is resolved		
	conditioning cartridge	Classification is Complaint 1	
	IF the code 41 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 41 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT	Ask customer if cartridges are available to be returned for	
	analyzers	investigation and document request(s)	
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Complaint	Description		
Code 42	Analyzer detected material on the sensors before it should have	/e	
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What is analyzer serial number(s)?		
– Use Another	2. How many code 42 have occurred?		
Cartridge	3. What cartridge lot number(s)/box number(s) has the code	e 42 been occurring?	
	4. What is being tested on the cartridge - QC material or pat	ient samples?	
RW Code:	 a. If code occurred while testing QC material, what 	t is the QC material lot number(s)?	
C1142	5. How are the cartridges handled?		
	 Did user press on the calibrant pack in the center 	er of the cartridge?	
Synonyms: N/A	 Did the user insert and test a previously used ca 	irtridge?	
	6. How are the cartridges stored?		
	a. Have the cartridges been frozen?		
	Troubleshooting		
	A. Verify the user is not pressing on the calibrant pouch of the	ne cartridge	
	B. Verify the cartridges have not been frozen		
	C. Verify the user is not testing a previously used cartridge		
	D. Run a new cartridge from the same cartridge lot number and box		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	Pacelution		
	Resolution	THEN the incident is resolved	
	artridges	Classification is Complete 1	
	Califinges	Classification is complaint 1 TUEN the suspect sectridge let(s) should be investigated	
	IF the code 42 is persistent on multiple I-STAT analyzers after troublesheating but only on specific cartridge let(s) AND	THEN the suspect calthoge lot(s) should be investigated	
	other cartridge lot(s) run without issue on the same i STAT	• Classification is complaint 2	
	other cartridge lot(s) run without issue on the same i-st Al		
		Ask customer in calcinges are available to be returned for	
		Investigation and document request(s)	
	IF the code 42 is persistent on specific I-STAT analyzer AND	IHEN the I-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
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Complaint	Description		
Code 43	Sensor reading out of specification		
	Prompts for Meaningful Data Collection		
Cartridge Error –	 What is analyzer serial number(s)? 		
Use Another	2. How many code 43 have occurred?		
Cartridge	3. What cartridge lot number(s)/box number(s) has the code 43 been occurring?		
	4. What is being tested on the cartridge - QC material or pati	ent samples?	
RW Code: C1143	5. If code occurred while testing QC material, what is the QC material lot number(s)?		
	6. How is the cartridge being handled?		
Synonyms: N/A	a. Did user press on the calibrant pack in the cente	r of the cartridge?	
	b. Did the user insert and test a previously used car	rtridge?	
	7. How are the cartridges stored?	Ū	
	a. Have the cartridges been frozen at any point?		
	Troubleshooting		
	A. Verify the user is not pressing on the calibrant pouch of th	e cartridge	
	B Verify the cartridges have not been frozen or dronned		
	C Verify the user is not testing a previously used cartridge		
	D. Run a new cartridge from the same cartridge lot and box		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	F. If code is persistent on specific analyzer, use the ceramic c	onditioning cartridge on analyzer experiencing the code	
	then run a new cartridge on the analyzer	<u> </u>	
	Resolution		
	IF the code 43 is due to improper storage or handling of the	THEN the incident is resolved	
	cartridges and a new cartridge is tested successfully	Classification is Complaint 1	
	Is after running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge the code 42 is resolved	Classification is Complaint 1	
	If the ends 42 is persistent on specific i STAT analyzer AND	Classification is Complaint 1 THEN the i CTAT analyzer should be replaced or repaired	
	IF the code 43 is persistent on specific I-STAT analyzer AND		
	those same cartridge lot(s) run without issue on the other i- STAT analyzers		
	IF the code 43 is persistent on multiple I-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same I-STAT		
	analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	

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Complaint	Description		
Code 44	The analyzer did not detect movement of sample across the sensors.		
	Note: Code 44 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only		
Unable to Position	Prompts for Meaningful Data Collection		
Sample – Use	1. What cartridge lot number(s)/box number(s) has the code	44 been occurring?	
Another Cartridge	2. How many code 44 have occurred?		
	3. What is analyzer serial number(s)?		
RW Code: C1244	4. What is being tested on the cartridge - QC material or pati	ent samples?	
	a. If code occurred while testing QC material, what	is the QC material lot number(s)?	
Answer pRE	5. How is the cartridge being handled?		
Questions!	a. Was the cartridge closed properly?		
Current NI/A	6. How is the patient sample being collected and handled?		
Synonyms: N/A	a. Is only one patient sample giving the code or mu	Itiple patients?	
	b. What is the sample type tested?		
	 c. How is the sample collected? d. What is time duration from comple collection to 	tasting on the contridge?	
	u. What is time duration from sample collection to	testing on the carthoger	
	7. In multiple codes occurred on ACT callinge.		
	b Did ACT cartridge produce a result?		
	i If yes what was result?		
	ii If no was sample tested on a different	instrument? What instrument and what was result?	
	c. Was patient being administered heparin?		
	Troubleshooting		
	A. Verify the cartridge is properly closed		
	B. Verify the patient sample type tested, sample collection ar	nd handling procedure	
	C. If code occurred with ACT cartridge, confirm patient was administered heparin.		
	1. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants		
	2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add <u>C1066</u>)		
	D. Run a new cartridge from the same cartridge lot number a	nd box	
	E. If code is persistent on a specific cartridge lot number, det	ermine and document code rate for the specific cartridge	
	lot number or box number		
	F. Verify times of codes, whether result was produced on i-S	TAT cartridge or alternate testing method.	
	Resolution		
	IF the code 44 is due to improper cartridge or sample	THEN the incident is resolved	
	handling and a new cartridge is tested successfully	Classification is Complaint 1	
	IF the code 44 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	
	IF the code 44 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge and QC lot(s) should be	
	troubleshooting but only on specific cartridge lot(s) AND	investigated	
	specific QC material lot(s). Other cartridge lots and other QC	Classification is Complaint 2	
	material lot(s) run without issue on the same I-STAT analyzers		
		Ask customer if cartridges and QC material are available	
		to be returned for investigation and document	
		request(s)	
	IF the code 44 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		

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Complaint	Description		
Code 45	Calibrant material was seen at an incorrect time in the testing sequence or the cartridges being run are not yet at room		
	temperature		
Cartridge Error –	Note: Code 45 is specific to 6+, CHEM8+, CG4+, CG8+, Crea,	E3+, EC4+, EC8+, EG6+, EG7+, G, G3+ cartridges	
Use Another	Prompts for Meaningful Data Collection		
Cartridge	1. What is analyzer serial number(s)?		
	2. How many code 45 have occurred?		
RW Code: C1245	3. What cartridge lot number(s)/box number(s) has the co	de 45 been occurring?	
	4. How long are cartridges allowed to equilibrate to room	temperature prior to testing?	
Synonyms: N/A	Troubleshooting		
	A. Verify the cartridges are being equilibrated to room temperature prior to testing		
	B. Run a new cartridge		
	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Note: if the code 45 occurs twice within 20 runs, then code 55 will occur and testing will be disabled		
	Resolution		
	IF the code 45 is due to improper cartridge handling and	THEN the incident is resolved	
	new cartridge tests successfully	Classification is Complaint 1	
	IF the code 45 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers Ask customer if cartridges are available to be returned		
		for investigation and document request(s)	
	IF the code 45 occurs again, resulting in a code 55	THEN the i-STAT analyzer should be replaced or repaired	
	Classification is Repair		
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Complaint	Description		
Code 46	Cartridge Error		
	Note: Code 46 occurs with coagulation (ACTc, ACTk, PT/INR) cartridges only		
Cartridge Error -	Prompts for Meaningful Data Collection		
Use Another	1. What cartridge lot number(s)/box number(s) has the code	e 46 been occurring?	
Cartridge	2. How many code 46 have occurred?		
	3. What is analyzer serial number(s)?		
RW Code: C1146	4. What is being tested on the cartridge - QC material or pat	ient samples?	
	a. If code occurred while testing QC material, wha	t is the QC material lot number(s)?	
Answer pRE	5. How is the cartridge being handled?		
Questions!	a. Was the cartridge closed properly?		
	6. How is the patient sample being collected and handled?		
Synonyms: N/A	a. Is only one patient sample giving the code or m	ultiple patients?	
	b. What is the sample type tested?		
	c. How is the sample collected?		
	d. What is the time duration from sample collection	on to testing on the cartridge?	
	7. If multiple codes occurred while testing ACT cartridge:		
	a. What are the times the code occurred?		
	b. Did ACT cartridge produce a result?		
	i. If yes, what was result?		
	ii. If no, was sample tested on a differen	t instrument? What instrument and what was result?	
	c. Was patient being administered heparin?		
	Troubleshooting		
	A. Verify that the cartridge is properly closed		
	B. Verify the sample type tested and patient sample collection	on and handling procedure	
	C. If code occurred with ACT cartridge, confirm patient was	administered neparin.	
	1. I-STAT ACT lest monitors neparin, not angiornal	so customer of intended use per CTI/IELI (add C1066)	
	2. If using Act callinge for any other reason, aux	id how	
	E If code is persistent on a specific cartridge lot number de	termine and document code rate for the specific cartridge lot	
	number or box number	termine and document code rate for the specific carthage for	
	F. Verify times of codes, whether result was produced on i-S	TAT cartridge or alternate testing method	
	Resolution		
	IF the code 46 is due to improper cartridge or sample	THEN the incident is resolved	
	handling and new cartridge tests successfully	Classification is Complaint 1	
	IF the code 46 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 46 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge and QC lot(s) should be	
	troubleshooting but only on specific cartridge lot(s) AND	investigated	
	specific QC material lot(s). Other cartridge lots and other QC	Classification is Complaint 2	
	material lot(s) run without issue on the same I-STAT		
	analyzers	Ask customer if cartridges and QC material are available	
		to be returned for investigation and document request(s)	
	IF the code 46 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
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Complaint	Description		
Code 47	Cartridge or external electronic simulator not inserted properly		
	Prompts for Meaningful Data Collection		
Cartridge Not	1. Is a cartridge or external simulator being tested at the	time of code 47?	
Inserted Properly	2. What is analyzer serial number(s)?		
– Reinsert	3. What cartridge type/lot number has the code 47 been	occurring?	
Cartridge	4. What is external simulator serial number?		
	a. Is the blue cap on the external simulator imp	eding proper insertion of the simulator?	
RW Code: C1147	Troubleshooting		
	A. Run a cartridge or external simulator by inserting straig	th into the analyzer until it clicks into place	
Synonyms: N/A	B. If code is occurring while testing external simulator:		
	1. Ensure that the blue cap on the simulator is not impeding proper insertion; remove blue cap if necessary		
	2. Rerun the same external simulator on a different i-STAT analyzer, or run a different external simulator on		
	the same i-STAT analyzer		
	C. Run a new cartridge to see if the issue persists		
	Resolution		
	IF the code 47 is due to improper insertion of the	THEN the incident is resolved	
	cartridge and a new cartridge is tested successfully after	 Classification is Complaint 1 	
	troubleshooting		
	IF the code 47 is resolved after re-testing the external	THEN the incident is resolved	
	simulator	Classification is Complaint 1	
	IF the code 47 is persistent on multiple i-STAT analyzers	THEN the external simulator should be replaced	
	after troubleshooting with a single external simulator	Classification is Repair	
	IF the code 47 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	after troubleshooting	Classification is Repair	

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Complaint	Description		
Code 48	The analyzer connector pins contacted the cartridge or external simulator sensors too soon, may be due to fiber		
	contamination		
Analyzer Error –	Prompts for Meaningful Data Collection		
See Manual	1. What is analyzer serial number(s)?		
	2. How many code 48 have occurred?		
RW Code: C2048	3. Is the code 48 occurring during cartridge or simulator te	sting?	
	a. Is the cartridge or simulator being inserted str	aight into the analyzer?	
Synonyms: N/A	4. What cartridge type/lot number(s) has the code 48 beer	n occurring?	
	5. What is simulator serial number?		
	Troubleshooting		
	A. Verify that the cartridge or external simulator are being inserted straight into analyzer		
	B. Run the contact pin cleaning kit on analyzer experiencing code 48		
	C. Run the external electronic simulator		
	Resolution		
	IF the code 48 is due to improper insertion of the cartridge	THEN the incident is resolved	
	or external simulator AND retest was successful	Classification is Complaint 1	
	IF running the contact pin cleaning kit and external	THEN the incident is resolved	
	simulator resolves the code 48 • Classification is Complaint 1		
	IF the code 48 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting.		
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Complaint	Description		
Code 49	Poor contact between the analyzer contact pins and cartridge		
	Prompts for Meaningful Data Collection		
Poor Contact	1. What cartridge type, lot number(s)/box number(s) has	the code 49 been occurring?	
Detected – See	2. What is analyzer serial number(s)?		
Manual	3. How many code 49 have occurred?		
	4. What is being tested on the cartridge - QC material or	patient samples?	
RW Code: C2049	a. If code occurred while testing QC material, w	hat is the QC material lot number(s)?	
	Troubleshooting		
Synonyms: N/A	A. If code is persistent on a specific cartridge lot number,	determine and document code rate for the specific	
	cartridge lot number or box number		
	B. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	C. Run a new cartridge		
	Resolution		
	IF running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge resolves the code 49	Classification is Complaint 1	
	IF the code 49 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers		
	IF the code 49 is persistent on multiple i-STAT analyzers THEN the suspect cartridge lot(s) should be investigated		
	after troubleshooting but only on specific cartridge lot(s) • Classification is Complaint 2		
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	

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Complaint	Description		
Code 50	Poor connection between the cartridge and i-STAT analyzer		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What cartridge type/lot number(s)/box number(s) has the code 50 been occurring?		
Use Electronic	2. How many code 50 have occurred?		
Simulator	3. What is analyzer serial number(s)?		
	a. What is battery voltage?		
RW Code: C2050	4. What is tested on the cartridge - QC material or patient samples?		
	a. If code occurred while testing QC material, what is the QC material lot number(s)?		
Synonyms: N/A	b. How is the QC material handled?		
	5. If code occurred while testing immunoassay (cTnI, CK-MB, BNP, β-hCG) cartridges		
	a. How is the patient sample collected?		
	b. What sample type (whole blood, plasma) is tested?		
	c. What is the elevation of the testing site? (i.e. customer is in CO, UT, AB, Peru)?		
	Troubleshooting		
	A. Verify the cartridge type tested		
	B. If the code occurs while testing non-immunoassay cartridges on a specific i-STAT Analyzer		
	1. Check the battery voltage		
	2. Run the external electronic simulator		
	3. Run a new cartridge		
	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	D. If the code 50 occurs when testing immunoassay cartridges on a specific i-STAT Analyzer		
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1. If code is pe	ersistent on a specific cartridge lot nu	umber, determir	he and document code rate for the specific
cartridge lo	ot number or box number		
2. Verify sam	ole type tested, sample collection and	d handling proce	edure (sample bubbles may cause code),
document	testing elevation if applicable		
3. If code is pe	ersistent on specific analyzer, use the	e <u>ceramic condit</u>	ioning cartridge on analyzer experiencing the
code then r	run a new cartridge on the analyzer		
Note: Codes 50, <u>126</u> and	<u>128</u> are sometimes related to electric	cal connection.	If multiple occurrences in a short period of
time of these 3 codes (50,	126, and 128) on specific analyzer se	erial number, an	alyzer requires replacement.
Resolution			
IF after testing external sin	mulator, a non-immunoassay	THEN the incid	dent is resolved
cartridge is tested success	ifully on the analyzer	Classification is Complaint 1	
IF the code 50 is persistent on specific i-STAT analyzer when testing <u>non-immunoassay</u> cartridge lot(s) AND those same		THEN the I-STAT analyzer should be replaced or repaired	
analyzers	analyzers		
IF running the ceramic cor	nditioning cartridge resolves the	THEN the incident is resolved	
code 50 when testing imm	nunoassay cartridges	Class	sification is Complaint 1
IF the code 50 is due to im	proper cartridge or sample	THEN the incid	dent is resolved
handling through troubles	hooting and additional cartridges	Class	sification is Complaint 1
were tested successfully			
IF the code 50 is persisten	t on multiple i-STAT analyzers only	THEN the susp	ect cartridge lot(s) should be investigated
on specific cartridge lot(s)	after troubleshooting AND other	Class	sification is Complaint 2
cartridge lot(s) run withou	It issue on the same I-STAT		
analyzers		Ask customer	If cartridges are available to be returned for
IE the code 50 is persisten	t on multiple i-STAT analyzers after	THEN the sush	pect cartridge lot(s) and OC material lot(s)
troubleshooting but only	on specific cartridge lot(s) AND	should be inve	estigated
specific QC material lot(s).	. Other cartridge lots and other QC	Class	sification is Complaint 2
material lot(s) run withou	t issue on the same i-STAT		
analyzers		Ask customer if cartridges and QC material are available	
		to be returned	for investigation and document request(s)
IF running the ceramic cor	nditioning cartridge on a specific	THEN the i-ST	AT analyzer should be replaced or repaired
analyzer does not resolves	s the code 50 when testing	Class	sification is Repair
<u>immunoassay</u> cartridges			
IF code 50 is occurring wit	h codes 126 and 128 when testing	THEN the i-ST	AT analyzer should be replaced or repaired
immunoassay cartridges o	on a specific analyzer and	Class	sification is Repair
troubleshooting does not	resolve		

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Complaint	Description	
Code 51	The motor moved for too long; may be due to a low battery.	
	For coagulation (ACTc, ACTk, PT/INR) cartridges this code may be due to an inability to position sample.	
Analyzer Error –	Prompts for Meaningful Data Collection	
Use Electronic	1. What cartridge type and lot number(s) has the code 51 beer	n occurring?
Simulator	2. How many code 51 have occurred?	
	3. What is tested on the cartridge - QC material or patient sam	nples?
RW Code: C2051	a. If code occurred while testing QC material, what is	is the QC material lot number(s)?
	4. What is analyzer serial number(s)?	
Synonyms: N/A	5. If code is occurring on specific analyzer, what is battery voltage on the analyzer?	
	Troubleshooting	
	A. If code is occurring on specific analyzer, check the battery ve	oltage; replace or recharge batteries if low voltage
	B. Run the external electronic simulator; if the simulator passes, test a new cartridge	
	C. If code is occurring on coagulation cartridges, review sample/QC material handling and filling.	
	1. Test a new cartridge from the same lot number and box	
	D. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge	
	lot number or box number	
	Resolution	
	IF the code 51 is resolved after testing the external T	THEN the incident is resolved
	simulator and new cartridge successfully on the analyzer	Classification is Complaint 1
	IF the code 51 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired
	those same cartridge lot(s) run without issue on the other i- • Classification is Repair	
	STAT analyzers	
	IF the code 51 is persistent on multiple i-STAT analyzers T	THEN the suspect cartridge lot(s) should be investigated
	after troubleshooting but only on specific cartridge lot(s) • Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	
	STAT analyzers	Ask customer if cartridges are available to be returned
	f	for investigation and document request(s)

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Complaint	Description		
Code 52	The motor stalled while moving; may be due to a low battery.		
	For coagulation (ACTc, ACTk, PT/INR) cartridges, this code may be due to an inability to position sample.		
Analyzer Error –	Prompts for Meaningful Data Collection		
Use Electronic	1. What cartridge type and lot number(s) has the code 52 beer	n occurring?	
Simulator	2. How many code 52 have occurred?		
	3. What is tested on the cartridge - QC material or patient sam	nples?	
RW Code: C2052	a. If code occurred while testing QC material, what is	s the QC material lot number(s)?	
	4. What is analyzer serial number(s)?		
Synonyms: N/A	5. If code is occurring on a specific analyzer		
	a. What is the type of battery used in the analyzer?		
	b. What is the battery voltage?		
	c. If 9-volt lithium, what is the color of the battery ca	arrier (i.e. red/green)?	
	d. If I-STAT rechargeable, what is the Born-on-Date (I	BOD)?	
	e. Is the cartridge or simulator being inserted straigh	nt into the analyzer?	
	Troubleshooting		
	A. If code is occurring on a specific analyzer		
	1. Verify that the cartridge or external simulator is being inserted straight into the analyzer		
	2. Check the battery voltage; replace or recharge batteries if low voltage		
	3. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
	B. If code is occurring on coagulation callinges, review sample	er QC material nationing and cartilities mining	
	1. Test a new callinge from the same callinge for the	rmine and document code rate for the specific cartridge	
	c. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	Besolution		
	IF the code 52 is resolved by testing the external simulator T	THEN the incident is resolved	
	and cartridge successfully on specific analyzer	Classification is Complaint 1	
	IF the code 52 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired	
	those same cartridge lot(s) run without issue on the other i-	Classification is Repair	
	STAT analyzers		
	IF the code 52 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	•	
	STAT analyzers	Ask customer if cartridges are available to be returned	
	f	or investigation and document request(s)	

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Complaint	Description	
Code 53	Software installed is incompatible with the revision of the i-STAT analyzer.	
	Prompts for Meaningful Data Collection	
Analyzer Error – See	1. What is analyzer serial number(s)?	
Manual	2. What CLEW/JAMS software version is currently installed on the impacted analyzer(s)?	
	Troubleshooting	
RW Code: C2053	A. Verify that the CLEW/JAMS software version is up to date	
	B. Install the current software (if applicable)	
Synonyms: N/A	Resolution	
	IF the code 53 is resolved after installing the current	THEN the incident can be closed
	software version	Classification is Complaint 1
	IF the code 53 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
	after the current software version has been installed	Classification is Repair
	successfully	

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Description	
i-STAT analyzer error	
Prompts for Meaningful Data Collection	
1. What is analyzer serial number(s)?	
2. What is battery voltage?	
Troubleshooting	
A. Check the battery voltage; replace or recharge batteries if lo	ow voltage
B. Run the external electronic simulator; if the simulator passes, the analyzer can be used	
Resolution	
IF the code 54 is resolved after testing the external simulator T	THEN the incident is resolved
successfully on the analyzer	Classification is Complaint 1
IF the code 54 is persistent on specific i-STAT analyzer after T	THEN the i-STAT analyzer should be replaced or repaired
running the electronic simulator	Classification is Repair
	Description i-STAT analyzer error Prompts for Meaningful Data Collection 1. What is analyzer serial number(s)? 2. What is battery voltage? Troubleshooting A. Check the battery voltage; replace or recharge batteries if lo B. Run the external electronic simulator; if the simulator passe Resolution IF the code 54 is resolved after testing the external simulator successfully on the analyzer IF the code 54 is persistent on specific i-STAT analyzer after running the electronic simulator

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Complaint	Description	
Code 55	Analyzer error, analyzer will not recover	
	Note: Code 55 is specific to 6+, CHEM8+, CG4+, CG8+, Crea, E3+, EC4+, EC8+, EG6+, EG7+, G, G3+ cartridges	
Analyzer Error –	Prompts for Meaningful Data Collection	
See Manual	1. What cartridge type/lot number has the code 55 been occurring on?	
	2. Is this a new lot number or has it been in use prior to code 55?	
RW Code: C2055	3. When did code 55 appear on the analyzer?	
	4. What was being testing on the analyzer when code 55 occurred?	
Synonyms: N/A	5. Did code 45 occur previously on analyzer?	
	6. How long are cartridges allowed to equilibrate to room temperature prior to testing?	
	7. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Verify cartridges are equilibrated to room temperature prior to testing	
	B. Check data review in analyzer to verify the number of <u>code 45</u> within the last 20 cartridge tests	
	C. Replace or repair analyzer	
	Resolution	
	IF the code 55 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired	
	Classification is Repair	

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Complaint	Description		
Code 56	i-STAT analyzer detects noise on the thermal circuit		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. Where in the facility is analyzer being used for testing?		
	a. Is the analyzer being used in a different location	n than it is typically used in?	
RW Code: C2056	Troubleshooting		
	A. Move the analyzer to a different location in the facility, away from potential sources of electronic interference		
Synonyms: N/A	B. Allow the analyzer to sit in the new environment for some time for the code to be resolved		
	Resolution		
	IF code 56 is due to location and electronic interference and	THEN the incident is resolved	
	is resolved after troubleshooting	Classification is Complaint 1	
	IF the code 56 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
		Classification is Repair	

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Complaint	Description		
Code 57	Failure to make proper pin connection inside the analyzer, may	Failure to make proper pin connection inside the analyzer, may be caused by fiber contamination	
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. How many code 57 have occurred?		
	3. What cartridge type/lot number(s)/ has the code 57 been of	occurring on?	
RW Code: C2057	Troubleshooting		
	A. Run the contact pin cleaning kit on any i-STAT analyzer gen	erating code 57	
Synonyms: N/A	B. Run the external electronic simulator to see if the issue persists		
	Resolution		
	IF running the contact pin cleaning kit and external simulator	THEN the incident is resolved	
	resolves the code 57	Classification is Complaint 1	
	IF the code 57 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting.	Classification is Repair	
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Complaint	Description		
Code 58	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
Use Electronic	2. What is the battery voltage on the analyzer?		
Simulator	Troubleshooting		
	A. Check the battery voltage; replace or recharge batteries if low voltage		
RW Code: C2058	B. Run the external electronic simulator; if the simulator passes, the analyzer can be used		
	Resolution		
Synonyms: N/A	IF after running the electronic simulator the code 58 is not THEN the incident is resolved		
	reproducible on the analyzer • Classification is Complaint 1		
	IF the code 58 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting		

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Complaint	Description		
Code 59	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
Use Electronic	2. What is the battery voltage on the analyzer?		
Simulator	Troubleshooting		
	A. Check the battery voltage; replace or recharge batteries if low voltage		
RW Code: C2059	B. Run the external electronic simulator; if the simulator passes, the analyzer can be used		
	C. Run a new cartridge to see if the issue persists		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the THEN the incident is resolved		
	code 59 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 59 is persistent on specific i-STAT analyzer after THEN the i-STAT analyzer should be replaced or repaired		
	troubleshooting		

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Complaint	Description	
Code 60	Analyzer error	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
Use Electronic	2. What is the battery voltage on the analyzer?	
Simulator	Troubleshooting	
	 A. Check the battery voltage; replace or recharge batteries if low voltage B. Run the external electronic simulator; if the simulator passes, the analyzer can be used 	
RW Code: C2060		
	C. Run a new cartridge to see if the issue persists	
Synonyms: N/A	Resolution	
	IF after running the electronic simulator and cartridge the	THEN the incident is resolved
	code 60 is not reproducible on the analyzer	Classification is Complaint 1
	IF the code 60 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	troubleshooting	Classification is Repair
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Complaint	Description			
Code 61	Analyzer error	Analyzer error		
	Prompts for Meaningful Data Collection			
Analyzer Error –	1. What is analyzer serial number(s)?			
Use Electronic	2. What is the battery voltage on the analyzer?			
Simulator	Troubleshooting			
	A. Check the battery voltage; replace or recharge batteries if low voltage			
RW Code: C2061	B. Run the external electronic simulator; if the simulator passes, the analyzer can be used			
	Resolution			
Synonyms: N/A	IF after running the electronic simulator the code 61 is not THEN the incident is resolved			
	reproducible on the analyzer	 Classification is Complaint 1 		
	IF the code 61 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired		
	troubleshooting	Classification is Repair		

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Complaint	Description		
Code 62	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
Use Electronic	2. What is the battery voltage on the analyzer?		
Simulator	Troubleshooting		
	A. Check the battery voltage; replace or recharge batteries if	low voltage	
RW Code: C2062	B. Run the external electronic simulator		
	C. If the simulator passed run a cartridge to verify if the code 62 persists		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the	THEN the incident is resolved	
	code 62 is not reproducible on the analyzer	Classification is Complaint 1	
	IF the code 62 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting	Classification is Repair	

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Complaint	Description	
Code 63	Analyzer error	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
See Manual	2. What is the battery voltage on the analyzer?	
	Troubleshooting	
RW Code: C2063	A. Check the battery voltage; replace or recharge batteries if low voltage	
	B. Run the external electronic simulator; if the simulator passes, the analyzer can be used	
Synonyms: N/A	Resolution	
	IF after running the electronic simulator the code 63 is not THEN the incident is resolved	
	reproducible on the analyzer • Classification is Complaint 1	
	IF the code 63 is persistent on specific i-STAT analyzer after THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting • Classification is Repair	
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Complaint	Description	
Code 64	Analyzer electronics error	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
Use Electronic	2. What is the battery voltage?	
Simulator	Troubleshooting	
	A. Check the battery voltage; replace or recharge batteries if low voltage	
RW Code: C2064	B. Run the external electronic simulator; if the simulator passes, the analyzer can be used	
	Resolution	
Synonyms: N/A	IF after running the electronic simulator the code 64 is not THEN the incident is resolved	
	reproducible on the analyzer	Classification is Complaint 1
	IF the code 64 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	troubleshooting	Classification is Repair

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Complaint	Description		
Code 65	Analyzer software error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2065	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Reinstall the current CLEW/JAMS software		
Synonyms: N/A	C. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
	Resolution		
	IF reinstalling the CLEW/JAMS software and testing the	THEN the incident is resolved	
	external simulator and cartridge resolves the code 65	Classification is Complaint 1	
	IF the code 65 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting	Classification is Repair	

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Complaint	Description	
Code 66	Analyzer thermistor is out of specification; temperature measurements cannot be made.	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
See Manual	2. What is the temperature reading on the analyzer status screen?	
	Troubleshooting	
RW Code: C2066	A. Verify the temperature reading on the Analyzer Status screen to be a valid number (not dashes)	
	B. Perform a cartridge test to verify analyzer functionality	
Synonyms: N/A	Resolution	
	IF the code 66 is not reproducible and the Analyzer Status THEN the incident is resolved	
	screen shows a valid temperature reading • Classification is Complaint 1	
	IF the analyzer status screen displays the temperature THEN the i-STAT analyzer should be replaced or repaired	
	reading as dashes () after troubleshooting and the code • Classification is Repair	
	66 persists	

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Complaint	Description		
Code 67	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2067	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the THEN the incident is resolved		
	code 67 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 67 is persistent on specific i-STAT analyzer after THEN the i-STAT analyzer should be replaced or repaired		
	troubleshooting Classification is Repair		

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Complaint	Description			
Code 68	Damaged contact pins or dirt on shorting bar			
	Prompts for Meaningful Data Collection	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?			
See Manual	2. What is battery voltage?			
	3. How many code 68 have occurred?			
RW Code: C2068	4. What cartridge type/lot number(s) has the code 68 been occurring on?			
	Troubleshooting			
Synonyms: N/A	A. Run the contact pin cleaning kit on any i-STAT analyzer generating code 68			
	B. Check the battery voltage; replace or recharge batteries if low voltage			
	C. Run the external electronic simulator to see if the issue persists			
	Resolution			
	IF running the contact pin cleaning kit and external THEN th	IF running the contact pin cleaning kit and external THEN the incident is resolved		
	simulator resolves the code 68 • Classification is Complaint 1			
	IF the code 68 is persistent on the specific i-STAT analyzer THEN the	IF the code 68 is persistent on the specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting.			

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Complaint	Description		
Code 69	The analyzer was unable to verify the cartridge type when read	ing the cartridge sensors.	
	Prompts for Meaningful Data Collection		
Cartridge Type	1. What is analyzer serial number(s)?		
Not Recognized –	2. How many code 69 have occurred?		
Use Another	3. Is a cartridge or external simulator being tested at the time	e of code 69?	
Cartridge	4. If cartridge was being tested		
	a. What is the lot number/box number?		
RW Code: C2069	b. What is the cartridge expiration date?		
	c. Was the barcode on the pouch of the cartridge te	ested scanned in response to the prompt "Scan Cartridge	
Synonyms: N/A	Lot Number"?		
	d. Is the code 69 occurring on a new cartridge type	being tested at the facility?	
	5. What CLEW/JAMS version is currently installed on the anal	yzer?	
	If external simulator was being tested		
	a. What is external simulator serial number?		
	b. Is the blue cap on external simulator impeding pr	roper insertion of simulator?	
	Troubleshooting		
	A. Verify that the cartridge tested is not expired		
	B. Verify that the user is scanning the barcode on the cartridg	e pouch that is going to be tested	
	C. Verify that the analyzer has the current CLEW/JAMS versio	n	
	D. Run a new cartridge to see if the issue persists		
	E. If code is persistent on a specific cartridge lot number, det	ermine and document code rate for the specific cartridge lot	
	number or box number		
	F. If code is persistent on specific analyzer, use the ceramic conditioning cartridge on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
	G. If code is occurring while running an external simulator		
	1. Ensure blue cap is not impeding proper insertion; remove if necessary		
	2. Rerun the same external simulator on a different i-STAT analyzer, or run a different external simulator on		
	the same I-STAT analyzer		
	Resolution		
	IF the code 69 is due to the use of an expired cartridge lot,	THEN the incident is resolved	
	older CLEW/JAMS software version or scanning incorrect	Classification is Complaint 1	
	barcode and after troubleshooting a new cartridge is tested		
	successfully		
	IF after running the ceramic conditioning cartridge the code	THEN the incident is resolved	
	69 is resolved on the specific analyzer(s)	Classification is Complaint 1	
	IF the code 69 occurs when running the external simulator	THEN the incident is resolved	
	only and is resolved by removing/adjusting the blue cap	Classification is Complaint 1	
	IF the code 69 is persistent on only specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers		
	IF the code 69 is persistent on multiple i-STAT analyzers after	THEN the external simulator should be replaced	
	troubleshooting with a single external simulator	Classification is Repair	
	IF the code 69 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned	
		for investigation and document request(s)	

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Complaint	Description			
Code 70	Analyzer error			
	Prompts for Meaningful Data Collection	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?			
See Manual	2. What is the battery voltage on the analyzer?			
	Troubleshooting			
RW Code: C2070	A. Check the battery voltage; replace or recharge batteries if low voltage			
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge			
Synonyms: N/A	Resolution			
	IF after running the electronic simulator and cartridge the code	THEN the incident is resolved		
	70 is not reproducible on the analyzer • Classification is Complaint 1			
	IF the code 70 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired		
	troubleshooting	Classification is Repair		

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Complaint	Description	
Code 72	Analyzer error	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
See Manual	2. What is the battery voltage?	
	Troubleshooting RW Code: C2072 A. Check the battery voltage; replace or recharge batteries if low voltage	
RW Code: C2072		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge	
Synonyms: N/A	Resolution	
	IF after running the electronic simulator and cartridge the	THEN the incident is resolved
	code 72 is not reproducible on the analyzer	Classification is Complaint 1
	IF the code 72 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	troubleshooting	Classification is Repair

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Complaint	Description		
Code 73	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2073	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the	THEN the incident is resolved	
	code 73 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 73 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting	Classification is Repair	

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Complaint	Description		
Code 74	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2074	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the	THEN the incident is resolved	
	code 74 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 74 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting	Classification is Repair	

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Complaint	Description	
Code 79	Bad contact between the thermal probes in the analyzer and the metallization on the back of the chips in the cartridge.	
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What is analyzer serial number(s)?	
Use Another	2. How many code 79 have occurred?	
Cartridge	3. What cartridge type/lot number(s) has the code 79 been occurring on?	
	Troubleshooting	
RW Code: C1279	A. Verify that the customer did not try to forcefully remove the cartridge or simulator while it was locked in the analyzer	
	B. Run a new cartridge	
Synonyms: N/A	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge	
	lot number or box number	
	D. If code is persistent on specific analyzer, replace the ana	lyzer
	Resolution	
	IF the code 79 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	troubleshooting on multiple cartridge lots AND those same	Classification is Repair
	cartridge lot(s) run without issue on the other i-STAT	
	analyzers	
	IF the code 79 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
	AND other cartridge lot(s) run without issue on the same i-	
	STAT analyzers	Ask customer if cartridges are available to be returned for
		investigation and document request(s)

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Complaint	Description	
Code 80	Bad contact between the thermal probes in the analyzer and the metallization on the back of the chips in the cartridge.	
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What is analyzer serial number(s)?	
Use Another	2. How many code 80 have occurred?	
Cartridge	3. What cartridge type/lot number has the code 80 been oc	curring on?
	Troubleshooting	
RW Code: C2080	A. Verify that the customer did not try to forcefully remove the cartridge or simulator while it was locked in the analyzer	
	B. Run a new cartridge	
Synonyms: N/A	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot	
	number or box number	
	D. If code is persistent on specific analyzer, replace the analyzer	
	Resolution	
	IF the code 80 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	troubleshooting on multiple cartridge lots AND those same	Classification is Repair
	cartridge lot(s) run without issue on the other i-STAT	
	analyzers	
	IF the code 80 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
	AND other cartridge lot(s) run without issue on the same i-	
	STAT analyzers	Ask customer if cartridges are available to be returned for
		investigation and document request(s)

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Complaint	Description		
Code 81	Bad contact between the thermal probes in the analyzer and the metallization on the back of the chips in the cartridge.		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What is analyzer serial number(s)?		
Use Another	2. How many code 81 have occurred?		
Cartridge	3. What cartridge type/lot number has the code 81 been o	ccurring on?	
	Troubleshooting		
RW Code: C1281	A. Verify that the customer did not try to forcefully remove the cartridge or simulator while it was locked in the analyzer		
	B. Run a new cartridge		
Synonyms: N/A	C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	D. If code is persistent on specific analyzer, replace the analyzer		
	Resolution		
	IF the code 81 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting on multiple cartridge lots AND those same	Classification is Repair	
	cartridge lot(s) run without issue on the other i-STAT		
	analyzers		
	IF the code 81 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	

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Complaint	Description	
Code 82	The two pressure transducers do not agree within specified limit.	
	Code 82 occurs when the average difference (averaged over several runs) between the two pressure transducers exceeds	
Analyzer Error –	7 mmHg.	
See Manual	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)?	
RW Code: C2082	2. What is the battery voltage on the analyzer?	
	3. What is the pressure reading?	
Synonyms: N/A	Troubleshooting	
	A. Check the battery voltage; replace or recharge batteries if low voltage	
	B. Verify pressure reading on the Analyzer Status screen	
	C. Run the external electronic simulator twice; if the simulator passes, test a new cartridge	
	Resolution	
	IF after running the electronic simulator and cartridge the THEN the incident is resolved	
	code 82 is not reproducible on the analyzer • Classification is Complaint 1	
	IF the code 82 is persistent on specific i-STAT analyzer after THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting • Classification is Repair	

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Complaint	Description	
Code 83	Underlying hardware failure in the i-STAT 1 Wireless Analyzer	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
See Manual	Troubleshooting	
	A. Replace or repair analyzer if wireless feature is required by customer	
RW Code: C3209	B. Wireless feature can be disabled on analyzer if customer would like to continue using the analyzer via wired	
	transmission	
Synonyms: N/A	Resolution	
	IF the code 83 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
	after troubleshooting	Classification is Repair
	IF wireless feature is disabled for continued use of	THEN the incident is resolved
	analyzer as non-wireless	Classification is Complaint 1

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Complaint	Description	
Code 84	Underlying hardware failure in the i-STAT 1 Wireless Analyzer	
	Prompts for Meaningful Data Collection	
Analyzer Error – See	1. What is analyzer serial number(s)?	
Manual	Troubleshooting	
	A. Replace or repair the analyzer if wireless feature is required by customer	
RW Code: C3210	B. Wireless feature can be disabled on analyzer if customer would like to continue using the analyzer via wired	
	transmission	
Synonyms: N/A	Resolution	
	IF the code 84 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
	after troubleshooting	Classification is Repair
	IF wireless feature is disabled for continued use of	THEN the incident is resolved
	analyzer as non-wireless	Classification is Complaint 1
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Code 85	Analyzer error			
	Prompts for Meaningful Data Collection	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?			
See Manual	2. What is the battery voltage?			
	Troubleshooting			
RW Code: C2085	A. Check the battery voltage; replace or recharge batteries if low voltage			
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge			
Synonyms: N/A	Resolution			
	IF after running the electronic simulator and cartridge the TH	HEN the incident is resolved		
	code 85 is not reproducible on the analyzer	Classification is Complaint 1		
	IF the code 85 is persistent on specific i-STAT analyzer after TH	HEN the i-STAT analyzer should be replaced or repaired		
	troubleshooting	Classification is Repair		

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Complaint	Description	
Code 86	Thermistor out of specification; suspect inadequate airflow	
	Prompts for Meaningful Data Collection	
Analyzer Error –	1. What is analyzer serial number(s)?	
See Manual	2. Is the analyzer stored on a downloader/recharger when	the code 86 occurs?
	3. Is the analyzer or downloader/recharger with the analyz	er close to a heat source, such as heater vents or electronic
RW Code: C2086	equipment?	
	4. What type of batteries are being used?	
Synonyms: N/A	a. If 9-volt lithium, what is the color of the batter	y carrier (i.e. red/green)?
	b. If i-STAT rechargeable, what is the Born-on-Da	te (BOD)?
	Troubleshooting	
	A. Move the analyzer (or analyzer and downloader/recharger) to an area with good ventilation that is away from any	
	potential heat sources	
	1. Allow the analyzer to equilibrate in the new area for the code 86 to be resolved (could be up to 30 mins)	
	B. If the code 86 is not resolved after equilibration, replace the battery pack or disposable batteries (if available)	
	C. Run the external electronic simulator twice; if the simulator passes, test a new cartridge	
	Resolution	
	IF moving the analyzer (or analyzer and	THEN the incident is resolved
	downloader/recharger) to an area with adequate	Classification is Complaint 1
	ventilation resolved the code 86	
	IF code 86 is resolved after switching to a different battery	THEN the incident is resolved
	(rechargeable/disposable) AND testing the external	Classification is Complaint 1
	simulator AND cartridge successfully	
	IF the code 86 is persistent on specific i-STAT analyzer after	THEN the i-STAT analyzer should be replaced or repaired
	troubleshooting	Classification is Repair

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Complaint	Description		
Code 87	Electrode reading out of specification		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What is analyzer serial number(s)?		
Use Another	2. How many code 87 have occurred?		
Cartridge	3. What cartridge lot number(s)/box number(s) has the code	e 87 occurred?	
	Troubleshooting		
RW Code: C1287	A. If code is persistent on specific analyzer, use the <u>ceramic conditioning cartridge</u> on analyzer experiencing the code		
	then run a new cartridge on the analyzer		
Synonyms: N/A	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	Resolution		
	IF after running the ceramic conditioning cartridge and new	THEN the incident is resolved	
	cartridge the code 87 is resolved	Classification is Complaint 1	
	IF the code 87 is persistent on only specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	 Classification is Repair 	
	other i-STAT analyzers		
	IF the code 87 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated	
	troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2	
	other cartridge lot(s) run without issue on the same i-STAT		
	analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	

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Complaint	Description		
Code 89	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage on the analyzer?		
	Troubleshooting		
RW Code: C2089	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the THEN the incident is resolved		
	code 89 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 89 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting • Classification is Repair		
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Complaint	Description		
Code 90	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	3. What cartridge lot number(s)/box number(s) has the code 90 occurred?		
RW Code: C2090	4. How is cartridge tested?		
	a. What testing pathway was selected (i.e. cartridge test, simulator)?		
Synonyms: N/A	Troubleshooting		
	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Review the correct cartridge and simulator pathways with the user. Testing a cartridge in the simulator pathway may		
	cause code 90		
	C. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
	Resolution		
	IF after running the electronic simulator and cartridge the THEN the incident is resolved		
	code 90 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the user confirms that the code 90 was due to selecting THEN the incident is resolved		
	the simulator pathway when running a cartridge • Classification is Complaint 1		
	IF the code 90 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting • Classification is Repair		

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Complaint	Description		
Code 91	Analyzer error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2091	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge THEN the incident is resolved		
	the code 91 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 91 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting • Classification is Repair		

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Complaint	Description		
Code 92	The two pressure transducers do not agree within specified limit.		
	Code 92 occurs when a single difference (average over several run) between the two transducers exceeds 12 mmHg.		
Analyzer Error –	Prompts for Meaningful Data Collection		
See Manual	1. What is analyzer serial number(s)?		
	2. What is the battery voltage?		
RW Code: C2092	3. What is pressure reading?		
	Troubleshooting		
Synonyms: N/A	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Verify pressure reading on analyzer status screen		
	C. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
	Resolution		
	IF after running the electronic simulator and cartridge the THEN the incident is resolved		
	code 92 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 92 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting		

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Complaint	Description		
Code 93	Power supply error		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. Was a CLEW/JAMS software update recently performed?		
	Troubleshooting		
RW Code: C2093	A. Verify if a CLEW/JAMS software update was recently performed		
	1. If the code occurred after the update was performed, then remove the batteries from the analyzer while		
Synonyms: N/A	the display is still on and then reinsert the batteries		
	B. Run the external electronic simulator		
	Resolution		
	IF after reseating batteries and running the electronic THEN the incident is resolved		
	simulator the code 93 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 93 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting		

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Complaint	Description		
Code 94	Memory allocation error; software self-test failure		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2094	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge the THEN the incident is resolved		
	code 94 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 94 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting		
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Complaint	Description		
Code 95	User did not enter required information on the analyzer before the analyzer powered down.		
	Prompts for Meaningful Data Collection		
Test Cancelled by	1. What is analyzer serial number(s)?		
Operator	2. How many code 95 errors have occurred?		
	3. What customization preference is currently loaded on the	e impacted analyzer(s)?	
RW Code: C2095	a. Are there any fields in the relevant preferences	set as "mandatory"?	
	b. Does customer still want these fields to be set a	as mandatory?	
Synonyms: N/A	4. Does customer use a data management system/program	(DMS)?	
	Troubleshooting		
	A. Verify the customization preferences being used on the ir	mpacted analyzer(s)	
	B. Verify in the customization workspace or in the analyzer of	customization if any fields such as sample type, patient	
	temperature, FIO2 etc. on the chart page or STATNotes (c	customized in DMS only) have been set to be "mandatory".	
	If the customer has mandatory data fields set in the chart page or STATNotes, does customer still want to use these		
	If customer does not use data management system (DMS	S) reset analyzer to factory default settings then test a	
	c. In customer does not use data management system (Divis), reset analyzer to factory default settings, then test a		
	D. Educate the customer that the user must enter all mandatory information on the chart page or via STATNotes before		
	the analyzer powers off (through inactivity or otherwise) to avoid a code 95		
	Note: There are variable inactivity timeouts that occur with mandatory fields as well as potential impact from the		
	STATNotes feature		
	E. Verify the DMS customization settings for Cartridge Patient Test options are checked:		
	1. Require Information Before Running Cartridge		
	 Scan Cartridge Barcode Run a cartridge to determine if the code 95 persists 		
	Important Note: Code OF can also ecour if the user does not so	a the mandatony promote such as notions ID on the analyzer	
	hefore a cartridge test: reset analyzer to factory default setting	e the munuatory prompts such as patient 10 on the analyzer	
	Resolution	gs, then test a curthage to verify code resolution.	
	IF it is determined that the code 95 was due to user not	THEN the incident is resolved	
	entering mandatory information before power down and	Classification is Complaint 1	
	after troubleshooting a new cartridge was tested		
	successfully		
	IF it is determined that the code 95 was due to incorrect	THEN the incident is resolved	
	customization setting and after troubleshooting a new	Classification is Complaint 1	
	cartridge was tested successfully		
	IF the code 95 is persistent on only specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	that are confirmed to have the correct preference AND all	Classification is Repair	
	other analyzers are functioning as expected with the same		
	preference		

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Complaint	Description		
Code 96	Electronic failure		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2096	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge THEN the incident is resolved		
	the code 96 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 96 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	• Classification is Repair		

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Complaint	Description		
Code 97	Electronic failure		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	2. What is the battery voltage?		
	Troubleshooting		
RW Code: C2097	A. Check the battery voltage; replace or recharge batteries if low voltage		
	B. Run the external electronic simulator twice; if the simulator passes, test a new cartridge		
Synonyms: N/A	Resolution		
	IF after running the electronic simulator and cartridge THEN the incident is resolved		
	the code 97 is not reproducible on the analyzer • Classification is Complaint 1		
	IF the code 97 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	after troubleshooting • Classification is Repair		
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Complaint	Description		
Code 120	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has	the code 120 been occurring?	
Use Another	2. How many code 120 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patien	it sample?	
	4. If code occurred while testing QC material, what is the	QC material lot number(s)?	
RW Code: C2120	5. What is analyzer serial number(s)?		
	6. What is the elevation of the testing site? (i.e. testing or	ccurred in CO, UT, AB)?	
Answer pRE	Troubleshooting		
Questions!	A. Run a new cartridge		
	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
Synonyms: N/A	lot number or box number		
	C. Document testing elevation when applicable		
	Resolution		
	IF after running additional cartridges the code 120 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 120 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 120 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s)	investigated	
	and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2	
	and other QC material lot(s) run without issue on the		
	same i-STAT analyzers Ask customer if cartridges and QC material are available to		
	be returned for investigation and document request(s)		
	IF the code 120 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on	Classification is Repair	
	other i-STAT analyzers		
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Complaint	Description		
Code 121	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has t	he code 121 been occurring?	
Use Another	2. How many code 121 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?	
	4. If code occurred while testing QC material, what is the C	QC material lot number(s)?	
RW Code: C2121	5. What is analyzer serial number(s)?		
	Troubleshooting		
Answer pRE	A. Run a new cartridge		
Questions!	B. If code is persistent on a specific cartridge lot number, d	etermine and document code rate for the specific cartridge lot	
	number or box number		
Current AL/A	Resolution		
Synonyms: N/A	IF after running additional cartridges the code 121 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 121 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 121 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s)	investigated	
	AND specific QC material lot(s). Other cartridge lots and	Classification is Complaint 2	
	other QC material lot(s) run without issue on the same i-		
STAT analyzers Ask customer if cartridges and QC material and		Ask customer if cartridges and QC material are available to	
	be returned for investigation and document request(s)		
	IF the code 121 is persistent on only specific i-STAT	THEN the i-STAT analyzer should be replaced or repaired	
	analyzer AND those same cartridge lot(s) run without issue	Classification is Repair	
	on other i-STAT analyzers		

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Complaint	Description		
Code 122	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has t	he code 122 been occurring?	
Use Another	2. How many code 122 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?	
	4. If code occurred while testing QC material, what is the C	C material lot number(s)?	
RW Code: C2122	5. What is analyzer serial number(s)?		
	Troubleshooting		
Answer pRE	A. Run a new cartridge		
Questions!	B. If code is persistent on a specific cartridge lot number, d	etermine and document code rate for the specific cartridge	
	lot number or box number		
Current AL/A	Resolution		
Synonyms: N/A	IF after running additional cartridges the code 122 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 122 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	 Classification is Complaint 2 	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 122 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should	
	after troubleshooting but only on specific cartridge lot(s)	be investigated	
	AND specific QC material lot(s). Other cartridge lots and	Classification is Complaint 2	
	other QC material lot(s) run without issue on the same i- STAT analyzers Ask customer if cartridges and QC material are available to be returned for investigation and document request		
	IF the code 122 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on other	Classification is Repair	
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Complaint	Description			
Code 123	Reagent compromised with immunoassay (cTnl, BNP, CK-MB	and β-hCG) cartridges		
	Prompts for Meaningful Data Collection			
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the	1. What cartridge type, lot number(s)/box number(s) has the code 123 been occurring?		
Use Another	2. How many code 123 have occurred?			
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?		
	4. If code occurred while testing QC material, what is the QC material lot number(s)?			
RW Code: C2123	5. What is the storage temperature for the cartridges?			
	6. How are cartridges handled?			
Answer pRE	a. Are cartridges closed completely before testing	g?		
Questions!	b. Is there any damage to cartridge pouch?			
	7. What is analyzer serial number(s)?			
Synonyms: N/A	8. What is the elevation of the testing site? (i.e. in CO, UT,	AB)?		
	Troubleshooting			
	A. Verify cartridge is closed properly			
	B. Verify the cartridge pouch is not damaged			
	C. Verify the storage temperature for the cartridges is not t	too high		
	D. Run a new cartridge	D. Run a new cartridge		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot			
	number or box number			
	F. Document testing elevation when applicable			
	IF after running additional cartridges the code 123 is not THEN the incident is resolved			
	IF after running additional cartridges the code 123 is not	THEN the incident is resolved		
	Feproducible on a specific analyzer • Classification is Complaint 1 Figure 4.22 is confirmed to be due to improve and the incident is reached.			
	IF the code 123 is confirmed to be due to improper	THEN the incident is resolved		
	cartridge handling AND additional cartridge(s) tested	• Classification is Complaint 1		
	IF the code 123 is persistent on multiple I-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated		
	AND other cartridge lot(s) run without issue on the same i	Classification is Complaint 2		
	STAT analyzors	Ask sustamor if cartridges are available to be returned for		
	STAT analyzers Ask customer if cartridges are available to be returned for			
	IF the code 123 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and OC lot(s) should be		
	after troubleshooting but only on specific cartridge lot(s)	investigated		
	AND specific OC material lot(s). Other cartridge lots and	Classification is Complaint 2		
	other OC material lot(s) run without issue on the same i-	Classification is complaint 2		
	STAT analyzers			
		Ask customer if cartridges and QC material are available to		
		be returned for investigation and document request(s)		
	IF the code 123 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired		
	AND those same cartridge lot(s) run without issue on other	Classification is Repair		
	i-STAT analyzers			

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Complaint	Description		
Code 124	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 124 been occurring?		
Use Another	2. How many code 124 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material, what is the QC material lot number(s)?		
RW Code: C2124	5. What is analyzer serial number(s)?		
	Troubleshooting		
Answer pRE	A. Run a new cartridge		
Questions!	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartrid		
	lot number or box number		
Synonyms: N/A	Resolution		
	IF after running additional cartridges the code 124 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 124 is persistent on multiple i-STAT analyzer(s)	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 124 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s)	investigated	
	and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2	
	and other QC material lot(s) run without issue on the		
	same i-STAT analyzers	Ask customer if cartridges and QC material are available to	
		be returned for investigation and document request(s)	
	IF the code 124 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on	Classification is Repair	
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Complaint	Description			
Code 125	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges			
	Prompts for Meaningful Data Collection			
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 125 been occurring?			
Use Another	2. How many code 125 have occurred?			
Cartridge	3. What is tested on the cartridge – QC material or patient sample?			
	4. If code occurred while testing QC material, what is the QC material lot number(s)?			
RW Code: C2125	5. What is analyzer serial number(s)?			
	Troubleshooting			
Answer pRE	A. Run a new cartridge			
Questions!	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot			
	number or box number			
Synonyms: N/A	Resolution			
	IF after running additional cartridges the code 125 is not	THEN the incident is resolved		
	reproducible on a specific analyzer	Classification is Complaint 1		
	IF the code 125 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated		
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2		
	AND other cartridge lot(s) run without issue on the same i-			
	STAT analyzers	Ask customer if cartridges are available to be returned for		
		investigation and document request(s)		
	IF the code 125 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should		
	after troubleshooting but only on specific cartridge lot(s) and	be investigated		
	specific QC material lot(s) AND other cartridge lots and other	Classification is Complaint 2		
	QC material lot(s) run without issue on the same i-STAT			
	analyzers	Ask customer if cartridges and QC material are available		
		to be returned for investigation and document request(s)		
	IF the code 125 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired		
	those same cartridge lot(s) run without issue on other i-STAT	Classification is Repair		
	analyzers			
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Complaint	Description	
Code 126	Cartridge error or poor connection between analyzer and imr	nunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the	ne code 126 been occurring?
Use Another	How many code 126 have occurred?	
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?
	4. If code occurred while testing QC material	
RW Code: C2126	a. What is lot number(s)?	
	b. How is QC material stored?	
Answer pRE	c. How is QC material testing performed?	
Questions!	If code occurred while testing patient sample:	
	 Is only one patient sample giving the code or n 	nultiple patients?
Svnonvms: N/A	b. What is the sample type tested (whole blood of the sample type tested)	or plasma)?
-, -, -,	c. How is the sample collected?	
	d. What is time duration from sample collection t	to testing on the cartridge?
	6. What is analyzer serial number(s)?	
	7. What is the elevation of the testing site? (i.e. in CO, UT,	AB)?
	Troubleshooting	
	A. If code 126 is on QC material, verify proper storage, han	dling, and testing of the QC material
	 Test a new cartridge with fresh QC material 	
	B. Verify the patient sample type tested, sample collection	and handling procedure
	 Test a fresh sample on a new cartridge from the 	e same cartridge lot number and box
	C. If code is persistent on a specific cartridge lot number, d	etermine and document code rate for the specific cartridge
	lot number or box number	
	D. Document testing site elevation when applicable	
	E. If code is persistent on specific analyzer, use the <u>ceramic</u>	c conditioning cartridge on analyzer experiencing the code
	then run a new cartridge on the analyzer	
	Note: Code 50, 42C and 420 are constituted whether the	in the second
	Note: Codes $\frac{50}{50}$, 126 and $\frac{128}{126}$ are sometimes related to electric time of these 2 and 6 (50, 126 and 128) an energies and 128 are sometimes related to electric time of the second s	rical connection. If multiple occurrences in a short period of
	time of these 3 codes (50, 126 and 128) on specific analyzer's	erial number, analyzer requires replacement.
	Resolution	THEN the incident is received
	IF the code 126 is confirmed to be due to improper sample	THEN the incident is resolved
	nandling and a new cartridge is tested successfully	Classification is Complaint 1
	IF the code 126 is resolved after running the ceramic	THEN the incident is resolved
	conditioning cartridge on the specific analyzer(s)	Classification is Complaint 1
	IF the code 126 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
	AND other cartridge lot(s) run without issue on the same i-	
	STAT analyzers	Ask customer if cartridges are available to be returned for
		Investigation and document request(s)
	IF the code 126 is persistent on multiple I-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should
	after troubleshooting but only on specific cartridge lot(s)	be investigated
	and specific QC material lot(s) AND other cartridge lots and	Classification is Complaint 2
	other QC material lot(s) run without issue on the same i-	A description of the statistic second OC successful and successful data
	STAT analyzers	Ask customer if cartridges and QC material are available
	IF the code 100 is nonsistent energy official CTAT and	to be returned for investigation and document request(s)
	IF the code 126 is persistent on specific I-STAT analyzer	THEN the I-STAT analyzer should be replaced or repaired
	AND those same cartriage lot(S) run without issue on other	Classification is Repair
	I-STAT analyzers	THEN MADE CTAT and man also did to produce discussion in the
	in code 126 is occurring with codes 50 and 128 on a specific	Include I-STAT analyzer should be replaced or repaired
	analyzer and troubleshooting does not resolve	Classification is Repair
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Complaint	Description	
Code 127	Overfilled cartridge or cartridge error with immunoassay (c	nl, BNP, CK-MB and β-hCG) cartridges
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has	the code 127 been occurring?
Use Another	2. How many code 127 have occurred?	
Cartridge	3. What is tested on the cartridge – QC material or patien	t sample?
	4. If code occurred while testing QC material, what is the	QC material lot number(s)?
RW Code: C2127	5. How is the cartridge being filled?	
	a. Is sample going beyond the fill mark?	
Answer pRE	6. How is the cartridge being handled?	
Questions!	a. Is pressure being applied to calibrant pack?	
Synonyms: N/A	b. Was a previously tested cartridge inserted into the analyzer?	
	7. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Verify that the cartridge tested was not overfilled	
	B. Verify that the calibrant pack was not pre-burst and a p	previously tested cartridge was not inserted
	C. Test a new cartridge from the same cartridge lot numb	er and box
	D. In code is persistent on a specific cartriage for number,	determine and document code rate for the specific cartridge
	IE after running additional cartridges the code 127 is not	THEN the incident is resolved
	reproducible on a specific analyzer	Classification is Complaint 1
	IE the code 127 is due to overfilling or michandling the	THEN the incident is resolved
	cartridge AND after troubleshooting additional	Classification is Complaint 1
	cartridge(s) tested successfully	
	IF the code 127 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
	AND other cartridge lot(s) run without issue on the same	
	i-STAT analyzers	Ask customer if cartridges are available to be returned for
		investigation and document request(s)
	IF the code 127 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should
	after troubleshooting but only on specific cartridge lot(s)	be investigated
	and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2
	and other QC material lot(s) run without issue on the	
	same i-STAT analyzers	Ask customer if cartridges and QC material are available
		to be returned for investigation and document request(s)
	IF the code 127 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
	AND those same cartridge lot(s) run without issue on	Classification is Repair
	other i-STAT analyzers	

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Complaint	Description	
Code 128	Cartridge error (may be due to invalid sample type) with imit	nunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has	the code 128 been occurring?
Use Another	How many code 128 have occurred?	
Cartridge	3. What is tested on the cartridge – QC material or patien	t sample?
	If code occurred while testing QC material:	
RW Code: C2128	a. What is lot number(s)?	
	b. How is the QC material stored?	
Answer pRE	 c. How is the QC material filled into the cartridg 	e? Dropper tip or other transfer device?
Questions!	5. If code occurred while testing patient sample:	
	a. Is only one patient sample giving the code or	multiple patients?
Synonyms: N/A	b. How is sample collected?	
	c. What is the sample type tested (whole blood	or plasma)?
	d. What transfer device is used to fill the cartrid	ge?
	6. How is the cartridge being inserted into the analyzer?	
	7. What is analyzer serial number(s)?	
	Troubleshooting	
	A. If the code is occurring only on QC material, verify the	materials are stored, tested and handled appropriately
	without introducing bubbles	
	1. Test a new cartridge with fresh QC material u	ising a transfer device instead of dropper tip (dropper tip can
	De removed)	an annumista completions used and collected preparly
	6. If the coue is occurring on patient samples, very that a	latin: Angluzer Coded Massages Art: 714260)
	C. Verify that the cartridge is miled properly (reclinical ball	zor until a soft click is board
	E Test a new cartridge with fresh sample on the same car	tridge lot number and hox
	E. If code is persistent on a specific cartridge lot number	determine and document code rate for the specific cartridge
	lot number or hox number	determine and document code rate for the specific carcinge
	Note: Codes 50, 126 and 128 are sometimes related to elec	trical connection. If multiple occurrences in a short period of
	time of these 3 codes (50, 126, and 128) on specific analyzer serial number, analyzer requires replacement	
	Resolution	
	IF the code 128 is determined to be due to improper	THEN the incident is resolved
	control storage or handling after troubleshooting and the	Classification is Complaint 1
	code is not reproducible on additional cartridges	
	IF the code 128 is due to improper cartridge handling or	THEN the incident is resolved
	filling after troubleshooting and the code is not	Classification is Complaint 1
	reproducible on additional cartridges.	
	IF the code 128 is due to improper sample type collection	THEN the incident is resolved
	or sample handling after troubleshooting and the code is	Classification is Complaint 1
	not reproducible on additional cartridges.	
	IF after running additional cartridges the code 128 is not	THEN the incident is resolved
	reproducible on a specific analyzer	Classification is Complaint 1
	IF code 128 is occurring with only OC material and is	THEN the suspect cartridge and OC material lot(s) should
	resolved after removing the dropper tip from OC vial and	be investigated
	using a transfer device to fill cartridge	Classification is Complaint 2
		Ask customer if cartridges and OC material are available
		to be returned for investigation and document request(s)
	IF the code 128 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2

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AND other cartridge lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges are available to be returned for investigation and document request(s)
IF the code 128 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) and specific QC material lot(s) AND other cartridge lots and other QC material lot(s) run without issue on the	 THEN the suspect cartridge and QC material lot(s) should be investigated Classification is Complaint 2
same I-STAT analyzers	Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the code 128 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on other i-STAT analyzers	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair
IF code 128 is occurring with codes 50 and 126 on a specific analyzer and troubleshooting does not resolve	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair

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Complaint	Description	
Code 129	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 129 been occurring?	
Use Another	2. How many code 129 have occurred?	
Cartridge	3. What is tested on the cartridge – QC material or patient sample?	
	4. If code occurred while testing QC material, what is the QC material lot number(s)?	
RW Code: C2129	5. If code occurred while testing patient sample:	
	a. Is only one patient sample giving the code or multiple patients?	
Answer pRE	b. What is the sample type tested (whole blood or plasma)?	
Questions!	c. How is the sample collected?	
Synonyms: N/A	6. How is the cartridge being handled?	
	a. Is pressure being applied to the center of the cartridge (calibrant pack)?	
	 b. Was a previously tested cartridge inserted into the analyzer? What is each year earier system or (a) 2 	
	7. What is analyzer serial number(s)?	
	8. What is the elevation of the testing site? (i.e. in CO, OT, AB)?	
	I roubleshooting	
	A. Verify that the sample was collected and handled preparly	
	C. Verify that calibrant pack was not pro-burst and a proviously tested cartridge was not inserted	
	C. Verify that calibrant pack was not pre-burst and a previously tested calibrage was not inserted	
	F If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge	
	lot number or hox number	
	F. Document testing elevation if applicable	
	Resolution	
	IF the code 129 is due to improper sample THEN the incident is resolved	
	type/collection/handling or improper cartridge handling • Classification is Complaint 1	
	and after troubleshooting code is not reproducible on	
	additional cartridges	
	IF the code 129 is persistent on multiple i-STAT analyzers THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s) • Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	
	STAT analyzers	

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	Ask customer if cartridges are available to be returned for investigation and document request(s)
IF the code 129 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) and specific QC material lot(s) AND other cartridge lots and other QC material lot(s) run without issue on the same i- STAT analyzers	 THEN the suspect cartridge and QC material lot(s) should be investigated Classification is Complaint 2 Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the code 129 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on other i-STAT analyzers	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair

Complaint	Description		
Code 130	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 130 been occurring?		
Use Another	2. How many code 130 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code: C2130	a. What is lot number(s)?		
	b. How is the QC material stored?		
Answer pRE	c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?		
Questions!	d. How is the QC material being handled?		
Synonyms: N/A	5. If code occurred while testing a patient sample:		
	a. Is only one patient sample giving the code or multiple patients?		
	b. What is the sample type tested (whole blood or plasma)?		
	c. How is the sample collected?		
	d. What transfer device is being used to fill the cartridge?		
	6. What is analyzer serial number(s)?		
	Troubleshooting		
	A. If code occurred when testing QC material, verify QC material is stored, tested and handled appropriately without		
	introducing bubbles		
	1. Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can		
	be removed)		
	B. If code occurred while testing patient samples, verify an appropriate sample type was used and collected properly		
	C. Verify the cartridge is filled properly (<i>Technical Bulletin: Analyzer Coded Messages Art: 714260</i>)		
	D. Test a new cartriage from the same cartriage lot number and box		
	Let number or box number		
	If the code 120 is due to improper control or complete the incident is recolled		
	handling or cartridge filling through troubleshooting and a		
	IF after running additional cartridges the code 130 is not THEN the incident is resolved		
	reproducible on a specific analyzer		

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IF code 130 is occurring with only QC material and is	THEN the suspect cartridge and QC material lot(s) should
resolved after removing the dropper tip from QC vial and	be investigated
using a transfer device to fill cartridge	Classification is Complaint 2
	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)
IF the code 130 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
AND other cartridge lot(s) run without issue on the same	Ask customer if cartridges are available to be returned for
i-STAT analyzers	investigation and document request(s)
IF the code 130 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should
after troubleshooting but only on specific cartridge lot(s)	be investigated
and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2
and other QC material lot(s) run without issue on the	Ask customer if cartridges and QC material are available
same i-STAT analyzers	to be returned for investigation and document request(s)
IF the code 130 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
AND those same cartridge lot(s) run without issue on	Classification is Repair
other i-STAT analyzers	

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Complaint	Description	
Code 131	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges	
	Prompts for Meaningful Data Collection	
Cartridge Error	1. What cartridge type, lot number(s)/box number(s) has the code 131 been occurring?	
– Use Another	2. How many code 131 have occurred?	
Cartridge	3. What is tested on the cartridge – QC material or patient sample?	
	4. If code occurred while testing QC material:	
RW Code:	a. What is lot number(s)?	
C2131	b. How is the QC material stored?	
	c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?	
Answer pRE	5. If code occurred while testing patient sample:	
Questions!	a. Is only one patient sample giving the code or multiple patients?	
	b. What is the sample type tested (whole blood or plasma)?	
Synonyms: N/A	c. How is the sample collected?	
	d. What transfer device is used to fill the cartridge?	
	e. Is the sample reaching the fill mark on the cartridge?	
	6. How is the cartridge being inserted into the analyzer?	
	7. What is analyzer serial number(s)?	
	Troubleshooting	
	A. If the code is occurring only on QC material, verify the QC material is stored, tested and handled appropriately without introducing bubbles	
	 Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can be removed) 	
	B. If the code is occurring on patient samples, verify that an appropriate sample type was used and collected properly	
	C. Verify that the cartridge is filled properly (Technical Bulletin: Analyzer Coded Messages Art: 714260)	
	D. Verify that the cartridge is guided gently into the analyzer until a soft click is heard	
	E. Test a new cartridge from the same cartridge lot number and box	
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot	
	number or box number	
	Resolution	

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IF the code 131 is determined to be due to improper	THEN the incident is resolved
control storage or handling after troubleshooting and the	Classification is Complaint 1
code is not reproducible on additional cartridges	
IF the code 131 is due to improper cartridge handling or	THEN the incident is resolved
filling after troubleshooting and the code is not	Classification is Complaint 1
reproducible on additional cartridges	
IF the code 131 is due to improper sample type, collection	THEN the incident is resolved
or sample handling after troubleshooting the code is not	Classification is Complaint 1
reproducible on additional cartridges.	
IF after running additional cartridges the code 131 is not	THEN the incident is resolved
reproducible on a specific analyzer	Classification is Complaint 1
IF code 131 is occurring with only QC material and is	THEN the suspect cartridge and QC material lot(s) should be
resolved after removing the dropper tip from QC vial and	investigated
using a transfer device to fill cartridge	Classification is Complaint 2
	Ask customer if cartridges and QC material are available to
	be returned for investigation and document request(s)
IF the code 131 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
AND other cartridge lot(s) run without issue on the same i-	
STAT analyzers	Ask customer if cartridges are available to be returned for
	investigation and document request(s)
IF the code 131 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be
after troubleshooting but only on specific cartridge lot(s)	investigated
and specific QC material lot(s) AND other cartridge lots and	Classification is Complaint 2
other QC material lot(s) run without issue on the same i-	
STAT analyzers	Ask customer if cartridges and QC material are available to
	be returned for investigation and document request(s)
IF the code 131 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
AND those same cartridge lot(s) run without issue on other	Classification is Repair
i-STAT analyzers	

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Complaint	Description		
Code 132	Cartridge error (may be due to invalid sample type) with immu	inoassay (cTnl, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What cartridge type, lot number(s)/box number(s) has the code 132 been occurring?		
– Use Another	2. How many code 132 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient s	ample?	
	4. If code occurred while testing QC material:		
RW Code:	a. What is lot number(s)?		
C2132	b. How is the QC material stored?		
	c. How is the QC material filled into the cartridge?	Dropper tip or other transfer device?	
Answer pRE	5. If testing occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or me	ultiple patients?	
	 What is the sample type tested (whole blood or 	plasma)?	
Synonyms: N/A	c. How is the sample collected?		
	d. What transfer device is used to fill the cartridge	?	
	6. How is the cartridge being inserted into the analyzer?		
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. If the code is occurring only on QC material, verify the QC	material is stored, tested and handled appropriately without	
	introducing bubbles		
	1. Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can be		
	removed)		
	B. If the code is occurring on patient samples, verify that an	appropriate sample type was used and collected properly	
	C. Verify that the cartridge is filled properly (Technical Bullet	tin: Analyzer Coded Messages Art: 714260)	
	D. Verify that the cartridge is guided gently into the analyzer until a soft click is heard		
	E. Test a new cartridge from the same cartridge lot number	and box	
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	Resolution		
	IF the code 132 is due to improper control storage or	THEN the incident is resolved	
	handling after troubleshooting and the code is not	Classification is Complaint 1	
	reproducible on additional cartridges.		
	IF the code 132 is due to improper cartridge handling or	THEN the incident is resolved	
	filling after troubleshooting and the code is not reproducible	Classification is Complaint 1	
	on additional cartridges.		
	IF the code 132 is due to improper sample type, collection or	THEN the incident is resolved	
	sample handling after troubleshooting the code is not	Classification is Complaint 1	
	reproducible on additional cartridges.		
	IF after running additional cartridges the code 132 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF code 132 is occurring with only QC material and is	THEN the suspect cartridge and QC material lot(s) should be	
	resolved after removing the dropper tip from QC vial and	investigated	
	using a transfer device to fill cartridge	Classification is Complaint 2	
		Ask customer if cartridges and QC material are available to	
		be returned for investigation and document request(s)	
	IF the code 132 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	Ask customer if cartridges are available to be returned for	
	STAT analyzers	investigation and document request(s)	
	IF the code 132 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s) and	investigated	
	specific QC material lot(s) AND other cartridge lots and other	Classification is Complaint 2	

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QC material lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the code 132 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on other i-STAT	THEN the i-STAT analyzer should be replaced or repaired
analyzers	

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Complaint	Description		
Code 133	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β -h	nCG) cartridges	
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the	he code 133 been occurring?	
Use Another	2. How many code 133 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?	
	4. If code occurred while testing QC material, what is the lo	ot number(s)?	
RW Code: C2133	5. What is analyzer serial number(s)?		
	6. What is the elevation of the testing site? (i.e. in CO, UT, <i>i</i>	AB)?	
Answer pRE	Troubleshooting		
Questions!	A. Test a new cartridge from the same cartridge lot number	er and box	
	B. If code is persistent on a specific cartridge lot number, de	letermine and document code rate for the specific cartridge	
Synonyms: N/A	lot number or box number		
	C. Document testing elevation if applicable		
	Resolution		
	IF after running additional cartridges the code 133 is not T	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 133 is persistent on multiple i-STAT analyzers T	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned for	
	i	investigation and document request(s)	
	IF the code 133 is persistent on multiple i-STAT analyzers T	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s) in	investigated	
	and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2	
	and other QC material lot(s) run without issue on the		
	same i-STAT analyzers	Ask customer if cartridges and QC material are available to	
		be returned for investigation and document request(s)	
	IF the code 133 is persistent on specific i-STAT analyzer T	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on	Classification is Repair	
	other i-STAT analyzers		

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Complaint	Description		
Code 134	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What cartridge type, lot number(s)/box number(s) has the code 134 been occurring?		
– Use Another	2. How many code 134 have occurred?	-	
Cartridge	3. What is tested on the cartridge – QC material or patient s	ample?	
	4. If code occurred while testing QC material:		
RW Code:	a. What is lot number(s)?		
C2134	b. How is the QC material stored?		
	c. How is the QC material filled into the cartridge?	P Dropper tip or other transfer device?	
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or mu	ultiple patients?	
	b. How is the sample collected (whole blood or pla	asma)?	
Synonyms: N/A	c. What is the sample type tested?		
	d. What transfer device is used to fill the cartridge	?	
	6. How is the cartridge being inserted into the analyzer?		
	7. What is analyzer serial number(s)?		
	8. What is the elevation of the testing site? (i.e. in CO, UT, A	В)?	
	Troubleshooting		
	A. If the code is occurring only on QC material, verify the QC	material is stored, tested and handled appropriately without	
	introducing bubbles		
	1. Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can be		
	removed)		
	B. If the code is occurring on patient samples, verify that an appropriate sample type was used and collected properly		
	C. Verify that the cartridge is filled properly (<i>Technical Bullet</i>	tin: Analyzer Coded Messages Art: 714260)	
	D. Verify that the cartridge is guided gently into the analyzer	r until a soft click is heard	
	E. Test a new cartridge with fresh sample from the same cartridge lot number and box		
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	G. Document testing elevation if applicable		
	Resolution		
	IF the code 134 is determined to be due to improper control	THEN the incident is resolved	
	storage or handling after troubleshooting and code is not	Classification is Complaint 1	
	reproducible on additional cartridges.		
	IF the code 134 is due to improper cartridge handling or	THEN the incident is resolved	
	an additional contrideos	Classification is Complaint 1	
	of additional calificacies.	TUEN the incident is received	
	are the code 134 is due to improper sample type, collection of	Classification is Completed	
	reproducible on additional cartridges		
	IE after running additional cartridges the code 124 is not	THEN the incident is received	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IE code 124 is accurring with only OC material and is	THEN the suspect cartridge and OC material lat(s) should be	
	resolved after removing the dropper tip from OC vial and	investigated	
	using a transfer device to fill cartridge	Resulting and the second secon	
	עטווא מ נומושופו עפעונפ נט וווו נמונוועצפ		
		Ask sustamor if contridges and OC material are available to	
		he returned for investigation and document request(s)	
	IF the code 134 is persistent on multiple i-STAT analyzors	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(c)	Classification is Complaint 3	
	AND other cartridge lot(s) run without issue on the same i		
	STAT analyzers		
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		Ask customer if cartridges are available to be returned for investigation and document request(s)
IF the after speci QC m analy	e code 134 is persistent on multiple i-STAT analyzers troubleshooting but only on specific cartridge lot(s) and fic QC material lot(s) AND other cartridge lots and other naterial lot(s) run without issue on the same i-STAT /zers	 THEN the suspect cartridge and QC material lot(s) should be investigated Classification is Complaint 2 Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the those analy	e code 134 is persistent on specific i-STAT analyzer AND e same cartridge lot(s) run without issue on other i-STAT /zers	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair

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Complaint	Description		
Code 135	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 135 been occurring?		
Use Another	2. How many code 135 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code: C2135	a. What is lot number(s)?		
	b. How is the QC material stored?		
Answer pRE	c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?		
Questions!	5. If code occurred while testing patient sample:		
_	a. Is only one patient sample giving the code or multiple patients?		
Synonyms: N/A	b. What is the sample type tested (whole blood or plasma)?		
	c. How is the sample collected?		
	d. What is used to load the sample into the cartridge?		
	6. How is the cartridge being inserted into the analyzer?		
	7. What analyzer is serial number(s)?		
	Troubleshooting		
	A. If the code is occurring on QC material, verify the QC material is stored, tested and handled appropriately without		
	introducing bubbles		
	1. Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can		
	be removed)		
	B. If the code is occurring on patient samples, verify that an appropriate sample type was used and collected properly		
	C. Verify that the cartridge is filled properly (<i>Technical Bulletin: Analyzer Coded Messages Art: 714260</i>)		
	D. Verify that the cartridge is guided gently into the analyzer until a soft click is heard		
	E. Test a new cartridge with fresh sample from the same cartridge lot number and box		
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF the code 135 is determined to be due to improper THEN the incident is resolved		
	• Classification is Complaint 1		
	code is not reproducible on additional cartridges.		
	IF the code 135 is due to improper cartridge handling or IHEN the incident is resolved		
	filling after troubleshooting and the code is not Classification is Complaint 1		
1	reproducible on additional cartridges.		

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IF the code 135 is due to improper sample type, collection	THEN the incident is resolved
or sample handling after troubleshooting the code is not	 Classification is Complaint 1
reproducible on additional cartridges.	
IF after running additional cartridges the code 135 is not	THEN the incident is resolved
reproducible on a specific analyzer	Classification is Complaint 1
IF code 135 is occurring with only QC material and is	THEN the suspect cartridge and QC material lot(s) should
resolved after removing the dropper tip from QC vial and	be investigated
using a transfer device to fill cartridge	Classification is Complaint 2
	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)
IF the code 135 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
AND other cartridge lot(s) run without issue on the same i-	
STAT analyzers	Ask customer if cartridges are available to be returned for
	investigation and document request(s)
IF the code 135 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should
after troubleshooting but only on specific cartridge lot(s)	be investigated
and specific QC material lot(s) AND other cartridge lots and	Classification is Complaint 2
other QC material lot(s) run without issue on the same i-	
STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)
IF the code 135 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
AND those same cartridge lot(s) run without issue on other	Classification is Repair
i-STAT analyzers	

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Complaint	Description		
Code 136	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error	 What cartridge type/lot number(s)/box number(s) has the code 136 been occurring? 		
– Use Another	2. How many code 136 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code:	a. What is lot number(s)?		
C2136	b. How is the QC material stored?		
	c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?		
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or multiple patients?		
	b. What is the sample type tested (whole blood or plasma)?		
Synonyms: N/A	c. How is the sample collected?		
	d. What transfer device is used to fill the cartridge?		
	6. How is the cartridge being inserted into the analyzer?		
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. If the code is occurring only on QC material, verify the QC material is stored, tested and handled appropriately without		
	introducing bubbles		
	 Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can be removed) 		
	B. If the code is occurring on patient samples, verify that an appropriate sample type was used and collected properly		
	C. Verify that the cartridge is filled properly (Technical Bulletin: Analyzer Coded Messages Art: 714260)		

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D. Verify that the cartridge is guided gently into the analyzer u	D. Verify that the cartridge is guided gently into the analyzer until a soft click is heard		
E. Test a new cartridge with fresh sample from same cartridge	e lot number and box		
F. If code is persistent on a specific cartridge lot number, determined and the specific cartridge lot number.	ermine and document code rate for the specific cartridge lot		
number or box number			
Resolution	Resolution		
IF the code 136 is determined to be due to improper control	THEN the incident is resolved		
storage or handling after troubleshooting and the code is not	Classification is Complaint 1		
reproducible on additional cartridges.			
IF the code 136 is due to improper cartridge handling or filling	THEN the incident is resolved		
after troubleshooting and the code is not reproducible on	Classification is Complaint 1		
additional cartridges.			
IF the code 136 is due to improper sample type, collection or	THEN the incident is resolved		
sample handling after troubleshooting the code is not	Classification is Complaint 1		
reproducible on additional cartridges.			
IF after running additional cartridges the code 136 is not	THEN the incident is resolved		
reproducible on a specific analyzer	Classification is Complaint 1		
IF code 136 is occurring with only QC material and is resolved	THEN the suspect cartridge and QC material lot(s) should		
after removing the dropper tip from QC vial and using a	be investigated		
transfer device to fill cartridge	Classification is Complaint 2		
	Ask customer if cartridges and QC material are available		
	to be returned for investigation and document request(s)		
IF the code 136 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated		
troubleshooting but only on specific cartridge lot(s) AND	Classification is Complaint 2		
other cartridge lot(s) run without issue on the same i-STAT			
analyzers	Ask customer if cartridges are available to be returned for		
	investigation and document request(s)		
IF the code 136 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge and QC material lot(s) should		
troubleshooting but only on specific cartridge lot(s) and	be investigated		
specific QC material lot(s) AND other cartridge lots and other	Classification is Complaint 2		
QC material lot(s) run without issue on the same i-STAT			
analyzers	Ask customer if cartridges and QC material are available		
	to be returned for investigation and document request(s)		
IF the code 136 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired		
those same cartridge lot(s) run without issue on other i-STAT	Classification is Repair		
analyzers			
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Complaint	Description		
Code 137	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What cartridge type, lot number(s)/box number(s) has the code 137 been occurring?		
– Use Another	2. How many code 137 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code:	a. What is lot number(s)?		
C2137	b. How is the QC material stored?		
	c. How is the QC material filled into the cartridge?	Dropper tip or other transfer device?	
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or me	ultiple patients?	
	 What is the sample type tested (whole blood or 	plasma)?	
Synonyms: N/A	c. How is the sample collected?		
	d. What is used to load the sample into the cartrid	ge?	
	6. How is the cartridge being inserted into the analyzer?		
	7. What analyzer serial number(s)?		
	Troubleshooting		
	A. If the code is occurring only on QC material, verify the QC material is stored, tested and handled appropriately without		
	introducing bubbles		
	 Test a new cartridge with fresh QC material usir 	ng a transfer device instead of dropper tip (dropper tip can be	
	removed)		
	B. If the code is occurring on patient samples, verify that an	appropriate sample type was used and collected properly	
	C. Verify that the cartridge is filled properly (<i>Technical Bullet</i>	tin: Analyzer Coded Messages Art: 714260)	
	D. Verify that the cartridge is guided gently into the analyzer until a soft click is heard		
	E. Test a new cartridge with fresh sample from same cartridge lot number and box		
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	IF the code 137 is determined to be due to improper control	THEN the incident is resolved	
	storage or nandling after troubleshooting and the code is	Classification is Complaint 1	
	not reproducible on additional cartridges.		
	IF the code 137 is due to improper cartridge handling or	THEN the inclaent is resolved	
	ming after troubleshooting and the code is not reproducible	Classification is Complaint 1	
	on additional cartridges.		
	IF the code 137 is due to improper sample type, collection or	THEN the incident is resolved	
	sample finding after troubleshooting the code is not	Classification is Complaint 1	
	IE after running additional cartridges the code 127 is not	THEN the incident is resolved	
	reproducible on specific analyzer	Classification is Complaint 1	
	Februari and the second and the second	Classification is complaint 1 TUEN the suggest certridge and OC meterial lat(a) should be	
	received after removing the drapper tip from OC vial and	investigated	
	using a transfor dovice to fill cartridge	Classification is Complaint 3	
	using a transfer device to fin caltridge	• Classification is complaint 2	
		Ask customer in cartridges and QC material are available to	
	IF the code 127 is persistent on multiple i STAT analyzers	THEN the suspect certridge let(c) should be investigated	
	IF the code 137 is persistent on multiple I-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	AND other cartridge lot(s) rup without issue on the same i	Classification is complaint 2 Ask systematic if contridece are systematic to be not used for	
	AND OTHER CALIFIAGE IOL(S) FUIL WILLIOUL ISSUE OF THE SAME I-	Ask customer if cartridges are available to be returned for investigation and document request(a)	
	IF the code 127 is persistent on multiple : STAT and there	THEN the suspect certridge and QC metavial let(a) should be	
	after troublesheeting but only on specific sertridge let(-) and	investigated	
	ancer troubleshooting but only on specific cartriage lot(s) and	Investigated	
	specific QC material lot(s) AND other cartridge lots and other	 Classification is complaint 2 	

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QC material lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)
IF the code 137 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on other i-STAT analyzers	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair

Complaint	Description		
Code 138	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error	1. What cartridge type, lot number(s)/box number(s) has the code 138 been occurring?		
– Use Another	2. How many code 138 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code:	a. What is lot number(s)?		
C2138	b. How is the QC material stored?		
	c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?		
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or multiple patients?		
	b. What is the sample type tested (whole blood or plasma)?		
Synonyms: N/A	c. How is the sample collected?		
	d. What is used to load the sample into the cartridge?		
	e. Did the sample reach the fill mark on the cartridge?		
	6. How is the cartridge being inserted into the analyzer?		
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. If the code is occurring only on QC material, verify the QC material is stored, tested and handled appropriately without		
	introducing bubbles		
	 Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can be removed) 		
	B If the code is occurring on patient samples, verify that an appropriate sample type was used and collected properly		
	C. Verify that the cartridge is filled properly (<i>Technical Bulletin: Analyzer Coded Messages Art: 714260</i>)		
	D. Verify that the cartridge is guided gently into the analyzer until a soft click is heard		
	E. Test a new cartridge with fresh sample from the same cartridge lot number and box		
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	Resolution		
	IF the code 138 is determined to be due to improper control THEN the incident is resolved		
	storage or handling after troubleshooting and the code is not • Classification is Complaint 1		
	reproducible on additional cartridges.		
	IF the code 138 is due to improper cartridge handling or filling THEN the incident is resolved		
	after troubleshooting and the code is not reproducible on • Classification is Complaint 1		
	additional cartridges.		
	IF the code 138 is due to improper sample type, collection or THEN the incident is resolved		
	sample handling after troubleshooting the code is not • Classification is Complaint 1		
	reproducible on additional cartridges.		
	IF after running additional cartridges the code 138 is not THEN the incident is resolved		
	reproducible on specific analyzer		

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I	F code 138 is occurring with only QC material and is resolved	THEN the suspect cartridge and QC material lot(s) should
a	after removing the dropper tip from QC vial and using a	be investigated
t	transfer device to fill cartridge	Classification is Complaint 2
		Ask customer if cartridges and QC material are available
		to be returned for investigation and document request(s)
I	F the code 138 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge lot(s) should be investigated
t	roubleshooting but only on specific cartridge lot(s) AND other	Classification is Complaint 2
c	cartridge lot(s) run without issue on the same i-STAT analyzers	Ask customer if cartridges are available to be returned for
		investigation and document request(s)
I	F the code 138 is persistent on multiple i-STAT analyzers after	THEN the suspect cartridge and QC material lot(s) should
t	roubleshooting but only on specific cartridge lot(s) and	be investigated
S	specific QC material lot(s) AND other cartridge lots and other	Classification is Complaint 2
C	QC material lot(s) run without issue on the same i-STAT	Ask customer if cartridges and QC material are available
а	analyzers	to be returned for investigation and document request(s)
I	F the code 138 is persistent on specific i-STAT analyzer AND	THEN the i-STAT analyzer should be replaced or repaired
t	hose same cartridge lot(s) run without issue on other i-STAT	Classification is Repair
a	analyzers	

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Complaint	Description		
Code 140	Lot number in cartridge barcode is expired with immunoassay	(cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection		
Lot Expired	1. What cartridge type, lot number(s)/box number(s) has the	e code 140 been occurring?	
	a. What is the expiration date on the cartridge?		
RW Code: C2140	b. What is the current date/time in the analyzer?		
	How many code 140 have occurred?		
Answer pRE	3. Is there a different non-expired cartridge lot or a second i	-STAT analyzer available for troubleshooting?	
Questions!	4. What analyzer serial number(s)?		
	Troubleshooting		
Synonyms: N/A	A. Verify the expiration date labeled on the cartridge pouch,	/box	
	B. Verify the current date/time on the i-STAT analyzer being	used	
	C. Test a cartridge from a different, non-expired, lot number	to determine if the issue is analyzer specific or cartridge	
	specific		
	D. Test a cartridge from the same cartridge lot number and box		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	IF the code 140 is due to improper date/time in the analyzer	THEN the incident is resolved	
	and after troubleshooting a new cartridge was tested	Classification is Complaint 1	
	Successfully	THEN the incident is received	
	IF the code 140 is due to use of expired carthoges and after		
	If the contridge let(c) are verified to not be evaluated for their	Classification is Complaint 1 TUEN the suspect certridge let(e) should be investigated	
	IF the calling AND the date (time in the analyzor(s) is confirmed to		
	habeling AND the code 140 is resolved after rupping a	Classification is complaint 2 Ack sustamer if cartridges are available to be returned for	
	different cartridge lot on the same analyzer(s)	Ask customer in cartinuges are available to be returned for investigation and document request(c)	
	IF the cartridge lot(s) are verified to not be expired por their	THEN the analyzer should be replaced or repaired	
	labeling AND the date/time in the analyzer is confirmed to	Classification is Renair	
	be correct AND the code 140 is not reproducible using the		
	same cartridge lot(s) on a different analyzer		
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Complaint	Description		
Code 141	Operator failed to enter required information with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Test Cancelled by	1. What analyzer serial number(s)?		
Operator	2. How many code 141 have occurred?		
	3. What cartridge type, lot number(s)/box number(s) has the	ne code 141 been occurring?	
RW Code: C2141	Troubleshooting		
	A. Verify customization settings in analyzer for required/ma	andatory information related to sample type, patient	
Answer pRE	temperature, etc. on the chart page		
Questions!	B. Restore to factory settings and download the analyzer to	pick up the specific customization profile	
	C. Run a new cartridge		
Synonyms: N/A	D. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF it is determined that the code 141 was caused by the	THEN the incident is resolved	
	user not entering mandatory information before power	 Classification is Complaint 1 	
	down and after troubleshooting a new cartridge was tested		
	successfully		
	IF the code 141 is persistent on specific i-STAT analyzer that	THEN the i-STAT analyzer should be replaced or repaired	
	are confirmed to have the current CLEW/JAMS software on	Classification is Repair	
	multiple cartridge lots AND those same cartridge lot(s) run		
	without issue on other i-STAT analyzers		
	IF the code 141 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	Ask customer if cartridges are available to be returned for	
	STAT analyzers	investigation and document request(s)	

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Complaint	Description	
Code 142	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 142 been occurring?	
Use Another	2. How many code 142 have occurred?	
Cartridge	3. What is tested on the cartridge – QC material or patient sample?	
	4. If code occurred while testing QC fluid, what is lot number(s)?	
RW Code: C2142	5. If code occurred while testing patient sample:	
	a. Is only one patient sample giving the code or multiple patients?	
Answer pRE	b. What is the sample type tested (whole blood or plasma)?	
Questions!	c. How is the sample collected?	
	d. What type of collection device?	
Synonyms: N/A	If evacuated tube: what is lot number and expiration date?	
Synonyms. Nyrt	6. What is analyzer serial number(s)?	
	7. What is the elevation of the testing site? (i.e. in CO, UT, AB)?	
	Troubleshooting	
	A. Verify that an appropriate sample type was tested	
	B. Verify that the sample was collected and handled properly	
	C. If using evacuated tubes for sample collection, obtain the tube lot number and suggest using a different lot of tubes	
	D. Test a new cartridge with fresh sample on the same cartridge lot number and box	
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge	
	lot number or box number	
	F. Document testing site elevation when applicable	
	Resolution	

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IF the code 142 is due to a specific lot of evacuated	THEN the incident is resolved
collection tubes being used AND after troubleshooting	 Classification is Complaint 1
code is not reproducible on additional cartridges of the	
same lot number	
IF after running additional cartridges of the same lot	THEN the incident is resolved
number the code 142 is not reproducible on a specific	Classification is Complaint 1
analyzer	
IF the code 142 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
AND other cartridge lot(s) run without issue on the same	Ask customer if cartridges are available to be returned for
i-STAT analyzers	investigation and document request(s)
IF the code 142 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be
after troubleshooting but only on specific cartridge lot(s)	investigated
and specific QC material lot(s) AND other cartridge lots	 Classification is Complaint 2
and other QC material lot(s) run without issue on the	Ask customer if cartridges and QC material are available to
same i-STAT analyzers	be returned for investigation and document request(s)
IF the code 142 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
AND those same cartridge lot(s) run without issue on	Classification is Repair
other i-STAT analyzers	

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Complaint	Description		
Code 143	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 143 been occurring?		
Use Another	2. How many code 143 have occurred?		
Cartridge	What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material, what is lot number(s)?		
RW Code: C2143	5. If code occurred while testing patient sample:		
	a. Is only one patient sample giving the code or multiple patients?		
Answer pRE	b. What is the sample type tested (whole blood or plasma)?		
Questions!	c. How is the sample collected?		
	d. What type of collection device?		
Synonyms: N/A	i. If evacuated tube: what is lot number and expiration date?		
	6. What is analyzer serial number(s)?		
	7. What is the elevation of the testing site? (i.e. in CO, UT, AB)?		
	Troubleshooting		
	A. Verify that an appropriate sample type was tested		
	B. Verify that the sample was collected and handled properly		
	C. If using evacuated tubes for sample collection, obtain the tube lot number and suggest using a different lot of tubes		
	D. Test a new cartridge with fresh sample on the same cartridge lot number and box		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot		
	number or box number		
	F. Document testing site elevation when applicable		
	Resolution		
	IF the code 143 is due to a specific lot of evacuated THEN the incident is resolved		
	collection tubes being used AND after troubleshooting code • Classification is Complaint 1		
	is not reproducible on additional cartridges of the same lot		
	number		

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IF after running additional cartridges of the same lot	THEN the incident is resolved
number the code 143 is not reproducible on a specific	 Classification is Complaint 1
analyzer	
IF the code 143 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated
after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2
AND other cartridge lot(s) run without issue on the same i-	Ask customer if cartridges are available to be returned for
STAT analyzers	investigation and document request(s)
IF the code 143 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be
after troubleshooting but only on specific cartridge lot(s)	investigated
and specific QC material lot(s) AND other cartridge lots and	Classification is Complaint 2
other QC material lot(s) run without issue on the same i-	Ask customer if cartridges and QC material are available to
STAT analyzers	be returned for investigation and document request(s)
IF the code 143 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired
AND those same cartridge lot(s) run without issue on other	Classification is Repair
i-STAT analyzers	

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Complaint	Description		
Code 144	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β -h	CG) cartridges	
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the	he code 144 been occurring?	
Use Another	How many code 144 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?	
	4. If code occurred while testing QC material, what is lot nu	umber(s)?	
RW Code: C2144	5. What is analyzer serial number(s)?		
	6. What is the elevation of the testing site? (i.e. in CO, UT,	AB)?	
Answer pRE	Troubleshooting		
Questions!	A. Test a new cartridge with fresh sample on the same cart	ridge lot number and box	
	B. If code is persistent on a specific cartridge lot number, d	etermine and document code rate for the specific cartridge	
Synonyms: N/A	lot number or box number		
	C. Document testing site elevation when applicable		
	Resolution		
	IF after running additional cartridges the code 144 is not THEN the incident is resolved		
	reproducible on a specific analyzer • Classification is Complaint 1		
	IF the code 144 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 144 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should	
	after troubleshooting but only on specific cartridge lot(s)	be investigated	
	and specific QC material lot(s) AND other cartridge lots and	Classification is Complaint 2	
	other QC material lot(s) run without issue on the same i-	Ask customer if cartridges and QC material are available	
	STAT analyzers	to be returned for investigation and document request(s)	
	IF the code 144 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on other	Classification is Repair	
	i-STAT analyzers		

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Complaint	Description		
Code 145	Sample not detected with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 145 been occurring?		
Use Another	2. How many code 145 have occurred?		
Cartridge	3. If code occurred while testing QC material:		
	a. What is lot number(s)?		
RW Code: C2145	b. How is the QC material filled into the cartridg	ge? Dropper tip or other transfer device?	
A	4. How was the cartridge handled?		
Answer pRE	a. Was the cartridge closed completely?		
Questions!	b. Was the cartridge filled to the fill mark?		
Suponums: N/A	5. What is analyzer serial number(s)?		
Synonyms. N/A	6. What is the elevation of the testing site? (i.e. in CO, UT, AB)?		
	Troubleshooting		
	A. If the code is occurring only on QC material, verify the	QC material is stored, tested and handled appropriately	
	without introducing bubbles		
	 Test a new cartridge with fresh QC material u 	using a transfer device instead of dropper tip (dropper tip can	
	be removed)		
	B. Verify that the cartridge is filled properly (<i>Technical Bu</i>	lletin: Analyzer Coded Messages Art: 714260)	
	C. Verify that the cartridge was filled to the fill mark and not underfilled		
	D. Verify that the cartridge was closed properly before inserting into analyzer		
	E. Test a new cartridge with fresh sample on the same cartridge lot number and box		
	F. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	G. Document testing site elevation when applicable Resolution		
	IF the code 145 is due to an underfilled cartridge and THEN the incident is resolved		
	through troubleshooting code is not reproducible on	Classification is Complaint 1	
	additional cartridges	Classification is complaint 1	
	IF the code 145 is due to the cartridge not being properly	THEN the incident is resolved	
	closed and through troubleshooting code is not	Classification is Complaint 1	
	reproducible on additional cartridges		
	IF after running additional cartridges the code 145 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF code 145 is occurring with only QC material and is	THEN the suspect cartridge and QC material lot(s) should be	
	resolved after removing the dropper tip from QC vial and	investigated	
	using a transfer device to fill cartridge	Classification is Complaint 2	
		Ask customer if cartridges and QC material are available to	
		be returned for investigation and document request(s)	
	IF the code 145 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same	Ask customer if cartridges are available to be returned for	
	i-STAT analyzers	investigation and document request(s)	
	IF the code 145 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s)	investigated	
	and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2	
	and other QC material lot(s) run without issue on the	Ask customer if cartridges and QC material are available to	
	same i-STAT analyzers	be returned for investigation and document request(s)	
	IF the code 145 is persistent on specific i-STAT analyzer AND	IHEN the I-STAT analyzer should be replaced or repaired	
	analyzers	Classification is Repair	
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Complaint	Description		
Code 146	Overfilled immunoassay (cTnl, BNP, CK-MB and β-hCG) cartridge		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has t	he code 146 been occurring?	
Use Another	2. How many code 146 have occurred?		
Cartridge	3. If code occurred while testing QC material, what is the lo	ot number(s)?	
	4. If code occurred while testing patient sample		
RW Code: C2146	a. What is the sample type tested (whole blood o	or plasma)?	
	b. How is the sample collected?		
Answer pRE	5. How was cartridge filled?		
Questions!	a. Did sample go past fill mark on cartridge?		
	6. What is analyzer serial number(s)?		
Synonyms: N/A	Troubleshooting		
	A. Verify that an appropriate sample type was tested		
	B. Verify that the sample was collected and handled properly before testing		
	C. Verify that the cartridge was not overfilled		
	D. Test a new cartridge with fresh sample on the same cartridge lot number and box		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF the code 146 is due to an overfilled cartridge	THEN the incident is resolved	
		Classification is Complaint 1	
	IF after running additional cartridges the code 146 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	 Classification is Complaint 1 	
	IF the code 146 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	Ask customer if cartridges are available to be returned for	
	STAT analyzers	investigation and document request(s)	
	IF the code 146 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on other	Classification is Repair	
	i-STAT analyzers		

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Complaint	Description		
Code 147	Analyzer not capable of running immunoassay (cTnI, BNP, CK-MB and β -hCG) cartridges		
	Prompts for Meaningful Data Collection		
Analyzer Error –	1. What is analyzer serial number(s)?		
See Manual	a. Check if the analyzer has the 'i' symbol that allows immunoassay cartridge testing		
	2. How many code 147 have occurred?		
RW Code: C2147	3. What cartridge type, lot number(s)/box number(s) has the code 147 been occurring?		
	4. What CLEW/JAMS version is the i-STAT analyzer currently using?		
Synonyms: N/A	Troubleshooting		
	A. Verify what CLEW/JAMS version is currently installed on the analyzer; the current JAMS software requires the		
	cartridge information to be scanned in BEFORE the cartridge can be inserted		
	B. Test a new cartridge		
	Resolution		
	IF the code 147 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	confirmed to have the current CLEW/JAMS software on Classification is Repair		
	multiple cartridge lots AND those same cartridge lot(s) run		
	without issue on other i-STAT analyzers		
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Complaint	Description		
Code 148	Sample not detected when testing immunoassay (cTnl, BNP,	, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	Prompts for Meaningful Data Collection	
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has	the code 148 been occurring?	
Use Another	2. How many code 148 have occurred?		
Cartridge	3. If code occurred while testing QC material:		
	a. What is lot number(s)?		
RW Code: C2148	4. How was the cartridge handled?		
	a. Was the cartridge closed completely?		
Answer pRE	b. Was the cartridge filled to the fill mark?		
Questions!	5. What is analyzer serial number(s)?		
	6. What is the elevation of the testing site? (i.e. in CO, UT	, AB)?	
Synonyms: N/A	Troubleshooting		
	A. Verify that the cartridge is filled properly (Technical Bulletin: Analyzer Coded Messages Art: 714260)		
	B. Verify that the cartridge was filled to the fill mark and not underfilled		
	C. Verify that the cartridge was closed properly before ins	serting into analyzer	
	D. Test a new cartridge with fresh sample on the same cartridge lot number and box		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	F. Document testing site elevation when applicable		
	Resolution		
	IF the code 148 is due to an underfilled cartridge and	THEN the incident is resolved	
	through troubleshooting code is not reproducible on	Classification is Complaint 1	
	additional cartridges		
	IF the code 148 is due to the cartridge not being properly	THEN the incident is resolved	
	closed and through troubleshooting code is not	Classification is Complaint 1	
	reproducible on additional cartridges		
	IF after running additional cartridges the code 148 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 148 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	I-STAT analyzers	Ask customer if cartridges are available to be returned for	
	IF the ender 140 is persistent on specific i CTAT and the	Investigation and document request(s)	
	IF the code 148 is persistent on specific I-STAT analyzer	Clossification is Benefit	
	AND those same caltriage lot(s) run without issue on	Classification is kepair	
	other i-STAT dildiyzers		

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Complaint	Description			
Code 149	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges			
	Prompts for Meaningful Data Collection			
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) has the code 149 occurred?			
Use Another	2. How many code 149 have occurred?			
Cartridge	3. What is being tested on the cartridge – QC material or patient sample?			
	4. If code occurred while testing QC material, applicable, what is lot number(s)?			
RW Code: C2149	5. If code occurred while testing patient sample:			
	a. Is only one patient sample giving the code or multiple patients?			
Answer pRE	b. What sample type is being tested (whole blood or plasma)?			
Questions!	c. How is sample collected?			
a	d. What collection device is being used?			
Synonyms: N/A	i. What anticoagulant is being used?			
	II. If evacuated tube: what is the lot number of the evacuated tub	oe?		
	e. How many minutes after collection are the samples tested?			
	6. What is analyzer serial number(s)?	6. What is analyzer serial number(s)?		
	7. What is the elevation of the testing site (i.e. CO, UT, AB)?			
	I roubleshooting			
	A. Verify sample type, collection and handling are correct			
	 B. If one code 149, then draw a fresh sample and test a new cartridge C. If code is persistent on a specific cartridge let number, determine and desument code rate for the specific cartridge 			
	In code is persistent on a specific cartilities for number, determine and document code rate for the specific cartilities			
	D. Document testing site elevation when applicable			
	Resolution			
	IF after running a new cartridge with fresh sample the THEN the incident is resolved	2d		
	code 149 is not reproducible on a specific analyzer • Classification is C	omplaint 1		
	IF the code 149 is persistent on specific cartridge lot(s) THEN the suspect cartridge	lot(s) should be investigated		
	Classification is Co	omplaint 2		
		•		
	Ask customer if cartridges a	are available to be returned for		
	investigation and documen	ıt request(s)		
	IF the code 149 is persistent on multiple i-STAT THEN the suspect cartridge	and QC material lot(s) should be		
	analyzers after troubleshooting but only on specific investigated			
	cartridge lot(s) and specific QC material lot(s) AND • Classification is Co	omplaint 2		
	other cartridge lots and other QC material lot(s) run			
	without issue on the same i-STAT analyzers Ask customer if cartridges a	and QC material are available to		
	be returned for investigation	on and document request(s)		

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Complaint	Description		
Code 150	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type, lot number(s)/box number(s) ha	s the code 150 been occurring?	
Use Another	2. How many code 150 have occurred?		
Cartridge	3. What is being tested on the cartridge – QC material of	r patient sample?	
	4. If code occurred while testing QC material, what is lot	number(s)?	
RW Code: C2150	5. If code occurred while testing patient sample:		
	a. Is only one patient sample giving the code o	or multiple patients?	
Answer pRE	b. What sample type is being tested (whole blo	ood or plasma)?	
Questions!	c. How is the sample collected?		
	d. What collection device is being used?		
Synonyms: N/A	i. What anticoagulant is being used	?	
	ii. If evacuated tube: what is the lot	number of the evacuated tube?	
	e. How many minutes after collection are the	samples being tested?	
	6. What is analyzer serial number(s)?		
	7. What is the elevation of the testing site (i.e. CO, UT, A	\B)?	
	Troubleshooting		
	A. Verify sample type, collection, and handling are correct		
	B. If only one code 150, retest cartridge with a fresh patient sample		
	C. If testing BNP cartridge with whole blood, recommend that the sample be centrifuged and repeat cartridge test		
	with plasma		
	E. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	E. In code is persistent on a specific carringe for number, determine and document code rate for the specific carringe		
	E Document testing site elevation when applicable		
	Resolution		
	IF after running a new cartridge the code 150 is not	THEN the incident is resolved	
	reproducible on a specific analyzer	Classification is Complaint 1	
	IF the code 150 is resolved after retesting BNP cartridge	THEN the incident is resolved	
	with plasma sample	Classification is Complaint 1	
	IF the code 150 is persistent on specific cartridge lot(s)	THEN the suspect cartridge lot(s) should be investigated	
		Classification is Complaint 2	
		Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 150 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge and QC material lot(s) should be	
	after troubleshooting but only on specific cartridge lot(s)	investigated	
	and specific QC material lot(s) AND other cartridge lots	Classification is Complaint 2	
	and other QC material lot(s) run without issue on the		
	same i-STAT analyzers	Ask customer if cartridges and QC material are available to	
		be returned for investigation and document request(s)	
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Complaint Description Code 151 Cartridge Error with immunoassay (CTnl, BNP, CK-MB and β-hCG) cartridges Prompts for Meaningful Data Collection Another Cartridge 1. W Code: C2151 1. W Code: C2151 1. W Code: C2151 1. W Code: C2151 1. Maxeer pRE Questions! 2. Synonyms: N/A 5. If code occurred while testing patient sample: a. 1. What is being tested on the cartridge – QC material or patients ample: b. 1. Synonyms: N/A 3. Synonyms: N/A 4. What collection device is being used? f. 6. What is analyzer serial number(s)? 7. Must collection of the testing site (i.e. C0, UT, AB)? Toubleshooting 7. A. Verify sample type, collection, and handling are correct B. Follow is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number Document testing site elevation when applicable THEN the incident is resolved Resolution IF after running a new cartridge with fr				
Code 151 Cartridge Error with immunoassay (cTn, BNP, CK-MB and β-hCG) cartridges Prompts for Meaningful Data Collection Cartridge Error - Use I. What cartridge tot number(s)/box number(s) has the code 151 been occurring? Another Cartridge I. What cartridge tot number(s)/box number(s) has the code 151 been occurring? W Code: C2151 If code occurred while testing DC material, what is lot number(s)? S. Moary pRE a. Is only one patient sample giving the code or multiple patients? Questions! b. What sample type is being used? C. How many minubes after collection are the samples tested? C. What is analyzer serial number(s)? Synonyms: N/A C. What is analyzer serial number(s)? Y. What is the elevation of the testing site (i.e. CO, UT, AB)? Troubleshooting A. Verify sample type, collection, and handling are correct B. If only one code 151 error, then draw a fresh sample and run a new cartridge D. Document testing site elevation when applicable C. If code is persistent on specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number D. Document testing site elevation when applicable THEN the incident is resolved Resolution If efter running a new cartridge lot for the fresh sample the code 151 is persistent on specific cartridge lot(s) THEN the suspect cartridge are available to be returned for inves	Complaint	Description		
Prompts for Meaningful Data Collection Another Cartridge 1. What cartridge lot number(s)/box number(s) has the code 151 been occurring? Another Cartridge 2. How many code 151 have occurred? 3. What is being tested on the cartridge – QC material or patient sample? RW Code: C2151 4. If code occurred while testing QC material, what is lot number(s)? 5. If code occurred while testing QC material, what is lot number(s)? 5. If code occurred while testing QC material, what is lot number(s)? 6. What sample type is being tested (whole blood or plasma)? 7. How is sample collected? 8. What at anticoaguinal is being used? 6. What is analyzer serial number(s)? 7. What is the elevation of the testing site (i.e. CO, UT, AB)? Troubleshooting A. Verify sample type, collection, and handling are correct B. If only one code 151 error, then draw a fresh sample and run a new cartridge C. If code is persistent on a specific cartridge to number, becurring elevation of the applicable Resolution IF after running a new cartridge with fresh sample the code 151 is persistent on specific cartridge lot(s) IF the code 151 is persistent on specific cartridge lot(s) IF the code 151 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) <	Code 151	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges		
Cartridge Error - Use 1. What cartridge lot number(s) box number(s) has the code 151 been occurring? Another Cartridge 2. How many code 151 have occurred? 3. What is being tested on the cartridge – QC material or patient sample? RW Code: C2151 4. If code occurred while testing QC material, what is lot number(s)? Synonyms: N/A 5. If code occurred while testing QC material, what is lot number(s)? Synonyms: N/A 6. What collection device is being used? e. What collection device is being used? e. What is the elevation of the testing site (i.e. CO, UT, AB)? Troubleshooting 7. A. Verify sample type, collection, and handling are correct B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number D. Document testing site elevation when applicable Resolution IF after running a new cartridge with fresh sample the code 151 is persistent on specific cartridge lot(s) IF the code 151 is persistent on specific cartridge lot(s) THEN the incident is resolved C. Classification is Complaint 2 As customer if cartridges are available to be returned for investigated Classification is Complaint 2		Prompts for Meaningful Data Collection		
Another Cartridge 2. How many code 151 have occurred? RW Code: C2151 3. What is being tested on the cartridge – QC material or patient sample? RW Code: C2151 4. If code occurred while testing QC material, what is lot number(s)? S. If code occurred while testing QC material, what is lot number(s)? S. If code occurred while testing QC material, what is lot number(s)? Cuestions! 5. If code occurred while testing QC material, what is lot number(s)? Synonyms: N/A 6. What sample type is being used? C. How is sample collected? 6. What collection device is being used? F. How many minutes after collection are the samples tested? 6. What anticoagulant is being used? 7. What is the elevation of the testing site (i.e. CO, UT, AB)? 7. What is the elevation of the testing site (i.e. CO, UT, AB)? Toubleshooting A. Verify sample type, collection, and handling are correct 8. If only one code 151 error, then draw a fresh sample and run a new cartridge 7. How many minutes after cartridge to number or box number D. Document testing site elevation when applicable 7. Her running a new cartridge with fresh sample the incident is resolved 6. If only one code 151 is persistent on specific cartridge lot(s) 7. HEN the incident is resolved C. If code is persistent on specific cartridge lot(s) 7. HEN the suspect cartridge are available to be returned	Cartridge Error – Use	1. What cartridge lot number(s)/box number(s) has the o	code 151 been occurring?	
3. What is being tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material or patient sample? Answer pRE Questions! a. Is only one patient sample giving the code or multiple patients? Answer pRE Questions! a. Is only one patient sample giving the code or multiple patients? Synonyms: N/A b. What sample type is being tested (whole blood or plasma)? c. How is sample collected? Synonyms: N/A d. What collection device is being used? e. What is being used? . f. How many minutes after collection are the samples tested? 6. What is nalyzer serial number(s)? . 7. What is nalyzer serial number(s)? . A. Verify sample type, collection, and handling are correct . 8. If only one code 151 error, then draw a fresh sample and run a new cartridge . C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number ob on number . 0. Document testing site elevation when applicable . Resolution IF after running a new cartridge with fresh sample the collestif is not reproducible . <th>Another Cartridge</th> <th>How many code 151 have occurred?</th> <th></th>	Another Cartridge	How many code 151 have occurred?		
RW Code: C2151 4. If code occurred while testing QC material, what is lot number(s)? Answer pRE Questions! a. Is only one patient sample giving the code or multiple patients? Description b. What sample type is being tested (whole blood or plasma)? C. How is sample collected? c. How many minutes after collection are the samples tested? Synonyms: N/A d. What collection device is being used? F. How many minutes after collection are the samples tested? f. How many minutes after collection are the samples tested? 6. What is analyzer serial number(s)? What is the elevation of the testing site (i.e. CO, UT, AB)? Troubleshooting A. Verify sample type, collection, and handling are correct B. If only one code 151 error, then draw a fresh sample and run a new cartridge C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number D. Document testing site elevation when applicable Resolution IF after running a new cartridge with fresh sample the code 151 is not reproducible THEN the incident is resolved IF the code 151 is persistent on specific cartridge lot(s) THEN the suspect cartridge and QC material lot(s) should be investigated IF the code 151 is persistent on multiple I-STAT analyzers and specific CQ material lot(s) AND other cartridge lot(s) THEN the suspect cartridge and QC material lot(s) should be investigate		3. What is being tested on the cartridge – QC material or	r patient sample?	
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Answer pRE Questions! a. Is only one patient sample giving the code or multiple patients? Questions! b. What sample type is being tested (whole blood or plasma)? Synonyms: N/A d. What collection device is being used? e. What anticoagulant is being used? f. How many minutes after collection are the samples tested? 6. What is analyzer serial number(s)? 7. What is the elevation of the testing site (i.e. CO, UT, AB)? Troubleshooting A. Verify sample type, collection, and handling are correct 8. If only one code 151 error, then draw a fresh sample and run a new cartridge C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number Document testing site elevation when applicable Resolution IF after running a new cartridge with fresh sample the code 151 is not reproducible Classification is Complaint 1 IF the code 151 is persistent on specific cartridge lot(s) THEN the suspect cartridge and QC material lot(s) should be investigated • Classification is Complaint 2 Ask customer if cartridge and QC material lot(s) should be investigated • Classification is Complaint 2 Ask customer if cartridge and QC material are available to be neturned for investigated and other QC material lot(s) AND other cartridge lots and other QC material lot(s) AND other cartridge lots • Classification is Complaint 2		If code occurred while testing patient sample:		
Questions! b. What sample type is being tested (whole blood or plasma)? Synonyms: N/A c. How is sample collected? Mat collection device is being used? e. What inticoagulant is being used? f. How many minutes after collection are the samples tested? 6. What is analyzer serial number(s)? 7. What is the elevation of the testing site (i.e. CO, UT, AB)? Troubleshooting A. Verify sample type, collection, and handling are correct 8. If only one code 151 error, then draw a fresh sample and run a new cartridge C. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number Document testing site elevation when applicable Resolution IF after running a new cartridge with fresh sample the code 151 is persistent on specific cartridge lot(s) THEN the incident is resolved IF the code 151 is persistent on specific cartridge lot(s) and specific QC material lot(s) run without issue on the same i-STAT analyzers THEN the suspect cartridge and QC material lot(s) should be investigated and other QC material lot(s) run without issue on the same i-STAT analyzers	Answer pRE	 a. Is only one patient sample giving the code o 	r multiple patients?	
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			to be returned for investigation and document request(s)	

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Complaint	Description		
Code 165	Material detected on sensors before expected due to testing a used cartridge or not allowing cartridges to equilibrate to		
	room temperature prior to testing.		
Cartridge Error –	Questions		
Use Another	1. What cartridge type and lot number(s)/box number(s)	has the code 165 been occurring?	
Cartridge	2. How many code 165 have occurred?		
	3. What is tested on the cartridge – QC material or patient sample?		
RW Code: C1103	4. If code occurred while testing QC material, what is lot r	number(s)?	
	5. If code occurred while testing patient sample:		
Answer pRE	a. How is sample collected?		
Questions!	b. How many minutes after collection are the sa	amples tested?	
	6. How is the cartridge being handled?		
Synonyms: N/A	 Was a used cartridge inserted into the analyz 	er?	
	 How long were cartridges allowed to equilibr 	ate prior to testing?	
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. Verify used cartridge is not being tested		
	B. Verify cartridges were equilibrated to room temperature for appropriate amount of time prior to testing		
	C. Test a new cartridge		
	D. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution	I	
	IF after running additional cartridges the code is not	THEN the incident is resolved	
	reproducible on the analyzer	Classification is Complaint 1	
	IF the code was due to testing a used cartridge or cold	THEN the incident is resolved	
	cartridge and the next cartridge(s) was tested successfully	Classification is Complaint 1	
	after proper cartridge handling the code 165 is resolved		
	IF the code 165 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	I-STAT analyzers	Ask customer if cartridges are available to be returned for investigation and document request(s)	
	IF the code 165 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers		
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Complaint	Description		
Code 166	Sample arrived at sensor too late, possible due to underfilled cartridge or air bubble in sample.		
	Questions		
Cartridge Error –	1. What cartridge type and lot number(s)/box number(s) has the code 166 been occurring?		
Use Another	2. How many code 166 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material, what is lot number(s)?		
RW Code: C1104	5. If code occurred while testing patient sample:		
	a. Is only one patient sample giving the code or multiple patients?		
Answer pRE	b. How is sample collected?		
Questions!	c. How many minutes after collection are the samples tested?		
Supersume: N/A	6. How are the cartridges being filled?		
Synonyms. N/A	a. Is the sample reaching the fill mark on the cartridge?		
	5. What is analyzer serial number(s)?		
	7. what is analyzer serial number(s)?		
	Verify proper sample handling and sample loading to cartridge		
	 A. Verify proper sample naturing and sample foduling to calchage B. Verify that a new cartridge is filled to the fill mark and tested successfully. 		
	C If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF the code 166 is due to underfilled cartridge through THEN the incident is resolved		
	troubleshooting and the new cartridge is tested • Classification is Complaint 1		
	successfully		
	IF after running additional cartridges the code is not THEN the incident is resolved		
	reproducible on the analyzer • Classification is Complaint 1		
	IF the code 166 is persistent on multiple i-STAT analyzers THEN the suspect cartridge lot(s) should be investigated		
	after troubleshooting but only on specific cartridge lot(s) • Classification is Complaint 2		
	AND other cartridge lot(s) run without issue on the same		
	Ask customer if cartridges are available to be returned for investigation and document request(s)		
	IF the code 166 is persistent on specific i-STAT analyzer THEN the i-STAT analyzer should be replaced or repaired		
	AND those same cartridge lot(s) run without issue on the • Classification is Repair		
	other i-STAT analyzers		

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Complaint	Description		
Code 167	Sample arrived at sensor too early, possible due to overfilled cartridge.		
0000 207	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type and lot number(s)/box number(s) h	as the code 167 been occurring?	
Use Another	2. How many code 167 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?	
-	4. If code occurred while testing QC material, what is lot no	umber(s)?	
RW Code: C1105	5. If code occurred while testing patient sample:		
	a. Is only one patient sample giving the code or r	nultiple patients?	
Answer pRE	b. How is sample collected?		
Questions!	c. How many minutes after collection are the sar	nples tested?	
	6. How are the cartridges being handled and filled?		
Synonyms: N/A	a. Is the sample filled beyond the fill mark on the	e cartridge?	
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. Verify that the cartridge is filled to the fill mark and tested successfully		
	B. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	lot number or box number		
	Resolution		
	IF the code 167 is due to overfilled cartridge through	THEN the incident is resolved	
	troubleshooting and the new cartridge is tested	Classification is Complaint 1	
	successfully		
	IF after running additional cartridges the code is not	THEN the incident is resolved	
	reproducible on the analyzer	Classification is Complaint 1	
	IF the code 167 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
	IF the code 107 is possistent on specific i CTAT analyzer	Investigation and document request(s)	
	IF the code 167 is persistent on specific I-STAT analyzer	Incivitie i-STAT analyzer should be replaced or repaired	
	AND those same cartriage lot(s) run without issue on the	Classification is kepair	
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Complaint	Description		
Code 170	Resistance values detected during test cycle was too high		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type and lot number(s)/box numbers(s)	has the code 170 been occurring?	
Use Another	2. How many code 170 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patien	t sample(s)?	
	4. If code occurred while testing QC material:		
RW Code: C1106	a. What is product name and lot number?		
	b. How is QC material handled? Describe testin	g procedure.	
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or	multiple patients?	
	b. What is the sample type tested?		
Synonyms: N/A	c. How is the sample collected?		
	d. What is the time between sample collection a	and testing?	
	6. How is the cartridge being handled?		
	a. Was a used cartridge inserted into the analyz	er?	
	b. Was the cartridge closed properly?		
	c. Was the cartridge filled to fill mark?		
	7. What is analyzer serial humber(s)?		
	Troubleshooting		
	A. If the code is with QC material, verify the proper handling and testing		
	B. Verify the sample type tested and if the sample is tested inimediately after collection		
	D If code is persistent on a specific cartridge lot number	determine and document code rate for the specific cartridge lot	
	pumber or box number		
	Resolution		
	IF after running additional cartridges the code is not	THEN the incident is resolved	
	reproducible on the analyzer	Classification is Complaint 1	
	IF after correcting any sample collection or handling issues	THEN the incident is resolved	
	the code 170 is resolved	Classification is Complaint 1	
	IF the code 170 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 170 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
1	other i-STAT analyzers		

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Compleint	Description		
Codo 171	Public detected on or near the concers		
Code 1/1	Dubble detected of of field the sensors		
Cortridgo Error	Prompts for Meaningful Data Collection		
Carthoge Error –	1. What cartridge type and lot number(s)/box numbers(s) n	has the code 171 been occurring?	
Ose Another Contridge	2. How many code 1/1 nave occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample(s)?		
PW Code: C1107	4. If code occurred while testing QC material:		
KW COUE. CIIO7	a. What is product name and lot number?		
Answer pBE	b. How is QC material nandled? Describe testing	procedure.	
Allswel pre	5. If code occurred while testing patient sample:	authints matin star	
Questions!	a. Is only one patient sample giving the code or m	nuitiple patients?	
Supervice N/A	b. What is the sample type tested?		
Synonyms. N/A	c. How is the sample collected?		
	a. What is the time between sample collection and	iu testing:	
	6. How is the cartridge being handled?		
	a. Was a used cartridge inserted into the analyzer	l r	
	b. Was the cartridge closed properly?		
	7 What is analyzer serial number(s)?		
	7. What is analyzer serial number(s)?		
	I roublesnooting		
	A. If the code is with QC material, verify the proper handling and testing		
	1. Test a new callinge with resh QC material	immediately often collection	
	B. Verify the sample type tested and if the sample is tested		
	C. Test a new callinge with nesh sample	atorming and document code rate for the specific cartridge	
	D. If code is persistent on a specific cartilitie for number, de	etermine and document code rate for the specific caltridge	
	Posolution		
	IE after running additional cartridges the code is not	THEN the incident is received	
	reproducible on the analyzer	Classification is Completed	
	IF ofter correcting any comple collection or handling issues	Classification is complaint 1	
	IF after correcting any sample collection or handling issues	THEN the incident is resolved	
	the code 1/1 is resolved	Classification is complaint 1	
	IF the code 1/1 is persistent on multiple I-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	I-STAT analyzers	Ask customer if cartridges are available to be returned for	
	IF the ends 174 is persistent on an effect CTAT and	Investigation and document request(s)	
	IF the code 1/1 is persistent on specific I-STAT analyzer	THEN the I-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
l	other I-STAT analyzers		

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Complaint	Description		
Code 172	Bubble detected on or near the sensors		
	Prompts for Meaningful Data Collection		
Cartridge Error –	 What cartridge type and lot number(s)/box numbers(s) 	has the code 172 been occurring?	
Use Another	How many code 172 have occurred?		
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code: C1108	a. What is product name and lot number?		
	b. How is QC material handled? Describe testing	g procedure.	
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	a. Is only one patient sample giving the code or	multiple patients?	
	b. What is the sample type tested?		
Synonyms: N/A	c. How is the sample collected?		
	d. What is the time between sample collection a	and testing?	
	6. How is the cartridge being handled?		
	a. Was a used cartridge inserted into the analyz	er?	
	b. Was the cartridge closed properly?		
	c. Was the cartridge filled to fill mark?		
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. If the code is with QC material, verify the proper handling and testing		
	1. Test a new cartridge with fresh QC material		
	B. Verify the sample type tested and if the sample is tested immediately after collection		
	C. Test a new cartridge with fresh sample		
	D. If code is persistent on a specific cartridge lot number,	determine and document code rate for the specific cartridge	
	lot number or box number		
	Resolution		
	IF after running additional cartridges the code is not	THEN the incident is resolved	
	reproducible on the analyzer	Classification is Complaint 1	
	IF after correcting any sample collection or handling issues	THEN the incident is resolved	
	the code 172 is resolved	Classification is Complaint 1	
	IF the code 172 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same		
	i-STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 172 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers		

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Complaint	Description		
Code 173	Bubble detected on or near the sensors		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type and lot number(s)/box number(s) h	as the code 173 been occurring?	
Use Another	2. How many code 173 have occurred?	U.	
Cartridge	3. What is tested on the cartridge – QC material or patient sample?		
	4. If code occurred while testing QC material:		
RW Code: C1109	a. What is product name and lot number?		
	b. How is QC material handled? Describe testing	procedure.	
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	 a. Is only one patient sample giving the code or r 	nultiple patients?	
	b. What is the sample type tested?		
Synonyms: N/A	c. How is the sample collected?		
	 What is the time between sample collection and 	nd testing?	
	6. How is the cartridge being handled?		
	 Was a used cartridge inserted into the analyze 	r?	
	b. Was the cartridge closed properly?		
	c. Was the cartridge filled to fill mark?		
	7. What is analyzer serial number(s)?		
	Troubleshooting		
	A. If the code is with QC material, verify the proper handling and testing		
	1. Test a new cartridge with fresh QC material		
	B. Verify the sample type tested and if the sample is tested immediately after collection		
	C. Test a new cartridge with fresh sample		
	D. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge		
	Paralutian		
	Resolution	THEN the incident is received	
	reproducible on the analyzer	THEN the incluent is resolved	
	IE after correcting any sample collection or handling issues	Classification is complaint 1	
	the code 173 is resolved	Classification is Complaint 1	
	IF the code 173 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troublesbooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-	Classification is complaint 2	
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 173 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other i-STAT analyzers	• *	

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Complaint	Description		
Code 174	Bubble detected on or near the sensors		
	Prompts for Meaningful Data Collection		
Cartridge Error –	1. What cartridge type and lot number(s)/box number(s) h	as the code 174 been occurring?	
Use Another	2. How many code 174 have occurred?	-	
Cartridge	3. What is tested on the cartridge – QC material or patient	sample?	
	4. If code occurred while testing QC material:		
RW Code: C1110	a. What is product name and lot number?		
	 How is QC material handled? Describe testing 	procedure.	
Answer pRE	5. If code occurred while testing patient sample:		
Questions!	 Is only one patient sample giving the code or r 	nultiple patients?	
c	b. What is the sample type tested?		
Synonyms: N/A	c. How is the sample collected?		
	d. What is the time between sample collection a	nd testing?	
	6. How is the cartridge being handled?		
	a. Was a used cartridge closed property?	11 f	
	b. Was the cartridge filled to fill mark?		
	7 What is analyzer serial number(s)?		
	Troubleshooting		
	Troubleshooting		
	1 Test a new cartridge with fresh OC material		
	B Verify the sample type tested and if the sample is tested immediately after collection		
	C. Test a new cartridge with fresh sample		
	D. If code is persistent on a specific cartridge lot number, d	letermine and document code rate for the specific cartridge lot	
	number or box number	· · · · ·	
	Resolution		
	IF after running additional cartridges the code is not	THEN the incident is resolved	
	reproducible on the analyzer	Classification is Complaint 1	
	IF after correcting any sample collection or handling issues	THEN the incident is resolved	
	the code 174 is resolved	Classification is Complaint 1	
	IF the code 174 is persistent on multiple i-STAT analyzers	THEN the suspect cartridge lot(s) should be investigated	
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2	
	AND other cartridge lot(s) run without issue on the same i-		
	STAT analyzers	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	IF the code 174 is persistent on specific i-STAT analyzer	THEN the i-STAT analyzer should be replaced or repaired	
	AND those same cartridge lot(s) run without issue on the	Classification is Repair	
	other I-STAT analyzers		

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Complaint	Description	Description		
Code 175	Bubble detected on or near the sensors			
	Prompts for Meaningful Data Collection			
Cartridge Error –	1. What cartridge type and lot number(s)/box number(s) has	the code 175 been occurring?		
Use Another	2. How many code 175 have occurred?			
Cartridge	3. What is tested on the cartridge – QC material or patient sa	mple?		
	4. If code occurred while testing QC material:			
RW Code: C1111	a. What is product name and lot number?			
	b. How is QC material handled? Describe testing pr	rocedure.		
Answer pRE	5. If code occurred while testing patient sample:			
Questions!	a. Is only one patient sample giving the code or mul	Itiple patients?		
	b. What is the sample type tested?			
Suponyms: N/A	c. How is the sample collected?	testing		
Synonymis. N/A	6 How is the cartridge being bandled?	testing:		
	Was a used cartridge inserted into the analyzer?			
	h Was the cartridge closed properly?			
	c. Was the cartridge filled to fill mark?			
	7. What is analyzer serial number(s)?			
	Troubleshooting			
	A. If the code is with QC material, verify the proper handling and testing			
	1. Test a new cartridge with fresh QC material			
	B. Verify the sample type tested and if the sample is tested immediately after collection			
	C. Test a new cartridge with fresh sample			
	D. If code is persistent on a specific cartridge lot number, dete	ermine and document code rate for the specific cartridge		
	lot number or box number			
	Resolution			
	IF after running additional cartridges the code is not THI	EN the incident is resolved		
	reproducible on the analyzer	Classification is Complaint 1		
	IF after correcting any sample collection or handling THI	EN the incident is resolved		
	issues the code 175 is resolved	Classification is Complaint 1		
	IF the code 175 is persistent on multiple i-STAT analyzers	EN the suspect cartridge lot(s) should be investigated		
	after troubleshooting but only on specific cartridge lot(s)	Classification is Complaint 2		
	AND other cartridge lot(s) run without issue on the same	la su de la seconda de la s		
	I-STAT analyzers Ask	(customer if cartridges are available to be returned for		
	IF the code 175 is persistent on specific i STAT analyzer TU	esugation and document request(s)		
	AND those same cartridge lot(c) run without issue on the	Classification is Panair		
	other i-STAT analyzers			
	other i STAT analyzers			

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2.0 Electronic Simulator Codes for the i-STAT 1 System

2.1 Internal Electronic Simulator Codes Description Complaint Code G Simulator Failure: Amperometric channel out of limits Internal simulator failure G may be analyzer or cartridge related Internal **Prompts for Meaningful Data Collection** Simulator What is the cartridge type/lot number(s) showing the internal simulator code G? 1. Is code occurring on one analyzer or multiple analyzers? 2. RW Code: C201G How many code G have occurred? 3. If multiple code G, are they all from the same box of cartridges? a. Synonyms: N/A How many total cartridges were used for the specific cartridge lot number? b. What is the internal simulator schedule customization setting on the analyzer (lock out enabled or disabled)? с. Troubleshooting If one internal simulator code G failure, perform the external electronic simulator test on analyzer(s) 1. If the external simulator passes, the analyzer(s) can be used For multiple internal simulator code G failures occurring on a specific cartridge lot number, document code rate Β. Check the internal simulator schedule for lock out enabled or disabled, on the analyzer if appropriate. C. Note: Allowable error rate or error count - A rate of 2-3% or no more than 3 out of an individual box Resolution IF the external simulator test displays PASS on one i-STAT THEN the incident is resolved Analyzer AND the error is not reproducible on additional Classification is Complaint 1 cartridges IF the internal simulator failure code G rate is less than THEN the incident is resolved allowable rate for a specific cartridge lot number Classification is Complaint 1 IF the internal simulator FAIL G is occurring on a specific i-**THEN** the i-STAT analyzer should be replaced or repaired STAT analyzer AND other i-STAT analyzer(s) test the same Classification is Repair ٠ cartridge lot successfully IF the internal simulator failure code G rate is greater than THEN the suspect cartridge lot should be investigated allowable rate (see note above) for a specific cartridge lot Classification is Complaint 2 number on multiple analyzers that pass the external simulator test Ask customer if cartridges are available to be returned for investigation and document request(s)

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Complaint	Description		
Code L	Simulator Failure: Potentiometric channel out of limits		
	Internal simulator failure L may be analyzer or cartridge related		
Internal Simulator	Prompts for Meaningful Data Collection		
Code L	1. What is the cartridge type/lot number(s) showing the in	ternal simulator code L?	
	2. Is code occurring on one analyzer or multiple analyzers?		
RW Code: C201L	3. How many code L have occurred?		
	a. If multiple code L, are they all from the same b	oox of cartridges?	
Synonyms: N/A	b. How many total cartridges were used for the s	pecific cartridge lot number?	
	c. What is the internal simulator schedule custor	nization setting on the analyzer (lock out enabled or	
	disabled)?		
	Troubleshooting		
	A. If one internal simulator code L failure, perform the external electronic simulator test on analyzer(s)		
	 If the external simulator passes, analyzer(s) ca 	n be used	
	B. For multiple internal simulator code L failures occurring on a specific cartridge lot number, document code rate		
	C. Check the internal simulator schedule for lock out enabled or disabled, on the analyzer if appropriate.		
	Note: Allowable error rate or error count - A rate of 2-3% or no more than 3 out of an individual box		
	IF the external simulator test displays PASS on one I-STAT	THEN the incident is resolved	
	analyzer AND the error is not reproducible on additional	Classification is Complaint 1	
	LE the internal simulator failure code L rate is less than	THEN the incident is resolved	
	allowable rate for a specific cartridge lot number	Classification is Complaint 1	
	IF the internal simulator FAIL L is occurring on a specific	Classification is Complaint 1	
	analyzer AND other analyzer(s) test the same cartridge lot	Classification is Donair	
	• Classification is Repair		
	IF the internal simulator failure code L rate is greater than	THEN the suspect cartridge lot should be investigated	
	allowable rate (see note above) for a specific cartridge lot	Classification is Complaint 2	
	number on multiple analyzers that pass the external		
	simulator test	Ask customer if cartridges are available to be returned for	
		investigation and document request(s)	
	1	investigation and document request(s)	
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Complaint	Description		
Code B	Simulator Failure: Potentiometric channel out of limits.		
	Prompts for Meaningful Data Collection		
Internal Simulator	1. What is analyzer serial number(s)?		
Code B	2. How many code B have occurred?		
	3. What is the cartridge type/lot number(s) showing the in	iternal simulator code B?	
RW Code: C201B	Troubleshooting		
	A. Perform the external electronic simulator test on the analyzer		
Synonyms: N/A	B. Repeat cartridge testing if the external simulator test passes		
	Resolution		
	IF the external simulator test displays PASS on one or	THEN the incident is resolved	
	multiple i-STAT analyzer(s) and code B was not	Classification is Complaint 1	
	reproduced with repeat cartridge testing		
	IF one i-STAT analyzer displays FAIL during the external	THEN the i-STAT analyzer should be replaced or repaired	
	simulator test AND other i-STAT analyzer(s) testing the	Classification is Repair	
	same external simulator PASS		

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Complaint	Description		
Code R	Simulator Failure: Resistance reading on conductometric channel out of limits.		
	Prompts for Meaningful Data Collection		
Internal Simulator	1. What is analyzer serial number(s)?		
Code R	2. How many code R have occurred?		
	3. What is the cartridge type/lot number(s) showing the internal simulator code R?		
RW Code: C201R+	Troubleshooting		
	A. Perform the external electronic simulator test on the analyzer		
Synonyms: N/A	B. Repeat cartridge testing if the external simulator test passes		
	Resolution		
	IF the external simulator test displays PASS on one or THEN the incident is resolved		
	multiple i-STAT analyzer(s) and code R was not • Classification is Complaint 1		
	reproduced with repeat cartridge testing		
	IF one i-STAT analyzer displays FAIL during the external THEN the i-STAT analyzer should be replaced or repaired		
	simulator test AND other i-STAT analyzer(s) testing the • Classification is Repair		
	same external simulator PASS		

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Complaint	Description		
Code r	Simulator Failure: Resistance reading on conductometric channel out of limits.		
	Prompts for Meaningful Data Collection		
Internal Simulator	1. What is analyzer serial number(s)?		
Code r	2. How many code r have occurred?		
	3. What is the cartridge type/lot number(s) showing the intern	nal simulator code r?	
RW Code: C201R-	Troubleshooting		
	A. Perform the external electronic simulator test on the analyzer		
Synonyms: N/A	B. Repeat cartridge testing if the external simulator test passes		
	Resolution		
	IF the external simulator test displays PASS on one or The test of	HEN the incident is resolved	
	multiple i-STAT analyzer(s) and code r was not reproduced	Classification is Complaint 1	
	with repeat cartridge testing		
	IF one i-STAT analyzer displays FAIL during the external TH	HEN the i-STAT analyzer should be replaced or repaired	
	simulator test AND other i-STAT analyzer(s) testing the	Classification is Repair	
	same external simulator PASS		

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Complaint	Description		
Code t	Simulator Failure: Thermal probe failure		
	Prompts for Meaningful Data Collection		
Internal Simulator	1. What is analyzer serial number(s)?		
Code t	2. How many code t have occurred?		
	3. What is the cartridge type/lot number(s) showing the internal simulator code t?		
RW Code: C201T-	Troubleshooting		
	A. Perform the external electronic simulator test on the analyzer		
Synonyms: N/A	B. Repeat cartridge testing if the external simulator test passes		
	Resolution		
	IF the external simulator test displays PASS on one or THEN the incident is resolved		
	multiple i-STAT analyzer(s) and code t was not reproduced • Classification is Complaint 1		
	with repeat cartridge testing		
	IF one i-STAT analyzer displays FAIL during the external THEN the i-STAT analyze should be replaced or repaired		
	simulator test AND other i-STAT analyzer(s) testing the • Classification is Repair		
	same external simulator PASS		

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Complaint	Description		
Code G	Simulator Failure: Amperometric channel out of limits. Can oc	cur if external simulator not inserted straight.	
	Prompts for Meaningful Data Collection		
External	1. What is analyzer serial number(s)?		
Simulator Code G	2. What is the serial number of the external electronic simulator(s) that experienced code G?		
	3. Has external simulator test been repeated on analyzer?		
RW Code: C200G	Troubleshooting		
	A. Clean the external simulator contacts and the inside of th	e blue cap with alcohol	
Synonyms: N/A	B. Repeat the external simulator test		
	C. If code G continues after cleaning, rerun the same extern	al simulator on a different i-STAT analyzer, or run a different	
	external simulator on the same i-STAT analyzer		
	D. If only one i-STAT analyzer and one external simulator are	e available, set the i-STAT analyzer to run the internal	
	simulator		
	Note: Change the internal simulator schedule on analyzer to enabled for every "1" patient test with "Lockout" enabled		
	(Administration Menu \rightarrow Customization \rightarrow Change \rightarrow Password \rightarrow QC Tests \rightarrow Simulator \rightarrow Int Simulator)		
	Resolution		
	IF the external simulator contacts/inside of the blue cap	THEN the incident is resolved	
	simulator tost displayed BASS on one or multiple i STAT	Classification is Complaint 1	
	Analyzors		
	IF multiple i-STAT analyzers continue to experience code G	THEN the external simulator should be replaced	
	after repeating the external simulator test using the same	Classification is Renair	
	external simulator		
	IF one i-STAT analyzer continues to experience code G after	THEN the i-STAT analyzer should be replaced or repaired	
	repeating the external simulator test AND other i-STAT	Classification is Renair	
	analyzers testing the same external simulator PASS		
	IF the internal simulator displays PASS on the analyzer AND	THEN the external simulator should be replaced	
	only one external simulator is available	Classification is Repair	
	IF the external and internal simulator displays FAIL on the	THEN the i-STAT analyzer should be replaced or repaired	
	analyzer AND only one external simulator is available	Classification is Repair	
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Complaint	Description		
Code L	Simulator Failure: Potentiometric channel out of limits. Can	n occur if moisture collects on the contact pins inside the	
	analyzer when the analyzer is subjected to ambient temperature change.		
External Simulator	Prompts for Meaningful Data Collection		
Code L	1. What is analyzer serial number(s)?		
	2. What is the serial number of the external electronic simulator(s) that experienced code L?		
RW Code: C200L	3. Has external simulator test been repeated on analyzer	?	
	Troubleshooting		
Synonyms: N/A	A. Equilibrate the i-STAT analyzer and external simulator the next ten	to the environment for 30 minutes (i.e. in the same room or	
	B Beneat the external simulator test		
	B. Repeat the external simulator test	ovtornal simulator on a different i STAT analyzor, or run a	
	different external simulator the same i STAT analyzer	external simulator on a uniferent i-STAT analyzer, or full a	
	D If only one i-STAT analyzer and one external simulator	are available, set the i-STAT analyzer to run the internal	
	simulator	are available, set the i-stati analyzer to full the internal	
	Simulator		
	Note: Change the internal simulator schedule on analyzer to enabled for every "1" patient test with "Lockout" enabled		
	(Administration Menu \rightarrow Customization \rightarrow Change \rightarrow Password \rightarrow QC Tests \rightarrow Simulator \rightarrow Int Simulator)		
	Resolution		
	IF the i-STAT analyzer(s) AND the external simulator(s) THEN the incident is resolved		
	have equilibrated to the environment for 30 minutes	Classification is Complaint 1	
	AND the repeat external simulator test displayed PASS	·	
	IF multiple i-STAT analyzers continue to experience code	THEN the external simulator should be replaced	
	L after repeating the external simulator test using the	Classification is Repair	
	same external simulator		
	IF one i-STAT analyzer continues to experience code L	THEN the i-STAT analyzer should be replaced or repaired	
	after repeating the external simulator test AND other i-	Classification is Repair	
	STAT analyzers testing the same external simulator PASS		
	IF the internal simulator displays PASS on the analyzer	THEN the external simulator should be replaced	
	AND only one external simulator is available	Classification is Repair	
	IF the external and internal simulator displays FAIL on	THEN the i-STAT analyzer should be replaced or repaired	
	the analyzer AND only one external simulator is available	Classification is Repair	

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Complaint	Description		
Code B	Simulator Failure: Potentiometric channel out of limits.		
	Prompts for Meaningful Data Collection		
External Simulator	1. What is analyzer serial number(s)?		
Code B	2. What is the serial number of the external electronic sin	nulator (s) that experienced code B?	
	3. Has external simulator test been repeated on analyzer?		
RW Code: C200B	Troubleshooting		
Synonyms: N/A	 Repeat the external simulator test, rerun the same extendifferent external simulator the same i-STAT analyzer If only one i STAT analyzer and one external simulator for the same is stated as a statement of the same is statement. 	ernal simulator on a different i-STAT analyzer, or run a	
	B. If only one I-STAT analyzer and one external simulator are available, set the I-STAT analyzer to run the internal simulator simulator		
	Note: Change the internal simulator schedule on analyzer to enabled for every "1" patient test with "Lockout" enabled (Administration Menu \rightarrow Customization \rightarrow Change \rightarrow Password \rightarrow QC Tests \rightarrow Simulator \rightarrow Int Simulator)		
	Resolution		
	IF the repeat external simulator test displays PASS on one	THEN the incident is resolved	
	or multiple i-STAT analyzer(s)	Classification is Complaint 1	
	IF multiple i-STAT analyzers continue to experience code B	THEN the external simulator should be replaced	
	after repeating the external simulator test using the same external simulator	Classification is Repair	
	IF one i-STAT analyzer continues to experience code B	THEN the i-STAT analyzer should be replaced or repaired	
	after repeating the external simulator test AND other i-	Classification is Repair	
	STAT analyzers testing the same external simulator PASS		
	IF the internal simulator displays PASS on the analyzer	THEN the external simulator should be replaced	
	AND only one external simulator is available	Classification is Repair	
	IF the external and internal simulator displays FAIL on the	THEN the i-STAT analyzer should be replaced or repaired	
	analyzer AND only one external simulator is available	Classification is Repair	

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Complaint	Description		
Code R	Simulator Failure: Resistance reading on conductometric channel out of limits.		
	Prompts for Meaningful Data Collection		
External Simulator	1. What is analyzer serial number(s)?		
Code R	2. What is the serial number of the external electronic sin	nulator(s) that experienced code R?	
	3. Has external simulator test been repeated on analyzer?		
RW Code: C200R+	Troubleshooting		
Synonyms: N/A	 Repeat the external simulator test, rerun the same external simulator on a different i-STAT analyzer, or run a different external simulator the same i-STAT analyzer If each end is STAT Analyzer and end out on the internal simulator and external simulator the internal simulator the same is started as a started simulator and end out of the same is started as a started simulator and end out of the same is started simulator the same is started as a started simulator and end out of the same is started simulator the same is started simulator and end out of the same is started simulator the same is started simulator and end out of the same is started simulator and end out of the same is started simulator and end out of the same is started simulator and end out of the same is started simulator and end out of the same is started simulator. 		
	simulator		
	Note: Change the internal simulator schedule on analyzer to enabled for every "1" patient test with "Lockout" enabled (Administration Menu \rightarrow Customization \rightarrow Change \rightarrow <i>Password</i> \rightarrow QC Tests \rightarrow Simulator \rightarrow Int Simulator)		
	Resolution		
	IF the repeat external simulator test displays PASS on one	THEN the incident is resolved	
	or multiple i-STAT analyzer(s)	Classification is Complaint 1	
	IF multiple i-STAT analyzers continue to experience code R	THEN the external simulator should be replaced	
	after repeating the external simulator test using the same external simulator	Classification is Repair	
	IF one i-STAT analyzer continues to experience code R	THEN the i-STAT analyzer should be replaced or repaired	
	after repeating the external simulator test AND other i-	Classification is Repair	
	STAT analyzers testing the same external simulator PASS		
	IF the internal electronic simulator displays PASS on the	THEN the external simulator should be replaced	
	analyzer AND only one external simulator is available	Classification is Repair	
	IF the external and internal simulator displays FAIL on the	THEN the i-STAT analyzer should be replaced or repaired	
	analyzer AND only one external simulator is available	 Classification is Repair 	

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Complaint	Description		
Code r	Simulator Failure: Resistance reading on conductometric channel out of limits.		
	Prompts for Meaningful Data Collection		
External Simulator	1. What is analyzer serial number(s)?		
Code r	2. What is the serial number of the external electronic simulator(s) that experienced code r?		
	3. Has external simulator test been repeated on analyzer?		
RW Code: C200R-	Troubleshooting		
Synonyms: N/A	 A. Repeat the external simulator test, rerun the same external simulator on a different i-STAT analyzer, or run a different external simulator the same i-STAT analyzer B. If only one i-STAT Analyzer and one external simulator are available, set the i-STAT analyzer to run the internal 		
	simulator Note: Change the internal simulator schedule on analyzer to enabled for every "1" patient test with "Lockout" enabled (Administration Manue) Customization & Change & Research & OC Tester & Simulator & Int Simulator)		
	Resolution		
	IF the repeat external simulator test displays PASS on THEN the incident is resolved		
	one or multiple i-STAT analyzer(s) • Classification is Complaint 1		
	IF multiple i-STAT analyzers continue to experience code THEN the external simulator should be replaced		
	r after repeating the external simulator test using the same external simulator external simulator		
	IF one i-STAT analyzer continues to experience code r after repeating the external simulator test AND other i-		
	STAT analyzers testing the same simulator PASS		
	IF the internal simulator displays PASS on the analyzer THEN the external simulator should be replaced		
	AND only one external simulator is available • Classification is Repair		
	IF the external and internal simulator displays FAIL on THEN the i-STAT analyzer should be replaced or repaired		
	the analyzer AND only one external simulator is available • Classification is Repair		

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Complaint	Description		
Code t	Simulator Failure: Thermal probe failure		
	Prompts for Meaningful Data Collection		
External Simulator	1. What is analyzer serial number(s)?		
Code t	2. What is the serial number of the external electronic sin	nulator(s) that experienced code t?	
	3. Has external simulator test been repeated on analyzer	?	
RW Code: C200T-	Troubleshooting		
Synonyms: N/A	 A. Repeat the external simulator test, rerun the same external simulator on a different i-STAT analyzer, or run a different external simulator the same i-STAT analyzer B. If only one i-STAT Analyzer and one external simulator are available, set the i-STAT analyzer to run the internal simulator 		
	Note: Change the internal simulator schedule on analyzer to enabled for every "1" patient test with "Lockout" enabled (Administration Menu \rightarrow Customization \rightarrow Change \rightarrow Password \rightarrow QC Tests \rightarrow Simulator \rightarrow Int Simulator)		
	Resolution		
	IF the repeat external simulator test displays PASS on one	THEN the incident is resolved	
	or multiple i-STAT analyzer(s)	Classification is Complaint 1	
	IF multiple i-STAT analyzers continue to experience code t	THEN the external simulator should be replaced	
	after repeating the external simulator test using the same external simulator	Classification is Repair	
	IF one i-STAT analyzer continues to experience code t	THEN the i-STAT analyzer should be replaced or repaired	
	after repeating the external simulator test AND other i-	Classification is Repair	
	STAT analyzers testing the same external simulator PASS		
	IF the internal simulator displays PASS on the analyzer	THEN the external simulator should be replaced	
	AND only one external simulator is available	Classification is Repair	
	IF the external and internal simulator displays FAIL on the	THEN the i-STAT analyzer should be replaced or repaired	
	analyzer AND only one external simulator is available	Classification is Repair	

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3.0 i-STAT 1 Handheld and Peripheral Issues

3.1 i-STAT 1 Power/Activation Decision Tree

RW Code	Code Description	
C2510	 No activation/power/screen refresh Analyzer not turning on at all and gives no audio or visual response when power on Analyzer screen stuck and will not respond to key presses, typically showing "Insert Cartridge", "Remove Cartridge", or "Cartridge Locked" Analyzer will activate when powered on; the screen activates/flashes then goes blank Printer will not power on Downloader will not power on 	→ Jump to Section
C2506	 Analyzer powers off during testing or when navigating through menus 	→ Jump to Section
C2525	 Display Screen Not Functioning Properly Analyzer screen is not functioning, is faded Garbled display screen Lines on the display screen Dim backlight Note: Refer to cosmetic damage if display screen is cracked 	→ Jump to Section
C2530	 Key(s) difficult to press/not responding Analyzer keys do not respond or are difficult to press 	\rightarrow Jump to Section

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3.1.1. i-STAT Power/Activation Issues

Complaint	Description			
Display Screen	Analyzer powers on and the display screen is either faded, completely blank or shows lines, dark spots,	Analyzer powers on and the display screen is either faded, completely blank or shows lines, dark spots, or blank portions.		
Not Functioning	Analyzer has dim back-lighting.			
Properly	Prompts for Meaningful Data Collection			
	1. What is analyzer serial number(s)?			
RW Code: C2525	2. What is the appearance of the screen?			
	3. What is the current battery voltage on the analyzer status screen?			
Synonyms: Screen	4. What type of batteries are being used?			
display scrambled,	a. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?			
lines, bars, pixels,	b. If i-STAT rechargeable, what is the Born-on-Date (BOD)?			
blurry, fuzzy, blank	Troubleshooting			
	A. Document screen appearance (if display screen is cracked, refer to <u>C2595</u>)			
	B. Change or charge the batteries to reach the required operational voltage			
	C. Verify battery carrier with a red fused bottom is being used with 9-volt Lithium batteries			
	D. Verify appropriate rechargeable battery is being used and is not exhausted			
	E. Ensure that the pins in the battery compartment are in good condition			
	F. Verify that the battery door is pushing down on the battery when installed; pull on the metal tab on the battery door			
	to increase force on the battery when installed			
	G. Test electronic simulator			
	Resolution			
	IF the analyzer display functions correctly after changing THEN the issue is resolved			
	or charging the batteries and checking battery door and • Classification is Complaint 1			
	contacts			
	IF troubleshooting does not resolve the issue and the THEN the i-STAT analyzer should be replaced	ced or repaired		
	analyzer display continues to not function • Classification is Repair			
	IF the analyzer display screen is cracked THEN refer to C2595			

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Complaint	Description		
Key(s) difficult to	Analyzer keys are not responsive or are difficult to push		
press / not	Prompts for Meaningful Data Collection		
responding	1. What is analyzer serial number(s)?		
	2. What is the current battery voltage on the analyzer statu	us screen?	
RW Code: C2530	3. What type of batteries are being used?		
	a. If 9-volt lithium, what is the color of the batter	y carrier (i.e. red/green)?	
Synonyms: Keys	b. If i-STAT rechargeable, what is the Born-on-Da	te (BOD)?	
nonresponsive,	Troubleshooting		
dead, press several	A. Change or charge the batteries to reach the required operational voltage		
times or multiple	B. Verify battery carrier with a red fused bottom is being used with 9-volt Lithium batteries		
times, squishy,	C. Verify appropriate rechargeable battery is being used and is not exhausted		
sticky, no click or	D. Ensure that the pins in the battery compartment are in good condition		
feedback	E. Verify that the battery door is pushing down on the batt	ery when installed; pull on the metal tab on the battery door	
	to increase force on the battery when installed		
	Resolution		
	IF the analyzer keypad functions correctly after changing or	THEN the issue is resolved	
	charging the batteries and checking battery door and • Classification is Complaint 1		
	contacts		
	IF troubleshooting does not resolve the issue and the THEN the i-STAT analyzer should be replaced or repaired		
	analyzer keypad continues to be unresponsive • Classification is Repair		
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Complaint	Description
No activation /	The i-STAT analyzer is not turning on at all and gives no audio or visual response when trying to power on.
power / screen	Analyzer will activate when powered on; the screen activates/flashes then goes blank.
refresh	The i-STAT logo appears and then the screen goes blank.
RW Code: C2510	Alternatively, the analyzer screen may be stuck and will not respond to key presses, typically showing "Insert Cartridge",
	"Remove Cartridge", or "Cartridge Locked".
Synonyms:	
Hardware not	i-STAT Printer, Martel Printer and i-STAT Downloaders (all models) will not power on.
turning on, not	Prompts for Meaningful Data Collection
responding, dead	1. If analyzer is not powering on or screen display will not change
	a. What is analyzer serial number(s)?
	b. What is the current battery voltage on the analyzer status screen?
	c. What type of batteries are being used?
	i. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?
	II. If I-STAT rechargeable, what is the Born-on-Date (BOD)?
	d. Has a CLEW/JAMS update been performed recently?
	e. If powers on with no keypad response, what screen is displayed (unable to refresh)?
	2. If printer has no power:
	a. What is printer senar humber(s)?
	b. This ballety been charged :
	3 If downloader has no nower:
	3. What is downloader serial number?
	h Is APOC supplied power source and cable being used?
	Troubleshooting
	If i-STAT Analyzer:
	A. Change or charge the batteries to reach the required operational voltage
	B. Install the CLEW/IAMS software if no activation, the screen activates/flashes then turns off or the i-STAT logo appears
	and then screen goes blank.
	C. Ensure 9-volt lithium batteries with red battery carrier or a new or fully charged APOC rechargeable battery is being
	used
	1. Check battery carrier for damage
	2. Try a different battery carrier
	D. Ensure the batteries are inserted with the correct orientation
	E. Ensure that the pins in the battery compartment are in good condition
	F. Verify that the battery door is pushing down on the battery when installed; pull on the metal tab on the battery door
	to increase force on the battery when installed
	G. If the analyzer screen is not refreshing or is stuck, replace with new or fully charged batteries.
	Note: CLEW/JAMS software can be installed on the analyzer via handheld-to-handheld or JammLite update method
	If Printer:
	A. Verify i-STAT printer power by connecting to A/C power (if applicable)
	B. Recharge the battery in the printer
	1. Martel Printer serial numbers below 240223657, must charge for 16 hours
	2. Martel Printer serial numbers above 240223657, must charge for 9 hours
	3. i-STAT Printer, charge for 3 hours
	C. If recharging the battery does not resolves printing issues, and all listed troubleshooting has been exhausted, expect
	the battery to be the root cause of the experienced issues and it is necessary for customer to replace the rechargeable
	battery, which is ordered via APOC, to resolve the printing issue. (i-STAT Printers and Martel Printers with access to
	battery compartment)
	D. Try a different power cable from a working printer (if available)

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	E. If i-STAT printer, provide replacement <u>cables</u> for trouble	shooting
	F. If Martel printer, replace printer (cables are not available	e)
	If downloader:	
	A. Verify the power cable is connected	
	B. Try a different power cable from a working downloader	(if available)
	C. If DRC-300 downloader, provide replacement <u>cables</u> for	troubleshooting
	D. If DS-300, DRS-300, DN-300 or DRN-300 model, replace of	downloaders (cables are not available)
	Resolution	
	IF the analyzer powers on successfully or the analyzer	THEN the issue is resolved
	screen refreshes successfully after changing or charging the	Classification is Complaint 1
	batteries and checking battery orientation, door, contacts	
	and carrier	
	IF the analyzer powers on successfully after reinstalling the	THEN the issue is resolved
	CLEW/JAMS software	Classification is Complaint 1
	IF replacement cables resolve power issue with i-STAT	THEN the issue is resolved
	printer and DRC-300 downloader	Classification is Complaint 1
	IF troubleshooting does not resolve the issue and the	THEN the i-STAT analyzer must be replaced or repaired
	analyzer will not power on or the display continues to be	Classification is Repair
	stuck on same screen	
	IF troubleshooting does not resolve the issue and the	THEN the downloader must be replaced
	downloader will not power on	Classification is Repair
	IF the printer Power lights do not indicate acceptable	THEN the printer must be replaced
	operating conditions AND the above troubleshooting does	Classification is Repair
	not allow printing	
		Note: Martel printers will be replaced with i-STAT Printer
		kit
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Complaint	Description	
Product powers	Analyzer does turn on successfully, however is turning off in the middle of a test or while running a test or when navigating	
down	through the analyzer menus.	
unexpectedly	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)?	
RW Code: C2506	2. What is the current battery voltage on the analyzer state	us screen?
	3. What type of batteries are being used?	
Synonyms:	a. If 9-volt lithium, what is the color of the batter	y carrier (i.e. red/green)?
Analyzer turning	b. If i-STAT rechargeable, what is the Born-on-Da	te (BOD)?
off, shutting	Troubleshooting	
down,	A. Replace with new 9-volt lithium batteries or a fully charge	ged i-STAT rechargeable battery pack.
prematurely	B. If using the i-STAT rechargeable battery pack, verify the four charging contacts on the analyzer and	
	downloader/recharger are intact	
	C. Verify battery carrier with a red fused bottom is being used with 9-volt Lithium batteries	
	D. Verify appropriate rechargeable battery is being used and is not exhausted	
	E. Ensure that the pins in the battery compartment are in good condition	
	F. Verify that the battery door is pushing down on the batt	ery when installed; pull on the metal tab on the battery door
	to increase force on the battery when installed	
	Resolution	
	IF the analyzer no longer powers off unexpectedly after THEN the issue is resolved	
	changing or charging the batteries and checking battery • Classification is Complaint 1	
	door, contacts and carrier	
	IF troubleshooting does not resolve the issue and the	THEN the i-STAT analyzer should be replaced or repaired
	analyzer continue to power off unexpectedly • Classification is Repair	

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Complaint	Description	
Cartridge/Sim	i-STAT cartridge, external simulator or troubleshooting tool can be inserted but does not lock into place on the i-STAT	
doesn't lock	analyzer.	
	Prompts for Meaningful Data Collection	
RW Code: C2521	1. Is the issue impacting one i-STAT analyzer or multiple and	nalyzers?
	a. What is analyzer serial number(s)?	
Synonyms: Not	2. Is the cartridge/simulator/tool inserting fully and not lo	cking into place in the analyzer?
clicking	3. Does the issue occur after running specific external sim	ulator(s)?
	a. What is the external simulator serial number(s)?
	b. Is there visible damage to the latch engageme	ent surface on the back of the simulator?
	Troubleshooting	
	1. If the cartridge/simulator can be fully inserted but is no	ot locking into place , perform the <u>Latch Return Tool</u>
	procedure	
	2. If the issue occurs after running a specific external electronic simulator on one or multiple analyzers, check for visible	
	damage to the latch engagement surface on the back o	t the simulator
	Resolution	
	IF the cartridge/simulator inserts and locks into place	THEN the issue is resolved
	successfully after running the Latch Return Tool AND	Classification is Complaint 1
	simulator is not damaged	
	IF the cartridge/simulator inserts but does not lock into	THEN the analyzer should be replaced or repaired
	place after running the Latch Return Tool AND simulator is	Classification is Repair
	not damaged	
	IF the cartridge/simulator inserts but does not lock into	THEN the external simulator should be replaced
	place after running the Latch Return Tool AND simulator is	Classification is Repair
	damaged OR latch is flipped following second simulator test	

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Complaint	Description		
Cartridge/Sim	i-STAT cartridge, external simulator or troubleshooting tool	cannot be inserted into the i-STAT analyzer.	
cannot be	Prompts for Meaningful Data Collection		
inserted	1. What is being tested (cartridge, external simulator, tro	ubleshooting tool) in the analyzer?	
RW Code: C2520	2. Is the issue impacting one i-STAT analyzer or multiple analyzers?a. What is analyzer serial number(s)?		
	Troubleshooting		
Synonyms:	A. If the cartridge/external simulator/troubleshooting tool cannot be fully inserted, repair or replace analyzer		
Cartridge blocked,	Resolution		
something in the way	IF the cartridge/external simulator/troubleshooting tool cannot be inserted in a specific analyzerTHEN the i-STAT analyzer should be replaced or repaired• Classification is Repair		
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Complaint	Description	
Cartridge/Simulator	The i-STAT analyzer has a cartridge or electronic simulator locked in the cartridge port and it cannot be released through	
Stuck	normal operation.	
	Prompts for Meaningful Data Collection	
RW Code: C2540	1. What is analyzer serial number(s)?	
	2. Is a cartridge or simulator stuck in analyzer?	
Synonyms:	a. If simulator, what is serial number?	
Cartridge jammed,	3. What is the current battery voltage on the analyzer status screen?	
locked, frozen	4. What type of batteries are being used?	
	a. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-Date (BOD)?	
	Troubleshooting	
	A. Change or charge the batteries to reach the required operational voltage	
	B. Verify battery carrier with a red fused bottom is being used with 9-volt Lithium batteries	
	C. Verify appropriate rechargeable battery is being used and is not exhausted	
	D. Ensure that the pins in the battery compartment are in good condition	
	E. Verify that the battery door is pushing down on the battery when installed; pull on the metal tab on the battery	
	door to increase force on the battery when installed	
	F. If the cartridge/simulator is released, run additional cartridges to ensure that the analyzer is functioning properly	
	Resolution	
	IF the cartridge/simulator is released after changing or THEN the issue is resolved	
	charging the batteries AND the analyzer is functioning • Classification is Complaint 1	
	properly	
	IF the cartridge/simulator is not released after THEN the i-STAT analyzer should be replaced or repaired	
	troubleshooting on specific analyzer • Classification is Repair	
	Note: If an external simulator is stuck in the analyzer, then it	
	will also need to be replaced	
	DO NOT EODOEELIU V DEMOVE the stuck simulator or	

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Complaint	Description		
Unexpected	The i-STAT analyzer is showing a barometric pressure reading that is different than a comparative analyzer or an external		
Barometric	barometer or is otherwise different than expected.		
Pressure Reading	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
RW Code: C2535	a. Have any code 82 or 92 occurred on the analyzer?		
	2. Is the barometric pressure reading being compared to another i-STAT analyzer or an external barometer?		
Synonyms: Pressure	a. Is the external barometer in same location as analyzer or at a remote location?		
off, wrong, doesn't	Troubleshooting		
match	A. For best comparison, the pressure reading on an analyzer should be compared to another analyzer or to a		
	barometer at the same location (same elevation); avoid referencing barometers at remote locations such as airports		
	or weather stations		
	Note: The barometric pressure transducers are calibrated in the factory and should not drift more than 1% over the 300		
	to 999.9 mmHg range; if the drift is greater than 1% the analyzer will display Code 82 or 92		
	Resolution		
	IF the analyzer barometric pressure is determined to be THEN the issue is resolved		
	accurate after troubleshooting		
	IF the analyzer barometric pressure is determined to be THEN the i-STAT analyzer should be replaced or repaired		
	inaccurate on specific analyzer after troubleshooting • Classification is Repair		

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Complaint			
Date/Time	The I-STAT analyzer is showing or reporting a date and time that is incorrect or unexpected.		
displayed is	Prompts for Meaningful Data Collection		
unexpected	1. What is analyzer serial number(s)?		
	2. What is the date/time displayed on the analyzer and what should it be showing?		
RW Code: C2512	a. Is the issue occurring due to daylight savings time?		
	b. Is this a new or replacement analyzer, being used for the first time?		
Answer pRE	3. Is a data management system being used?		
Questions!	a. What is the data management system?		
	b. Has the analyzer communicated with data management system recently?		
Synonyms: Date or	c. Where is the main data management server located?		
time is wrong,	Troubleshooting		
incorrect	A. If a data management system is being used, ensure that the customization setting to "Synchronize Clock to CDS" is		
	enabled and those settings are uploaded to the analyzer		
	B. Verify that the analyzer has communicated with the data management system recently		
	C. If the main data management server is in a different time zone, then the time on the data management server may		
	be different than the analyzer location; correct the time on the analyzer and communicate with the data manager		
	to see if the issue is persistent		
	D. If no data management is being used, correct the date/time manually on the i-STAT analyzer through the		
	Administration Menu		
	E. Ensure the analyzer date/time is correctly maintained after the troubleshooting		
	Resolution		
	IF the date/time is corrected after enabling "Synchronize THEN the issue is resolved		
	Clock to CDS" setting and communicating with the data • Classification is Complaint 1		
	management system		
	IF the date/time is corrected after verifying the time on THEN the issue is resolved		
	the data management server and communicating with the • Classification is Complaint 1		
	data management system		
	IF the date/time is NOT corrected after troubleshooting THEN the issue is resolved		
	and a third party DMS is in use: issue referred to DMS • Classification is Complaint 1		
	vendor support; issue is confirmed to be resolved		
	IF the date/time is corrected manually on the analyzer THEN the issue is resolved		
	and is maintained • Classification is Complaint 1		
	IF specific analyzer is unable to maintain the correct THEN the i-STAT analyzer should be replaced or repaired		
	date/time after troubleshooting and all other analyzers • Classification is Repair		
	have correct date/time		

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Complaint	Description		
Analyte displayed	The i-STAT analyzer is not identifying the correct cartridge being inserted; Analyzer is reporting analytes that are		
is inconsistent with	different than the labeling on the cartridge being run.		
cartridge labeling			
	For example, analyzer incorrectly identifies ACT cartridge when PT/INR cart is inserted; the analyzer reports ACT results		
RW Code: C5559	when running a PT/INR cartridge. Quality check code may have occurred before the i-STAT 1 analyzer was able to		
	complete cartridge identification so default coagulation panel code (24) or incorrect cartridge type was displayed.		
Answer pRE	Prompts for Meaningful Data Collection		
Questions!	1. What is analyzer serial number(s)?		
	2. What is the lot number / box number of the cartridges being used?		
Synonyms: Results	3. What analytes were reported on the analyzer? What analytes were expected?		
missing, wrong,	Troubleshooting		
different, incorrect	A. If debris is introduced as the analyzer is resetting itself after the last cartridge run, it can cause the next cartridge to		
	be misidentified; run the ceramic conditioning cartridge on analyzer		
	B. Run a new cartridge to verify that the analyzer is functioning as expected		
	Resolution		
	IF running the ceramic conditioning cartridge resolves THEN the issue is resolved		
	the issue and subsequent cartridge runs produce the • Classification is Complaint 1		
	expected results		
	IF specific i-STAT analyzer continues to misidentify THEN the i-STAT analyzer should be replaced or repaired		
	cartridges after troubleshooting and same cartridge lot • Classification is Repair		
	number(s) run successfully on another i-STAT analyzer		
	IF misidentification is persistent with specific cartridge THEN the suspect cartridge lot(s) should be investigated		
	lot(s) on multiple i-STAT analyzers after troubleshooting • Classification is Complaint 2		
	Request cartridges be returned for investigation and		
	document request(s)		

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3.2 Barcode Sc	anning Decision Tree	
RW Code	Code Description	
C2585	 Unable to Enter/Scan ID (pRE) Scanner beam emits, analyzer does not read operator or patient ID barcode Scanner reads operator or patient ID barcode, analyzer displays "Invalid Length" message 	\rightarrow Jump to Section
C2562	 Scanner beam not functioning as expected No light emitted from scanner Partial scanner light emitted Scanner light flickers or works intermittently Scanner light is blurry or skewed 	→ Jump to Section
C2563	 Analyzer message "ID Not in Valid ID List" Scanner reads barcode, analyzer displays "ID Not in Valid ID List" message Common Phrase: Invalid ID, ID not on list, etc. 	→ Jump to Section
C3200	 Barcode scanned- Unexpected info displayed (pRE) Scanner reads the barcode, analyzer displays unexpected characters Analyzer may add/delete/change characters or symbols from the ID/product barcode Analyzer may also show an error message due to unexpected characters scanned from the ID/product barcode 	→ Jump to Section
C3223	 Product barcode will not scan/Invalid Number Scanner beam emits, APOC product barcodes are not read Scanner reads the product barcode, analyzer displays "Invalid Number" message 	\rightarrow Jump to Section

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3.2.1. Barcode Scanning Issues

Complaint	Description		
Scanner beam not	No light is emitted from the barcode scanner, light functions intermittently, or the light is otherwise compromised, be it		
functioning as	blurry, skewed, partial, a single dot, or flickering. This code	should not be used if the laser scanner light on the analyzer is	
expected	emitted and looks as expected and is not scanning the barcode or IDs.		
	Prompts for Meaningful Data Collection		
RW Code: C2562	1. What is analyzer serial number(s)?		
	2. At what prompt on the i-STAT analyzer display is the user pressing the scan button?		
Synonyms:	a. Is the user holding down the scan button or just pressing it?		
Scanner dead,	3. What is the appearance of the scanner beam?		
fuzzy, blurry,	4. Is there dirt or debris on the scanner window?		
partial, off, not	5. What is the current battery voltage on the Analyzer Sta	itus screen?	
scanning	6. What type of batteries are being used?		
	a. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?		
	b. If i-STAT rechargeable, what is the Born-on-Date (BOD)?		
	Troubleshooting		
	A. Document if the light is not emitting or is emitting but is blurry, skewed, partial, a single dot, or flickering		
	B. Change or charge the batteries to reach the required operational voltage		
	C. Verify battery carrier is red, battery contacts are in good condition and battery door is holding battery secure		
	D. Verify that the user is pressing the scan button when the i-STAT analyzer is giving an appropriate prompt to scan and		
	verify that the user is holding the scan button down		
	E. Clean the barcode scanner window		
	Resolution		
	IF the analyzer barcode scanner functions correctly after	THEN the issue is resolved	
	changing or charging the batteries	Classification is Complaint 1	
	IF the analyzer barcode scanner functions correctly after	THEN the issue is resolved	
	cleaning the barcode scanner	Classification is Complaint 1	
	IF the analyzer barcode scanner functions after correcting	THEN the issue is resolved	
	the analyzer handling, either pressing at the wrong • Classification is Complaint 1		
	analyzer prompt or not holding the button down long		
	enough		
	IF troubleshooting does not resolve the issue and the	THEN the i-STAT analyzer should be replaced or repaired	
	analyzer barcode scanner continues to emit no light,	Classification is Repair	
	function intermittently, or be otherwise compromised		

Examples of different scenarios of scanner beam projections

 Good scan beam; straight and uniform	Red dot may indicate an issue with the barcode scanner hardware
May indicate issue with scan button on the keypad or scanner beam Note : scanner beam only emits during prompts where barcodes may be scanned	Sticky residue, film or dirt found on the scanner window. Clean scanner window with a lint free cloth. If customer uses wipes that are wet, the excess moisture may leave a residue on scanner window.

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Complaint	Description		
Analyzer	Analyzer barcode scanner beam turns on and reads the operato	r or patient ID barcode (or manual entry) but the analyzer	
message "ID	displays message "ID Not in Valid ID List".		
Not in Valid ID	Prompts for Meaningful Data Collection		
List"	1. How far away is the i-STAT analyzer from the barcode being scanned and at what angle? Is the laser light emitting when		
	the scan key is used?		
RW Code:	What ID is being scanned – operator ID or patient ID?		
C2563	a. How many IDs are showing this issue?		
.	b. Are the ID(s) in question new or old?		
Synonyms: Not	c. Were any changes made to the specific ID(s) in q	uestion?	
scanning, ID	i. If yes, when and what are the changes		
not in list,	d. Are the ID(s) successfully scanned by other analy	zers?	
Invalla ID	e. Was the analyzer docked/communicating with D	MS after the changes to the ID(s)?	
	f. Do the analyzer(s) have the current operator/pat	tient list number under customization?	
	3. Is customization done on a data management system or di	rectly on the analyzer?	
	4. Does the analyzer have the correct customization profile to	or that location?	
	a. Are the ID(s) on the list in DE system for that loca	ation/racility?	
	b. Is customization enabled globally and for the loca	ation in customization workspace?	
	$\frac{1}{2} = \frac{1}{2} $	4	
	A. Verify the humber of analyzer(s) and $D(s)$ that are affected P Verify if the $D(s)$ in question are scapped successfully by a	anthor analyzor(s)	
	C Verify if any changes were made to the ID(s) recently to call	use this issue	
	C. Verify that the customization settings on the analyzer are a	use this issue	
	information on the operator/patient list (check truncation	settings)	
	E. Verify the analyzer is uploading the correct customization r	profile	
	F. Verify in the data management system (DMS) that the ID(s) in question are in the system and that those ID(s) show in the		
	DE System.		
	1. If using Info HQ, check "Group Certification" for a	operator to ensure "i-STAT1" is checked	
	G. Triage to DMS vendor support if the ID(s) cannot be found in DE system		
	H. Verify the use patient/operator lists boxes are checked in c	sustomization workspace and the correct lists are on the	
	analyzer(s) under customization		
	I. Verify that customization is enabled globally and enabled for the location in customization workspace		
	J. Verify the i-STAT analyzer has recently communicated with the data management		
	K. Reset analyzer to factory settings and have the analyzer communicate with the data management system		
	L. Clean barcode scanner window		
	M. Verify that the user is holding the barcode scanner an appr	opriate distance from the barcode being scanned (3-9 in/8-23	
	cm) and at a proper angle (about 10 degrees)		
	N. Verify scanner beam is covering entire length of barcode	ing lights off when securing	
	O. Inquire if hubrescent of LED lighting is being used; try turni	ing lights off when scanning	
	Note: For any system using DE, when an operator certification of	expires, it translates to the DE as Operator Not on List and	
	therefore will display "Operator Not on List" instead of "Certific	ation Expired". The handheid will perform the actions	
	customized for operator not on list. Verify operator certification	n dates in Divis.	
	Resolution		
	IF the analyzer accepts the operator/patient ID the above	THEN the issue is resolved	
	troubleshooting	Classification is Complaint 1	
	IF the analyzer accepts the operator/patient ID after	THEN the issue is resolved	
	resolution by DMS vendor support	Classification is Complaint 1	
	IF the analyzer accepts the operator ID after cleaning barcode	THEN the issue is resolved	
	scanner or after following proper scanning procedure	Classification is Complaint 1	
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Complaint	Description		
Barcode	Analyzer barcode scanner light turns on and reads the barcode, but the analyzer display shows unexpected characters,		
scanned -	either adding, deleting, or changing characters/symbols.		
Unexpected	Prompts for Meaningful Data Collection		
info displayed	1. What is analyzer serial number(s)?		
	2. Which barcode(s)/ID is being scanned?		
RW Code:	3. Are all barcodes/IDs impacted or only specific barcodes/IDs?		
C3200	4. If product barcode, what is the lot number / box number of the product being scanned?		
	5. If operator or patient ID		
Answer pRE	a. What are the characteristics of the operator or patient ID barcode being scanned (length, type, etc.)?		
Questions!	b. What characters are showing when scanned?		
	c. Were any changes made to the ID(s) in question?		
Synonyms: Not	d. What is the barcode format of the ID in question?		
scanning	6. How far away is the analyzer from the barcode being scanned and at what angle?		
	What is the current battery voltage on the Analyzer Status screen?		
	8. What type of batteries are being used?		
	a. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?		
	b. If i-STAT rechargeable, what is the Born-on-Date (BOD)?		
	Troubleshooting		
	A. Verify the barcode being scanned (product barcode/operator ID/patient ID)		
	B. Document what the expected scanned information should be and what the analyzer is showing after scanning – request		
	pictures or screenshots of the issue		
	C. Verify barcode format is the appropriate type for the i-STAT analyzer.		
	D. Verify if any changes were made to the IDs in question		
	E. Verify that correct product barcode was scanned		
	F. Change or charge the batteries to reach the required operational voltage		
	G. Verify battery carrier is red, battery contacts are in good condition and battery door is holding battery secure		
	H. Clean barcode scanner window		
	I. Verify that the user is holding the barcode scanner an appropriate distance from the barcode being scanned (3-9 in/8-		
	23 cm) and at a proper angle (about 10 degrees) and scanner beam is covering entire length of barcode		
	J. Induire if fluorescent or LED lighting is being used; try turning lights off when scanning		
	IF the analyzer scans the barcode correctly after above IHEN the issue is resolved		
	troubleshooting steps • Classification is Complaint 1		
	IF specific analyzer continues to show unexpected characters THEN the i-STAT analyzer must be replaced or repaired		
	after troubleshooting AND the same barcodes are found to Classification is Repair		
	scan without issue on other I-STAT analyzers using same		
	customization settings		

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Complaint	Description		
Product barcode	Analyzer barcode scanner beam emits but the cartridge or the APOC QC material barcodes are not read or the analyzer		
will not scan /	reads the barcodes and gives the error message "Invalid Number".		
Invalid Number			
	Blue CG4+ Cartridges part number 03P85-51 scanned with message "Invalid Cart." Message displayed.		
RW Code: C3223	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
Synonyms: Not	2. What is the lot number / box number of the product bein	ng scanned?	
scanning	3. What barcode on APOC product is being scanned?		
	4. Is the issue occurring with one barcode or multiple barco	odes?	
	5. How far away is the i-STAT analyzer from the barcode be	ing scanned and at what angle?	
	6. What type of lighting is used in the operating environme	nt?	
	7. What is the current battery voltage on the analyzer statu	us screen?	
	8. What type of batteries are being used?		
	a. If 9-volt lithium, what is the color of the batter	y carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-Da	te (BOD)?	
	"Invalid Cart." Message		
	1. What is analyzer serial number?		
	2. What is cartridge lot number scanned?		
	3. What is preference number in analyzer?		
	4. Have the action and/or references ranges for any of the	3 analytes (pH, PCO2 or PO2) been customized for this	
	preference?		
	5. Are any of these ranges for any of the 3 analytes (pH, PC	O2 and PO2) outside of the reportable range on Blue CG4	
	cartridge?		
	Troubleshooting		
	A. Inquire if fluorescent or LED lighting is being used; try tu	rning lights off or shielding the scanner from the light when	
	scanning		
	B. Clean barcode scanner window		
	C. Verify that the user is holding the barcode scanner an ap	propriate distance from the barcode being scanned (3-9	
	inches/8-23 cm) and at a proper angle (about 10 degrees	5)	
	D. Verify scanner beam is covering entire length of barcode		
	E. Change or charge the batteries to reach the required ope	erational voltage	
	F. Verify battery carrier is red, battery contacts are in good	condition and battery door is holding battery secure	
	G. Verify that the customer is scanning the barcode on the	control vial/ampoule	
	H. Verify that the cartridge barcode is scanned from the inc	lividual cartridge pouch	
	I. Verify that the cal ver material lot is scanned from the ba	arcode on the box of the kit not ampule/vial	
	"Invalid Cart." Message		
	Occurs when Blue CG4+ Cartridges part number 03P85-51 is t	peing tested and the user has customized reference and/or	
	action ranges set outside of the Blue CG4+ reportable ranges.		
	A. Explain why message occurs		
	B. Check customization settings for action and/or reference	e ranges.	
	C. Assist customer with adjusting ranges (if applicable)		
	D. Assist customer with disabling analyte(s) on Blue CG4+ c	artridge panel (if applicable)	
	E. Download updated customization preference to analyze	r and retest cartridge	
	Resolution		
	IF the analyzer scans the product correctly after above	THEN the issue is resolved	
	troubleshooting	Classification is Complaint 1	
	IF specific analyzer continues to either not scan	THEN the i-STAT analyzer must be replaced or repaired	
	cartridge/control barcodes or give the error "Invalid	Classification is Repair	

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Number" after troubleshooting AND the same lots are	
found to scan without issue on other analyzers	
IF specific cartridge/control lot(s) persist in generating the	THEN the suspect product lot(s) should be investigated
error "Invalid Number" or will not scan at all after	Classification is Complaint 2
troubleshooting AND the issue occurs on multiple i-STAT	
analyzers AND other product lots are found to scan without	Request product be returned for investigation and
issue on the same analyzers	document request(s)

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Complaint	Description		
Unable to	Analyzer barcode scanner emits light but does not recognize/read the operator or patient ID barcode. Alternatively, scanner		
Enter / Scan ID	reads barcode (or manual entry) but shows "Invalid Length".		
	Prompts for Meaningful Data Collection		
RW Code:	1. What is analyzer serial number(s)?		
C2585	2. Is a DMS used or is the customization set directly on the analyzer? Is the issue occurring with one ID or all ID(s)?		
	3. If the analyzer displays "invalid length" after scanning the ID barcode		
Answer pRE	a. What is the length of the ID barcode scanned?		
Questions!	b. What is the minimum and maximum length customized in analyzer/ DMS customization workspace?		
	c. What is the truncate digits for 'first' and 'last' in analyzer/ DMS customization workspace?		
Synonyms: Not	4. If the ID is not recognized by the analyzer and no message is displayed		
scanning	a. Can the ID be entered manually?		
	b. Did the facility make any changes to the ID format/type?		
	c. What is the barcode format of the ID(s) in question?		
	d. What are the sub-settings under barcode options for code 39 and code I2of5?		
	e. How far away is the i-STAT analyzer from the barcode being scanned and at what angle?		
	f. What type of lighting is used in the operating environment?		
	Troubleshooting		
	A. If the analyzer displays 'invalid length' after scanning the ID barcode		
	 Verify the length of the barcode/ID being scanned 		
	2. Verify the minimum and maximum length customized in analyzer/DMS customization workspace		
	3. Verify the truncate digits for 'first' and 'last' in analyzer/DMS customization workspace		
	The customization settings should match the length of the ID barcode being scanned.		
	B. Verify the barcode format used is appropriate for the i-STAT analyzer		
	 Try different barcode sub-settings under code 39 and I2of5 		
	C. If using a data management system		
	 Verify that the correct customization preferences are uploaded to the analyzer 		
	2. Verify that customization is enabled globally and for the location in DE customization workspace		
	3. Verify that the appropriate barcode types are enabled in ID Entry settings (length and truncation settings are		
	appropriate for the operator ID or patient ID)		
	Note: To verify the analyzer is functioning properly, reset analyzer to factory default and scan barcode using default		
	settings. If analyzer successfully scans, then issue is customization related. Review settings on analyzer or in customization		
	workspace.		
	D. Verify if other I-STAT analyzer(s) scan the ID(s) in question		
	E. In nuclescent of LED lighting is being used; ity turning lights off of shielding the scatter from the light when scatning		
	F. Cledit valuation statistic willow		
	cm) and at a proper angle (about 10 degrees)		
	Unif and a a proper angle (about 10 degrees) H Verify scapper beam is covering entire length of barcode		
	Change or charge the batteries to reach the required operational voltage		
	Change of charge the battery contacts are in good condition and battery door is holding battery control		
L	3. Verify battery carrier is real, battery contacts are in good condition and battery door is notating battery secure		

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	Resolution	
	IF the analyzer scans the barcode correctly after the above troubleshooting	 THEN the issue is resolved Classification is Complaint 1
	IF specific analyzer continues to either not scan barcodes or give the error "Invalid Length" (scanned or manual entry) after troubleshooting AND the same barcodes are found to scan without issue on other i-STAT analyzers using same customization settings	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair
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3.3 Battery Related Issues

Complaint	Description		
Battery –	The i-STAT hardware or analyzer indicates low battery voltage or requires frequent charging/replacement of batteries to		
Low/frequently	maintain functionality		
replaced	Prompts for Meaningful Data Collection		
	1. What i-STAT hardware is being impacted?		
RW Code: C2581	a. What is the serial number(s)?		
	2. If an i-STAT analyzer is impacted:		
Synonyms:	a. What type of batteries are being used?		
Battery low,	b. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?		
dead, weak, icon	c. If i-STAT rechargeable,		
flashing	i. What is the Born-on-Date (BOD)?		
	ii. Are the charging pins present on the downloader/recharger and the charging pads present on the		
	Dduk of the issue associated with specific downloader/resharger serial number?		
	III. Is the issue associated with specific downloader/recharger serial number?		
	u. All the ballery contacts in good condition:		
	Troubleshooting		
	A Varify that the sustamer is using the correct battery type and number		
	A. Verify that the customer is using the correct battery type and number		
	 B. If using rechargeable batteries: 1. Verify i-STAT branded rechargeable battery pack is being used 2. Verify Born-on-Date within the operational life of the rechargeable battery (Note: Minimum battery life is the lesser of 1 year or 400 recharge cycles.) 3. Verify analyzer is seated properly in the downloader/recharger and red or green light illuminates on 		
	downloader/recharger		
	4. Verify all four gold charging pins are present on the downloader/recharger and that all four gold pads are		
	present on the i-STAT analyzer		
	5. Advise the battery life of fully charged battery is 30% less than set of 9V Lithium batteries		
	C. If using 9-volt lithium batteries		
	1. i-STAT analyzers must use two disposable 9V Lithium batteries with a red base battery carrier		
	2. Disposable batteries may lose voltage depending on the age and storage conditions of the batteries;		
	recommend that new 9V Lithium batteries be used		
	D. Verify the battery door is applying sufficient downward force on the battery; pull on the metal tab on the battery door		
	to increase the downward force on the battery		
	E. Advise the battery life on a wireless analyzer is 30% less than a set of 9V Lithium batteries		
	F. Check if the cartridge type(s) used has longer test timing (i.e. cTnI, BNP or β-hCG cartridges), thus using more battery		
	voltage		
	Resolution		
	IF the issue is resolved by changing or charging exhausted THEN the issue is resolved		
	batteries • Classification is Complaint 1		

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IF it is identified that the i-STAT analyzer and/or downloader/recharger are missing or have damaged charging pins/contacts	THEN the damaged hardware should be replacedClassification is Repair
IF specific i-STAT analyzer has persistent low battery message or batteries are frequently replaced and changing the batteries has not resolved the issue AND the same batteries are confirmed to work without issue in other i- STAT analyzers	 THEN the i-STAT analyzer should be replaced or repaired Classification is Repair

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Complaint	Description		
Battery –	The i-STAT hardware - the user is unable to recharge the battery or unable to replace the battery		
Unable to	Prompts for Meaningful Data Collection		
recharge/	1. What i-STAT hardware is impacted?		
replace	a. What are the serial numbers of the impacted device(e(s)?	
	2. If an i-STAT analyzer is impacted: are i-STAT rechargeable batte	eries being used?	
RW Code:	a. What is the born-on date of the battery?		
C2582	b. Are the charging pins present on the i-STAT downloa STAT analyzer?	ader/recharger and the charging pads present on the i-	
Synonyms:	c. Is the issue associated with a specific downloader/re	echarger serial number?	
Battery dead,	3. Is the battery oriented correct and the contacts in good condit	tion?	
weak, low,	Troubleshooting		
stuck, jammed,	A. Ensure that the analyzer is seated properly in the downloader/	/recharger and that red or green light illuminates on	
broken	downloader/recharger		
	B. Verify that all four gold charging pins are present on the down	nloader/recharger and that all four gold pads are present	
	on the i-STAT analyzer		
	C. Verify that the customer is using an Abbott sold rechargeable b	battery pack; disposable 9V batteries will NOT recharge	
	through the i-STAT downloader/recharger		
	D. Verify that the batteries are inserted into the device with the c	correct orientation	
	E. Verify that the battery door is applying sufficient downward force on the battery; pull on the metal tab on the battery		
	door to increase the downward force on the battery		
	F. Verify that the born-on date of the rechargeable battery is within the operational life of the battery		
	G. Verify analyzer has all of the feet (analyzer will not sit properly	y in downloader). If analyzer is missing feet, send	
	replacement <u>feet</u> to customer and add <u>C2595</u>		
	H. Perform the Self-Test on the printer (i-STAT 1 System Manual,	Section 7: Portable Printer (Martel and i-STAT 1 Printer)	
	Art: 714369). If "charging disabled" indicated with i-STAT print	iter using rechargeable battery, battery requires	
	replacement.		
	Resolution		
	IF the issue is resolved by the above troubleshooting	IEN the issue is resolved	
		Classification is Complaint 1	
	IF it is identified that the battery cannot be charged because THE	IEN refer to <u>C3213</u>	
	the I-STAT analyzer and/or downloader/recharger have		
	missing or damaged charging pins/contacts		
	IF specific I-STAT analyzer cannot recharge the battery AND	IEN the I-STAT analyzer should be replaced or repaired	
	the same battery is confirmed to work without issue in other	Classification is Repair	
CTAT Commont Cod	I-STAT analyzers	Determine the TOO	

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Complaint	Description		
Damaged or	The i-STAT 1 analyzer has damaged or missing charging pads/contacts or the i-STAT downloader/recharger has damaged		
missing charging	or missing charging pins		
pins/ contacts	Prompts for Meaningful Data Collection		
	1. What i-STAT hardware is being impacted?		
RW Code: C3213	a. What are the serial numbers of the impacted device(s)?		
	2. Are the charging pins/contacts damaged or missing?		
Synonyms: Pins,	a. If damaged, what is the nature of the damage?		
pads, contacts,	Troubleshooting		
broken, snapped,	A. Verify that there is damage/compromise to the charging contacts; there should be four gold charging pins on the		
bent, smashed,	downloader/recharger and four corresponding gold charging pads/contacts on the i-STAT analyzer		
sunk, wedged,	B. If the charging contacts are all in place, determine if the customer is having any other specific issues that require		
down	troubleshooting; see codes <u>C2581</u> or <u>C2582</u>		
	Resolution		
	IF the gold charging pads/pins/contacts are damaged, THEN the i-STAT hardware should be replaced		
	missing, or otherwise compromised • Classification is Repair		

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Complaint	Description		
Leaky/Damaged/	The i-STAT battery is damaged, distorted, melted, or leaking		
Distorted/Melted	Questions		
(Battery)	1. What is the serial number of the product (if applicable)?		
	2. What is the battery type?		
RW Code: C2561	a. What is the rechargeable battery BOD and seria	al number (if applicable)?	
	b. What color is the battery carrier (if applicable)?		
Answer pRE	Troubleshooting		
Questions!	A. Request specific details		
	B. Verify the battery was stored, used, and handled per APOC recommendations		
Synonyms:	C. Verify shipping conditions, if new shipment		
Dripping	Resolution		
	IF the i-STAT battery is damaged, distorted, melted or THEN the battery should be replaced and investigated		
	leaking AND the battery was stored, used and handled	Classification is Complaint 2	
	correctly		
		Request product be returned for investigation and	
		document request(s)	

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3.4 Smoking/Burning/Injury Related Issues

Complaint	Description		
Equipment	i-STAT hardware suffered a failure resulting in exploding/combusting, being on fire, or emitting smoke		
(Smoking/Burning	Prompts for Meaningful Data Collection		
/Fire/Explosion)	1. What are the serial numbers of the impacted i-STAT hardware?		
	a. If an i-STAT analyzer was impacted, did the i	issue occur while placed in a downloader/recharger?	
RW Code: C1070	2. What power cables were being used with the i-STAT h	hardware at the time of the event?	
	3. When (date/time) did the event occur and what was t	peing done with the hardware during the event?	
Answer pRE	4. What type of batteries are being used?		
Questions!	a. If 9-volt lithium, what is the color of the bat	tery carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-	Date (BOD)?	
Synonyms: melted,	5. Was the user injured because of the smoking/burning	/fire/explosion event?	
damaged,	Troubleshooting		
combusting, fire,	A. Verify if the user was injured during the event; if injur	y occurred see code <u>C1065</u>	
sparks, smoke,	B. Verify if the user was using the correct APOC supplied	power cables and/or batteries for the device that was	
charred	compromised (Note: May request images of the cables if unable to verify during customer contact to assist with the		
	troubleshooting)		
	C. Notify Technical Service Management of the event		
	Note: If it is determined the customer is using incorrect power cables/adaptor or batteries, replacement products will		
	<u>not</u> be replaced at no charge if hardware is not under warranty or service agreement		
	Resolution		
	IF the i-STAT hardware is found to be compromised and THEN the i-STAT hardware should not be replaced at no		
	incorrect battery/cables were used	charge unless the hardware is under warranty or service	
		agreement. The complaint will be investigated.	
		Classification is Complaint 2	
	Ask customer to return the power cables/batteries/battery		
	carrier that were in use at the time of the event		
	IF the i-STAT hardware is found to be compromised and	THEN the i-STAT hardware should be replaced and	
	correct battery/cables were used	investigated	
		Classification is Complaint 2	
		Ask customer to return the power cables/batteries/battery	
		carrier that were in use at the time of the event	

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Product "Hot" to The i-STAT hardware is hot enough to burn or harm the user touch Prompts for Meaningful Data Collection RW Code: C2580 1. What are the serial numbers of the impacted i-STAT hardware a. If an i-STAT analyzer was impacted, did the issue occur while placed in a downloader/recharger 2. When (date/time) did this occur and what was being done with the hardware during the event? 3. What power cables were being used with the i-STAT hardware at the time of the event?	?		
touch Prompts for Meaningful Data Collection RW Code: C2580 1. What are the serial numbers of the impacted i-STAT hardware RW Code: C2580 a. If an i-STAT analyzer was impacted, did the issue occur while placed in a downloader/recharger 2. When (date/time) did this occur and what was being done with the hardware during the event? 3. What power cables were being used with the i-STAT hardware at the time of the event?	?		
RW Code: C2580 1. What are the serial numbers of the impacted i-STAT hardware RW Code: C2580 a. If an i-STAT analyzer was impacted, did the issue occur while placed in a downloader/recharger 2. When (date/time) did this occur and what was being done with the hardware during the event? 3. What power cables were being used with the i-STAT hardware at the time of the event?	?		
RW Code: C2580a. If an i-STAT analyzer was impacted, did the issue occur while placed in a downloader/recharger2.When (date/time) did this occur and what was being done with the hardware during the event?Answer pRE3.3.What power cables were being used with the i-STAT hardware at the time of the event?	?		
Answer pRE2.When (date/time) did this occur and what was being done with the hardware during the event?3.What power cables were being used with the i-STAT hardware at the time of the event?	a. If an i-STAT analyzer was impacted, did the issue occur while placed in a downloader/recharger?		
Answer pRE 3. What power cables were being used with the i-STAT hardware at the time of the event?	2. When (date/time) did this occur and what was being done with the hardware during the event?		
Questions! 4. What type of batteries are being used?			
a. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)?			
Synonyms: hot, b. If i-STAT rechargeable, what is the Born-on-Date (BOD)?			
<i>burning,</i> c. Is the issue attributable to a specific rechargeable battery?			
uncomfortable, 5. Was the user injured because of the hot product?			
painful, dangerous Troubleshooting			
A. Verify if the user was injured during the event; if injury occurred see code <u>C1065</u>			
B. Verify if the user was using the correct power cables and/or batteries for the device that was compromise	ed (Note:		
May request images of the cables if unable to verify during customer contact to assist with the troublesho	May request images of the cables if unable to verify during customer contact to assist with the troubleshooting)		
C. Notify Technical Services Management of the event	C. Notify Technical Services Management of the event		
Note: If it is determined the customer is using incorrect power cables/adaptor or batteries, replacement pro	Note: If it is determined the customer is using incorrect power cables/adaptor or batteries, replacement products will		
<u>not</u> be replaced at no charge if hardware is not under warranty or service agreement	<u>not</u> be replaced at no charge if hardware is not under warranty or service agreement		
Resolution	Resolution		
IF the i-STAT hardware is found to be compromised and THEN the i-STAT hardware should not be replaced	l at no		
incorrect battery/cables were used charge unless the hardware is under warranty or s	service		
agreement. The complaint will be investigated.			
Classification is Complaint 2			
Ask customer to return the power cables / batter	Ask customer to return the power cables /batteries/battery		
carrier that were in use at the time of the event			
IF the I-STAT hardware is found to be compromised and IFEN the I-STAT hardware should be replaced and	3		
correct battery/cables were used			
Classification is Complaint 2			
Ack sustament to native the native seles /hattavi	oc/hottors		
Ask customer to return the power cables/batteri	esy ballery		
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Complaint	Description		
Product warm but	The i-STAT hardware is warmer than expected by the customer, but not hot enough to cause burns or harm the user		
not "Hot to	Prompts for Meaningful Data Collection		
Touch"	1. What are the serial numbers of the impacted i-STAT device(s)?		
	a. If an i-STAT analyzer was impacted, did the issue occur while placed in a downloader/recharger?		
RW Code: C5571	2. When (date/time) did this occur and what was being de	one with the hardware during the event?	
	3. What power cables were being used with the i-STAT ha	ardware at the time of the event?	
Answer pRE	4. What type of batteries are being used?		
Questions!	a. If 9-volt lithium, what is the color of the batte	ery carrier (i.e. red/green)?	
	b. If i-STAT rechargeable, what is the Born-on-D	ate (BOD)?	
Synonyms: hot,	 Is the issue attributable to a specific recharge 	eable battery?	
burning,	5. Was the user injured because of the warm product?		
uncomfortable	Troubleshooting		
	A. Verify if the user was injured during the event; if injury	occurred see code C1065	
	Verify if the user was using the correct power cables ar	nd/or batteries for the device that was compromised (Note:	
	May request images of the cables if unable to verify during customer contact to assist with the troubleshooting)		
	Note: If it is determined the customer is using incorrect power cables/adaptor or batteries, replacement products will		
	<u>not</u> be replaced at no charge if hardware is not under warranty or service agreement		
	Resolution		
	IF the i-STAT hardware is found to be compromised and THEN the i-STAT hardware should not be replaced at no		
	incorrect battery/cables were used	charge unless the hardware is under warranty or service	
		agreement. The complaint will be investigated.	
	Classification is Complaint 2		
		Ash sustained to action the measure achieve (heathering (heathering	
	Ask customer to return the power cables/batteries/battery		
	carrier that were in use at the time of the event		
	IF the i-STAT hardware is found to be compromised and THEN the i-STAT hardware should be replaced and		
	correct battery/cables were used	Rectingeneration is Completer 2	
		Ask customer to return the nower cables (battorios /battory	
		carrier that were in use at the time of the event	
		carrier that were in use at the time of the event	

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Complaint	Description		
User Injured	The user was injured in some capacity by i-STAT hardware or consumable items (i.e. cut by a control ampule, shocked by a		
	power supply, bruised while handling an i-STAT, etc.).		
RW Code: C1065	Prompts for Meaningful Data Collection		
	1. Was the injury caused by i-STAT hardware or consumat	ble product?	
Answer pRE	a. What is the lot number or serial number of th	ne product that caused the injury?	
Questions!	2. If the user was shocked: were Abbott power cables or b	patteries/battery carrier used for the i-STAT hardware	
C	involved?		
Synonyms: cut,	a. How was the hardware handled?		
bleeding, blood,	b. Did the user touch electrical contacts?		
bruised, hurt,	3. If the user was cut or bruised: how was the product bei	ng handled?	
sпоскеа, smackea,	a. If cut on a control ampule: was the appropria	te protective equipment worn and precautions taken to	
zapped	prevent injury (gloves and protective gauze)?		
	4. What treatment was provided to user?		
	Troubleshooting		
	A. Verify that the user was using the correct power cables	and/or batteries for devices that caused a shock	
	B. Verify that the user was following the correct handling procedure for the product involved; control ampules should		
	be opened wearing gloves and using gauze to cover the tip of the ampule		
	C. Notify Technical Services Management of the event		
	D. Confirm user injury and treatment provided (if applicable)		
	Resolution		
	IF the injury is found to be due to mishandling of the	THEN the issue is resolved	
	product or use of incorrect power	Classification is Complaint 1	
	cables/batteries/battery carrier AND the user confirms		
	understanding of correct use of the product AND the		
	product is currently functioning without issue		
	IF the user was cut on I-STAT product due to a	THEN the I-STAT product should be investigated	
	Montracturing defect or damage incurred from snipment	Classification is Complaint 2	
	(NOT caused by mishandling or physical damage incurred at customer site)		
	IF the user was shocked by I-STAT hardware and It is	Include I-STAT nardware should be investigated	
	cables (batteries /battery carrier at the time of the incident	Classification is complaint 2	
	AND the issue is not attributable to incorrect handling of	Ask sustained to return the neuron cohies (hetterios /hetterios	
	the bardware	Ask customer to return the power cables/batteries/battery	
		carrier that were in use at the time of the event	

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3.5 Cosmetic Damage Issues

Complaint	Description	
Cosmetic Damage	The i-STAT hardware has physical damage. The customer may also report rattling noises or unusual smells.	
	Prompts for Meaningful Data Collection	
RW Code: C2595	1. What i-STAT hardware is impacted?	
	2. What is the serial number(s)?	
Synonyms: Cracked,	3. What components are damaged?	
dented, split,	4. What is the damage to the hardware?	
marred, smashed,	5. If damage is to battery compartment, is the damage external or internal?	
dropped, scuffed,	6. Was the hardware dropped?	
frayed, torn, IR	Troubleshooting	
window lens	A. Document the specific damage to the i-STAT hardware	
missing	B. If cracked casing, request what is used to clean the analyzer or hardware	
	C. If the damage is to the analyzer <u>battery carrier</u> or <u>battery door</u> those components can be replaced at no charge	
	D. Replacement <u>feet</u> can be sent for the i-STAT analyzer if they are missing	
	E. Replacement <u>cables</u> for the i-STAT hardware can be sent if they are frayed or any other damage	
	Resolution	
	IF the damage is to the analyzer battery carrier or battery THEN the issue is resolved	
	door and replacing those components restores the • Classification is Complaint 1	
	analyzer	
	IF the i-STAT analyzer is missing feet and replacement feet THEN the issue is resolved	
	are sent Classification is Complaint 1	
	IF the damage is to cables and replacement cables are THEN the issue is resolved	
	sent Classification is Complaint 1	
	IF the i-STAT analyzer has physical damage THEN the i-STAT analyzer should be replaced or repaired	
	Classification is Repair	
	IF the i-STAT hardware has physical damage THEN the i-STAT hardware should be replaced	
	Classification is Repair	

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3.6 Miscellaneous Analyzer Issues

Complaint	Description		
Thermal Probe-	The Thermal Probe reading is ""or is out of range.		
No/Out of Range	Prompts for Meaningful Data Collection		
Result	1. What is the analyzer serial number(s)?		
	2. What is the external simulator serial number(s)?		
	3. What is the thermal probe delta reading?		
RW Code: C2546	Troubleshooting		
	A. Verify the thermal probe reading is a value from -0.1 to -	+0.1 inclusive	
Synonyms: thermal	B. Verify the analyzer and external simulator have been sto	red in the same place (away from drafts) for 30 minutes	
probe check failed,	prior to testing		
dashes	C. Inform user to handle the simulator as little as possible t	o maintain its thermal uniformity and stability	
	D. If "" is displayed, partially insert the simulator into an	nalyzer and let it stand for 15 minutes before inserting all the	
	way		
	E. Re-test the simulator and confirm the thermal probe del	ta reading is acceptable	
	Resolution		
	IF the thermal probe result is a value from -0.1 to +0.1	THEN the incident is resolved	
	inclusive on the analyzer	Classification is Complaint 1	
	IF the re-test thermal probe result produces acceptable	THEN the incident is resolved	
	result	Classification is Complaint 1	
	IF specific external simulator serial number fails on multiple	THEN the simulator should be replaced	
	analyzers after troubleshooting and a different simulator	Classification is Repair	
	serial number(s) produces acceptable thermal probe result		
	IF specific analyzer serial number fails after troubleshooting	THEN the i-STAT analyzer should be repaired or replaced	
	with multiple simulators and same simulators produce	Classification is Repair	
	acceptable thermal probe results on other analyzer serial		
	numbers		

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Complaint	Description
Testing	The i-STAT 1 Analyzer(s) does not display the test result(s) or testing is disabled (i-STAT 1 Analyzer displays "Upload
Disabled/No Result	Required" or "Simulator Required" when powered on) or ACT result is displayed as zero "0"
Displayed	Prompts for Meaningful Data Collection
	1. What is analyzer serial number(s)?
	What is displayed (error/message) on the i-STAT 1 Analyzer?
RW Code: C2591	3. What is cartridge type/lot number (if applicable)?
	a. Which analyte result is impacted (if applicable)?
Synonyms: Cannot	b. Was test cancelled/stopped during ACT cartridge test cycle? (ACT result will be "0")
be found, can't be	Is Data Management used with the i-STAT 1 Analyzer(s)?
found, "pre-warm"	a. If yes, what data manager is being used?
error for ACT test;	b. Can the user access customization workspace in DMS?
Zero for ACT	5. Is Operator Test Select being used during testing on the i-STAT 1 Analyzer(s)?
	Is analyte(s) in question disabled globally or by panel in DMS?
	Is there an upload schedule or external simulator testing schedule customized in DMS?
	8. Is testing disabled due to not satisfying the liquid QC schedule using eVAS?
	Troubleshooting
	A. Verify what is displayed or occurring on analyzer to determine the cause of the disabled testing on the analyzer.
	Note: May need to power analyzer off and turn on again to see start up message or code displayed.
	 Based on the startup message displayed, review action required to enable testing
	2. Verify customization settings in analyzer or customization workspace
	3. Determine if actions are set to "lock out" i.e. upload required, external simulator testing required)
	4. Perform the needed actions to enable testing on the analyzer, i.e. dock the analyzer, test the external
	simulator etc.
	B. Verify if disabled testing is due to not performing the scheduled QC using eVAS
	1. Check if the customer performed QC as unscheduled QC (confirm by checking if the scheduled QC option is
	active/available for use)
	2. Ask the customer to test QC in the scheduled path on the analyzer to enable testing
	C. Verify the analyte result(s) cannot be located on the I-STAT I Analyzer
	F Determine if analyte(s) on the cartridges are disabled: either globally or by nanel under DMS sustamization
	worksnace
	F Determine if Operator Test Select is being used on the analyzer
	1. Review how operator test selects option functions (selection must be made for results to be displayed)
	Note: Bicarbonate (HCO3) will not display if TCO2 is not selected.
	I COTTAN ISTAT ISTAT
	HOUSE FSTAT HISTART HUMBLING
	Pti333 Pti333
	INa 6Hct ZK 7Hct 72K 72Ppp
	2 K 7 P02 3 iCa 8 P02 3 ch 102
	CIPH B
	Gelect Tests Select Tests
	To Report Depart
	Page Cantridge Locked Page Cantridge Locked Results Readu
	G. If ACT test result display as "0" (zero), inform user this is because the ACT test was cancelled. When testing a Celite
	ACT or Kaolin ACT cartridge, an option to cancel the test will appear on the analyzer screen. The cancel test option
	will only appear after all the data entry has been completed. If the operator chooses to cancel the test, the result
	Will display as "U".
	H. Re-test the cartridge to verify that the issue is resolved after the above troubleshooting

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Resolution	
IF the result cannot be located on the i-STAT 1 Analyzer	THEN the issue is resolved
AND Operator Test Select or Analyte enable settings	Classification is Complaint 1
were corrected AND the re-test result was displayed	
successfully	
If testing is enabled after testing liquid QC in the	THEN the issue is resolved
scheduled path	Classification is Complaint 1
IF action displayed is taken and testing is enabled on the	THEN the issue is resolved
analyzer	Classification is Complaint 1
IF the ACT result was obtained after retesting the ACT	THEN the issue is resolved
cartridge when "0" was previously displayed for ACT	Classification is Complaint 1
result	

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Complaint	Description	
Device Message	The i-STAT 1 Analyzer(s) memory is full	
"Memory Full"	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)?	
	2. Is Data Management used with the i-STAT 1 Analyzer(s)?	
RW Code: C2572	a. If yes, what data manager is being used?	
	Troubleshooting	
Synonyms: N/A	A. If Data Management is being used, download and transmit the results to "free" up memory	
	 B. If Data Management is not being used, review and delet discretion) 	e results (as necessary) to "free" up memory (per customer's
	Note: The analyzer does not warn if there are 1000 unsent re require deleting unsent results. Results are stored in sequent needs to overwrite the oldest results. This warning indicates transmitted.	esults. It warns if it detects that storing more results will ial order, so eventually to store new results the analyzer that doing so will delete records that were not previously
	Resolution	
	IF downloading results OR deleting results resolves the	THEN the issue is resolved
	"Memory Full" message	Classification is Complaint 1

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Complaint	Description	
Product Received	The new or replaced i-STAT 1 Analyzer was shipped and receiv	ved with data saved to memory.
with Data in	Prompts for Meaningful Data Collection	
Memory	1. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Verify the impacted i-STAT 1 analyzer was shipped as a new order or replacement/repair	
RW Code: C5552	B. Verify specific data saved to memory (i.e. customization settings, results etc.)	
	Resolution	
Synonyms: N/A	IF the i-STAT analyzer is verified to be shipped as a new or THEN the i-STAT analyzer should be replaced/repaired	
	repair/replacement AND data is verified to be saved in	and investigated
	memory	Classification is Complaint 2
		Ask customer to return the analyzer investigation and
		document request(s).

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Complaint	Description	
Cleaning Tool	The i-STAT 1 Analyzer has a Contact Pin Cleaning Tool, Ceramic Conditioning Cartridge or Latch Return Tool stuck in the	
Stuck	cartridge port and cannot be removed	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)?	
RW Code: C3211	2. Which tool is stuck in analyzer?	
	3. What quality check code or issue occurred leading to use	e of tool?
Synonyms:	Troubleshooting	
Jammed, locked	If Contact Pin Cleaning Tool is stuck:	
	A. Review Contact Pin Cleaning Tool use procedure	
	B. Attempt to repeat cleaning procedure (push in and pull	back to arrows, then try to pull cleaning tool out)
	C. If the Contact Pin Cleaning Tool is removed, run addition properly	nal cartridges to ensure that the analyzer is functioning
	 If Ceramic Conditioning Cartridge or Latch Return Tool is stu A. Change or charge the batteries to reach the required op Verify battery carrier with a red fused bottom Verify appropriate rechargeable battery is beir B. Ensure that the pins in the battery compartment are in g C. Verify that the battery door is pushing down on the batter to increase force on the battery when installed D. If Ceramic Conditioning Cartridge or Latch Return Tool is functioning properly 	ick: erational voltage is being used with 9-volt Lithium batteries ing used and is not exhausted good condition erry when installed; pull on the metal tab on the battery door s released, run cartridge or simulator to ensure the analyzer is
	Resolution	
	IF the tool is removed after troubleshooting AND the	THEN the issue is resolved
	analyzer is functioning properly	Classification is Complaint 1
	IF the tool is not removed after troubleshooting	THEN the i-STAT analyzer should be replaced or repaired
		Classification is Repair
		DO NOT FORCEFULLY REMOVE the stuck tool. Send new tool to customer.

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Complaint	Description	
Handheld	The i-STAT 1 Analyzer is not performing as expected and no specific error codes are being generated or user does not	
Functionality not as	know the specific details of the issue with the analyzer	
Expected per	Note: C2568 should only be used when there is no other specific complaint code available	
Customer	Examples:	
	 Analyzer displays "Remove Cartridge" when simulator is inserted 	
	 Analyzer displays "Temperature Out of Range, Check Status Page" 	
RW Code: C2568	 User expecting the analyzer to perform a function it is not capable of performing 	
	• i-STAT analyzer does not beep when testing is completed	
Synonyms: does not	• When running test on analyzer, the results are not displaying on the initial page. User must arrow over to see	
work, has an	results.	
issue/error	User not able to get into the utility menu on analyzer	
	Wireless analyzer is losing configuration settings	
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	Dromats for Magningful Data Collection			
-	1	1 What is the analyzer serial number?		
	1. 2	What is the analyzer serial humber:		
	2.	Are any codes or messages being displayed by the analyzer/s/2		
-	J. Tro	Froubleshooting		
ŀ	Δ	Request specific details regarding complaint (request screenshots or pictures of the issue)		
	R R	Verify if the analyzer shows the message/error currently		
	C.	For "Temperature Out of Range, Check Status Page" message:		
	0.	1. Check temperature reading		
		2. Move analyzer to warmer/cooler area and allow analyzer to acclimate to new environment		
	D.	Review customization settings in analyzer or DMS, testing procedures and performance specifications		
	Ε.	If wireless analyzer displays or no settings, confirm procedure for viewing set up with customer. No		
		information will be displayed if the wireless status is between associated and not associated states. Customer must		
		wait for wireless menu to display a "state" of either Not Assoc. or Associated.		
		1. To view settings (no IP address)		
		a. Power on analyzer		
		b. Press Menu to access Administration menu		
	c. Press 8 - Wireless			
		d. Press 1 - Cancel to cancel "Initializing Wireless Module"		
		e. Must wait for Status to indicate State: Not Assoc.		
	f. Press 1 - View Setup (Wireless settings except IP address will display)			
	2. To view IP address, analyzer must associate:			
	a. Power on analyzer			
		b. Press Menu to access Administration menu		
		C. Press 8 - Wireless		
		d. Press 1 - Cancel to cancel initializing wireless Module		
		e. Press 4 - Resel f Must wait for Status to indicate State: Associated		
		 a Press 1 - View Setun (All wireless settings including IP address will display) 		
	Res	olution		
	IF the complaint is resolved with discussion of THEN issue is resolved			
	cust	tomization settings on the analyzer/DMS, testing • Classification is Complaint 1		
	pro	cedures and performance specifications AND product		
	is d	etermined to be functioning as expected		
	IF ti	he wireless configuration settings are viewed by THEN issue is resolved		
	follo	owing troubleshooting above • Classification is Complaint 1		

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4.0 Accessories

Components	Description		
Cables	The i-STAT downloaders and printers require various power	adapters and cables to interface with power outlets or other	
	devices. These cables may be misplaced, damaged, or otherwise require replacement for proper operation.		
	Prompts for Meaningful Data Collection		
	1. What i-STAT hardware is impacted?		
Synonyms: N/A	a. What are the serial number(s) of the hardwar	re?	
	2. Are the cables missing or damaged?		
	3. Is the hardware experiencing an issue?		
	Additional Information		
	A. The i-STAT DRC-300 downloader and i-STAT PR-300 prin	nter utilize the same type of power adapter (currently	
	orderable), while the DS-300, DRS-300, DN-300, DRN-3	00, and Martel Printer use different power adapters (not	
	Currently orderable)	tor namer cable consists of two components, the namer	
	B. A complete DRC-300 downloader of I-STAT PR-300 prin	ic to the country of use	
	C Replacement cables can be sent at no charge if require	d to troubleshoot or resolve a current issue reported by	
	customer		
	Scenarios		
	IF the customer reported damaged cables for a DRC-300 THEN the cables can be sent at no charge		
	downloader or i-STAT (PR-300) printer • Classification is Complaint 1 with C2595		
	IF the customer has lost/misplaced cables or has damaged	THEN the cables can be sent at no charge	
	cables for a DRC-300 downloader or i-STAT (PR-300) • Classification is Complaint 1		
	printer and the cables are needed to resolve a currently documented issue (i.e. software update, transmission issues, power issues)		
	IF the customer has lost/misplaced cables for a DRC-300	THEN the customer should purchase the cables through	
	downloader or i-STAT (PR-300) printer and the customer	Customer Service	
	has not reported a currently documented issue that needs		
	to be resolved		
	IF the customer has lost/misplaced cables or has damaged	THEN the I-STAT hardware should be replaced	
	cables for a DS-300, DRS-300, DN-300, DRN-300	Classification is Repair	
	uowinioauer or a marter printer and they require		
	replacement cables (power cable of DB9 senar cable)	300 DRS-300 DN-300 DRN-300) only available through	
		the RGA process	
		Martel printers will be replaced with i-STAT Printer kit.	
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Components	Description		
Feet	The i-STAT 1 analyzer and downloader/recharger have feet that stick to the bottom of the device. These feet may come off		
	and the customer will require replacements for proper operation.		
	Prompts for Meaningful Data Collection		
Synonyms: N/A	1. What i-STAT hardware is impacted?		
	a. What are the serial number(s) of the hardware?		
	2. How many feet are missing or need to be replaced?		
	Additional Information		
	A. The i-STAT analyzer must be on a level surface to properly run the test; missing feet can cause the analyzer to not be level		
	B. The i-STAT downloader/recharger must be able to act as a stable and level surface for the i-STAT analyzer; missing feet can cause the downloader/recharger to not be level		
	C. The customer must report that feet are missing from specific i-STAT hardware; spare or additional feet cannot be provided		
	Scenarios		
	IF the customer is missing feet from the i-STAT analyzer or THEN the feet can be sent at no charge		
	downloader/recharger Classification is Complaint 1 with C2595 Classification is Complaint 1 with C2595 		
	IF the customer is not currently missing feet from the i-STAT THEN the feet CANNOT be sent per OEC re		
	analyzer or downloader/recharger, but would like to order		
	additional feet as spares		

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Components	Description		
Battery Door(s)	The i-STAT 1 Analyzer has a removable door to hold the batteries in place.		
	Prompts for Meaningful Data Collection		
	1. What i-STAT hardware is impacted?		
	a. What are the serial number(s) of the hardware? (Note: battery doors for printers are not available)		
Synonyms: N/A	2. Is the battery door of the i-STAT 1 Analyzer damaged or misplaced?		
	3. Is the hardware experiencing an issue (not powering on	, powering off prematurely, etc.)?	
	Additional Information		
	A. If the battery door is damaged, verify with the user if the	e case of the i-STAT analyzer that houses the battery door is	
	also damaged; the entire analyzer may need to be replaced or repaired rather than just sending the door		
	B. If the battery door is not providing sufficient downward force on the battery, the metal tab on the underside of the		
	door can be manually pulled down to increase the amount of force without needing to replace the door		
	Scenarios		
	IF the battery door for the analyzer is misplaced THEN the door can be sent at no charge		
	Classification is Inquiry		
	IF the battery door for the analyzer is damaged	THEN the door can be sent at no charge	
	Classification is Complaint 1 with <u>C2595</u>		
	IF the battery door is not damaged or misplaced and the THEN the door CANNOT be sent per OEC regulations		
	customer is requesting spare doors		
	IF the battery door is damaged and the customer confirms THEN the i-STAT hardware should be replaced		
	that the i-STAT analyzer also has damage, specifically	Classification is Repair	
	around the battery compartment		

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Components	Description		
Battery Carrier(s)	The i-STAT 1 Analyzer utilizes a removable plastic battery ca	rrier to house two disposable 9-Volt Lithium batteries. The	
	disposable batteries can be replaced with a rechargeable ba	ittery pack if desired.	
	Prompts for Meaningful Data Collection		
	1. What i-STAT Analyzer serial number?		
Synonyms: N/A	2. Is the battery carrier damaged or misplaced?		
	3. Is the hardware experiencing an issue (not powering or	n, powering off prematurely, etc.)?	
	Additional Information		
	A. If the battery carrier is damaged, verify if the i-STAT an	alyzer is compromised; document the nature any damage that	
	occurred		
	B. The battery carrier initially shipped with a green base,	which was later updated to a red base that contained a fuse to	
	prevent the battery from overheating in the event of a	circuitry failure in the i-STAT analyzer; all battery carriers with	
	a green base must be replaced with a red base regardle	ess of the customer complaint	
	New Battery Carrier Old Battery Carrier		
	Scenarios		
	IE the battery carrier is misplaced	THEN the carrier can be sent at no charge	
	in the battery carrier is misplaced	Classification is Inquiry	
	IF the battery carrier is damaged	THEN the carrier can be sent at no charge	
	in the battery currents duringed	Classification is Complaint 1 with C2595	
	IF the battery carrier is not damaged or missing and the	THEN the carriers CANNOT be sent per OEC regulations	
	customer is requesting spare carriers AND the customer		
	has the battery carrier with red base		
	IF the battery carrier is not damaged but has a green base	THEN the carrier can be sent at no charge	
	, , ,	Classification is Inquiry	
		The replacement carrier will have a red base; the old carrier	
		does not need to be returned	
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5.0 Tools for Troubleshooting

Tool	Description		
Ceramic	In case of contact related errors such as suppressed (***) results for hematocrit and Quality Check Codes 20, 23, 27, 28,		
Conditioning	29, 31, 32, 34, 38, 41, 43, 49, 50, 69, 87, and 126, they may be reduced by restoring an analyzer with the reusable i-STAT		
Cartridge (CCC)	Ceramic Conditioning Cartridge.		
	Instructions		
Synonyms: N/A	 Run an external Electronic Simulator Running the external Electronic Simulator ensures the Internal Simulator cycle will not execute during the restoration cycle, which could lead to the premature termination of restoration cycle Run the CCC two times Initiate the CCC cycle as you would initiate an external Electronic Simulator The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete; disregard the code as this is expected behavior Update the CCC Usage Log Update the CCC Usage Log to keep track of the number of restoration cycles performed with the current ceramic strip in the CCC. 		
Synonyms: N/A	Lerdific scrip in the CCC h If peressary, replace or rotate the ceramic strip so CCC is ready for future use (Note: Use a No. 1 Phillips		
	b. In necessary, replace of rotate the ceranic strip so coccis ready for ruthe use (Note: Ose a No. 1 Phillips screwdriver to loosen gold plate to rotate/replace strip)		
	4. Repeat CCC testing cycle above		
	5. Test a new cartridge with patient sample/OC material		
	a. If code resolved, return the analyzer to service		
	b. If code is not resolved, repeat CCC procedure		
	Additional Information		
	A. Refer to Technical Bulletin: Instructions for Restoring Analyzers that produce *** for Hematocrit and Quality Check		
	Code 23 Art: 721215 or 714962, for CCC usage logs		
	B. Perform cartridge testing with QC/sample to confirm code is resolved		
	Scenarios		
	IF the customer is requesting a CCC or the strip for the THEN the CCC can be sent at no charge		
	CCC but they are not currently experiencing a quality • Classification is Inquiry		
	check code that warrants the use of the CCC		
	IF the customer reports that a quality check code is THEN the CCC can be sent at no charge for troubleshooting		
	occurring that warrants the use of the CCC • Classification is Complaint 1 (<u>C1071</u>)		
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Tool	Description		
Contact Pin	The Contact Pin Cleaning Kit may be used when Quality Check Code 48, 57, or 68 is generated on the i-STAT 1 Analyzer		
Cleaning Kit	and is intended to be discarded after one cleaning procedure. The Contact Pin Cleaning Kit is a two-part kit containing [A]		
-	Contact Pin Cleaning Tool Guide (frosted clear plastic) and [B] Contact Pin Cleaning Tool (clear plastic).		
Flap	Instructions		
6	1. Power OFF the analyzer and remove the batteries		
A CONTRACTOR	2. Hold the Tool Guide [A] with thumb on the arrow and insert it into the cartridge port		
B. Tool	a. Push the Tool Guide in until it snaps into place, similar to a cartridge		
A. (Guide)	3. Hold the tool [B] with thumb placed on the single arrow immediately before the line and insert it into the guide		
	within the cartridge port with the flap facing up		
Synonyms: N/A	4. Push the tool in until the line at the tip of the "Single Arrow" meets the rear edge of the guide (some resistance and		
	the sound and/or feeling of scraping can be expected)		
	5. To perform the cleaning action, pull the tool back until the line at the tips of the "Double Arrows" meets the rear		
	edge of the guide (some resistance is expected) and then push the tool in again until the line at the tip of the "Single Arrow" meets the rear edge of the guide (user may hear/feel a snap) a. Repeat this step one additional time		
	6. Keep the tool flat on the guide and push the tool all the way in until the extended edges of the tool handle hit the		
	rear of the guide		
	7. Pull the tool back to remove the tool from the analyzer		
	8. Discard the tool and guide in a biohazard waste container according to local, state, and national regulatory guidelines		
	9. Insert the batteries, power ON the analyzer, and run an electronic simulator to ensure that the Quality Check Code(s)		
	nas cleared		
	Additional Information		
	A Poter to Technical Bulletin: Contact Din Cleaning Kit Procedure Art: 720566 for more information		
	Scenarios		
	IF the customer is requesting a Contact Pin Cleaning Kit THEN the Contact Pin Cleaning Kit can be sent at no charge		
	but they are not currently experiencing a quality check • Classification is Inquiry		
	code that warrants the use of the Contact Pin Cleaning Kit		
	per the support guide		
	IF the customer reports that a quality check code is THEN the Contact Pin Cleaning Kit can be sent at no charge		
	occurring that warrants the use of the Contact Pin for troubleshooting		
	Cleaning Kit per the support guide • Classification is Complaint 1 (<u>C1071</u>)		

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Tool	Description		
Latch Return Tool	If the i-STAT 1 Analyzer is not locking cartridges and/or simulato	rs into place, then the Latch Return Tool may resolve the	
	issue.		
	Instructions		
Synonyms: N/A	1. Insert the Latch Return Tool into the cartridge port of the h the port	andheld with the arrow facing up and in the direction of	
	 Push the tool into the cartridge port until it stops and a click Attempt to run a cartridge: ensure that it locks into place 	k is heard, then remove by pulling it from the handheld	
	 Attempt to run a cartridge; ensure that it locks into place Attempt to run an electronic simulator twice to rule out simulator as cause of the issue 		
	4. Attempt to run an electronic simulator twice to rule out simulator as cause of the issue		
	Wear on the underside of the simulator can cause latch issues; if the issue appears to coincide with the use of a specific simulator, check on the underside of the simulator to check condition Broken Simulator will cause the latch issue		
	Worn Simulator will not cause the latch issue, but may eventually break		
	Refer to Technical Bulletin: Latch Return Tool Art: 730131 for inf	ormation.	
	Scenarios		
	IF the customer is requesting a latch return tool but they are	THEN the latch return tool can be sent at no charge	
	not currently experiencing a locking issue that warrants the	Classification is Inquiry	
	use of the latch return tool per the support guide		
	IF the customer reports that they are experiencing a locking	THEN the latch return tool can be sent at no charge for	
	issue that warrants the use of the latch return tool per the	troubleshooting	
	support guide	Classification is complaint 1 (<u>C10/1</u>)	
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6.0 Software Update

6.1 Unable to Perform Software Update Decision Tree

RW Code	Description	
C1069	"Downloader could not be configured to perform the update" message via JammLite	\rightarrow Jump to Section
C1069	 • TCP/IP is only option 	\rightarrow Jump to Section
C1069	"Port specified for the update could not be opened" message via JammLite	→ Jump to Section
C1069	 No/Incorrect software available in JammLite CLEW and/or Application displays "none" CLEW and/or Application is not current revision 	\rightarrow Jump to Section
C1069	"IR Link cannot be configured to perform CLEW update" message	\rightarrow Jump to Section
C1069	 Update does not start via JammLite Nothing happens on analyzer Nothing happens when analyzer is placed in downloader 	→ Jump to Section
C1069	 Unable to update software via customization workspace Not able to select current CLEW and/or JAMS Nothing happens Analyzer screen goes back to Administration Menu 	→ Jump to Section
C1069	 Unable to download software to computer Cannot find downloaded software Computer is not allowing download 	→ Jump to Section
C1069	Handheld-to-Handheld update will not occur Nothing happens	→ Jump to Section

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6.1.1 Unable to Perform Software Update Scenarios

Complaint	Description		
JammLite:	"Downloader could not be configured to perform the update" message appears in JammLite Utility.		
"Downloader	Prompts for Meaningful Data Collection		
Could Not Be	1. What is analyzer serial number(s)?		
Configured to	2. What is the battery voltage?		
Perform the	3. Which comport was selected?	3. Which comport was selected?	
Update"	4. What is the downloader serial number?		
Message	a. Are appropriate downloader cables connected	to power and computer?	
	b. Have USB drivers been installed on the comput	ter (if applicable)?	
RW Code: C1069	c. Does customer have administrative rights?		
	5. Are there any programs running on computer that may be u	using the comport?	
	Troubleshooting		
Synonyms: N/A	A. Review software update procedure (Technical Bulletin: Insti	ructions for Updating i-STAT 1 Handheld Software using	
	www.pointofcare.abbott Art: 731335)		
	B. If DRC-300 downloader, assist with installing USB drivers (administrative rights required)		
	1. Note: Use another computer with admin rights if	available	
	C. After download of the USB drivers for DRC-300 downloader (<i>Technical Bulletin: i-STAT 1 Downloader/Recharger</i>		
	(model number DRC-300) Art: 728690), verify under device manager and ports if the USB drivers for the downloader		
	are installed		
	> 🖵 Network adapters		
	> Portable Devices		
	V 💭 Ports (COM & LPT)		
	USB Serial Port (COM4)		
	> Fint queues		
	1. May have to restart the computer after the driver has been downloaded to see ports		
	DR9:DR9 cable for the (DRS/DS downloaders)	ned power capies and OSB capie in case for DRC-500 of the	
	E Verify correct compart is selected and no programs are one	an which could be using comport	
	E. Try plugging the USE cable or the DE9:DE9 cable to a different	ant port if multiple ports are available on the	
	computer/lanton	ent port il multiple ports are available on the	
	Resolution		
	IF software undate is successful after connecting	THEN the incident is resolved	
	downloader cables correctly	Classification is Complaint 1	
	Classification is Complaint 1 Figure 1 Fi		
	drivere	Classification is Completed	
		Classification is Complaint 1	
	IF software update is successful after selecting correct	THEN the incluent is resolved	
	comport or closing any open program	Classification is Complaint 1	
	IF customer referred to facility II department due to lack of	THEN THE INCIDENT IS RESOLVED	
	admin rights; and the update successful with help from IT or	Classification is Complaint 1	
	atter obtaining admin rights		
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Complaint	Description		
JammLite: No	No comports available in JammLite Utility (TCP/IP only port available)		
Comports Available	Prompts for Meaningful Data Collection		
(TCP/IP only	1. What is analyzer serial number(s)?		
option)	2. What is the battery voltage?		
	3. Which comport is available?		
	4. What is the downloader serial number?		
RW Code: C1069	a. Are appropriate downloader cables connected to power and computer?		
	 Have USB drivers been installed on the compute 	ter (if applicable)?	
Synonyms: TCP/IP	c. Does customer have administrative rights?		
only port available	5. Are there any programs running on computer that may be u	using the comport?	
	Troubleshooting		
	A. Review software update procedure (Technical Bulletin: Insti	ructions for Updating i-STAT 1 Handheld Software using	
	www.pointofcare.abbott Art: 731335)		
	B. If DRC-300, assist with installing USB drivers (administrative rights required)		
	1. Using another computer with admin rights is an option if available		
	C. After download of the USB drivers for DRC-300 downloader (<i>Technical Bulletin: i-STAT 1 Downloader/Recharger</i>		
	(model number DRC-300) Art: 728690) verify under device manager and ports if the USB drivers for the downloader		
	are installed		
	Intwork adapters Destable Devices		
	Portable Devices		
	✓ ■ Ports (COM & LPT) ■ USB Seriel Beet (COM 0)		
	USB Serial Port (COM4)		
	> 🚍 Print queues		
	 May have to restart the computer after the driver 	has been downloaded to see the ports	
	D. Verify downloader is connected properly using i-STAT suppl	ied power cables and USB cable in case for DRC-300 or	
	the DB9:DB9 cable for the (DRS/DS downloaders)		
	E. Verify correct comport is selected and no programs are ope	n which could be using comport	
	F. Try plugging the USB cable or the DB9:DB9 cable to a different	ent port if multiple ports are available on the	
	computer/laptop		
	Resolution		
	IF software update is successful after connecting downloader	THEN the incident is resolved	
	cables correctly	Classification is Complaint 1	
	IF software update is successful after installing DRC-300	THEN the incident is resolved	
	drivers	Classification is Complaint 1	
	IF software update is successful after selecting correct	THEN the incident is resolved	
	comport or closing any other open program	Classification is Complaint 1	
	IF customer referred to facility IT department due to lack of	THEN the incident is resolved	
	admin rights; and the update successful with help from IT or	Classification is Complaint 1	
	after obtaining admin rights		

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Complaint	Description			
JammLite: "Port	"Port specified for the update could not be opened" message appears in JammLite Utility			
Specified for Update	Prompts for Meaningful Data Collection			
Could Not Be Opened"	1. What is analyzer serial number(s)?			
Message	2. What is the battery voltage?			
	3. Which comport was selected?			
	4. What is the downloader serial number?			
RW Code: C1069	a. Are appropriate downloader cables connec	cted to power and computer?		
	b. Have USB drivers been installed (if applicable)?			
Synonyms: N/A	c. Does customer have administrative rights?			
	5. Are there any programs running on computer that may be using the comport?			
	Troubleshooting			
	A. Review software update procedure (Technical Bullet	in: Instructions for Updating i-STAT 1 Handheld Software		
	using www.pointofcare.abbott Art: 731335)			
	B. If DRC-300, assist with installing USB drivers (adminis	strative rights required)		
	1. Using another computer with admin rights	1. Using another computer with admin rights is an option if available		
	C. After download of the USB drivers for DRC-300 down	nloader (Technical Bulletin: i-STAT 1 Downloader/Recharger		
	(model number DRC-300) Art: 728690) verify under c	levice manager and ports if the USB drivers for the		
	downloader are installed			
	> 🚽 Network adapters			
	> 📃 Portable Devices			
	V 💭 Ports (COM & LPT)			
	USB Serial Port (COM4)			
	> 🚍 Print queues			
	1 May have to restart the computer after the	e driver has been downloaded to see the ports		
	D Verify downloader is connected properly using i-STA	T supplied power cables and USB cable in case for DBC-300		
	or the DB9:DB9 cable for the (DRS/DS downloaders)			
	E. Verify correct comport is selected and no programs a	are open which could be using comport		
	F. Try plugging the USB cable or the DB9:DB9 cable to a	a different port if multiple ports are available on the		
	computer/laptop	· · · · · · · · · · · · · · · · · · ·		
	Resolution			
	IF software update is successful after connecting	THEN the incident is resolved		
	downloader cables correctly	 Classification is Complaint 1 		
	IF software update is successful after installing DRC-300	THEN the incident is resolved		
	drivers	 Classification is Complaint 1 		
	IF software update is successful after selecting correct	THEN the incident is resolved		
	comport or closing any open program(s)	Classification is Complaint 1		
	IF customer referred to facility IT department due to	THEN the incident is resolved		
	lack of admin rights; and the update successful with	Classification is Complaint 1		
	help from IT or after obtaining admin rights			

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Complaint	Description		
	Description		
	No/incorrect CLE w and Application (JAWS) available in JammLite Utility		
Incorrect CLEW and/or	Prompts for Meaningful Data Collection		
Application (JAMS)	 What is analyzer serial number(s)? 		
	What is the battery voltage?		
	3. What displayed for CLEW and Application?		
RW Code: C1069	4. What is the downloader serial number?		
	Troubleshooting		
Synonyms: no CLEW	A. Review software update procedure		
and/or JAMS	1. Technical Bulletin: Instructions for Updatin	a i-STAT 1 Handheld Software usina	
(application)	www.nointofcare.abbott Art: 731335		
	2 Ouick Reference Instructions for Undating the i-STAT 1 with Serial Downloaders and IAMMUTE using		
	www.nointofcare.abhott Art: 732159		
	B Select correct software from dron down menu in Jammi ite Litility		
	C Download current software		
	Note: Suggest sustemer create a folder on the computer to save software file. Old software files may require		
	deletion from computer		
	D Vorify if outtomor have administrative rights to down	pland the coffusion to the computer/lanton refer to facility	
	D. Verify in customer have administrative rights to down	moad the software to the computer/laptop, refer to facility	
	Production		
	Resolution		
	IF software update is successful after selecting correct	THEN the incident is resolved	
	software from drop down menu Classification is Complaint 1		
	IF software update is successful after downloading the THEN the incident is resolved		
	current software • Classification is Complaint 1		
	IF customer referred to facility IT department due to	THEN the incident is resolved	
	lack of administrative rights; and the update successful	Classification is Complaint 1	
	with help from IT or after obtaining administrative		
	rights		

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Complaint	Description		
JammLite: "IR Link	"IR Link cannot be configured to perform CLEW update" message appears when attempting to perform software update		
Cannot Be	with JammLite Utility.		
Configured to	Prompts for Meaningful Data Collection		
Perform CLEW	1. What is analyzer serial number(s)?		
Update" Message	2. What is the battery voltage?		
	3. Which instrument was selected in JammLite Utility?		
	4. What is the serial number of the downloader?		
RW Code: C1069	Troubleshooting		
	A. Review software update procedure		
Synonyms: N/A	1. Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using www.pointofcare.abbott		
	Art: 731335		
	2. Quick Reference Instructions for Updating the i-STAT 1 with Serial Downloaders and JAMMLITE, using		
	www.pointofcare.abbott Art: 732159		
	B. Verify correct instrument is selected in the JammLite Utility Window. JammLite defaults to i-STAT 200 Analyzer.		
	Customer must select i-STAT 300 Analyzer from drop down menu.		
	Note: IR link is no longer a supported product. Do not troubleshoot IR link connection.		
	Resolution		
	IF software update is successful after selecting correct THEN the incident is resolved		
	instrument Classification is Complaint 1		
CTAT Commonst Coulde I		~~	

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Complaint	Description		
JammLite: Nothing	Unable to perform the i-STAT CLEW and JAMS software update via JammLite Utility. Nothing happens when analyzer is		
Happens When	placed in downloader.		
Analyzer is Placed	Prompts for Meaningful Data Collection		
in Downloader	1. What is analyzer and downloader serial numbers?		
	2. What is the battery voltage?		
	3. Was analyzer in the downloader when "Update" was pressed in JammLite Utility?		
RW Code: C1069	4. Was analyzer powered off when placed in downloader?		
	Troubleshooting		
Synonyms: N/A	A. Review software update procedure		
	1. Technical Bulletin: Instructions for Updatina i-STAT 1 Handheld Software using www.pointofcare.abbott		
	Art: 731335		
	2. Quick Reference Instructions for Updating the i-STAT 1 with Serial Downloaders and JAMMLITE, using		
	www.pointofcare.abbott Art: 732159		
	B. Remind user of computer message:		
	Lindate: JAMS141C RIN + A32 CI W		
	1) If an analyzer is already in the Downloader		
	remove it.		
	2) Ensure the analyzer to be updated is off. Cancel		
	3) Place the analyzer in the Downloader.		
	Waiting for analyzer (CDM1)		
	Resolution		
	IF software update is successful after following software THEN the incident is resolved		
	update instructions • Classification is Complaint 1		
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Complaint	Description		
Customization	Unable to undate CLEW and IAMS in customization workspace		
Workspace:	CLEW and IAMS not available		
Unable to	Prompts for Magningful Data Collection		
Opdate CLEW	1. What data management program is being used?		
and JAIVIS	2. What is DE version?		
	Troubleshooting		
	A. Review software update procedure (Technical Bulletin: No	etwork Options for Updating the i-STAT 1 Handheld using	
RW Code: C1069	www.pointofcare.abbott Art: 731336)		
	B. Reminder: CLEW and JAMS do not automatically populate customization workspace. They must be selected.		
Synonyms: no	C. Verify DE version		
CLEW or JAMS	1. If version is > 2.0 , repeat software upload via "Update i-STAT/DF" > "Upload Update File"		
	i User may have to save software in a folder on deskton (instead of directly on deskton) or save		
	software file on shared drive		
	2 If the software still not available in customization worksnace refer user to Data manager support (for third		
	2. In the software still not available in customization workspace refer user to bata manager support (for third		
	party Data Manager)		
	Posolution		
	Resolution	TUEN the incident is received	
	IF customization workspace is successfully updated after	THEN the incident is resolved	
	following correct steps for the procedure	Classification is Complaint 1	
	IF customization workspace is not successfully updated after	THEN the incident is resolved	
	repeating upload procedure in DE customization and user is	 Classification is Complaint 1 	
	referred to 3 rd party data manager vendor and update was		
	successfully completed by the vendor support		

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Complaint	Description		
Customization	Unable to perform the i-STAT CLEW and JAMS software update	via Customization Workspace. Nothing happens when	
Workspace: Will	analyzer is placed in downloader, analyzer display reverts to Administration Menu.		
Not Update, Goes	Prompts for Meaningful Data Collection		
Back to	1. What is analyzer serial number(s)?		
Administration	2. What is the battery voltage?		
Menu	3. What data management program is being used?		
	4. What is DE version?		
RW Code: C1069	5. Was the correct software file uploaded to Customization v	workspace?	
	Troubleshooting		
Synonyms: N/A	A. Review software update procedure (Technical Bulletin: Ne	twork Options for Updating the i-STAT 1 Handheld using	
	www.pointofcare.abbott Art: 731336)		
	B. Verify the following in customization workspace:		
	 "Enable Customization" is checked 		
	2. i-STAT Analyzer CLEW is current		
	3. i-STAT 1 Software is current		
	"Enabled" or "Enable Updates" is checked for lo	cation	
	"Update CLEW" is checked for location		
	6. i-STAT Analyzer CLEW is current for location		
	Customization Workspace Preferences STATIXes Profile Update -STATIOE		
	Enable Customization Institution: Fiction Hospital		
	Default customization profiles: Language: Location Enabled State Default Update CLEW-STAT Analyzer CLEW Philips BAM CLEW Preferences STAT	Tilotes	
	English AITHES V V A33 [binne] 1880157 CK Unit Set: CVOR V V A32 [binne] 1880180W CK	ARTO A	
	UNITSETTIG MPACU V A32 [None] 16A190C7 CH I-STAT Analyzer CLEV: ORTHO V V V A33 [None] 1680157 CH	ARTO A	
	A33 PACU V V A33 Plonet 660167 CK Philips BAM CLEW: PECER V V A33 Plonet 660167 CK	ARTO D	
	Picnel POCT V V A33 Picnel 1660167 CH		
	JAMS142E BN - RESP V V A33 [None] 1680157 CK	ARTO	
	16801157 STCU V V A33 Plonej 1680157 CK	ARTO	
	CHARTE		
	Ø Use eVAS APOC20162801.VAS		
	Use Operator List		
	I-STATOE Version 2.7		
	C. Repeat software update with analyzer seated in download	der	
	D. Run simulator on analyzer and download test, then repeat	t update.	
	E. Verify software installed in analyzer (update process will r	not occur if analyzer has current software installed)	
	F. If update still does not occur, use JammLite Utility. Select TCP/IP for port and enter downloader IP address.		
	Note: Network traffic may affect the ability of the analyzer to update the software via customization workspace. Advise		
	user to attempt to receive software update at a different time of day.		
	Resolution		
	IF software update is successful after updating settings in THEN the incident is resolved		
	customization workspace	Classification is Complaint 1	
	IF software update is successful after repeating update	THEN the incident is resolved	
	procedure or analyzer has current software already installed	Classification is Complaint 1	

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Complaint	Description		
Software Will Not	Software will not download to computer or cannot find after download		
Download. Unable	Prompts for Meaningful Data Collection		
to Locate After	1. What is analyzer serial number(s)?		
Download	2. What is computer operating system?		
	3. Which web browser was used to download software?		
	Troubleshooting		
RW Code: C1069	A. Review download procedure (Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using		
	www.pointofcare.abbott Art: 731335)		
Synonyms: Will not	B. Verify user has admin rights and/or firewall is not blocking download of software		
update, won't	C. Verify computer operating system. Software has been validated with Windows XP and 7, 64 bit, and Windows 10.		
update, cannot	D. Verify web browser used for download.		
update, can't	1. Google Chrome automatically saves to Downloads folder		
update, software	2. Internet Explorer has "save as" option		
not updating	Note: User may have to save software in a folder on desktop (instead of directly on desktop) or save software file on		
	shared drive		
	E. Refer user to their facility IT department if the computer does not have admin rights		
	Resolution		
	IF software update is successful after locating software file THEN the incident is resolved		
	or repeated download of software • Classification is Complaint 1		
	IF customer referred to facility IT department due to lack THEN refer user to IT department		
	of admin rights or possible firewall; and the update • Classification is Complaint 1		
	successful with help from IT or after obtaining admin		
	rights		
	IF user is using a computer with Macintosh operating THEN refer user to use a different computer with validated		
	system operating system		
	Classification is Complaint 1		

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Complaint	Description		
Handheld-to-	Unable to perform the i-STAT CLEW and JAMS software update via handheld-to-handheld procedure		
Handheld:	Prompts for Meaningful Data Collection		
Unable to	1. What is analyzer serial number(s)?		
Perform	2. What is the battery voltage?		
Software Update	Troubleshooting		
	A. Review software update procedure		
	1. Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using www.pointofcare.abbott Art:		
RW Code: C1069	731335		
	2. Quick Reference Instructions for Handheld-to-Handheld Transfer Art: 732160		
Synonyms:	B. Verify:		
software update	1. Analyzers IR windows are lined up correctly		
not working	2. Receiving analyzer is not powered on		
	C. Clean IR windows on the analyzers		
	Resolution		
	IF software update is successful after following software THEN the incident is resolved		
	update instructions • Classification is Complaint 1		
	IF software update is successful after cleaning IR windows THEN the incident is resolved		
	Classification is Complaint 1		
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6.2 Other Software Issues

Complaint	Description		
Shipment Error	Customer did not receive the software update package		
	Prompts for Meaningful Data Collection		
RW Code: C1004	1. Request customer's contact information		
	Troubleshooting		
Synonyms: N/A	A. Check mailing list		
	1. Verify contact information on software mailing.		
	2. If not correct or missing, notify administrator to u	update the mailing list	
	B. Explain software is available on APOC website		
	1. If customer is willing to perform update via APOC website, assist customer with update procedure.		
	C. Explain no-web (CD) software packages may take up to 10 business days after software release to be received		
	Resolution		
	IF customer is on mailing list to receive web package and THEN advise customer that the software is available on the		
	did not received package APOC website		
	Classification is Complaint 1		
	IF customer is not on mailing list or information is TH	HEN advise customer that the software is available on the	
	incorrect on mailing APOC website		
	Classification is Complaint 1		
	IF customer is on mailing list to receive no- web package THEN request no-web (CD) software package be sent to		
	and did not receive package after 10 business days from cus	istomer	
	software release	Classification is Complaint 1	
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Complaint	Description		
Product Received	Customer received software package with broken CD		
Damaged	Prompts for Meaningful Data Collection		
	1. Request customer's contact information		
RW Code: C5560	Troubleshooting		
Synonyms: Software CD received broken, Software update not working from CD	 A. Check mailing list Verify contact information on software mailing. If not correct or missing, notify administrator to update the mailing list Explain software is available on APOC website 		
Resolution			
	IF software update CD is broken THEN request replacement no-web (CD) software package		
	and investigate shipping		
	Classification is Complaint 2		
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7.0 Quality Material Results Issues

Complaint	Description		
Quality Material	The precision study results using APOC Control products are not acceptable, do not match the expected %CV and/or SD		
Precision	Prompts for Meaningful Data Collection		
	1. What cartridge lot number(s) is used?		
RW Code: C1620	2. What is control lot number and level(s)?		
	3. Which analyte is not meeting precision expectations?		
Synonyms: failed,	4. Which control is not matching the expected %CV/SD?		
low, high, bias, failed	5. What is the control result (with units of measure), %CV and SD of the precision study?		
precision	6. Are the control results in VAS range?		
	7. Were duplicates included for the control tested?		
	8. How many total replicates used for each control?		
	9. How was the study performed, over 2 days or 10 days or something else?		
	10. What is CLEW/JAMS software version on analyzer?		
	11. How are cartridges stored and handled?		
	12. What is analyzer serial number(s)?		
	Troubleshooting		
	A. Verify the analytes that are imprecise		
	B. Document the details of the observed imprecision (%CV/SD) and the expected %CV/SD		
	C. Document the control results in question		
	D. Verify the correct VAS and acceptable ranges are used		
	E. Verify the control results are in range or out of range per VAS ranges		
	F. Verify the control material is not expired		
	G. Verify cartridge storage and handling		
	H. Verify that a single control and a single cartridge lot number is used for the entire study		
	 Verify QC Material testing procedure was followed by asking the customer how they performed testing (per i-STAT 1 System Manual, Section 14: Quality Control Art: 714376) 		
	J. Compare the %CV/SD of the customer results to Precision Data in Performance Characteristics section of CTI		
	sheets of analyte(s) in question, Precision Data in Performance Characteristics section of individual cartridge IFUs		
	or QC section 14 of System Manual for TriControls		
	1. If the customer's results are lower or equal to those in the CTI sheets, IFUs or QC section 14, then the		
	results are considered acceptable		
	2. If the results are greater, Chi-Square test can be performed to determine if those results are statistically		
	equivalent to the values in the CTI sheet, IFUs or QC section 14		
	a. Multiply the SD in the CTI sheet, IFU or QC section 14 by a Chi-Square factor (multiplier)		
	appropriate for the number of control levels tested and the number of times each control was		
	tested to determine the upper limit for an acceptable SD.		

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	T		
	Chi-Square Multipliers for use	when 2 levels of control are test	ted
	Sample size (<i>n</i>)	Multiplier	
	4	1.77	
	8	1.51	
	10	1.45	
	12	1.43	
	13	1.39	—
	14	1.38	
	16	1.35	
	20	1.31	
	24	1.29	
	28	1.26	
	36	1.25	—
	40	1.20	—
	44	1.21	-
	48	1.20	
	52	1.19	
	56	1.19	
	60	1.18	
	68	1.17	—
	72	1.16	—
	76	1.16	—
	80	1.16	
	b. If the Note: APOC do can be tolerate 3. If results are sti K. If the results are not acce	customer's SD is at or below es not provide acceptance cr d by the medical/lab director ill higher than the Chi-Square eptable after repeating the pr	v the upper limit, the precision is acceptable. riteria. The facility should determine the imprecision which r. e value, precision study should be repeated with 20 replicates. recision study, provide a replacement control from a different
	Resolution		
	IF the %CV/SD of the control r	esults are within the	THEN the incident is resolved
	Precision Data in Performance	Characteristics section of	Classification is Complaint 1
	CTI sheets or IFUs or QC section	on 14	
	IF the %CV/SD of the control r	esults are within the	THEN the incident is resolved
	Precision Data in Performance	Characteristics section of	Classification is Complaint 1
	CTI shoots or IEUs or OC sostis	an 14 ofter using the chi	- classification is complaint 1
		ni 14 aitei usiilg tile till-	
	square value		
	IF the %CV/SD of the control r	esults are within the	THEN complaint is resolved
	Precision Data in Performance	e Characteristics section of	Classification is Complaint 1
	CTI sheets or IFUs or QC section	on 14 after precision study	
	is repeated with 20 replicates		
	IF the precision study is still up	naccentable and a new	THEN the OC material lot in question should be
	control lot number is provided		investigated
	control lot number is provided	1	
			Classification is complaint 2
			Ask customer if QC material are available to be returned
			for investigation and document request(s)
CTAT Come and Colds D	FE 11 F1 C Continue 7 0		Detune to the TOC

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Complair	nt	Description		
Sodium (Na)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
i-STAT or	r TriControl	Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable		
Control o	or Calibration VAS ranges.			
Verificati	ion Results	Prompts for Meaningful Data Collection		
are Out of Range 1. What cartridge type and lot number(s) is the out of range result occurring?		ange result occurring?		
		2. What is QC material lot number and level?		
Synonym	is: failed, low,	3. What is the Na result (with units of measure)?		
high, bias	S	4. Which VAS is being reviewed? What is the VAS acce	otable range?	
		5. How is the control/cal ver stored and handled?		
DW/ Code		6. Was the correct pathway used on the analyzer for te	sting of control/cal ver material?	
RW Code	S No. Lligh	7. Are the other analytes from the cartridge testing wit	nin range?	
C1321		8. Is the control/cal ver lot number being used for the f	irst time on this cartridge lot number?	
01521	Ver	a. If not used for the first time – were the cor	itrol/cal ver results in range on previous testing?	
	Na - Low	9. What is CLEW version on the analyzer?		
C1322	QC/Cal	10. How are cartridges stored and handled?		
	Ver	11. What is analyzer serial number(s)?		
		I roubleshooting		
		A. Collect and document the control results with units of	it measure	
		B. Verify correct VAS and acceptable ranges are used	C ranges	
		C. Verify the control/cal ver lot number showed accent	able results in any previous tests on the same cartridge lot	
		number (initial vs monthly OC)	able results in any previous tests on the same cartiluge lot	
		F Verify control/cal ver is not expired (refrigerated and	room temperature)	
		E. Verify control/curver is not expired (reingerated and		
		G. Verify control/cal ver testing procedure was followed	d (ask customer how they performed testing)	
		1. Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days)		
2. Verify ampules were shaken vigorously for 5-1		2. Verify ampules were shaken vigorously for	5-10 seconds to equilibrate liquid and gas phases by holding	
the ampule at the tip and bottom with forefinger and thumb to minimize increasing the ten		finger and thumb to minimize increasing the temperature of		
		the solution		
		3. Verify no delay in transferring solution to cartridge once ampule is opened		
		4. Verify transfer device used		
		5. If testing cartridges without sensors for pH, PCO2, PO2 and ionized calcium (i.e. 6+, EC4+, E3+) the same		
		ampule may be tested with remaining fluids if within 10 minutes of opening the ampule.		
		6. Verify cartridge was closed and tested immediately after filling		
		H. Retest a cartridge from the same lot number using a	new ampule of control/cal ver from the same lot number	
		tollowing proper handling and transfer instructions		
		i STAT 1 System Manual Section 14: Ouglity Control Arts	714276	
		i-STAT 1 System Manual Section 15: Calibration Verifica		
		Rules of Replacement		
		1. Provide a different lot number of QC material for tro	ubleshooting when trying to determine QC lot specific issue.	
	If the problem is occurring on more than one lot of cartridges and with one level of control only then the		artridges and with one level of control only, then the	
	problem is probably being caused by the control.			
		2. Provide a different cartridge lot number for troubles	hooting if the same QC material lot number is showing	
	acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC m		er(s) or if the results for more than one level of QC material	
are out of range on a specific lot of cartridges.				
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	Classification is Complaint 1	

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I IF control/cal ver results are in range per VAS I THEN the incident is resolved	
acceptable ranges • Classification is Complaint 1	
IF after running a new cartridge with a new ampule of THEN complaint is resolved	
control/cal ver (from the same lot numbers) the results • Classification is Complaint 1	
are acceptable	
IF after following correct handling instructions produces THEN complaint is resolved	
acceptable results • Classification is Complaint 1	
IF the out of range result is persistent on multiple i- THEN the QC material should be investigated	
STAT 1 analyzers and cartridges type/lot number for a • Classification is Complaint 2	
specific lot number of QC material after	
troubleshooting AND other QC material lot numbers Ask customer if QC material are available to be in	eturned
are producing acceptable results with the same for investigation and document request(s)	
analyzers and cartridges lot numbers.	
IF the out of range result is persistent on multiple i- THEN the suspect cartridge and QC material should be a support of the suspect cartridge and QC material should be a support of the suspect cartridge and QC material should be a support of the support of th	ld be
STAT 1 analyzers after troubleshooting but only on investigated	
specific cartridge lot(s) and specific QC material lot(s) • Classification is Complaint 2	
AND other cartridge lots and other QC material lot(s)	
run without issue on the same i-STAT analyzers Ask customer if cartridges and QC material are a	vailable
to be returned for investigation and document r	equest(s)

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Complain	nt	Description		
Potassiur	ssium (K) Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).			
i-STAT or	[·] TriControl	Control Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable		
Control or		VAS ranges.		
Calibration		Prompts for Meaningful Data Collection		
Verificati	ion Results	1. What cartridge type and lot number(s) is the out of ran	ze result occurring?	
are Out of Range 2. What is QC material lot number and level?				
		3. What is the K result (with units of measure)?		
Synonym.	s: failed,	4. Which VAS is being reviewed? What is the VAS accepta	ble range?	
low, high	, bias	5. How is the control/cal ver stored and handled?	C C C C C C C C C C C C C C C C C C C	
		6. Was the correct pathway used on the analyzer for testing	ng of control/cal ver material?	
RW Code	s	7. Are the other analytes from the cartridge testing within	range?	
	K - High	8. Is the control/cal ver lot number being used for the first	: time on this cartridge lot number?	
C1323	QC/Cal	a. If not used for the first time – were the control	ol/cal ver results in range on previous testing?	
	Ver	9. What is CLEW version on the analyzer?		
C1324		10. How are cartridges stored and handled?		
01324	Ver	11. What is analyzer serial number(s)?		
		Troubleshooting		
		A. Collect and document the control results with units of r	neasure	
		B. Verify correct VAS and acceptable ranges are used		
		C. Verify the results are in range or out of range per VAS ra	anges	
		D. Verify the control/cal ver lot number showed acceptabl	e results in any previous tests on the same cartridge lot	
		number (initial vs monthly QC)		
		E. Verify control/cal ver is not expired (refrigerated and ro	om temperature)	
		F. Verify cartridge storage and handling		
		G. Verify control testing or cal ver testing procedure was for	ollowed (ask customer how they performed testing)	
		 Verify room temperature equilibration (30 mi 	nutes at minimum, no longer than 5 days)	
		Verify ampules were shaken vigorously for 5-2	10 seconds to equilibrate liquid and gas phases by holding	
the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temp		ger and thumb to minimize increasing the temperature of		
the solution				
		3. Verify no delay in transferring solution to cart	ridge once ampule is opened	
		4. Verify transfer device used		
		5. If testing cartridges without sensors for pH, PCO2, PO2 and ionized calcium (i.e. 6+, EC4+, E3+) the same		
		ampule may be tested with remaining fluids if within 10 minutes of opening the ampule.		
		6. Verify cartridge was closed and tested immed	lately after filling	
		H. Retest a cartridge from the same lot number using a ne	w ampule of control/cal ver from the same lot number	
		Tonowing proper handling and transfer instructions		
		i-STAT 1 System Manual Section 14: Quality Control Art: 71	1276	
		i-STAT 1 System Manual Section 14. Quality Control Art. 71	+370 h Art: 71/1377	
		Rules of Replacement		
		1 Provide a different lot number of OC material for troub	eshooting when trying to determine OC lot specific issue. If	
	1. Frovide a different for fumber of QC material for inoubleshooting when rights to determine QC for specific i		tiges and with one level of control only then the problem is	
	nrobably being caused by the control		Bes and what one level of control only, then the problem is	
	 Provide a different cartridge lot number for troubleshooting if the same OC material lot number is showing 		oting if the same OC material lot number is showing	
	2. Trovide a different calculage for number for troubleshooting in the same de material for humber is showing accentable results on other cartridge type/lot number(s) or if the results for more than one level of OC mate		a) or if the results for more than one level of OC material are	
		out of range on a specific lot of cartridges.		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	• Classification is Complaint 1	

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IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	 Classification is Complaint 1
IF after running a new cartridge with a new ampule/vial of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results	 Classification is Complaint 1
are acceptable	
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	 Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material should be investigated
Analyzers and cartridges type/lot number for a specific lot	Classification is Complaint 2
number of QC material after troubleshooting AND other	
QC material lot numbers are producing acceptable results	Ask customer if QC material are available to be returned
with the same analyzers and cartridges lot numbers.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT 1	THEN the suspect cartridge and QC material should be
Analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complaint Description				
Chloride	(CI)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
i-STAT or TriControl		Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable		
Control or		VAS ranges.		
Calibration		Prompts for Meaningful Data Collection		
Verificati	ion Results	1. What cartridge type and lot number(s) is the out of ran	ze result occurring?	
are Out o	of Range	 What is OC material lot number and level? 		
		3. What is the Cl result (with units of measure)?		
Synonym	s: failed,	 Which VAS is being reviewed? What is the VAS accepta 	ble range?	
low, high	n, bias	5. How is the control/cal ver stored and handled?		
		6. Was the correct pathway used on the analyzer for testi	ng of control/cal ver material?	
RW Code	es	7. Are the other analytes from the cartridge testing withir	range?	
	Cl - High	8. Is the control/cal ver lot number being used for the firs	time on this cartridge lot number?	
C1325	QC/Cal	a. If not used for the first time – were the control	ol/cal ver results in range on previous testing?	
	Ver	9. What is CLEW version on the analyzer?		
C122C	CI - Low	10. How are cartridges stored and handled?		
C1326	UC/Cal Ver	11. What is analyzer serial number(s)?		
	VEI	Troubleshooting		
		A. Collect and document the control results with units of r	neasure	
		B. Verify if correct VAS and acceptable ranges are used		
		C. Verify if the results are in range or out of range per VAS	ranges	
		D. Verify if the control/cal ver lot number showed pass res	ults in any previous tests on the same cartridge lot number	
		(initial vs monthly QC)		
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)		
		F. Verify cartridge storage and handling		
		G. Verify control/cal ver testing procedure was followed (ask customer how they performed testing)		
		1. Verify room temperature equilibration (30 m	nutes at minimum, no longer than 5 days)	
		2. Verify ampules were shaken vigorously for 5-	10 seconds to equilibrate liquid and gas phases by holding	
		the ampule at the tip and bottom with forefir	ger and thumb to minimize increasing the temperature of	
		the solution		
		3. Verify no delay in transferring solution to car	ridge once ampule is opened	
		Verify transfer device used		
		5. If testing cartridges without sensors for pH, P	CO2, PO2 and ionized calcium (i.e. 6+) the same ampule may	
		be tested with remaining fluids if within 10 m	inutes of opening the ampule.	
		6. Verify cartridge was closed and tested immed	iately after filling	
		H. Retest a cartridge from the same lot number using a ne	w ampule of control/cal ver making sure to follow proper	
		handling and transfer instructions (Note: the remaining fluid in the original ampule may be tested if within 10		
		minutes of opening that ampule)		
		i-STAT 1 System Manual, Section 14: Quality Control Art: 714376		
		i-STAT 1 System Manual, Section 15: Calibration Verification	n Art: 714377	
		Rules of Replacement		
1. Pr		. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If		
the problem is occurring on more than one lot of cartridges and with one level of control only,		lges and with one level of control only, then the problem is		
probably being caused by the control.				
 Provide a different cartridge lot number for troubleshooting if the same QC material lot number acceptable results on other cartridge type/lot number(s) or if the results for more than one level 		oting if the same QC material lot number is showing		
		acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material are	
		out of range on a specific lot of cartridges.		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	 Classification is Complaint 1 	

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IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	Classification is Complaint 1
IF after running a new cartridge with a new ampule/vial of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results are acceptable	Classification is Complaint 1
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material lot should be investigated
analyzers and cartridges type/lot number for a specific lot	Classification is Complaint 2
number of QC material after troubleshooting AND other	
QC material lot numbers are producing acceptable results	Ask customer if QC material are available to be returned
with the same analyzers and cartridges lot numbers.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT 1	THEN the suspect cartridge and QC material should be
analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	 Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complain	nt	Description	
Ionized C	alcium (iCa)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).	
i-STAT or TriControl		Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable	
Control or		VAS ranges.	
Calibration		Prompts for Meaningful Data Collection	
Verificati	on Results	1. What cartridge type and lot number(s) is the out of range result occurring?	
are Out o	of Range	2. What is QC material lot number and level?	
		3. What is the iCa result (with units of measure)?	
Synonym	s: failed,	4. Which VAS is being reviewed? What is the VAS acceptable range?	
low, high,	, bias	5. How is the control/cal ver stored and handled?	
		6. Was the correct pathway used on the analyzer for testing of control/cal ver material?	
RW Code	S	7. Are the other analytes from the cartridge testing within range?	
	iCa -	8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?	
C1327	High	a. If not used for the first time – were the control/cal ver results in range on previous testing?	
01527	QC/Cal	9. What is CLEW version on the analyzer?	
	Ver	10. How are cartridges stored and handled?	
	iCa -	11. What is analyzer serial number(s)?	
C1328	Low	Troubleshooting	
	QC/Cal	A. Collect and document the control results with units of measure	
	Ver	B. Verify correct VAS and acceptable ranges are used	
		C. Verify the results are in range or out of range per VAS ranges	
		D. Verify the control/cal ver lot number showed pass results in any previous tests on the same cartridge lot number	
		(initial vs monthly QC)	
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)	
		F. Verify cartridge storage and handling	
		G. Verify control testing or cal ver testing procedure was followed (ask customer how they performed testing	
		1. Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days)	
		2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by holding	
		the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of	
		the solution	
		3. Verify no delay in transferring solution to cartridge once ampule is opened	
		4. Verify transfer device used (Plain transfer devices should be used). Note: The calcium in balanced	
		neparin capillary tubes can cause an increase in iCa results	
		5. Verify cartridge was closed and tested immediately after filling	
		6. Verify single control/cal ver ampoule was used for each cartridge when testing ica	
		H. Relest a cartridge from the same for number using a new ampule of control/cal ver from the same for number making such to follow proper bandling and transfer instructions.	
		making sure to ronow proper nandning and transfer instructions	
		Note: When using cartridges that contain sensors for ionized calcium, a senarate ampule must be used for each	
		cartridge being tested. Do not use the solution left in a syringe, ampule or canillary tube for additional testing of	
		cartridges that contain sensors for ionized calcium.	
		i-STAT 1 System Manual. Section 14: Quality Control Art: 714376	
		i-STAT 1 System Manual, Section 15: Calibration Verification Art: 714377	
		Rules of Replacement	
		1. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If	
		the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is	
		probably being caused by the control.	
		2. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing	
		acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material	
		are out of range on a specific lot of cartridges.	

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Resolution	
IF results are acceptable when using the correct VAS or	THEN the incident is resolved
correct ranges on VAS	Classification is Complaint 1
IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	Classification is Complaint 1
IF after running a new cartridge with a new ampule of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results	Classification is Complaint 1
are acceptable	
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT	THEN the QC material should be investigated
1 Analyzers and cartridges type/lot number for a specific	Classification is Complaint 2
lot number of QC material after troubleshooting AND	
other QC material lot numbers are producing acceptable	Ask customer if QC material are available to be returned
results with the same analyzers and cartridges lot	for investigation and document request(s)
numbers.	
IF the out of range result is persistent on multiple i-STAT	THEN the suspect cartridge and QC material should be
1 Analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complair	nt	Description
рН		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).
i-STAT or	r TriControl	Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable
Control or		VAS ranges.
Calibratio	on	Prompts for Meaningful Data Collection
Verificati	ion Results	1. What cartridge type and lot number(s) is the out of range result occurring?
are Out o	of Range	2. What is QC material lot number and level?
		3. What is the pH result?
Synonym	ns: failed,	4. Which VAS is being reviewed? What is the VAS acceptable range?
low, high	n, bias	5. How is the control/cal ver stored and handled?
		6. Was the correct pathway used on the analyzer for testing of control/cal ver material?
RW Code	es	7. Are the other analytes from the cartridge testing within range?
	pH -	8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?
C1329	High	a. If not used for the first time – were the control/cal ver results in range on previous testing?
01525	QC/Cal	9. What is CLEW version on the analyzer?
	Ver	10. How are cartridges stored and handled?
	рН -	11. What is analyzer serial number(s)?
C1330	Low	Troubleshooting
01000	QC/Cal	A. Collect and document the control results with units of measure
	Ver	B. Verify if correct VAS and acceptable ranges are used
		C. Verify if the results are in range or out of range per VAS ranges
		D. Verify if the control/cal ver lot number showed pass results in any previous tests on the same cartridge lot number
		(initial vs monthly QC)
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)
		F. Verify cartridge storage and handling
		G. Verify control testing or cal ver testing procedure was followed (ask customer how they performed testing)
		1. Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days)
		2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by holding
		the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of
		the solution.
		3. Verify no delay in transferring solution to cartridge once ampule is opened
		4. Verify transfer device used (Plain syringes (1 cc or 3 cc with 16-20 gauge needles) or plain capillary tube).
		5. Verify no air bubbles are drawn in transfer device
		a. Verify syringe was not inverted
		b. Verify one or two drops were expelled from the syringe before filling the cartridge.
		 Verify sample was drawn from bottom of ampule with capillary tube
		6. Verify cartridge was closed and tested immediately after filling
		7. Verify single control/cal ver ampoule was used for each cartridge when testing pH
		H. Retest a cartridge using a new ampule of control/cal ver making sure to follow proper handling and transfer
		instructions
		Note: When using cartridges that contain sensors for pH, a separate ampule must be used for each cartridge being
		tested. Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that
		contain sensors for pH.
		Rules of Replacement
		1. Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage when
		user no longer has any control/cal ver product left (e.g. customer did not equilibrate control/cal ver product to
		room temperature for minimum of 30 mins or control/cal ver product was at room temperature for more than 5
		days)

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	2. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If		
	the problem is occurring on more than one lot of cart	ridges and with one level of control only, then the problem is	
	Provide a different cartridge let number for troublesheeting if the same OC material let number is showing		
	3. Provide a different cartridge for number for troublesh	(s) or if the results for more than one level of OC material	
	are out of range on a specific lot of cartridges		
	Resolution		
	IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
	correct ranges on VAS	Classification is Complaint 1	
	IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved	
	ranges	Classification is Complaint 1	
	IF after running a new cartridge with a new ampule/vial	THEN complaint is resolved	
	of control/cal ver (from the same lot numbers) the	 Classification is Complaint 1 	
	results are acceptable		
	IF after following correct handling instructions produces	THEN complaint is resolved	
	acceptable results	Classification is Complaint 1	
	IF the out of range result is persistent on multiple i-STAT	THEN the QC material should be investigated	
	1 Analyzers and cartridges type/lot number for a specific	Classification is Complaint 2	
	lot number of QC material after troubleshooting AND		
	other QC material lot numbers are producing acceptable	Ask customer if QC material are available to be returned	
	results with the same analyzers and cartridges lot numbers.	for investigation and document request(s)	
	IF the out of range result is persistent on multiple i-STAT	THEN the suspect cartridge and QC material should be	
	1 Analyzers after troubleshooting but only on specific	investigated	
	cartridge lot(s) and specific QC material lot(s) AND other	 Classification is Complaint 2 	
	cartridge lots and other QC material lot(s) run without		
	issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available	
		to be returned for investigation and document request(s)	
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Complair	nt	Description	
pCO2 Control or Calibration Verificatio		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).	
i-STAT or	r TriControl Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within accept		
Control or		VAS ranges.	
Calibratio	on	Prompts for Meaningful Data Collection	
Verificati	ion Results	1. What cartridge type and lot number(s) is the out of range result occurring?	
are Out o	of Range	2. What is QC material lot number and level?	
		3. What is the pCO2 result (with units of measure)?	
Synonym	is: failed,	4. Which VAS is being reviewed? What is the VAS acceptable range?	
low, high	n, bias	5. How is the control/cal ver stored and handled?	
		6. Was the correct pathway used on the analyzer for testing of control/cal ver material?	
RW Code	es	Are the other analytes from the cartridge testing within range?	
	PCO2 -	8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?	
C1331		a. If not used for the first time – were the control/cal ver results in range on previous testing?	
	Ver	9. What is CLEW version on the analyzer?	
	PCO2 -	10. How are cartridges stored and handled?	
C1332	Low	11. What is analyzer serial number(s)?	
C1332	QC/Cal	Troubleshooting	
	Ver	A. Collect and document the control results with units of measure	
		B. Verify if correct VAS and acceptable ranges are used	
		C. Verify if the results are in range or out of range per VAS ranges	
		D. Verify if the control/cal ver lot number showed pass results in any previous tests on the same cartridge lot number	
		(initial vs monthly QC)	
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)	
		F. Verify cartridge storage and nandling	
		6. Verify control testing of call verifesting procedure was followed (ask customer now they performed testing)	
		1. Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days)	
		2. Verify ampules were snaken vigorously for 5-10 seconds to equilibrate inquid and gas phases by notaling the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of	
		the solution	
		3 Verify no delay in transferring solution to cartridge once ampule is opened	
		4 Verify transfer device used (Plain syringes (1 cc or 3 cc with 16-20 gauge needles) or plain canillary tube)	
		5. Verify no air bubbles are drawn in transfer device	
		a. Verify svringe was not inverted	
		b. Verify one or two drops were expelled from the syringe before filling the cartridge.	
		c. Verify sample was drawn from bottom of ampule with capillary tube	
		6. Verify cartridge was closed and tested immediately after filling	
		7. Verify single control/cal ver ampoule was used for each cartridge when testing pCO2	
		H. Retest a cartridge using a new ampule of control/cal ver making sure to follow proper handling and transfer	
		instructions	
		Note: When using contridges that contain concerts for pCO2 a concerts amount must be used for each contridge being	
		tocted. Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that	
		contain concors for nCO2	
		i-STAT 1 System Manual, Section 14: Quality Control Art: 714376	
		i-STAT 1 System Manual, Section 15: Calibration Verification Art: 714377	
		Rules of Replacement	
		1. Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage when	
		user no longer has any control/cal ver product left (e.g. customer used more than one ampule to test more than	

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3.	 one cartridge, customer did not equilibrate control/cal ver product to room temperature for minimum of 30 mins or control/cal ver product was at room temperature for more than 5 days) Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is probably being caused by the control. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material are out of range on a specific lot of cartridges. 		
R	esolution		
IF	results are acceptable when using the correct VAS or	THEN the incident is resolved	
cc	prrect ranges on VAS	Classification is Complaint 1	
IF	control/cal ver results are in range per VAS acceptable	THEN the incident is resolved	
ra	anges	Classification is Complaint 1	
IF	after running a new cartridge with a new ampule of	THEN complaint is resolved	
cc	ontrol/cal ver (from the same lot numbers) the results re acceptable	Classification is Complaint 1	
IF	after following correct handling instructions produces	THEN complaint is resolved	
ac	cceptable results	Classification is Complaint 1	
IF	the out of range result is persistent on multiple i-STAT	THEN the QC material lot(s) should be investigated	
1 0	Analyzers and cartridges type/lot number for a specific ot number of QC material after troubleshooting AND	Classification is Complaint 2	
ot re ni	ther QC material lot numbers are producing acceptable esults with the same analyzers and cartridges lot umbers.	Ask customer if QC material are available to be returned for investigation and document request(s)	
IF	the out of range result is persistent on multiple i-STAT	THEN the suspect cartridge and QC material lot(s) should be	
1	Analyzers after troubleshooting but only on specific	investigated	
Ca	artridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2	
Ca	artridge lots and other QC material lot(s) run without		
is	sue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available to	
		be returned for investigation and document request(s)	

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Complaint		Description		
pO2		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
i-STAT or TriControl		Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable		
Control or		VAS ranges.		
Calibratio	on	Prompts for Meaningful Data Collection		
Verificati	ion Results	1. What cartridge type and lot number(s) is the out of range result occurring?		
are Out o	of Range	2. What is QC material lot number and level?		
		3. What is the pO2 result (with units of measure)?		
Synonym.	s: failed,	4. Which VAS is being reviewed? What is the VAS acceptable range?		
low, high	, bias	5. How is the control/cal ver stored and handled?		
		6. Was the correct pathway used on the analyzer for testing of control/cal ver material?		
RW Code	!S	7. Are the other analytes from the cartridge testing within range?		
	PO2 -	8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?		
C1333	High	a. If not used for the first time – were the control/cal ver results in range on previous testing?		
01555	QC/Cal	9. What is CLEW version on the analyzer?		
	Ver	10. How are cartridges stored and handled?		
	PO2 -	11. What is analyzer serial number(s)?		
C1334	Low	Troubleshooting		
01001	QC/Cal	A. Collect and document the control results with units of measure		
	Ver	B. Verify if correct VAS and acceptable ranges are used		
		C. Verify if the results are in range or out of range per VAS ranges		
		D. Verify if the control/cal ver lot number showed pass results in any previous tests on the same cartridge lot number		
		(initial vs monthly QC)		
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)		
		F. Verify cartridge storage and handling		
		G. Verify control testing or cal ver testing procedure was followed (ask customer how they performed testing)		
		(Note: pO2 results are most affected by not following directions)		
		1. Verify room temperature equilibration (4 hours at minimum, no longer than 5 days)		
		2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by holding		
		the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of		
		the solution.		
		3. Verify no delay in transferring solution to cartridge once ampule is opened		
		4. Verity transfer device used		
		a. Plain syringes (1 cc or 3 cc with 16-20 gauge needles) or plain capillary tube (for best results)		
		b. Do not use disposable transfer pipettes. Best results are obtained when a plain (non-heparin)		
		capillary tube is used to transfer sample from ampule to cartridge.		
		5. Verify no air bubbles are drawn in transfer device		
		a. Verify syringe was not inverted		
		b. Verify one of two drops were expensed from the syninge before hinning the carthoge.		
		C. Verify sample was closed and tested immediately after filling		
		 Verify calculate was closed and tested inimediately after himing Verify circles control/calculate amount was used for each cartridge when testing pQ2 		
		7. Verify single control/carvel ampoule was used for each carried when testing po_2 H If nO_2 is out of range verify customer site elevation. Correct nO_2 results (if applicable)		
		Retect a cartridge using a new ampule of control/cal ver making sure to follow proper handling and transfer		
		instructions		
		Note: When using cartridges that contain sensors for pO2, a separate ampule must be used for each cartridge being		
		tested. Do not use the solution left in a syringe, ampule or canillary tube for additional testing of cartridges that		
		contain sensors for pO2.		
		i-STAT 1 System Manual, Section 14: Quality Control Art: 714376		
		i-STAT 1 System Manual, Section 15: Calibration Verification Art: 714377		

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 ules of Replacement Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage when user no longer has any control/cal ver product left (e.g. customer used a transfer pipette, customer did not equilibrate control/cal ver product to room temperature for minimum of 4 hours or control/cal ver product was at room temperature for more than 5 days) Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is probably being caused by the control. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material are out of range on a specific lot of cartridges. 	
Resolution	
IF results are acceptable when using the correct VAS or	THEN the incident is resolved
correct ranges on VAS	Classification is Complaint 1
IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	Classification is Complaint 1
IF after running a new cartridge with a new ampule of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results	Classification is Complaint 1
are acceptable	
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	Classification is Complaint 1
IF pO2 out of range controls are acceptable after	THEN the incident is resolved
correcting for altitude	Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material should be investigated
Analyzers and cartridges type/lot number for a specific lot	Classification is Complaint 2
number of QC material after troubleshooting AND other	
QC material lot numbers are producing acceptable results	Ask customer if QC material are available to be returned
with the same analyzers and cartridges lot numbers.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT 1	THEN the suspect cartridge and QC material should be
Analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2
cartriage lots and other QC material lot(s) run without	
issue on the same I-STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complain	nt	Description		
Glucose ((Glu)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
i-STAT or TriControl Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still		rol or Calibration Verification results but still within acceptable		
Control or		VAS ranges.		
Calibratio	on	Prompts for Meaningful Data Collection		
Verificati	on Results	1. What cartridge type and lot number(s) is the out of ra	nge result occurring?	
are Out o	of Range	2. What is QC material lot number and level?		
		3. What is the glucose result (with units of measure)?		
Synonym.	s: failed,	4. Which VAS is being reviewed? What is the VAS accep	table range?	
low, high	, bias	5. How is the control/cal ver stored and handled?		
		6. Was the correct pathway used on the analyzer for tes	ting of control/cal ver material?	
RW Code	S	7. Are the other analytes from the cartridge testing with	in range?	
	Glucose	8. Is the control/cal ver lot number being used for the fin	st time on this cartridge lot number?	
C1335	- High	 If not used for the first time – were the cont 	rol/cal ver results in range on previous testing?	
	QC/Cal	9. What is CLEW version on the analyzer?		
	Ver	10. How are cartridges stored and handled?		
	Glucose	11. What is analyzer serial number(s)?		
C1336	- Low	Troubleshooting		
	QC/Cal	A. Collect and document the control results with units of	measure	
	ver	B. Verify if correct VAS and acceptable ranges are used		
		C. Verify if the results are in range or out of range per VA	AS ranges	
		D. Verify if the control/cal ver lot number showed pass results in any previous tests on the same cartridge lot number		
		(initial vs monthly QC)		
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)		
		F. Verify cartridge storage and handling		
		G. Verify control/cal ver testing procedure was followed (ask customer now they performed testing)		
1. Verify room temperature ed		Verify room temperature equilibration (30 r Verify ampules were shaken vigorously for F	5 10 seconds to equilibrate liquid and gas phases by holding	
		 Verify ampules were snaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by note that the tamperature of tamperature of the tamperature of tamperatur		
		the solution		
		3 Verify no delay in transferring solution to ca	rtridge once ampule is opened	
		4 Verify transfer device used		
		5. If testing cartridges without sensors for pH,	PCO2, PO2 and ionized calcium (i.e. G, EC4+) the same ampule	
		may be tested with remaining fluids if within 10 minutes of opening the ampule.		
		6. Verify cartridge was closed and tested immediately after filling		
		H. Retest a cartridge from the same lot number using a r	new ampule of control/cal ver from the same lot number	
		making sure to follow proper handling and transfer in	structions	
		i-STAT 1 System Manual, Section 14: Quality Control Art: 7	714376	
		i-STAT 1 System Manual, Section 15: Calibration Verificati	on Art: 714377	
		Rules of Replacement		
		1. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue.		
		the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is		
	probably being caused by the control.		e eties if the serve OC meterial let work on is showing	
		2. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing		
		acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material		
		out of range on a specific lot of cartridges.		
		IF regults are acceptable when using the correct VAC are TUEN the insident is received		
		correct ranges on VAS	Classification is Complaint 1	

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IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	Classification is Complaint 1
IF after running a new cartridge with a new ampule of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results	Classification is Complaint 1
are acceptable	
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT	THEN the QC material should be investigated
1 Analyzers and cartridges type/lot number for a specific	Classification is Complaint 2
lot number of QC material after troubleshooting AND	
other QC material lot numbers are producing acceptable	Ask customer if QC material are available to be returned
results with the same analyzers and cartridges lot	for investigation and document request(s)
numbers.	
IF the out of range result is persistent on multiple i-STAT	THEN the suspect cartridge and QC material should be
1 Analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available to
	be returned for investigation and document request(s)

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Compla	int	Description			
BUN/Urea		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).			
i-STAT o	or TriControl	Customer reports a positive or negative trend/bias in Contro	ol or Calibration Verification results but still within acceptable		
Control	or	VAS ranges.			
Calibrat	tion	Prompts for Meaningful Data Collection			
Verifica	tion Results	1 What cartridge type and lot number(s) is the out of ran	ge result occurring?		
are Out	of Range	2. What is OC material lot number and level?			
	-	3 What is the BUN or Urea result (with units of measure)	2		
Synonyr	ms: failed,	 Which VAS is being reviewed? What is the VAS accenta 	ble range?		
low, hig	ıh, bias	5 How is the control/cal ver stored and handled?			
_		6. Was the correct pathway used on the analyzer for testi	ng of control/cal ver material?		
RW Codes		7. Are the other analytes from the cartridge testing within range?			
	BUN -	8. Is the control/cal ver lot number being used for the firs	t time on this cartridge lot number?		
C1337	High	a. If not used for the first time – were the contr	ol/cal ver results in range on previous testing?		
01007	QC/Cal 9 What is CLEW version on the analyzer?				
	Ver	10. How are cartridges stored and handled?			
	BUN -	11. What is analyzer serial number(s)?			
C1338		Troubleshooting			
	Ver	A Collect and document the control results with units of	measure		
		B Verify if correct VAS and acceptable ranges are used			
		C Verify if the results are in range or out of range per VAS ranges			
		D. Verify if the control/cal ver lot number showed nass results in any previous tests on the same cartridge lot number			
		(initial vs monthly QC)			
		E. Verify that control/cal ver is not expired (refrigerated a	nd room temperature)		
		F. Verify cartridge storage and handling	······································		
		G. Verify control/cal ver testing procedure was followed (ask customer how they performed testing)		
		1. Verify room temperature equilibration (30 m	nutes at minimum, no longer than 5 days)		
		2. Verify ampules were shaken vigorously for 5-	10 seconds to equilibrate liquid and gas phases by holding		
		the ampule at the tip and bottom with forefi	inger and thumb to minimize increasing the temperature of		
		the solution			
		3. Verify no delay in transferring solution to cartridge once ampule is opened			
		4. Verify transfer device used			
		5. If testing cartridges without sensors for pH, P	CO2, PO2 and ionized calcium (i.e. 6+) the same ampule may		
		 be tested with remaining fluids if within 10 minutes of opening the ampule. 6. Verify cartridge was closed and tested immediately after filling 			
		H. Retest a cartridge using a new ampule of control/cal ve	r making sure to follow proper handling and transfer		
		instructions (Note: the remaining fluid in the original a	mpule may be tested if within 10 minutes of opening that		
ampule)		ampule)			
	i-STAT 1 System Manual, Section 14: Quality Control Art: 714376				
		i-STAT 1 System Manual, Section 15: Calibration Verification	n Art: 714377		
		Rules of Replacement			
		1. Provide a different lot number of QC material for troub	leshooting when trying to determine QC lot specific issue. If		
		the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is			
		probably being caused by the control.			
		2. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing			
		acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material are			
		out of range on a specific lot of cartridges.			
		Resolution			
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved		
		correct ranges on VAS	Classification is Complaint 1		
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IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	Classification is Complaint 1
IF after running a new cartridge with a new ampule of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results	Classification is Complaint 1
are acceptable	
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material should be investigated
Analyzers and cartridges type/lot number for a specific lot	Classification is Complaint 2
number of QC material after troubleshooting AND other	
QC material lot numbers are producing acceptable results	Ask customer if QC material are available to be returned
with the same analyzers and cartridges lot numbers.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT 1	THEN the suspect cartridge and QC material should be
Analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	 Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complaint	Description		
Hematocrit (Hct)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
TriControl Control or	rol or Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable		
Calibration	VAS ranges.		
Verification Results	Prompts for Meaningful Data Collection		
are Out of Range	1. What cartridge type, lot number(s) is the out of range	result occurring?	
	2. What is QC material lot number and level?	-	
Synonyms: failed,	3. What is the Hct result (with units of measure)?		
low, high, bias	4. Which VAS is being reviewed? What is the VAS accept	able range?	
	5. What is the EDTA customization setting on the analyze	r? Is the correct VAS range (K2/K3 EDTA) used?	
RW Codes	6. How is the control/cal ver stored and handled?		
Hematocrit	7. Was the correct pathway used on the analyzer for test	ing of control/cal ver material?	
C1339 - High	8. Are the other analytes from the cartridge testing withi	n range?	
Hematocrit	9. Is the control/cal ver lot number being used for the first	st time on this cartridge lot number?	
C1340 - Low	a. If not used for the first time – were the contr	ol/cal ver results in range on previous testing?	
QC/Cal Ver	10. What is CLEW version on the analyzer?		
	11. How are cartridges stored and handled?		
	12. What is analyzer serial number(s)?		
	Troubleshooting		
	A. Collect and document the control results with units of	measure	
	B. Verify if correct VAS and acceptable ranges are used		
	C. Verify if the results are in range or out of range per VA	S ranges	
	D. Verify if the control/cal ver lot number showed pass re	sults in any previous tests on the same cartridge lot number	
	(initial vs monthly QC)		
	E. Verify that control/cal ver is not expired (refrigerated a	and room temperature)	
	F. Verify cartridge storage and handling	· · · · · · · · · · · · · · · · · · ·	
	G. Verify control/cal ver testing procedure was followed (ask customer how they performed testing)		
	 Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days) Verify ampulae upper challen upper except for 5 40 according to a public set of a set of the set o		
	 Verify ampules were snaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by holding the ampule at the tin and bettern with forefinger and thumb to minimize increasing the temperature of 		
	the angule at the tip and bottom with foreinger and thumb to minimize increasing the temperature of the solution		
	3 Verify no delay in transferring solution to ca	tridge once ampule is opened	
	4. Verify transfer device used		
	5. If testing cartridges without sensors for pH. I	PCO2, PO2 and ionized calcium (i.e. 6+, E3+, EC4+) the same	
	ampule may be tested with remaining fluids	if within 10 minutes of opening the ampule	
	6. Verify cartridge was closed and tested imme	diately after filling	
	H. Retest a cartridge from the same lot number using a n	ew ampule of control/cal ver from the same lot number	
	making sure to follow proper handling and transfer ins	tructions)	
	i-STAT 1 System Manual, Section 14: Quality Control Art: 7	14376	
	i-STAT 1 System Manual, Section 15: Calibration Verification	on Art: 714377	
	Rules of Replacement		
	1. Provide a different lot number of QC material for troul	pleshooting when trying to determine QC lot specific issue. If	
	the problem is occurring on more than one lot of cartr	idges and with one level of control only, then the problem is	
	probably being caused by the control.		
	2. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing		
	acceptable results on other cartridge type/lot number	s) or if the results for more than one level of QC material	
	are out of range on a specific lot of cartridges.		
	Kesolution		
	IF results are acceptable when using the correct VAS or	THEN the inclaent is resolved	
	correct ranges on VAS	 Classification is complaint 1 	

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	IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
	ranges	Classification is Complaint 1
	IF after running a new cartridge with a new ampule of	THEN complaint is resolved
	control/cal ver (from the same lot numbers) the results	Classification is Complaint 1
	are acceptable	
	IF after following correct handling instructions produces	THEN complaint is resolved
	acceptable results	Classification is Complaint 1
	IF the out of range result is persistent on multiple i-STAT	THEN the QC material should be investigated
	1 Analyzers and cartridges type/lot number for a specific	Classification is Complaint 2
	lot number of QC material after troubleshooting AND	
	other QC material lot numbers are producing acceptable	Ask customer if QC material are available to be returned
	results with the same analyzers and cartridges lot	for investigation and document request(s)
	numbers.	
	IF the out of range result is persistent on multiple i-STAT	THEN the suspect cartridge and QC material should be
	1 Analyzers after troubleshooting but only on specific	investigated
	cartridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2
	cartridge lots and other QC material lot(s) run without	
	issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
		to be returned for investigation and document request(s)
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Complai	int	Description		
Lactate	(Lac)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
i-STAT o	r TriControl Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within accepta		ithin acceptable	
Control	or	VAS ranges.		
Calibrat	ion	Prompts for Meaningful Data Collection		
Verifica	tion Results	1. What cartridge type, lot number(s)/box number(s) is the out of range result occurring?		
are Out	of Range	2. What is QC material lot number and level?		
		3. What is the Lactate result (with units of measure)?		
Synonyr	ns: failed,	4. Which VAS is being reviewed? What is the VAS acceptable range?		
low, hig	h, bias	5. How is the control/cal ver stored and handled?		
		6. Was the correct pathway used on the analyzer for testing of control/cal ver material?		
RW Cod	es	7. Are the other analytes from the cartridge testing within range?		
	Lactate -	8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?		
C1342	OC/Cal	a. If not used for the first time – were the control/cal ver results in range on previous testing	?	
	Ver	9. What is CLEW version on the analyzer?		
	Lactate -	10. How are cartridges stored and handled?		
C1343	Low	11. What is analyzer serial number(s)?		
01010	QC/Cal	Troubleshooting		
	ver	A. Collect and document the control results with units of measure		
		B. Verify if correct VAS and acceptable ranges are used		
		C. Verify if the results are in range or out of range per VAS ranges		
		(initial vs monthly QC)	ige lot number	
		E. Verify that control/cal ver is not expired (refrigerated and room temperature)		
		F. Verify cartridge storage and handling		
		G. Verify control/cal ver testing procedure was followed (ask customer how they performed testing)		
		1. Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days)		
2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phase		2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phase	es by holding	
		the ampule at the tip and bottom with forefinger and thumb to minimize increasing the te	mperature of	
		the solution		
		3. Verify no delay in transferring solution to cartridge once ampule is opened		
		4. Verify transfer device used		
		5. Verify cartridge was closed and tested immediately after filling		
		H. Retest a cartridge from the same lot number using a new ampule of control/cal ver from the same lot number		
		making sure to follow proper handling and transfer instructions		
		i-STAT 1 System Manual Section 14: Quality Control Art: 71/276		
		i-STAT 1 System Manual, Section 14: Quarty control Net 714377		
		Rules of Replacement		
		1. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot s	pecific issue. If	
the problem is occurring on more than one lot of cartridges and with one level of control only, then probably being caused by the control.		the problem is		
		probably being caused by the control.		
		2. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is sh	nowing	
acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC		QC material are		
	out of range on a specific lot of cartridges.			
	Resolution			
		IF results are acceptable when using the correct VAS or IHEN the incident is resolved		
correct ran		Classification is complaint 1 Classification is complaint 1		
IF control/cal ver results are in range per VAS acceptable THEN the incident is resolved				
ranges • Classification is Complaint 1				

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IF after running a new ca control/cal ver (from the are acceptable	artridge with a new ampule of a same lot numbers) the results	 THEN complaint is resolved Classification is Complaint 1
IF after following correct acceptable results	t handling instructions produces	 THEN complaint is resolved Classification is Complaint 1
IF the out of range result Analyzers and cartridges number of QC material a QC material lot numbers	t is persistent on multiple i-STAT 1 type/lot number for a specific lot after troubleshooting AND other are producing acceptable results	 THEN the QC material lot(s) should be investigated Classification is Complaint 2 Ask customer if QC material are available to be returned
with the same analyzers	and cartridges lot numbers.	for investigation and document request(s)
IF the out of range result Analyzers after troublest cartridge lot(s) and spec cartridge lots and other	t is persistent on multiple i-STAT 1 hooting but only on specific ific QC material lot(s) AND other QC material lot(s) run without	 THEN the suspect cartridge and QC material lot(s) should be investigated Classification is Complaint 2
issue on the same i-STAT	analyzers	Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)

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Complai	int	Description		
Creatini	ne (Crea)	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
i-STAT o	or TriControl	iControl Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptab		
Control	or	VAS ranges.		
Calibrat	ion	Prompts for Meaningful Data Collection		
Verificat	tion Results	 What cartridge type and lot number(s) is the out of range result occurring? 		
are Out	of Range	2. What is QC material lot number and level?		
		3. What is the Creatinine result (with units of measure)?		
Synonyn	ns: failed,	4. Which VAS is being reviewed? What is the VAS acceptable range?		
low, hig	h, bias	5. How is the control/cal ver stored and handled?		
		6. Was the correct pathway used on the analyzer for testing of control/cal ver material?		
RW Cod	es	7. If testing CHEM8+ cartridge, are the other analytes from the cartridge testing within range?		
	Creatinine	8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?		
C1344	- High	a. If not used for the first time – were the control/cal ver results in range on previous testing?		
	UC/Cdi Ver	9. What is CLEW version on the analyzer?		
	Creatinine	10. How are cartridges stored and handled?		
	- Low	11. What is analyzer serial number(s)?		
C1345	QC/Cal	Troubleshooting		
	Ver	A. Collect and document the control results with units of measure		
		B. Verify correct VAS and acceptable ranges are used		
		C. Verify the results are in range or out of range per VAS ranges		
		D. Verify the control/cal ver lot number showed acceptable results in any previous tests on the same cartridge lot		
		number (initial vs monthly QC)		
		E. Verify control/cal ver is not expired (refrigerated and room temperature)		
		F. Verify cartridge storage and handling		
		G. Verify control/cal ver testing procedure was followed (ask customer how they performed testing)		
		1. Verify room temperature equilibration (30 minutes at minimum, no longer than 5 days)		
		2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by holding		
		the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of		
		the solution		
		3. Verify no delay in transferring solution to cartridge once ampule is opened		
		4. Verify transfer device used		
		5. In testing calculages without sensors for pri, PCO2, PO2 and formed talcular (i.e. clea) the same ampule		
		6 Verify cartridge was closed and tested immediately after filling		
		H Retest a cartridge from the same lot number using a new ampule of control/cal ver from the same lot number		
		making sure to follow proper handling and transfer instructions		
		i-STAT 1 System Manual. Section 14: Quality Control Art: 714376		
		i-STAT 1 System Manual, Section 15: Calibration Verification Art: 714377		
		Rules of Replacement		
1. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specified		1. Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If		
the problem is occurring on more than one lot of cartridges and with		the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is		
probably being caused by the control.		probably being caused by the control.		
		2. Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing		
acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC m		acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material are		
		out of range on a specific lot of cartridges.		
		Resolution		
		IF results are acceptable when using the correct VAS or THEN the incident is resolved		
	correct ranges on VAS • Classification is Complaint 1			

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IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved
ranges	 Classification is Complaint 1
IF after running a new cartridge with a new ampule of	THEN complaint is resolved
control/cal ver (from the same lot numbers) the results	Classification is Complaint 1
are acceptable	
IF after following correct handling instructions produces	THEN complaint is resolved
acceptable results	Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material lot(s) should be investigated
Analyzers and cartridges type/lot number for a specific lot	Classification is Complaint 2
number of QC material after troubleshooting AND other	
QC material lot numbers are producing acceptable results	Ask customer if QC material are available to be returned
with the same analyzers and cartridges lot numbers.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT 1	THEN the suspect cartridge and QC material lot(s) should
Analyzers after troubleshooting but only on specific	be investigated
cartridge lot(s) and specific QC material lot(s) AND other	 Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complai	plaint Description	
TCO2		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).
i-STAT or TriControl Customer reports a positive or negative trend/bias in Control or		Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable
Control or VAS ranges.		VAS ranges.
Calibrati	ion	Prompts for Meaningful Data Collection
Verificat	ion Results	1. What cartridge type and lot number(s) is the out of range result occurring?
or CHEM	18+ Level 1b	2. What is QC material lot number and level?
Results a	are Out of	3. What is the TCO2 result (with units of measure)?
Range		4. Which VAS is being reviewed? What is the VAS acceptable range?
C	(. : ! !	5. How is the control/cal ver stored and handled?
Synonym	ns: Jallea,	6. Was the correct pathway used on the analyzer for testing of control/cal ver material?
low, nigr	n, blas	7. Are the other analytes from the cartridge testing within range?
		8. Is the control/cal ver lot number being used for the first time on this cartridge lot number?
RW COUE		a. If not used for the first time – were the control/cal ver results in range on previous testing?
	High -	9. What is CLEW version on the analyzer?
C1420	QC/Cal	10. How are cartridges stored and handled?
	Ver	11. What is analyzer serial number(s)?
	TCO2 Low	Troubleshooting
C1421	- QC/Cal	A. Collect and document the control results with units of measure
	Ver	B. Verify correct VAS and acceptable ranges are used
		C. Verify the results are in range or out of range per VAS ranges
		D. Verify the control/cal verific humber showed acceptable results in any previous tests on the same caltridge lot
		F Verify control/cal ver is not evolved (refrigerated and room temperature)
		E. Verify control/callver is not expired (reingerated and room temperature)
		G Verify control/cal ver testing procedure was followed (ask customer how they performed testing)
		1. Verify control testing proceeding was followed (ask castomer now and) performed testing)
		2. Verify ampules were shaken vigorously for 5-10 seconds to equilibrate liquid and gas phases by holding
		the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of
		the solution
		3. Verify no delay in transferring sample to cartridge once ampule is opened
		4. Verify transfer device used (Plain syringes (1 cc or 3 cc with 16-20 gauge needles) or plain capillary tube).
		5. Verify no air bubbles are drawn in transfer device
		a. Verify one or two drops were expelled from the syringe before filling the cartridge.
		b. Verify sample was drawn from bottom of ampule with capillary tube
		6. Verify cartridge was closed and tested immediately after filling
		7. Verify single control/cal ver ampoule was used for each cartridge when testing TCO2
		H. Retest a cartridge using a new ampule of control/cal ver following proper handling and transfer instructions
		Note: When using cartridges that contain sensors for ICO2, a separate ampule must be used for each cartridge being
		tested. Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that
		contain sensors for TCO2.
		i-STAT 1 System Manual Section 14: Quality Control Art: 71/1376
		i-STAT 1 System Manual, Section 15: Calibration Verification Art: 714377
	I-STAT I System Manual, Section 15: Calibration Verification Art: /143//	
		Rules of Replacement
		1. Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage when
		user no longer has any control/cal ver product left (e.g. customer did not equilibrate control/cal ver product to
		room temperature for minimum of 30 mins or control/cal ver product was at room temperature for more than 5
		days)

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 Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem probably being caused by the control. Provide a different cartridge lot number for troubleshooting if the control/cal ver material is showing acceptable results on other cartridge type/lot number(s) Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing acceptable results on other cartridge type/lot number(s) or if the results for more than one level of QC material are out of range on a specific lot of cartridges 	 Provide a different lot number of QC material for troubleshooting when trying to determine QC lot specific issue. If the problem is occurring on more than one lot of cartridges and with one level of control only, then the problem is probably being caused by the control. Provide a different cartridge lot number for troubleshooting if the control/cal ver material is showing acceptable results on other cartridge type/lot number(s) Provide a different cartridge lot number for troubleshooting if the same QC material lot number is showing acceptable results on other cartridge type/lot number is showing acceptable results on other cartridge type/lot number is showing acceptable results on other cartridge type/lot number (s) are out of range on a specific lot of cartridges 		
Resolution			
IF results are acceptable when using the correct VAS or THEN the incident is resolved			
correct ranges on VAS Classification is Complaint 1			
IF control/cal ver results are in range per VAS THEN the incident is resolved			
acceptable ranges			
IF after running a new cartridge with a new ampule of THEN complaint is resolved			
control/cal ver (from the same lot numbers) the results • Classification is Complaint 1			
are acceptable			
IF after following correct handling instructions produces THEN complaint is resolved			
acceptable results			
IF the out of range result is persistent on multiple i- THEN the QC material should be investigated			
STAT 1 Analyzers and cartridges type/lot number for a • Classification is Complaint 2			
specific lot number of QC material after			
troubleshooting AND other QC material lot numbers Ask customer if QC material are available to be returned			
are producing acceptable results with the same for investigation and document request(s)			
analyzers and cartridges lot numbers.			
IF the out of range result is persistent on multiple i- GTAT 1 Analyzes after travelable paties but ask as			
STAT I Analyzers after troubleshooting but only on investigated			
AND other cartridge lots and other OC material lot(s) • Classification is Complaint 2			
AND other cartridge fors and other QC material for(s)	+0		
Ask customer in cartriages and QC material are available	10		
i-STAT Sunnort Guide REF-1151C Section 7.0	C		

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Complai	int	Description		
Troponiu	n (cTnl)	Control or Calibration Verification results are outside of the accentable ranges on the value assignment sheets (VAS)		
Controls	or Calibration	Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within		
Verificat	tion Results are	accontable VAS ranges	control of calibration vernication results but still within	
Out of R	lange			
outorn	unge	Prompts for ivieaningful Data Collection		
Synonyn	ns: failed. low.	1. What cartridge type and lot number (s) is the out of r	range result occurring?	
hiah, hia	nor janea, ieir,	2. What is QC material for number and level?		
		3. What is the troponin result (with units of measure)?	ntable range?	
RW Code	es for	4. Which vas is being reviewed? What is the vas accept	prable range:	
	Troponin	5. How is the control/callver stored and handled?	octing of control/colver material?	
C1348	High -	7 Is the control/cal yer let number being used for the	first time on this cartridge lot number?	
	QC/Cal Ver	7. Is the control/cal ver for the first time – were the control	ntst time on this callinge for number:	
	Troponin	8 What is CLEW version on the analyzer?	intolycal ver results in range on previous testing:	
C1349	Low -	9 How are cartridges stored and handled?		
	QC/Cal Ver	10 What is analyzer serial number(s)?		
		Troubleshooting		
		A Collect and document the control results with units	of measure	
		 B. Verify correct VAS and ranges are being viewed per if 	CLEW	
		C Verify if the results are in range or out of range per V	/AS ranges	
		D Vorify if the control (calver chowed pass results in a	ny provious tasts on the same sartridge lat number (initial vs	
		D. Verify if the control/carver showed pass results in al	in previous tests on the same cartriage lot number (initial vs	
		E Verify control/calver is not expired		
		E. Verify control/carver is not expired		
		G Verify control/cal ver storage and handing		
		1 Verify there was no room temperature equ	uilibration prior to testing	
		 Verify the vials have not reached 30-day expiration if previously used and stored in refrigerator tightly. 		
		capped. Use new vial if 30-day expiration	has been reached.	
		H. Verify proper control testing or cal ver testing proce	dure was followed	
		1. Verify vials were gently mixed, avoiding fo	aming	
		2. Verify transfer method (tube dropper top)	or transfer device)	
		3. Verify cartridges are tested immediately after filling		
		i-STAT 1 System Manual, Section 14: Quality Control Art:	: 714376	
		i-STAT 1 System Manual, Section 15: Calibration Verifica	tion Art: 714377	
		Rules of Replacement		
		1. Provide the same lot of QC materials for troubleshoe	oting to rule out improper handling technique or storage	
		(e.g. user no longer has any control/cal ver product	left)	
		2. Provide a different lot number of QC materials for tr	oubleshooting when trying to determine QC specific issue	
		3. Provide a different cartridge lot number for troubles	shooting if the control/cal ver material is showing	
		acceptable results on other cartridge type/lot number(s)		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	Classification is Complaint 1	
		IF after running a new cartridge with a new vial of	THEN the incident is resolved	
		control/cal ver (from the same lot numbers) the result	Classification is Complaint 1	
		is in range		
		IF after running a new cartridge with a new vial of	THEN complaint is resolved	
	control/cal ver the result is in range		Classification is Complaint 1	
		IF after following correct handling instructions	THEN complaint is resolved	
		produces acceptable results	 Classification is Complaint 1 	

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IF the out of ran	ge result is persistent on multiple i-	THEN the QC material lot(s) should be investigated
STAT 1 Analyzers	and cartridge lot number for a specific	Classification is Complaint 2
lot of QC materia	al after troubleshooting AND other QC	·
material lot num	bers are producing acceptable results	Ask customer if QC material are available to be returned
with the same a	nalyzers and cartridges lot numbers.	for investigation and document request(s)
IF the issue is pe	rsistent on multiple i-	THEN the suspect cartridge and QC material lot(s) should
STAT 1 Analyzers	after troubleshooting but only on	be investigated
specific cartridge	e lot(s) and specific QC material lot(s)	Classification is Complaint 2
AND other cartri	dge lots and other QC material lot(s)	
run without issu	e on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available
		to be returned for investigation and document
		request(s)

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Complaint		Description		
CK-MB Cor	ntrols or	Control or Calibration Verification results are outside of	the acceptable ranges on the value assignment sheets (VAS).	
Calibration	ו	Customer reports a positive or negative trend/bias in Con	trol or Calibration Verification results but still within acceptable	
Verification	n Results	VAS ranges.		
are Out of	Range	Prompts for Meaningful Data Collection		
are out of number Prompts for Meaningful Data Collection Synonyms: failed, low, high, bias 1. What cartridge type and lot number and level? RW Codes for 2. What is QC material lot number and level? RW Codes for 3. What is the CK-MB result (with units of measure)? RW Codes for 4. Which VAS is being reviewed? What is the VAS acceptable range? C1422 CK-MB High - QC/Cal Ver 6. Was the correct pathway used on the analyzer for testing of control/cal ver material? 7. Is the control/cal ver lot number being used for the first time on this cartridge lot number? a. If not used for the first time – were the control/cal ver results in range on previous testing? 8. What is CLEW version on the analyzer? 9. How are cartridges stored and handled? 10. What is analyzer serial number(s)? 10. What is analyzer serial number(s)?		range result occurring? eptable range? esting of control/cal ver material? first time on this cartridge lot number? ontrol/cal ver results in range on previous testing?		
VerA.Collect and document the collB.Verify correct VAS and rangeC.Verify if the results are in randD.Verify if the control/cal ver is not effectF.Verify control/cal ver is not effectG.Verify control/cal ver is not effectF.Verify control/cal ver is not effectG.Verify the vials have capped. Use new effectH.Verify proper control testing 1.I.Verify cartridges and 3. <i>i-STAT 1 System Manual, Section 1.i-STAT 1 System Manual, Section 1.</i> I.Provide the same lot of QC r user no longer has any contrG.Provide a different lot numbG.Provide a different cartridge user the entertide the test		 B. Verify correct VAS and ranges are being viewed per C. Verify if the results are in range or out of range per D. Verify if the control/cal ver showed pass results in a monthly QC) E. Verify control/cal ver is not expired F. Verify cartridge storage and handling G. Verify control/cal ver storage and handing 1. Verify there was no room temperature ec 2. Verify the vials have not reached 30-day e capped. Use new vial if 30-day expiration H. Verify proper control testing or cal ver testing proce 1. Verify vials were gently mixed, avoiding for 2. Verify transfer method (tube dropper top 3. Verify cartridges are tested immediately a <i>i-STAT 1 System Manual, Section 14: Quality Control Arth</i> <i>i-STAT 1 System Manual, Section 15: Calibration Verification Verif</i>	CLEW VAS ranges any previous tests on the same cartridge lot number (initial vs pullibration prior to testing expiration if previously used and stored in refrigerator tightly has been reached. edure was followed barning or transfer device) after filling <i>tr: 714376</i> <i>ation Art: 714377</i> poting to rule out improper handling technique or storage (e.g. roubleshooting when trying to determine QC specific issue shooting if the control/cal ver material is showing acceptable	
		IF results are accentable when using the correct VAS	THEN the incident is resolved	
		or correct ranges on VAS	Classification is Complaint 1	
		IF control/cal ver results are in range per VAS	THEN the incident is resolved	
		accentable ranges	Classification is Complaint 1	
		IF after running a new cartridge with a new vial of	THEN complaint is resolved	
		control/cal ver (from the same lot numbers) the result	Classification is Complaint 1	
		is in range	- classification is complaint 1	
		IF after following correct handling instructions	THEN complaint is resolved	
		produces acceptable results	Classification is Complaint 1	

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IF the out of range result is persistent on multiple i-	THEN the QC material lot(s) should be investigated
STAT 1 Analyzers and cartridge lot number for a	Classification is Complaint 2
specific lot of QC material after troubleshooting AND	
other QC material lot numbers are producing	Ask customer if QC material are available to be returned
acceptable results with the same analyzers and	for investigation and document request(s)
cartridges lot numbers.	
IF the issue is persistent on multiple i-	THEN the suspect cartridge and QC material lot(s) should be
STAT 1 Analyzers after troubleshooting but only on	investigated
specific cartridge lot(s) and specific QC material lot(s)	 Classification is Complaint 2
AND other cartridge lots and other QC material lot(s)	·
run without issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available to
	he returned for investigation and decompart request(s)
	be returned for investigation and document request(s)

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Complaint		Description		
BNP Controls or		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
Calibration Customer reports a positive or negative trend/bias in Control or Calibration Verifi		ol or Calibration Verification results but still within acceptable		
Verification Results		VAS ranges.		
are Out	of Range	Prompts for Meaningful Data Collection		
		1. What cartridge type and lot number(s) is the out of ran	ge result occurring?	
Synonym	ns: failed,	2. What is QC material lot number and level?		
low, high	h, bias	3. What is the BNP result (with units of measure)?		
		4. Which VAS is being reviewed? What is the VAS accepta	ble range?	
RW Code	es for	5. How is the control/cal ver stored and handled?		
	BNP	6. Was the correct pathway used on the analyzer for testi	ng of control/cal ver material?	
C1424	High -	Is the control/cal ver lot number being used for the firs	t time on this cartridge lot number?	
	QC/Cal	 If not used for the first time – were the contr 	ol/cal ver results in range on previous testing?	
	Ver	8. What is CLEW version on the analyzer?		
	BNP	9. How are cartridges stored and handled?		
C1425	Low -	10. What is analyzer serial number(s)?		
	QC/Cal	Troubleshooting		
	Ver	A. Collect and document the control results with units of	measure	
		B. Verify correct VAS and ranges are being viewed per CLI	EW	
		C. Verify if the results are in range or out of range per VAS	Sranges	
		D. Verify if the control/cal ver showed pass results in any	previous tests on the same cartridge lot number (initial vs	
		monthly QC)		
		E. Verify control/cal ver is not expired		
		F. Verify cartridge storage and handling	Verify cartridge storage and handling	
		G. Verity control/cal ver storage and handing		
		1. Verify there was no room temperature equili	bration prior to testing	
		2. Verify the vials have not reached 30-day expiration if previously used and stored in refrigerator tight		
		capped. Use new vial if 30-day expiration has been reached.		
		Verify proper control testing of call verifesting procedure was followed		
		1. Verify viais were gently mixed, avoiding toaming		
2. Verify transfer method (tube dropper top of transfer device)		r filling		
		5. Verify callinges are tested infinediately arte	i ining	
		i-STAT 1 System Manual Section 14: Quality Control Art: 7	14376	
		i-STAT 1 System Manual, Section 15: Calibration Verification Art: 714377		
		Rules of Replacement		
		1. Provide the same lot of QC materials for troubleshooti	ng to rule out improper handling technique or storage (e.g.	
		user no longer has any control/cal ver product left)		
		2. Provide a different lot number of QC materials for trou	bleshooting when trying to determine QC specific issue	
		3. Provide a different cartridge lot number for troublesho	oting if the control/cal ver material is showing acceptable	
		results on other cartridge type/lot number(s)		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	Classification is Complaint 1	
		IF control/cal ver results are in range per VAS acceptable	THEN the incident is resolved	
		ranges	Classification is Complaint 1	
		IF after running a new cartridge with a new vial of	THEN complaint is resolved	
		control/cal ver (from the same lot numbers) the result is	Classification is Complaint 1	
		in range		
		IF after following correct handling instructions produces	THEN complaint is resolved	
		acceptable results	Classification is Complaint 1	

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IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material lot(s) should be investigated
Analyzers and cartridge lot number for a specific lot of QC	 Classification is Complaint 2
material after troubleshooting AND other QC material lot	
numbers are producing acceptable results with the same	Ask customer if QC material are available to be returned
analyzers and cartridges lot numbers.	for investigation and document request(s)
IF the issue is persistent on multiple i-	THEN the suspect cartridge and QC material lot(s) should
STAT 1 Analyzers after troubleshooting but only on	be investigated
specific cartridge lot(s) and specific QC material lot(s)	 Classification is Complaint 2
AND other cartridge lots and other QC material lot(s) run	
without issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Complaint Description		Description		
β-hCG Controls or		Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS).		
Calibration		Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable		
Verification Results VAS		VAS ranges.		
are Out	of Range	Prompts for Meaningful Data Collection		
	<i></i>	1. What cartridge type and lot number(s) is the out of range result occurring?		
Synonyn	ns: failed,	2. What is QC material lot number and level?		
low, hig	h, bias	3. What is the β -hCG result (with units of measure)?		
		4. Which VAS is being reviewed? What is the VAS acceptable range?		
RW Cod	es for	5. How is the control/cal ver stored and handled?		
	B-NCG	6. Was the correct pathway used on the analyzer for testing of control/cal ver material?		
C1427	OC/Cal	7. Is the control/cal ver lot number being used for the first time on this cartridge lot number?		
	Ver	a. If not used for the first time – were the control/cal ver results in range on previous testing?		
	B-hCG	8. What is CLEW version on the analyzer?		
C1428	Low -	9. How are cartridges stored and handled?		
01420	QC/Cal	10. What is analyzer serial number(s)?		
	Ver	Troubleshooting		
		A. Collect and document the control results with units of measure		
		B. Verify correct VAS and ranges are being viewed per CLEW		
		C. Verify if the results are in range or out of range per VAS ranges		
		D. Verify if the control/cal ver showed pass results in any previous tests on the same cartridge lot number (initial vs		
monthly QC)		monthly QC)		
		E. Verify control/cal ver is not expired		
F. Verify cartridge storage and handling		F. Verify cartridge storage and handling		
G. Verify control/cal ver storage and handing		G. Verify control/cal ver storage and handing		
	1. Verify there was no room temperature equilibration prior to testing			
	2. Verify the vials have not reached 30-day expiration if previously used and stored in refrige			
		Vorify proper control testing or cal ver testing procedure was followed		
	H. Verify proper control testing or call verifesting procedure was followed			
		2. Verify transfer method (tube dropper top or transfer device)		
		3 Verify cartridges are tested immediately after filling		
		5. Verify carendges are rested inifications when mining		
		i-STAT 1 System Manual, Section 14: Quality Control Art: 714376		
		Technical Bulletin: i-STAT Total 8-hCG Controls and Calibration Verification Material Art: 730475		
		Cartridae and Test Information Sheet: Total Beta-Human Chorionic Gonadotropin (8-hCG) Art: 730474		
		Rules of Replacement		
		1. Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage (e.g.		
		user no longer has any control/cal ver product left)		
		2. Provide a different lot number of QC materials for troubleshooting when trying to determine QC specific issue		
		3. Provide a different cartridge lot number for troubleshooting if the control/cal ver material is showing acceptable		
		results on other cartridge type/lot number(s)		
		Resolution		
		IF results are acceptable when using the correct VAS or THEN the incident is resolved		
		correct ranges on VAS • Classification is Complaint 1		
		IF control/cal ver results are in range per VAS acceptable THEN the incident is resolved		
		ranges Classification is Complaint 1		
		IF after running a new cartridge with a new vial of THEN complaint is resolved		
		control/cal ver (from the same lot numbers) the result is • Classification is Complaint 1		
		in range		

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IF after following correct handling instructions produces acceptable results	 THEN complaint is resolved Classification is Complaint 1
IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridge lot number for a specific lot of QC material after troubleshooting AND other QC	 THEN the QC material lot(s) should be investigated Classification is Complaint 2
material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	Ask customer if QC material are available to be returned for investigation and document request(s)
IF the issue is persistent on multiple i- STAT 1 Analyzers after troubleshooting but only on specific cartridge lot(s) and specific OC material lot(s)	THEN the suspect cartridge and QC material lot(s) should be investigated
AND other cartridge lots and other QC material lot(s) run without issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available to
	be returned for investigation and document request(s)

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Compla	nplaint Description			
Prothro	Prothrombin Time Control results are outside of the acceptable ranges on the value assignment sheets (VAS).			
(PT/INR	k)	Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.		
Control	Results	Prompts for Meaningful Data Collection		
are Out	of Range	1. What cartridge type and lot number(s) is the out of range result occurring?		
		2. What is OC material lot number and level?		
Synonyı	ms: failed, high,	3. What is the PT/INR result (with units of measure)?		
low, bia	IS	 Which VAS is being reviewed? What is the VAS accer 	otable range?	
		5. How is the control stored and handled?		
RW Cod	les	6. Was the correct pathway used on the analyzer for te	sting of control material?	
	Prothrombin	7. Is the control lot number being used for the first tim	e on this cartridge lot number?	
C1346	Time High -	a. If not used for the first time – were the cor	ntrol results in range on previous testing?	
	QC/Cal Ver	8. What is CLEW version on the analyzer?	5 1 5	
642.47	Prothrombin	9. How are cartridges stored and handled?		
C1347	Time Low -	10. What is analyzer serial number(s)?		
	QC/Cal Vel	Troubleshooting		
		A. Collect and document the control results with units of	of measure	
		B. Verify correct VAS and ranges are being viewed per (CLEW	
		C. Verify if the results are in range or out of range per \	/AS ranges	
		D. Verify if the control showed pass results in any previ	ous tests on the same cartridge lot number (initial vs	
		monthly QC)		
		E. Verify control is not expired		
		F. Verify cartridge storage and handling		
		G. Verify QC Material testing procedure was followed		
		1. Verify equilibrated to room temperature for at least 45 minutes, no longer than 4 hours		
		2. Verify proper reconstitution procedure:		
		a. Add Calcium Chloride (CaCl2) vial contents to lyophilized plasma vial		
		b. Allow vial to sit for 1 minute		
		c. Gently swirl contents for 1 minute		
		d. Slowly invert for 30 seconds		
		3. Verify plastic transfer device was used to f	ill the cartridge	
		4. Verify cartridge filled immediately after re-	constitution and tested	
		H. Retest cartridge with a new vial of the control.		
		i-STAT 1 System Manual, Section 14: Quality Control Art:	714376	
		Rules of Replacement		
		1. Provide the same lot of QC materials for troubleshoo	oting to rule out improper handling technique or storage (e.g.	
		user no longer has any control product left)		
		2. Provide a different lot number of QC materials for tr	oubleshooting when trying to determine QC specific issue	
		3. Provide a different cartridge lot number for troubles	hooting if the control material is showing acceptable results	
		on other cartridge type/lot number(s)		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	 Classification is Complaint 1 	
		IF control results are in range per VAS acceptable	THEN the incident is resolved	
		ranges	Classification is Complaint 1	
		IF testing a new cartridge with new QC material vial	THEN complaint is resolved	
		(from the same lot numbers) AND the results are	Classification is Complaint 1	
		acceptable		
		IF after following correct handling instructions	THEN complaint is resolved	
		produces acceptable results	 Classification is Complaint 1 	

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IF the out of range result is persistent on multiple i-	THEN the QC material lot(s) should be investigated
STAT 1 Analyzers and cartridges for a specific lot of QC	 Classification is Complaint 2
material after troubleshooting AND other QC material	
lot numbers are producing acceptable results with the	Ask customer if QC material are available to be returned
same analyzers and cartridges.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-	THEN the suspect cartridge and QC material lot(s) should
STAT analyzers after troubleshooting but only on	be investigated
specific cartridge lot(s) and specific QC material lot(s)	 Classification is Complaint 2
AND other cartridge lots and other QC material lot(s)	
run without issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available
	to be returned for investigation and document request(s)

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Compla	int	Description		
ACT Cel	ite Control	trol Control results are outside of the acceptable ranges on the value assignment sheets (VAS).		
Results are Out of Cust		Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.		
Range		Prompts for Meaningful Data Collection		
		1. What cartridge type and lot number(s) is the out of range result occurring?		
Synonyms: failed, 2. What is QC material lot number and level?				
high, lo	w, bias	3. What is the ACT result (with units of measure)?		
		4. Which VAS is being reviewed? What is the VAS accepta	ble range?	
RW Cod	les	5. How is the control stored and handled?		
	ACT Celite	6. Is the control lot number being used for the first time c	on this cartridge lot number?	
C1376	Low -	a. If not used for the first time – were the contr	ol results in range on previous testing?	
	QC/Cal Ver	7. What is CLEW version on the analyzer?		
C1277	ACT Celite	8. How are cartridges stored and handled?		
C13//	High -	9. What is analyzer serial number(s)?		
		Troubleshooting		
		A. Collect and document the control results with units of	measure	
		B. Verify correct VAS and ranges are being viewed per CLE	W	
		C. Verify if the results are in range or out of range per VAS	5 ranges	
		D. Verify if the control showed pass results in any previou	s tests on the same cartridge lot number (initial vs monthly	
		QC)		
		E. Verify control is not expired		
		F. Verify cartridge storage and handling		
		G. Verify QC Material testing procedure was followed		
		1. Verify equilibrated to room temperature for	at least 45 minutes, no longer than 4 hours	
		2. Verify proper reconstitution procedure:		
		a. Add Calcium Chloride (CaCl2) vial co	ontents to lyophilized plasma vial	
		b. Allow vial to sit for 1 minute		
		c. Gently swirl contents for 1 minute		
		d. Slowly invert for 30 seconds		
		3. Verify plastic transfer device was used to fill the cartridge		
		4. Verify cartridge filled immediately after reconstitution and tested		
		H. Retest cartridge with a new vial of the control.		
		i-STAT 1 System Manual, Section 14: Quality Control Art: 714376		
		Rules of Replacement		
		1. Provide the same lot of QC materials for troubleshooting	1. Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage (e.g.	
		user no longer has any control product left)		
		2. Provide a different lot number of QC materials for trou	bleshooting when trying to determine QC specific issue	
		3. Provide a different cartridge lot number for troublesho	oting if the control material is showing acceptable results	
		on other cartridge type/lot number(s)		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	Classification is Complaint 1	
		IF control results are in range per VAS acceptable ranges	THEN the incident is resolved	
			Classification is Complaint 1	
		IF testing a new cartridge with new QC material vial (from	THEN complaint is resolved	
		the same lot numbers) AND the results are acceptable	Classification is Complaint 1	
		IF after following correct handling instructions produces	THEN complaint is resolved	
		acceptable results	Classification is Complaint 1	
		IF the out of range result is persistent on multiple i-STAT 1	THEN the QC material lot(s) should be investigated	
		Analyzers and cartridges for a specific lot of QC material	Classification is Complaint 2	

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after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges.	Ask customer if QC material are available to be returned for investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) and specific QC material lot(s) AND other cartridge lots and other QC material lot(s) run without	 THEN the suspect cartridge and QC material lot(s) should be investigated Classification is Complaint 2
issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available to be returned for investigation and document request(s)

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Complaint Description			
ACT Kaolin Control Control results are outside of the acceptable ranges on the value assignment sheets (VAS).			
Results are Out of Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ra	inges.		
Range Prompts for Meaningful Data Collection			
1. What cartridge type and lot number(s) is the out of range result occurring?	1. What cartridge type and lot number(s) is the out of range result occurring?		
Synonyms: failed, 2. What is QC material lot number and level?			
high, low, bias 3. What is the ACT result (with units of measure)?			
4. Which VAS is being reviewed? What is the VAS acceptable range?			
RW Codes 5. How is the control stored and handled?			
ACT Kaolin 6. Is the control lot number being used for the first time on this cartridge lot number?			
C1378 Low - a. If not used for the first time – were the control results in range on previous testing?			
ACT Kaplin 7. What is CLEW version on the analyzer?			
C1379 High - 8. How are cartridges stored and handled?			
QC/Cal Ver 9. What is analyzer serial number(s)?			
Troubleshooting			
A. Collect and document the control results with units of measure			
B. Verify correct VAS and ranges are being viewed per CLEW			
C. Verify if the results are in range or out of range per VAS ranges			
D. Verify if the control showed pass results in any previous tests on the same cartridge lot number (initial vs monthly		
QC)			
E. Verify control is not expired			
F. Verify cartridge storage and handling			
G. Verify QC Material testing procedure was followed			
 Verify equilibrated to room temperature for at least 45 minutes, no longer than 4 hour 	S		
2. Verify proper reconstitution procedure:			
a. Add Calcium Chloride (CaCl2) vial contents to lyophilized plasma vial	a. Add Calcium Chloride (CaCl2) vial contents to lyophilized plasma vial		
b. Allow vial to sit for 1 minute	b. Allow vial to sit for 1 minute		
c. Gently swirl contents for 1 minute	c. Gently swirl contents for 1 minute		
d. Slowly invert for 30 seconds			
3. Verify plastic transfer device was used to fill the cartridge			
4. Verify cartridge filled immediately after reconstitution and tested			
H. Retest cartridge with a new vial of the control.			
STAT 1 Sustan Manual Costian 14. Quality Control Arts 714276			
I-STAT I System Manual, section 14: Quality Control Art: 714376			
Dulas of Daulasoment			
Rules of Replacement	o or storage lo g		
1. Provide the same lot of QC materials for troubleshooting to fulle out improper handling technique	e of storage (e.g.		
2 Provide a different let number of OC materials for troublesheating when trying to determine OC	specific issue		
2. Provide a different cartridge lot number for troubleshooting if the control material is showing ac	contable results		
on other cartridge type/lot number/of troubleshooting if the control material is showing act			
Resolution			
IF results are acceptable when using the correct VAS THEN the incident is resolved			
or correct ranges on VAS			
IE control results are in range per VAS accentable.			
ranges			
Is testing a new cartridge with new OC material vial			
(from the same lot numbers) AND the results are Classification in Complaint 1			
accentable			
IF after following correct handling instructions THEN complaint is resolved			
and the topological state of topological s			

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IF the out of range result is persistent on multiple i-	THEN the QC material lot(s) should be investigated
STAT 1 Analyzers and cartridges for a specific lot of QC	 Classification is Complaint 2
material after troubleshooting AND other QC material	
lot numbers are producing acceptable results with the	Ask customer if QC material are available to be returned
same analyzers and cartridges.	for investigation and document request(s)
IF the out of range result is persistent on multiple i-	THEN the suspect cartridge and QC material lot(s) should be
STAT analyzers after troubleshooting but only on	investigated
specific cartridge lot(s) and specific QC material lot(s)	 Classification is Complaint 2
AND other cartridge lots and other QC material lot(s)	
run without issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available to
	be returned for investigation and document request(s)

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Complaint Des		Description		
PT ^{plus} Co	ntrol	Control results are outside of the acceptable ranges on the value assignment sheets (VAS).		
Results a	are Out of	Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.		
Range		Prompts for Meaningful Data Collection		
Synonyms: failed, 1. What cartridge type and lot number(s) is the out of range result occurring? Synonyms: failed, 2. What is QC material lot number and level? high, low, bias 3. What is the PT/INR result (with units of measure)?		nge result occurring? able range?		
RW Code	es	5. How is the control stored and handled?	able range:	
C1429	PT plus High – QC/Cal Ver PT plus	 6. Is the control lot number being used for the first time a. If not used for the first time – were the cont 7. What is CLEW version on the analyzer? 8. How are cartridges stored and handled? 	on this cartridge lot number? rol results in range on previous testing?	
	Low –	9. What is analyzer serial number(s)?		
C1430	QC/Cal	Troubleshooting		
	CL43U Troubleshooting A. Collect and document the control results with units of measure B. Verify correct VAS and ranges are being viewed per CLEW C. Verify if the results are in range or out of range per VAS ranges D. Verify if the control showed pass results in any previous tests on the same cartridge lot number (initial vs mont QC) E. Verify control is not expired F. Verify cartridge storage and handling G. Verify quilibrated to room temperature for at least 45 minutes, no longer than 4 hours 2. Verify opper reconstitution procedure: a. Add CaCl2 vial contents to lyophilized plasma vial b. Allow vial to sit for 1 minute c. Gently swirl contents for 1 minute d. Slowly invert for 30 seconds 3. Verify cartridge filled immediately after reconstitution and tested H. Retest cartridge with a new vial of the control. Technical Bulletin: i-STAT PTP ^{lus} /aPTT Controls Art: 757539		i measure LEW AS ranges us tests on the same cartridge lot number (initial vs monthly r at least 45 minutes, no longer than 4 hours zed plasma vial the cartridge onstitution and tested	
		 Provide the same lot of QC materials for troubleshooting to rule out improper handling technique or storage (e.g. user no longer has any control product left) Provide a different lot number of QC materials for troubleshooting when trying to determine QC specific issue Provide a different cartridge lot number for troubleshooting if the control material is showing acceptable results or 		
		Resolution		
		IF results are acceptable when using the correct VAS or	THEN the incident is resolved	
		correct ranges on VAS	Classification is Complaint 1	
		IF control results are in range per VAS acceptable ranges	THEN the incident is resolved Classification is Complaint 1	
		IF testing a new cartridge with new QC material vial (from the same lot numbers) AND the results are acceptable	 THEN complaint is resolved Classification is Complaint 1 	
		IF after following correct handling instructions produces acceptable results	 THEN complaint is resolved Classification is Complaint 1 	

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IF the out of range result is persistent on multiple i-STAT	THEN the QC material lot(s) should be investigated
1 Analyzers and cartridges for a specific lot of QC	Classification is Complaint 2
material after troubleshooting AND other QC material lot	
numbers are producing acceptable results with the same	Ask customer if QC material are available to be returned for
analyzers and cartridges.	investigation and document request(s)
IF the out of range result is persistent on multiple i-STAT	THEN the suspect cartridge and QC material lot(s) should be
analyzers after troubleshooting but only on specific	investigated
cartridge lot(s) and specific QC material lot(s) AND other	Classification is Complaint 2
cartridge lots and other QC material lot(s) run without	
issue on the same i-STAT 1 Analyzers	Ask customer if cartridges and QC material are available to
	be returned for investigation and document request(s)

Return to the TOC

Complaint	Description			
3 rd Party Vendor	Third Party Quality Control Material is out of range or failed when tested on i-STAT cartridges. Customer is not using			
Quality Material	APOC quality control material (e.g. Bio-Rad, Eurotrol)			
Out of Range	Prompts for Meaningful Data Collection			
	1. What cartridge type and lot number(s) is the out of range result occurring?			
RW Code: C1426	2. What is 3 rd party QC material lot number and level?			
	3. Which analyte(s) is out of range?			
Synonyms:	4. What are the results (with units of measure)?			
Eurotrol or Bio-Rad	5. How are cartridges stored and handled?			
QC is not in	6. What is the analyzer serial number?			
	Troubleshooting			
	A. Verify shipment and storage of the cartridges being used			
	B. Verify cartridge handling			
	C. Send APOC QC materials for troubleshooting and review proper QC material handling of APOC materials			
	D. Document APOC QC material lot number provided			
	E. Collect and document the APOC QC material results with units of measure after testing by user			
	F. Verify if the APOC QC material results passed			
	Resolution			
	IF APOC QC materials produce acceptable results THEN issue is resolved. Refer customer to 3 rd Party vendor.			
	Classification is Complaint 1			
	IF APOC QC materials are unacceptable THEN troubleshoot the APOC QC materials per appropriate			
	complaint code			

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8.0 Cartridge Results Unexpected/Unacceptable

Sodium (Na)	Patient's sodium (Na) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Patient Results	STAT retect results
i atient nesults	STATICES (FESHES
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1501	Why is the i-STAT result considered to be discrepant/unexpected:
Svnonvms: i-STAT	Unexpected Results Table
results - high low	
discrepant not	All results from i STAT cartridge (can request a result printout or picture of the i STAT results):
uisciepuiit, not	Air results non restar carriage (carrieduest a results pintout of picture of the restar results).
renuble, aijjerent,	Was the patient sample retested on a new I-STAT cartridge?
cannot trust	
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Detient completives used
	Patient sample type used.
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected
	Transfer device used for loading the nationt sample to the cartridge:
	ransier device used for folduling the patient sample to the califordia.
	-STAT Analyzer Senar Number(S).
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation):
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to nation?
	If national treatment was based on lab results, what was the treatment?
	A. verify reason for considering the I-STAT Sodium results to be unexpected/different
	B. Verity if the I-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verify sample type used
	1. Must be whole blood

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2. If some	ething other than whole blood is used	for testing, advised cus	stomer of correct sample type and
review	intended use per Cartridge IFU (add <u>C</u>	<u>:1066)</u>	
E. Verify anticoagu	lant used for sample collection		
1. Sodiur	n heparin will increase sodium (Na) res	sults	
F. Verify the patier	it sample is being tested within 30 min	utes of collection if tes	ting anticoagulated samples or
immediately if te	esting samples collected without antico	bagulant	
G. Verify the patier	it sample is being collected correctly		
1. Evacua	ated lubes:		
a.	Plain (no anticoagulant, red top tub	be) or lithium heparin ()	green top tube)
	I. CHEIVI8+ cartriage: Use (or a sample collected v	vithout an anticoaguiant is not
L	supported in US	roct filling loads to high	har hanarin ta blaad ratios
D. 2 Svringe	- Fill tubes to labeled capacity. Incor	rect ming leads to high	
2. Syring	z. Dlain (no anticoagulant) or lithium	honorin or holoncod ho	narin
d.		neparin or balanced he	parin without an anticoagulant is not
	i. Chelviot caltiluge. Use o	or a sample conected v	without an anticoagulant is not
h	Fill honorin syringes to laboled can	city Incorroct filling l	ands to higher honorin to blood ratios
3 Capilla	 b. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratio 		
3. Capilia	Balanced benarin or lithium benari	n labeled for electrolyt	e measurement
	i CHEM8+ cartridge: Use	of a canillary sample is	a not supported
h	Milking of collection site (finger he	el) may cause hemolys	sis
4. Indwe	lling line: back flush line 5-6 times the	volume of catheter, co	nnectors and needle to avoid
contar	nination	,	
H. Verify the patier	it sample is being handled correctly		
1. Mixed	well to avoid clotting		
I. Verify medicatio	ns/treatments patient is receiving are	not known to interfere	e per Cartridge IFU
Note: Analyzer is sus	pected only when multiple unexpected	d results are generated	on a specific serial number compared
to different analyzer(s) that generate expected results for the	ne specific patient sam	ple(s).
Resolution			
IF incorrect sample ty	pe (something other than whole	THEN the incident is	resolved
blood) is used for i-ST	AT cartridge testing	 Classification 	on is Complaint 1
		C1066 will be added	as supplemental code
IF the sample is colled	cted with an incorrect anticoagulant	THEN the incident is	resolved
		Classification	on is Complaint 1
	and a statistic all a second statistics of the		
IF the sample is not to	ested within the required time after	THEN the suspect ca	rtriage lot(s) should be investigated
collection per APOC I	iterature	Classification	on is complaint 2
IE the nationt results	or cartridgo tupo/lot number is still	THEN the contridee la	at(c) should be investigated
IF the patient results	iliganca DOA/TS will determine		on is Complaint 2
cartridge let number	via internal systems		
IF unexpected patien	t results are reported and incorrect	THEN the suspect ca	rtridge lot(s) should be investigated
sample type and anti	coagulant use is ruled out	 Classification 	on is Complaint 2

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Complaint	Description
Potassium (K)	Patient's potassium (K) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Patient Results	STAT retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
, questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1502	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT Potassium results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verify sample type used
	1. Must be whole blood (serum will cause elevated potassium (K) results)
	2. If something other than whole blood is used for testing, advised customer of correct sample type and
	review intended use per Cartridge IFU (add <u>C1066</u>)

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E. Verify anticoagulan	t used for sample collection			
1. EDTA (pu	rple top tube) will cause elevated po	assium (K) results		
F. Ventry the patient s	ample is being tested within 30 minut	es of collection if testing anticoa	agulated samples or	
G Verify that the patie	ant sample is being collected correctly	educate customer on proper c	ollection if needed	
1 Evacuated	Tubes	, cuddate customer on proper e		
a.	Plain (no anticoagulant) or lithium he	parin (green top tube)		
	i. CHEM8+ cartridge: Use of	a sample collected without an a	anticoagulant is not	
	supported in US	•	5	
b.	Fill tubes to labeled capacity. Incorre	ct filling leads to higher heparin	-to-blood ratios	
с.	Ensure 16-20 gauge needle used for o	ollection (higher than 20 g may	cause hemolysis)	
2. Syringe:				
a.	Plain (no anticoagulant) or lithium he	parin or balanced heparin		
	i. CHEM8+ cartridge: Use of	a sample collected without an a	anticoagulant is not	
	supported in US		an bananin ta blaad natioo	
b.	Fill heparin syringes to labeled capaci	ty. Incorrect filling leads to high	er neparin-to-blood ratios	
C. 3 Canillary	Elisule 10-20 gage fieldue used for co		ause hemolysis)	
J. Capitaly	Balanced heparin or lithium heparin l	abeled for electrolyte measuren	nent	
	i. CHEM8+ cartridge: Use of a capillary sample is not supported			
b.	Milking of collection site (finger, heel	may cause hemolysis (will caus	se elevated K results)	
4. Indwelling	gline: back flush line 5-6 times the vo	lume of catheter, connectors ar	nd needle to avoid	
contamin	ation			
H. Verify the patient s	ample is being handled correctly			
1. Mixed we	Il to avoid clotting			
2. Sample w	as not hemolyzed (will cause elevated	ot hemolyzed (will cause elevated K results)		
3. Sample w	as not put on ice (will cause elevated	a K results) not known to interfere per Cartridge IEU		
i. verify medications/	treatments patient is receiving are no	t known to interfere per Cartrid	ige if 0	
Note: Analyzer is susper	ted only when multiple unexpected r	esults are generated on a specif	ic serial number compared	
to different analyzer(s) t	hat generate expected results for the	specific patient sample(s).	ie senar namber compared	
Resolution				
IF incorrect sample type	is used for i-STAT cartridge testing	THEN the incident is resolved		
	0	Classification is Com	nplaint 1	
		C1066 will be added as supple	emental code	
IF the sample is collected	with an incorrect anticoagulant	THEN the incident is resolved		
(i.e. EDTA)	-	Classification is Con	nplaint 1	
IF the sample is not teste	IF the sample is not tested within the required time after THEN the suspect cartridge lot(s) should be investigated			
collection per APOC liter	ature	Classification is Com	nplaint 2	
IF the patient results or	cartridge type/ lot number is still	THEN the cartridge lot(s) shou	uld be investigated	
unknown after due dilige	ence, PQA/TS will determine	Classification is Com	nplaint 2	
cartridge lot number via internal systems				
	oute and reported and incoment		t(a) abouid be investigated	
IF unexpected patient re	suits are reported and incorrect	Classification is Car	n(s) should be investigated	
sample type and anticoa	guiant use is ruleu out	Classification is Con	iplaint 2	

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Complaint	Description
Chloride (Cl)	Patient's chloride (CI) results from the i-STAT system are not what the customer was expecting i-STAT results do not
Unevnected Patient	match the nation's clinical nicture or are different when compared to lab instrument results, other i-STAT results or i-
Results	STAT ratest results
Results	
4 may 10 m m D F	Neter The mean should be used to callect information during the initial call/anatorian conditable to consulate
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1503	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and accentable:
	Patient cample type used:
	Fatterit sample type used.
	Collection devices (aviews averaged type, conjugated type
	Collection device (synthese, evaluated tube, capitary):
	Type of anticoagulant used in the conjection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample nemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	A. Verity reason for considering the i-STAT Chloride results to be unexpected/different
	B. Verity if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verify sample type used
	1. Must be whole blood

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L				
E. F. G.	 If something other than whole blood is used for testing, advised customer of correct sample type and review intended use per Cartridge IFU (add <u>C1066</u>) Verify anticoagulant used for sample collection Verify the patient sample is being tested within 30 minutes of collection if testing anticoagulated samples or immediately if testing samples collected without anticoagulant Verify that the patient sample is being collected correctly Evacuated Tubes: Plain (no anticoagulant) or lithium heparin (green top tube) CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US 			
	b. Fi	Il tubes to labeled capacity. Inco	orrect filling leads to	o higher heparin-to-blood ratios
H. I. Note to dif	 Syringe: a. P b. F 3. Capillary Tu a. B b. N 4. Indwelling I contaminat Verify the patient sar Mixed well Verify medications/tr e: Analyzer is suspector fferent analyzer(s) that 	 Syringe: a. Plain (no anticoagulant) or lithium heparin or balanced heparin a. CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US b. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios Capillary Tube: a. Balanced heparin or lithium heparin labeled for electrolyte measurement i. CHEM8+ cartridge: Use of a capillary sample is not supported b. Milking of collection site (finger, heel) may cause hemolysis Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid contamination erify the patient sample is being handled correctly Mixed well to avoid clotting erify medications/treatments patient is receiving are not known to interfere per Cartridge IFU Analyzer is suspected only when multiple unexpected results are generated on a specific serial number compared erent analyzer(s) that generate expected results for the specific patient sample(s). 		
IF inc testin	correct sample type is ng	used for i-STAT cartridge	THEN the inciden Classific <u>C1066</u> will be add	it is resolved cation is Complaint 1 ded as supplemental code
IF the	e sample is collected	with an incorrect anticoagulant	THEN the inciden Classifie	t is resolved cation is Complaint 1
IF the colle	e sample is not testec ction per APOC literat	l within the required time after cure	THEN the suspect • Classifie	t cartridge lot(s) should be investigated cation is Complaint 2
IF the unkn cartr	e patient results or ca own after due diligen idge lot number via ir	rtridge type/ lot number is still ice, PQA/TS will determine iternal systems	THEN the cartridg Classifie	ge lot(s) should be investigated cation is Complaint 2
IF un samp	expected patient resu ple type and anticoage	ults are reported and incorrect ulant use is ruled out	• Classifie	t cartridge lot(s) should be investigated cation is Complaint 2

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Complaint	Description
Ionized Calcium	Patient's jonized calcium (iCa) results from the i-STAT system are not what the customer was expecting. i-STAT results
(iCa) Unexpected	do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results
Patient Results	or i-STAT retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
auestions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1504	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	Name of the comparative lab instrument (if applicable):
	Is lab result for Total Calcium or ionized Calcium (if applicable)?
	······································
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A Verify reason for considering the i-STAT iCa results to be unexpected/different
	R Verify if the i-STAT test was repeated
	C Collect information for the results table (Annendix F)
	D Verify sample type used
	1 Must be whole blood

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2. If som	ething other than whole blood is used fo	or testing, advised customer of correct sample type and
review	/ intended use per Cartridge IFU (add <u>C1</u>	<u>066</u>)
E. Verify anticoagu	lant used for sample collection	
1. EDTA	will cause decreased iCa results	
F. Verify the patier	nt sample is being tested within 10 minu	tes of collection if testing anticoagulated samples or
immediately if te	esting samples collected without anticoa	ngulant
G. Verify the patier	nt sample is being collected correctly	
1. Evacua	ated lubes:	
	a. Plain (no anticoaguiant) or litnium n	eparin is comple collected without on ontices sulent is not
	i. Chewio+ cartridge. Use of	a sample confected without an anticoagulant is not
	h Fill tubes to labeled canacity Incorr	ect filling leads to higher benarin-to-blood ratios and will
	cause decreased iCa results	cet ming leads to higher heparin to blood ratios and win
2. Svring	e:	
	a. Plain (no anticoagulant) or lithium h	eparin or balanced heparin
	i. CHEM8+ cartridge: Use of	a sample collected without an anticoagulant is not
	supported in US	
	b. Fill heparin syringes to labeled capac	tity. Incorrect filling leads to higher heparin-to-blood ratios
	and will cause decreased iCa results	
3. Capilla	ary Tube:	
	a. Balanced heparin or lithium heparin	labeled for electrolyte measurement
	i. CHEM8+ cartridge: Use of	a capillary sample is not supported
4 Instruct	b. Milking of collection site (finger, hee	I) may cause hemolysis
4. Indwe	ning line: back nush line 5-6 times the v	olume of catheter, connectors and needle to avoid
	nination at cample is being bandled correctly	
1 Miyed	well to avoid clotting	
I Transfer devices	with henarin will decrease iCa	
J. Verify the patier	nt sample is being handled correctly for	each analyte.
1. Air exp	posure will decrease iCa	
K. Verify medicatio	ons/treatments patient is receiving are n	ot known to interfere per cartridge IFU
	· · · · · ·	
Note: Analyzer is sus	spected only when multiple unexpected	results are generated on a specific serial number compared
to different analyzer(s) that generate expected results for the	e specific patient sample(s).
Resolution		
IF incorrect sample ty	pe is used for i-STAT cartridge testing	THEN the incident is resolved
		Classification is Complaint 1
		<u>C1066</u> will be added as supplemental code
IF the sample is colled	cted with an incorrect anticoagulant	IHEN THE INCIDENT IS RESOLVED
	acted within the required time of the	Classification is Complaint 1 TUEN the suspect contrided lat(a) should be investigated.
IF the sample is not to	ested within the required time after	Classification is Completed
collection per APOCT	or optridgo tupo (let purchar is still	Classification is complaint 2 TUEN the contrided lot(a) should be investigated
IF the patient results	or cartriage type/ lot number is still	Classification is Completed
unknown after due d	via internal systems	Classification is complaint 2
	t results are reported and incorrect	THEN the suspect cartridge $lot(c)$ should be investigated
sample type and anti-	coagulant use is ruled out	Classification is Complaint 2
sample type and anti-	coaguiant use is ruleu out	

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Complaint	Description
Glucose (Glu, G)	Patient's glucose results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected Patient	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Results	STAT retest results
Answer pRE questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1505	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
cannot trust	Was the patient sample retested on a new i-STAT cartridge?
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	ransfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Detient informations
	Patient Information:
	Age and gender:
	Clinical symptoms at presentation:
	Current Medications:
	Populte from other tests (procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If nation treatment was based on lab results, what was the treatment?
	Troubleshooting
	A Verify reason for considering the i-STAT Glucose results to be unexpected / different
	B. Verify if the i-STAT test was repeated
	C Collect information for the results table (Appendix F)
	D. Verify sample type used
	1. Must be whole blood
	2. If something other than whole blood is used for testing, advised customer of correct sample type and
	review intended use per Cartridge IFU (add C1066)
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E. Verify anticoage	lant used for sample collection	
F. Verify the patie	ent sample is being tested within 30 m	nutes of collection if testing anticoagulated samples or
immediately if t	esting samples collected without antic	oagulant
G. Verify that the p	patient sample is being collected corre	ctly
1. Evacu	ated Tubes:	honorin (groon ton tubo)
	i. CHEM8+ cartridge: Use	of a sample collected without an anticoagulant is not
.	supported in US	and filling to detail the back of the state
	 Fill tubes to labeled capacity. Inco. 	rrect tilling leads to higher heparin-to-blood ratios
2. Syring	je: Diain (no anticocculent) en litti	honorin or holoncod honorin
	i. CHEM8+ cartridge: Use	of a sample collected without an anticoagulant is not
	supported in US	
k	 Fill heparin syringes to labeled cap 	acity. Incorrect filling leads to higher heparin-to-blood
	ratios	
3. Capill	ary lube:	in takalari fan alartus luta managunan sat
6	i. Balanced heparin or lithium hepar	in labeled for electrolyte measurement
	I. CHEIM8+ cartridge: Use	of a capillary sample is not supported
	bling line: back flush line 5-6 times the	volume of catheter, connectors and needle to avoid
conta	mination	
H. Verify the patie	nt sample is being handled correctly	
1. Mixed	I well to avoid clotting	
I. Verify medication	ons/treatments patient is receiving are	not known to interfere per Cartridge IFU
Note: Analyzer is su	spected only when multiple unexpecte	d results are generated on a specific serial number
compared to differen	nt analyzer(s) that generate expected r	esults for the specific patient sample(s).
Resolution		
IF incorrect sample t	ype is used for i-STAT cartridge	THEN the incident is resolved
testing		Classification is Complaint 1
		C1066 will be added as supplemental code
IF the sample is colle	cted with an incorrect anticoagulant	THEN the incident is resolved
		Classification is Complaint 1
IF the sample is not t	ested within the required time after	THEN the suspect cartridge lot(s) should be investigated
collection per APOC	literature	Classification is Complaint 2
IF the patient results	or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated
unknown after due o cartridge lot number	liligence, PQA/TS will determine via internal systems	Classification is Complaint 2
IF unexpected patier sample type and ant	nt results are reported and incorrect icoagulant use is ruled out	 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2

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Complaint	Description			
	Description			
BUN/Urea	Patient's BON or urea results from the I-STAT system are not what the customer was expecting. I-STAT results do not			
Unexpected Patient	match the patient's clinical picture of are different when compared to lab instrument results, other I-STAT results of I-			
Results	STAT retest results			
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint			
questions!	Prompts for Meaningful Data Collection			
	Cartridge type and lot number used:			
RW Code: C1506	Why is the i-STAT result considered to be discrepant/unexpected:			
Synonyms: i-STAT	Unexpected Results Table			
results - high, low,				
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):			
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?			
cannot trust				
	Name of the comparative lab instrument (if applicable):			
	Cartridge storage information:			
	Cartridge handling information:			
	Are cartridges available to be returned for investigation:			
	Controls tested on the i-STAT cartridges and acceptable:			
	Patient sample type used:			
	How is sample collected?			
	Collection device (syringe, evacuated tube, capillary):			
	Type of anticoagulant used in the collection device:			
	Collection device filled to labeled capacity:			
	Sample mixed thoroughly:			
	Sample hemolysis detected:			
	Sample clotting detected:			
	Transfer device used for loading the patient sample to the cartridge:			
	i-STAT Analyzer Serial Number(s):			
	Patient information:			
	Age and gender:			
	Current Diagnosis:			
	Clinical symptoms at presentation:			
	Current Medications:			
	Results from other tests/procedures performed:			
	Date and time admitted:			
	Date and time discharged:			
	What was impact to patient?			
	If patient treatment was based on lab results, what was the treatment?			
	Troubleshooting			
	A. Verify reason for considering the i-STAT BUN/Urea results to be unexpected/different			
	B. Verify if the i-STAT test was repeated			
	C. Collect information for the results table (Appendix F)			
	1. Ensure same analyte is tested. BUN and Urea results will not match.			
	D. Verify sample type used			
	1. Must be whole blood			
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	2. If someti review ir	ning other than whole blood is used for ntended use per Cartridge IFU (add <u>C1</u> at used for sample collection	r testing, advised customer of corre <u>066</u>)	ect sample type and
	F Verify the natient	sample is being tested within 30 minu	tes of collection if testing anticoagu	lated samples or
	immediately if test	ing samples collected without antico	gulant	
	G. Verify that the pat	ient sample is being collected correct	V 8	
	1. Evacuate	ed Tubes:	,	
	а	. Plain (no anticoagulant) or lithium h	eparin (green top tube)	
		i. CHEM8+ cartridge: Use of	a sample collected without an ant	icoagulant is not
		supported in US		-
	b	. Fill tubes to labeled capacity. Incorr	ect filling leads to higher heparin-to-	-blood ratios
	2. Syringe:			
	а	. Plain (no anticoagulant) or lithium h	eparin or balanced heparin	
		i. CHEM8+ cartridge: Use of	a sample collected without an ant	icoagulant is not
		supported in US		
	b	. Fill heparin syringes to labeled capac	ity. Incorrect filling leads to higher	heparin-to-blood ratios
	3. Capillary	Tube:		
	a. Balanced heparin or lithium heparin labeled for electrolyte measurement			
	i. CHEM8+ cartridge: Use of a capillary sample is not supported			
	b. Milking of collection site (finger, heel) may cause hemolysis			
	4. muwemi contami	ig line. Dack hush line 5-6 times the v	Southe of Catheter, connectors and i	
	H Verify the natient	sample is being handled correctly		
	1 Mixed w	ell to avoid clotting		
	I. Verify medications	/treatments patient is receiving are n	ot known to interfere per Cartridge	IFU
	iii veniy mealeations			
	Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number compared to different analyzer(s) that generate expected results for the specific patient sample(s).		serial number compared	
	Resolution			
	IF incorrect sample type	e is used for i-STAT cartridge testing	THEN the incident is resolved	
			 Classification is Complai 	int 1
			C1066 will be added as supplement	ntal code
	IF the sample is collected	ed with an incorrect anticoagulant	THEN the incident is resolved	
			Classification is Complai	int 1
	IF the sample is not test	ted within the required time after	THEN the suspect cartridge lot(s)	snould be investigated
	collection per APOC lite		Classification is complai	
	IF the patient results or	cartridge type/ lot number is still	THEN the cartridge lot(s) should b	e investigated
	unknown after due dilig	ence, PQA/TS will determine	Classification is Complai	int 2
	cartridge lot number via	a internal systems		
	IF unexpected patient r	esults are reported and incorrect	THEN the suspect cartridge lot(s)	should be investigated
	sample type and antico	agulant use is ruled out	Classification is Complai	int 2

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Complaint	Description
pH Unexpected	Patient's pH results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the
Patient Results	patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest
	results
Answer pRE	
questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1507	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
cannot trust	Was the patient sample retested on a new i-STAT cartridge?
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls to study on the distance of the control of the second seco
	Controis tested on the I-STAT cartridges and acceptable:
	Datient completions used
	Patient sample type used:
	Collection device (suringe evacuated tube capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT pH results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verify sample type used
	1. Must be whole blood
	2. It something other than whole blood is used for testing, advised customer of correct sample type and
	review intended use per Cartridge IFU (add <u>C1066</u>)

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E. Verify anticoagula	nt used for sample collection	
F. Verify the patient	sample is being tested within 10 minu	tes of collection if testing anticoagulated samples or
immediately if test	ing samples collected without anticoa	gulant
G. Verify that the pat	ient sample is being collected correctl	ý
1. Evacuate	ed Tubes:	
а	. Plain (no anticoagulant) or lithium he	eparin (green top tube)
	i. Blue CG4+ cartridge: Use	of a sample collected without an anticoagulant is not
	supported in US	
b	. Fill tubes to labeled capacity. Incorre	ect filling leads to higher heparin-to-blood ratios
2. Syringe:		and the second beauty
а	. Plain (no anticoagulant) or litnium ne	eparin or balanced neparin
	supported in US	of a sample collected without an anticoagulant is not
h	Fill benarin syringes to labeled canac	ity Incorrect filling leads to higher henarin-to-blood ratios
3. Capillary	Tube:	
a	. Balanced heparin or lithium heparin	labeled for electrolyte measurement
	i. Blue CG4+ cartridge: Use	of a capillary sample is not supported
b	. Milking of collection site (finger, hee	I) may cause hemolysis
4. Indwellir	ng line: back flush line 5-6 times the v	plume of catheter, connectors and needle to avoid
contami	contamination	
H. Verify the patient	sample is being handled correctly	
1. Air expo	sure will increase in pH	
2. Mixed w	ell to avoid clotting	the sum to interference of the lift
I. Verify medications	freatments patient is receiving are n	ot known to interfere per Cartridge IFU
Note: Analyzer is suspe	acted only when multiple unexpected	results are generated on a specific serial number compared
to different analyzer(s)	that generate expected results for the	specific patient sample(s).
Resolution		
IF incorrect sample type	e is used for i-STAT cartridge testing	THEN the incident is resolved
		Classification is Complaint 1
		C1066 will be added as supplemental code
IE the sample is collected	ad with an incorrect anticoagulant	THEN the incident is resolved
if the sample is collecte		Classification is Complaint 1
		Classification is complaint 1
IF the sample is not test	ted within the required time after	THEN the suspect cartridge lot(s) should be investigated
collection per APOC lite	rature	Classification is Complaint 2
IF the patient results or	cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated
unknown after due dilig	gence, PQA/TS will determine	Classification is Complaint 2
cartridge lot number via	a internal systems	
IE unoverside estigation	osults are reported and incorrect	THEN the suspect cartridge let(s) should be investigated
ir unexpected patient r	agulant use is ruled out	Classification is Complaint 2
sample type and antico		

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Complaint	Description	
PCO2 Unexpected	Patient's pCO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the	
Patient Results	patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest	
	results	
Answer pRE		
questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint	
DW Carlas C1500	Prompts for Meaningful Data Collection	
RW Code: C1508	Cartridge type and lot number used:	
Suponyms: i STAT	why is the I-STAT result considered to be discrepant/unexpected:	
results - high low	Linexpected Results Table	
discrepant. not		
reliable, different,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):	
cannot trust	Was the patient sample retested on a new i-STAT cartridge?	
	Name of the comparative lab instrument (if applicable):	
	Cartridge storage information:	
	Cartridge handling information:	
	Are cartridges available to be returned for investigation:	
	Controls tested on the i-STAT cartridges and acceptable:	
	Patient sample type used:	
	Collection device (suringe evacuated tube capillary):	
	Type of anticoagulant used in the collection device:	
	Collection device filled to labeled capacity:	
	Sample mixed thoroughly:	
	Sample hemolysis detected:	
	Sample clotting detected:	
	Transfer device used for loading the patient sample to the cartridge:	
	i-STAT Analyzer Serial Number(s):	
	Patient information:	
	Age and gender:	
	Current Diagnosis:	
	Current Medications:	
	Results from other tests/procedures performed:	
	Date and time admitted:	
	Date and time discharged:	
	What was impact to patient?	
	If patient treatment was based on lab results, what was the treatment?	
	Troubleshooting	
	A. Verify reason for considering the i-STAT pCO2 results to be unexpected/different	
	B. Verify if the i-STAT test was repeated	
	C. Collect information for the results table (<u>Appendix F</u>)	
	D. Verify sample type used	
	1. Must be whole blood	
	 If something other than whole blood is used for testing, advised customer of correct sample type and review intended use per Cartridge IEL (add C1056). 	
	review intended use per Cartridge IFU (add <u>CLUBB</u>)	

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E. Verify anticoagulan	t used for sample collection		
F. Verify the patient sa	ample is being tested within 10 mi	nutes of collection if testing anticoagulated samples or	
immediately if testi	ng samples collected without antic	oagulant	
G. Verify that the patie	ent sample is being collected corre	τιγ	
1. EVacuated	a rubes. Plain (no anticoagulant) or lithium	heparin (green top tube)	
	i. Blue CG4+ cartridge: Us	e of a sample collected without an anticoagulant is not	
	supported in US		
b.	Fill tubes to labeled capacity. Und heparin-to-blood ratios	erfilled tubes decrease pCO2. Incorrect filling leads to highe	
2. Syringe:			
a.	Plain (no anticoagulant) or lithium	heparin or balanced heparin	
	i. Blue CG4+ cartridge: Us	e of a sample collected without an anticoagulant is not	
h	Fill henarin syringes to labeled can	pacity Incorrect filling leads to higher henarin-to-blood ratio	
3. Capillarv	Tube:	active mean content mining reads to higher heparin-to-blood ratio	
a.	Balanced heparin or lithium hepar	in labeled for electrolyte measurement	
	i. Blue CG4+ cartridge: Us	e of a capillary sample is not supported	
b.	Milking of collection site (finger, h	eel) may cause hemolysis	
4. Indwelling	4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid		
H Verify the patient s	auon ample is being handled correctly		
1. Air expos	ure will decrease pCO2		
2. Avoid but	bbling with pipet when filling cartri	dge	
3. Mixed we	ell to avoid clotting		
I. Verify medications/	I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU		
Note: Analyzer is suspected to different apply ar() to	cted only when multiple unexpected	ed results are generated on a specific serial number compare	
Resolution	nat generate expected results for t	היב אבנווג אמוואופ(ג).	
IF incorrect sample type	is used for i-STAT cartridge	THEN the incident is resolved	
testing	Ŭ	Classification is Complaint 1	
		C1066 will be added as supplemental code	
IF the sample is collected	d with an incorrect anticoagulant	THEN the incident is resolved	
	C C	Classification is Complaint 1	
IF the sample is not teste	ed within the required time after	THEN the suspect cartridge lot(s) should be investigated	
collection per APOC liter	ature	Classification is Complaint 2	
IF the patient results or o	cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated	
unknown after due dilige	ence, PQA/TS will determine	Classification is Complaint 2	
cartridge lot number via internal systems			
IF unexpected patient re	sults are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated	
sample type and anticoa	gulant use is ruled out	Classification is Complaint 2	

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Complaint	Description
PO2 Unexpected	Patient's pO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the
Patient Results	patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest
	results
Answer pRE	
questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1509	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
cannot trust	Was the patient sample retested on a new i-STAT cartridge?
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
Type of anticoagulant used in the collection device:	
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i STAT Apply for Social Number(s):
	Patient information:
	Age and gender:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT pO2 results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verify cartridge is handled correctly
	 pO2 results will be decreased when testing in cold cartridge.
	E. Verify sample type used
	1. Must be whole blood

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2. If somet review i F. Verify anticoagula	hing other than whole blood is used f ntended use per Cartridge IFU (add <u>C</u> nt used for sample collection	or testing, advised customer of correct sample type and <u>1066</u>)	
G. Verify the patient	sample is being tested within 10 min	utes of collection if testing anticoagulated samples or	
immediately if tes	ting samples collected without antico	agulant	
H. Verify that the pat	ient sample is being collected correct	ly	
1. Evacuat	ed Tubes:		
	i. Plain (no anticoagulant) or lithium i i. Blue CG4+ cartridge: Use supported in US	eparin (green top tube) of a sample collected without an anticoagulant is not	
l t	 Fill tubes to labeled capacity. Incor 	rect filling leads to higher heparin-to-blood ratios	
2. Syringe:			
ā	i. Plain (no anticoagulant) or lithium l	neparin or balanced heparin	
	i. Blue CG4+ cartridge: Use	of a sample collected without an anticoagulant is not	
	supported in US	city Incorrect filling loads to higher henerin to blood ratios	
2 Capillan	y Tube:	city. Incorrect mining leads to higher heparin-to-blood ratios	
S. Capillary	Balanced benarin or lithium benari	a labeled for electrolyte measurement	
	i. Blue CG4+ cartridge: Us	e of a capillary sample is not supported	
l t	b. Milking of collection site (finger, he	el) may cause hemolysis	
4. Indwelli contami	ng line: back flush line 5-6 times the nation	volume of catheter, connectors and needle to avoid	
I. Verify the patient	sample is being handled correctly		
1. Avoid ai	exposure. pO2 values in sample will equilibrate to room air pO2 due to air exposure.		
2. Sample	should not be iced. pO2 values will b	e falsely elevated if iced samples are tested.	
3. Mixed w	ell to avoid clotting		
J. Verify medication	s/treatments patient is receiving are	not known to interfere per Cartridge IFU	
Note: Analyzer is susp to different analyzer(s)	Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number compared to different analyzer(s) that generate expected results for the specific patient sample(s).		
Resolution			
IF incorrect sample typ testing	e is used for i-STAT cartridge	 THEN the incident is resolved Classification is Complaint 1 C1066 will be added as supplemental code 	
IF the sample is collect	ed with an incorrect anticoagulant	 THEN the incident is resolved Classification is Complaint 1 	
IF the sample is not tes collection per APOC lite	ted within the required time after erature	 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 	
IF the patient results or unknown after due dili cartridge lot number vi	r cartridge type/ lot number is still gence, PQA/TS will determine a internal systems	 THEN the cartridge lot(s) should be investigated Classification is Complaint 2 	
IF unexpected patient is sample type and antico	esults are reported and incorrect agulant use is ruled out	 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 	

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Complaint	Description
Hematocrit (Hct)	Patient's hematocrit (Hct) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT
Patient Results	retest results
	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
Answer pRE	Prompts for Meaningful Data Collection
questions!	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
RW Code: C1511	
Current CTAT	Unexpected Results Table
Synonyms: I-STAT	
levu dicerenant	All results from I-STAT cartridge (can request a results printout or picture of the I-STAT results):
not raliable	was the patient sample retested on a new I-STAT cartridge?
different cannot	Hemoglobin (HD) result:
trust	I-STAT Critical cut-off values for HCt and HD:
11451	Name of the comparative lab instrument (if applicable):
	Critical cut-off values for Hct and Hb for comparative instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly (review sample mixing procedure from Cartridge IFU):
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	I-STAT Analyzer Serial Number(S):
	CDD a maline for testing in i STAT Analyzer (we are a)
	CPB applied for testing in FSTAT Analyzer (yes of ho).
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	Is patient actively bleeding?
	Was blood transfused:
	Type of blood transfused and amount (if applicable):
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting

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A. Verify reason for considering the i-STAT Hematocrit result	ts to be unexpected/different	
B. Verify if the i-STAT test was repeated		
C. Collect information for the results table (<u>Appendix F</u>)		
D. Verify sample type used		
1. Must be whole blood		
2. If something other than whole blood is used for	testing, advised customer of correct sample type and review	
intended use per Cartridge IFU (add C1066)		
E. Verify anticoagulant used for sample collection		
F. Verify the patient sample is being tested within 30 minute	es of collection if testing anticoagulated samples or	
immediately if testing samples collected without anticoag	ulant	
G. Verify that the patient sample is being collected correctly		
1. Evacuated Tubes:		
a. Plain (no anticoagulant) or lithium her	parin (green top tube)	
i. CHEM8+ cartridge: Use of a	a sample collected without an anticoagulant is not	
supported in US		
b. Fill tubes to labeled capacity. Incorrec	ct filling leads to higher heparin-to-blood ratios	
2. Syringe:		
a. Plain (no anticoagulant) or lithium her	parin or balanced heparin	
i. CHEM8+ cartridge: Use of a	a sample collected without an anticoagulant is not	
supported in US		
 Fill heparin syringes to labeled capacit 	ty. Incorrect filling leads to higher heparin-to-blood ratios	
3. Capillary Tube:		
a. Balanced heparin or lithium heparin la	abeled for electrolyte measurement	
i. CHEM8+ cartridge: Use of a	a capillary sample is not supported	
 b. Milking of collection site (finger, heel) 	may cause hemolysis	
Indwelling line: back flush line 5-6 times the vol	lume of catheter, connectors and needle to avoid	
contamination		
H. Verify the patient sample is being handled correctly		
 Mixed well as instructed in Cartridge IFU 		
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU		
Note: Analyzer is suspected only when multiple unexpected re	esults are generated on a specific serial number compared to	
different analyzer(s) that generate expected results for the spe	ecific patient sample(s).	
Resolution		
IF incorrect sample type is used for i-STAT cartridge testing	THEN the incident is resolved	
	Classification is Complaint 1	
	<u>C1066</u> will be added as supplemental code	
IF the sample is collected with an incorrect anticoagulant	THEN the incident is resolved	
	Classification is Complaint 1	
IF the sample is not tested within the required time after	THEN the suspect cartridge lot(s) should be investigated	
collection per APOC literature	Classification is Complaint 2	
IF the patient results or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated	
unknown after due diligence, PQA/TS will determine	Classification is Complaint 2	
cartridge lot number via internal systems		
IF unexpected patient results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated	
sample type and anticoagulant use is ruled out	Classification is Complaint 2	
sample type and anticougaiant use is fuice out		

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Complaint	Description
Hemoglobin (Hb)	Patient's hemoglobin (Hb) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT
Patient Results	retest results
	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
Answer pRE	Prompts for Meaningful Data Collection
questions!	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
RW Code: C1512	
	Unexpected Results Table
Synonyms: I-STAT	
results - nign,	All results from I-STAT cartridge (can request a results printout or picture of the I-STAT results):
low, discrepant,	Was the patient sample retested on a new I-STAT cartridge?
not reliable, different connet	Hematocrit (Hct) result:
trust	I-STAT Critical cut-off values for Hct and Hb:
liust	Name of the comparative lab instrument (if applicable):
	Critical cut off values for Het and Hb for comparative instrument (if applicable):
	Critical cut-on values for fict and fib for comparative instrument (if applicable).
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly (review sample mixing procedure from Cartridge IFU):
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	I-STAT Analyzer Serial Number(s):
	EDTA (K2/K3) calibration customization setting on analyzer:
	CPB applied for testing in I-STAT Analyzer (yes or no):
	Patient information:
	Age and gender:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	Is patient actively bleeding?
	Was blood transfused:
	Type of blood transfused and amount (if applicable):
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting

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A. Verify reason for considering the i-STAT Hemoglobin results to be unexpected/different			
B. Verify if the i-STAT test was repeated			
C. Collect information for the results table (<u>Appendix F</u>)			
D. Verify sample type used	D. Verify sample type used		
1. Must be whole blood			
2. If something other than whole blood is used for	testing, advised customer of correct sample type and review		
intended use per Cartridge IFU (add C1066)			
E. Verify anticoagulant used for sample collection			
F. Verify the patient sample is being tested within 30 minute	es of collection if testing anticoagulated samples or		
immediately if testing samples collected without anticoag	ulant		
G. Verify that the patient sample is being collected correctly			
1. Evacuated Tubes:			
a. Plain (no anticoagulant) or lithium her	parin (green top tube)		
i. CHEM8+ cartridge: Use of a	a sample collected without an anticoagulant is not		
supported in US	······································		
b. Fill tubes to labeled capacity. Incorrec	ct filling leads to higher heparin-to-blood ratios		
2. Svringe:			
a. Plain (no anticoagulant) or lithium her	parin or balanced heparin		
i. CHEM8+ cartridge: Use of a	a sample collected without an anticoagulant is not		
supported in US	······································		
h Fill benarin syringes to labeled canacity. Incorrect filling leads to higher benarin-to-blood ratios			
3. Capillary Tube:			
a. Balanced heparin or lithium heparin la	abeled for electrolyte measurement		
i. CHEM8+ cartridge: Use of a	a capillary sample is not supported		
b. Milking of collection site (finger, heel)	may cause hemolysis		
4. Indwelling line: back flush line 5-6 times the vol	lume of catheter, connectors and needle to avoid		
contamination	· · · · · · · · · · · · · · · · · · ·		
H. Verify the patient sample is being handled correctly			
1. Mixed well as instructed in Cartridge IFU			
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU			
Note: Analyzer is suspected only when multiple unexpected re	esults are generated on a specific serial number compared to		
different analyzer(s) that generate expected results for the spe	ecific patient sample(s).		
Resolution			
IF incorrect sample type is used for i-STAT cartridge testing	THEN the incident is resolved		
······································	Classification is Complaint 1		
	C1066 will be added as supplemental code		
IF the sample is collected with an incorrect anticoagulant	THEN the incident is resolved		
i the sample is concered with an incorrect anticougaiant	Classification is Complaint 1		
IF the second is not tooted within the required time of too	THEN the suggest eastridge lat(a) should be investigated		
IF the sample is not tested within the required time after	THEN the suspect cartridge lot(s) should be investigated		
collection per APOC literature	Classification is Complaint 2		
IF the patient results or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated		
unknown after due diligence, PQA/TS will determine	Classification is Complaint 2		
cartridge lot number via internal systems			
IF unexpected patient results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated		
sample type and anticoagulant use is ruled out	Classification is Complaint 2		

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Complaint	Description
TCO2 Unexpected	Patient's TCO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the
Patient Results	patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest
	results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1513	Why is the i-STAT result considered to be discrepant/unexpected:
Suponume: i STAT	Uncomported Deputte Table
results - high low	Onexpected Results Table
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results).
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	······································
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the I-STAT cartridges and acceptable:
	Patient cample type used:
	How is sample collected?
	Collection device (svringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Datiant information:
	Age and gender:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT ICO2 results to be unexpected/different
	B. Verify if the I-STAT test was repeated
	D Verify sample type used
	1. Must be whole blood
	 If something other than whole blood is used for testing, advised customer of correct sample type and
	review intended use per Cartridge IFU (add C1066)
	E. Verify anticoagulant used for sample collection

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F. Verify the patient sample is being tested within 10 minutes of collection if testing anticoagulated samples or
immediately if testing samples collected without anticoagulant
G. Verify that the patient sample is being collected correctly
1. Evacuated lubes:
a. Plain (no anticoagulant) or lithium neparin (green top tube)
I. CHEINIO+ CATTRIDGE: USE OF a sample collected without an anticoaguiant is not supported in LIS
ii Blue CG4+ cartridge: Lise of a sample collected without an anticoagulant is not
supported in US
b. Fill tubes to labeled capacity. Underfilled tubes decrease TCO2. Incorrect filling leads to higher
heparin-to-blood ratios
2. Syringe:
a. Plain (no anticoagulant) or lithium heparin or balanced heparin
i. CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not
supported in US
II. Blue CG4+ cartridge: Use of a sample collected without an anticoagulant is not
supported in US Eill benarin suringes to labeled canacity. Incorrect filling loads to higher benarin to blood ratios
3 Canillary Tube:
a. Balanced heparin or lithium heparin labeled for electrolyte measurement
i. CHEM8+ cartridge: Use of a capillary sample is not supported
ii. Blue CG4+ cartridge: Use of a capillary sample is not supported
b. Milking of collection site (finger, heel) may cause hemolysis
4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid
contamination
H. Verify the patient sample is being handled correctly
1. Air exposure will decrease TCO2
2. Avoid bubbling with pipet when ming cartridge
 While well to avoid clothing Verify medications/treatments patient is receiving are not known to interfere per Cartridge IEU
Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number compared
to different analyzer(s) that generate expected results for the specific patient sample(s).
Resolution
IF incorrect sample type is used for i-STAT cartridge THEN the incident is resolved
testing • Classification is Complaint 1
<u>C1066</u> will be added as supplemental code
IF the sample is collected with an incorrect anticoagulant
Classification is complaint 1 If the sample is not tested within the required time after THEN the suspect carteridge lat(e) should be investigated
collection per APOC literature
IF the national results or cartridge type/ lot number is still THEN the cartridge lot(s) should be investigated
unknown after due diligence. POA/TS will determine • Classification is Complaint 2
cartridge lot number via internal systems
IF unexpected patient results are reported and incorrect THEN the suspect cartridge lot(s) should be investigated
sample type and anticoagulant use is ruled out • Classification is Complaint 2

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Complaint	Description
Anion Gap (AG.	Patient's Anion Gap (AG) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
AnGan)	match the national network of the provided and the second se
Unexpected	STAT retest results
Patient Results	
i dicite neodito	Anion Gan is available with CHEM8+ and EC8+ cartridges
Answer nRF	
auestions	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions:	Promets for Meaningful Data Collection
BW Code: C1514	Cartridge type and let number used:
KW COUE. CIJI4	Callinge type and for number used.
Suponyms: i-STAT	why is the FSTAT result considered to be discrepant/unexpected.
recults high low	Unoversided Docults Table
discrepant not	
rolighto different	
renuble, uijjerent,	All results from I-STAT cartridge (can request a results printout or picture of the I-STAT results):
cunnot trust	Was the patient sample refested on a new I-STAT cartridge?
	Name of the comparative lab instrument (if applicable):
	What calculation is used on comparative instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the CTAT contridees and essentially.
	Controls tested on the I-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the natient sample to the cartridge.
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT Anion Gap results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (Appendix F)
	D. Verify sample type used
	Lot verify sumple type used

Abbott Point of Care DOCUMENT NUMBER REF-1151 DOCUMENT REVISION C REF-1151 C IFSTAT Support Guide PAGE 27-jan-2021 231 of 363 I-STAT Support Guide 1. Must be whole blood 231 of 363 I-STAT Support Guide 1. Must be whole blood 231 of 363 I-STAT Support Guide 2. If something other than whole blood is used for testing, advised customer of correct sample type and review intended use per Carridge IFU (add £1065) 2. I	Abbott Point of Care DOCUMENT NUME REF-1151 EFFECTIVE DATE 27-Jan-2021	ER DOCUMENT REVISION C PAGE 231 of 363
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testing• Classification is Complaint 1 C1066 will be added as supplemental codeIF the sample is collected with an incorrect anticoagulantTHEN the incident is resolved • Classification is Complaint 1IF the sample is not tested within the required time after collection per APOC literatureTHEN the suspect cartridge lot(s) should be investigated • Classification is Complaint 2IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determineTHEN the cartridge lot(s) should be investigated • Classification is Complaint 2	IF incorrect sample type is used for i-STAT cartridge	THEN the incident is resolved
IF the sample is collected with an incorrect anticoagulant THEN the incident is resolved IF the sample is not tested within the required time after collection per APOC literature THEN the suspect cartridge lot(s) should be investigated IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine THEN the cartridge lot(s) should be investigated	testing	Classification is Complaint 1
IF the sample is collected with an incorrect anticoagulant THEN the incident is resolved IF the sample is not tested within the required time after collection per APOC literature THEN the suspect cartridge lot(s) should be investigated IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine THEN the cartridge lot(s) should be investigated		C1066 will be added as supplemental code
IF the sample is collected with an incorrect anticoagulant IF the incident is resolved IF the sample is not tested within the required time after collection per APOC literature THEN the suspect cartridge lot(s) should be investigated IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine THEN the cartridge lot(s) should be investigated	IF the complete collected with an incorrect entire endert	TUEN the incident is received
 Classification is Complaint 1 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine Classification is Complaint 1 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 	IF the sample is collected with an incorrect anticoagulant	THEN the incident is resolved
IF the sample is not tested within the required time after collection per APOC literatureTHEN the suspect cartridge lot(s) should be investigated • Classification is Complaint 2IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determineTHEN the cartridge lot(s) should be investigated • Classification is Complaint 2		Classification is Complaint 1
collection per APOC literature • Classification is Complaint 2 IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine • Classification is Complaint 2	IF the sample is not tested within the required time after	THEN the suspect cartridge lot(s) should be investigated
IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine • Classification is Complaint 2	collection per APOC literature	Classification is Complaint 2
IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine • Classification is Complaint 2		
unknown after due diligence, PQA/TS will determine • Classification is Complaint 2	IF the patient results or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated
	unknown after due diligence, PQA/TS will determine	Classification is Complaint 2
cartridge lot number via internal systems	cartridge lot number via internal systems	
IF unexpected patient results are reported and incorrect THEN the suspect cartridge lot(s) should be investigated	IF unexpected patient results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated
in an expected participation are reported and monitorical interaction subject carried by should be investigated	sample type and anticoagulant use is ruled out	Classification is Complaint 2

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Complaint	Description
Base Excess (BE)	Patient's Base Excess (BE) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected Patient	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Results	STAT retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1515	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	
	Name of the comparative lab instrument (if applicable):
	What calculation was used on comparative instrument (if applicable):
	Cortridge storage information:
	Cartridge storage information:
	Cartridge nationing information.
	Ale califinges available to be returned for investigation.
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Base Excess (BEecf or BEh) customization setting on analyzer:
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation):
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verity reason for considering the i-STAT Base Excess results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verity sample type used
	1. Must be whole blood

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E. Verif F. Verif imm G. Verif	 If something other than whole blood is us review intended use per Cartridge IFU (ad y anticoagulant used for sample collection by the patient sample is being tested within 10 rediately if testing samples collected without an y that the patient sample is being collected cor Evacuated Tubes: a. Plain (no anticoagulant) or lithin b. Fill tubes to labeled capacity. Ir Syringe: a. Plain (no anticoagulant) or lithin i. Blue CG4+ cartridge: supported in US b. Fill tubes to labeled capacity. Ir Syringe:	 ised for testing, advised customer of correct sample type and idd <u>C1066</u>) iminutes of collection if testing anticoagulated samples or inticoagulant orrectly ium heparin (green top tube) : Use of a sample collected without an anticoagulant is not Incorrect filling leads to higher heparin-to-blood ratios ium heparin or balanced heparin : Use of a sample collected without an anticoagulant is not 	nd nt nt i ratios
H. Verif I. Verif Note: An	 a. Balanced heparin or lithium heparin labeled for electrolyte measurement Blue CG4+ cartridge: Use of a capillary sample is not supported Milking of collection site (finger, heel) may cause hemolysis 4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid contamination H. Verify the patient sample is being handled correctly Mixed well to avoid clotting 1. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU 		npared
to differe	nt analyzer(s) that generate expected results for	for the specific patient sample(s).	iparcu
Resolutio	n		
IF incorre testing	ct sample type is used for i-STAT cartridge	 THEN the incident is resolved Classification is Complaint 1 C1066 will be added as supplemental code 	
IF the san	nple is collected with an incorrect anticoagulan	nt THEN the incident is resolved • Classification is Complaint 1	
IF the san collection	nple is not tested within the required time after per APOC literature	er THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 	ated
IF the pat unknown cartridge	ient results or cartridge type/ lot number is stil after due diligence, PQA/TS will determine lot number via internal systems	ill THEN the cartridge lot(s) should be investigated • Classification is Complaint 2	
IF unexpe sample ty	ected patient results are reported and incorrect ope and anticoagulant use is ruled out	THEN the suspect cartridge lot(s) should be investigated • Classification is Complaint 2	ated

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Complaint	Description
sO2 Unexpected	Patient's sO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the
Patient Results	patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest
	results
Answer pRE	
questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1516	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
cannot trust	Was the patient sample retested on a new i-STAT cartridge?
	Name of the comparative lab instrument (if applicable):
	Contridge storege information
	Cartridge bandling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and accentable.
	Patient sample type used):
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation):
	Current ineulations.
	Results from other tests/procedures performed.
	Date and time discharged:
	What was impact to patient?
	If nations treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT sO2 results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (Appendix F)
	D. Verify sample type used
	1. Must be whole blood
	2. If something other than whole blood is used for testing, advised customer of correct sample type and
	review intended use per Cartridge IFU (add <u>C1066</u>)

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E Verify anticoagula	nt used for sample collection		
F. Verify the patient	sample is being tested within 10 min	utes of collection if testing anticoagulated samples or	
immediately if tes	ting samples collected without antico	agulant	
G. Verify that the pat	ient sample is being collected correct	tly	
1. Evacuat	ed Tubes:	,	
a	. Plain (no anticoagulant) or lithium ł	neparin (green top tube)	
	i. Blue CG4+ cartridge: Use	of a sample collected without an anticoagulant is not	
	supported in US		
l t	 Fill tubes to labeled capacity. Incor 	rect filling leads to higher heparin-to-blood ratios	
2. Syringe:			
a a a a a a a a a a a a a a a a a a a	n. Plain (no anticoagulant) or lithium l	neparin or balanced heparin	
	i. Blue CG4+ cartridge: Use of a sample collected without an anticoagulant is not		
	supported in US		
	 Fill heparin syringes to labeled capa 	icity. Incorrect filling leads to higher heparin-to-blood rat	.10S
3. Capillary	/ TUDE: Palancod honorin or lithium honori	a labeled for electrolyte measurement	
c	i. Blue CG4+ cartridge: Lise	of a capillary sample is not supported	
	Milking of collection site (finger be	el) may cause hemolysis	
4 Indwelli	ng line: back flush line 5-6 times the	volume of catheter, connectors and needle to avoid	
contami	nation sample is being handled correctly ell to avoid clotting		
H. Verify the patient			
1. Mixed w			
I. Verify medication	s/treatments patient is receiving are	atments patient is receiving are not known to interfere per Cartridge IFU	
Note: Analyzer is susp	ected only when multiple unexpected	I results are generated on a specific serial number compa	red
to different analyzer(s)	that generate expected results for th	e specific patient sample(s).	
Resolution			
IF incorrect sample typ	e is used for i-STAT cartridge	THEN the incident is resolved	
testing		Classification is Complaint 1	
		<u>C1066</u> will be added as supplemental code	
IF the sample is collect	ed with an incorrect anticoagulant	THEN the incident is resolved	
		 Classification is Complaint 1 	
	and the second state of the		-1
IF the sample is not tes	ted within the required time after	THEN the suspect cartridge lot(s) should be investigated	Ľ
collection per APOC life	erature	Classification is complaint 2	
IF the patient results of	r cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated	
unknown after due dili	gence, PQA/TS will determine	 Classification is Complaint 2 	
cartridge lot number vi	a internal systems		
IF unexpected patients	results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated	d
sample type and antico	agulant use is ruled out	Classification is Complaint 2	-
sumple type and antice			

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Complaint	Description
HCO3 (Bicarbonate)	Patient's bicarbonate (HCO3) results from the i-STAT system are not what the customer was expecting. i-STAT results
Unexpected Patient	do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT
Results	results or i-STAT retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1517	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the I-STAT cartridges and acceptable:
	Datient completion used
	Patient sample type used:
	Collection device (swinge, everywated tube, capillary):
	Turne of anticeagulant used in the collection device:
	Collection device filled to labolad capacity:
	Sample mixed theroughly:
	Sample hemolysis detected
	Sample flotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verity reason for considering the i-STAT Bicarbonate (HCO3) results to be unexpected/different
	B. Verity if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verity sample type used
	1. Must be whole blood
	2. It something other than whole blood is used for testing, advised customer of correct sample type and
	review intended use per Cartridge IFU (add <u>C1066</u>)

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E. Verify anticoagula	nt used for sample collection		
F. Verify the patient	sample is being tested within 10 min	nutes of collection if t	esting anticoagulated samples or
immediately if tes	ting samples collected without antic	oagulant	
G. Verify that the part	tient sample is being collected corre-	ctly	
I. Evacuat	ed Tubes: Plain (no anticoagulant) or lithium	henarin (green ton tu	ube)
	i. Blue CG4+ cartridge: Us	e of a sample collect	ed without an anticoagulant is not
	supported in US		
t	p. Fill tubes to labeled capacity. Und	erfilled tubes decreas	e HCO3. Incorrect filling leads to
	higher heparin-to-blood ratios		-
2. Syringe:			
a	a. Plain (no anticoagulant) or lithium	heparin or balanced	heparin
	I. Blue CG4+ cartridge: Us	e of a sample collect	ed without an anticoagulant is not
	Supported in US Fill benarin syringes to labeled can	acity Incorrect filling	t leads to higher henarin-to-blood ratios
3. Capillary	/ Tube:		
	a. Balanced heparin or lithium hepar	in labeled for electrol	yte measurement
	i. Blue CG4+ cartridge: Us	e of a capillary samp	, le is not supported
t t	 Milking of collection site (finger, h 	eel) may cause hemol	lysis
4. Indwelli	ng line: back flush line 5-6 times the	volume of catheter,	connectors and needle to avoid
contami	nation		
H. Verify the patient	sample is being handled correctly	s being handled correctly decrease HCO3 vith pipet when filling cartridge	
2. Avoid bu	ubbling with pipet when filling cartri		
3. Mixed w	vell to avoid clotting s/treatments patient is receiving are not known to interfere per Cartridge IFU		
I. Verify medication			
Note: Analyzer is susp	ected only when multiple unexpecte	d results are generate	ed on a specific serial number
compared to different	analyzer(s) that generate expected r	esults for the specific	patient sample(s).
IF incorrect sample typ	e is used for i-STAT cartridge	THEN the incident is	resolved
testing	e is ascarior i strat cartiluge	Classificat	ion is Complaint 1
county		C1066 will be added	l as supplemental code
IE the completic collect	ed with an incorrect anticoagulant	THEN the incident is	resolved
ir the sample is collect	ea with an incorrect anticoaguiant		ion is Complaint 1
IF the sample is not tes	ted within the required time after	THEN the suspect ca	artridge lot(s) should be investigated
collection per APOC lite	erature	 Classificat 	ion is Complaint 2
IF the patient results o	r cartridge type/ lot number is still	THEN the cartridge	lot(s) should be investigated
unknown after due dili	gence, PQA/TS will determine	Classificat	ion is Complaint 2
cartridge lot number vi	a internal systems		
IF unexpected patient	results are reported and incorrect	THEN the suspect ca	artridge lot(s) should be investigated
sample type and antico	agulant use is ruled out	Classificat	ion is Complaint 2
	3	0.000.1001	

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Complaint	Description
Creatinine (Crea)	Patient's creatinine (crea) results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected Patient	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Results	STAT retest results
Answer nRF	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
auestions!	Prompts for Meaningful Data Collection
4	Cartridge type and lot number used:
RW Code: C1518	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	·····
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Is patient taking hydroxyurea?
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verity reason for considering the i-STAT Creatinine results to be unexpected/different
	B. Verity if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verity sample type used
	1. Must be whole blood

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2. If some	thing other than whole blood is used	I for testing, advised customer of correct sample type and	
E Verify anticeagul	Intended use per Cartridge IFO (add)	<u>(1066</u>)	
E. Verify difficulture	and used for sample collection	nutes of collection if testing anticoagulated samples or	
immediately if te	sting samples collected without antic	nates of conection in testing anticoagulated samples of	
G Verify that the na	tient sample is being collected corre	ctly	
1 Evacuat	ted Tubes:		
1. 20000	a Plain (no anticoagulant) or lithium	henarin (green ton tube)	
	i. CHEM8+ cartridge: Use	of a sample collected without an anticoagulant is not	
	supported in US		
	b. Fill tubes to labeled capacity. Inco	prrect filling leads to higher heparin-to-blood ratios	
2. Syringe	: , ,		
	a. Plain (no anticoagulant) or lithium	heparin or balanced heparin	
	i. CHEM8+ cartridge: Use	of a sample collected without an anticoagulant is not	
	supported in US		
	b. Fill heparin syringes to labeled cap	pacity. Incorrect filling leads to higher heparin-to-blood ratios	
3. Capillar	y Tube:		
	a. Balanced heparin or lithium hepar	in labeled for electrolyte measurement	
	i. CHEM8+ cartridge: Use	e of a capillary sample is not supported	
	b. Milking of collection site (finger, h	 Milking of collection site (finger, heel) may cause hemolysis 	
4. Indwell	ing line: back flush line 5-6 times the	e volume of catheter, connectors and needle to avoid	
contam	ination		
H. Verify the patient	sample is being handled correctly		
1. Mixed V	ell to avoid clotting (mantenantication in a static second biogeneration interference of Castellary 1511 (hadronymeneration)		
I. verify medication	is/treatments patient is receiving are	e not known to interfere per Cartridge IFU (hydroxyurea will	
Medication note: Hyd	droxyurea is generic name and may h	e known by trade names (i.e. Drovia, Hydrea, etc.)	
Wedication note. The	aroxyurea is generic name and may c	e known by trade names (i.e. brokia, nydrea, etc.)	
Note: Analyzer is susr	pected only when multiple unexpected	ed results are generated on a specific serial number compared	
to different analyzer(s) that generate expected results for t	the specific patient sample(s).	
Resolution	,		
IF incorrect sample type	pe is used for i-STAT cartridge	THEN the incident is resolved	
testing		Classification is Complaint 1	
		<u>C1066</u> will be added as supplemental code	
IF the sample is collect	ted with an incorrect anticoagulant	THEN the incident is resolved	
		Classification is Complaint 1	
IF the sample is not te	sted within the required time after	THEN the suspect cartridge lot(s) should be investigated	
collection per APOC lit	erature	Classification is Complaint 2	
IF the patient is taking	Hydroxyurea with Crea	THEN the incident is resolved	
unexpected patient re	sults	Classification is Complaint 1	
IF the patient results of	or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated	
unknown after due dil	igence, PQA/IS will determine	Classification is Complaint 2	
cartridge lot number v	na internal systems		
IF unexpected patient	results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated	
sample type and antic	oagulant use is ruled out	Classification is Complaint 2	
	0		

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Complaint	Description
ACT Celite (ACT C)	Patient's ACT Celite results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected Patient	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Results	STAT retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1519	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
discrepant, not	Was the patient sample retested on a new i-STAT cartridge?
reliable, different,	Baseline ACT result for the patient:
cannot trust	Was Heparin administered to the patient?
	The procedure being performed on the patient (if applicable):
	Heparin administration Dosage:
	Heparin administration (Date and Time):
	Heparin vendor and lot number:
	Heparin source:
	Upperin reversel agent used (if applicable).
	Heparin reversal agent used (if applicable):
	Repartir reversal agent automistration, date and time (if applicable).
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Was patient on Low Molecular Weight Heparin (LMWH):
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:

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What was impact to patient? If patient treatment was based on lab results, what was the treatment? Troubleshooting A. Verify reason for considering the i-STAT ACT results to be unexpected/different B. Verify if the i-STAT test was repeated C. Collect information for the results table (Appendix F) D. Verify intended use of the cartridge 1. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants 2. If testing cartridge for any other reason, advise customer of intended use and review per CTI sheet (add C1066) E. Verify sample type used (whole blood) F. Verify no anticoagulant was used for sample collection G. Verify the patient sample is being tested immediately after collection H. Verify that the patient sample is being collected correctly 1. Evacuated Tubes: a. Plain (no anticoagulant) b. Must be plastic (glass activates clotting) 2. Syringe: a. Plain (no anticoagulant) b. Must be plastic (glass activates clotting) 3. Capillary Tube: not recommended Indwelling line: flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes of the 4. catheter should be discarded Verify the patient sample is being handled correctly I. 1. Transfer devices must be plastic and free of anticoagulant J. Verify test limitations per CTI sheet Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number compared to different analyzer(s) that generate expected results for the specific patient sample(s). Resolution **IF** incorrect sample type is used for i-STAT cartridge testing THEN the incident is resolved Classification is Complaint 1 C1066 will be added as supplemental code THEN the incident is resolved **IF** the sample is collected with an incorrect anticoagulant Classification is **Complaint 1** ٠ IF the sample is not tested within the required time after THEN the suspect cartridge lot(s) should be investigated collection per APOC literature Classification is Complaint 2 IF patient is not receiving heparin for ACT unexpected **THEN** the suspect cartridge lot(s) should be investigated patient results Classification is Complaint 2 <u>C1066</u> will be added as supplemental code IF the patient results or cartridge type/ lot number is still **THEN** the cartridge lot(s) should be investigated unknown after due diligence, PQA/TS will determine Classification is Complaint 2 cartridge lot number via internal systems IF unexpected patient results are reported and incorrect **THEN** the suspect cartridge lot(s) should be investigated sample type and anticoagulant use is ruled out Classification is Complaint 2

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Complaint	Description
ACT Kaolin (ACT K)	Patient's ACT Kaolin results from the i-STAT system are not what the customer was expecting. i-STAT results do not
Unexpected Patient	match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-
Results	STAT retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1521	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
results - high, low,	
aiscrepant, not	Was the patient sample retested on a new i-STAT cartridge?
reliable, alfferent,	Baseline ACT result for the patient:
	Was Heparin administered to the patient?
	The procedure being performed on the patient (if applicable):
	Heparin administration Dosage:
	Heparin administration (Date and Time):
	Heparin vendor and fot humber.
	nepann source.
	Heparin reversal agent used (if applicable):
	Heparin reversal agent administration, date and time (if applicable):
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Define the second state of
	Patient sample collected?
	Flow is sample collected:
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled canacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	was patient on Low Molecular Weight Heparin (LMWH):
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:

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	What was impact to patient?	
If patient treatment was based on lab results, what was the treatment?		e treatment?
	Troubleshooting	
	A. Verify reason for considering the i-STAT ACT results to	be unexpected/different
	B. Verify if the i-STAT test was repeated	
	C. Collect information for the results table (<u>Appendix F</u>)	
	D. Verify intended use of the cartridge	may or other anticeagulants
	I. I-STAT ACT test monitors neparin, not anglo Jf testing cartridge for any other reason, adv	rice sustement of intended use and review per CTI sheet (add
	<u>C1066</u>)	ise customer of intended use and review per chisneet (add
	E. Verify sample type used (whole blood)	
	F. Verify no anticoagulant was used for sample collection	1 often collection Verify that the notions complete being
	collected correctly	after collection verify that the patient sample is being
	1. Evacuated Tubes:	
	a. Plain (no anticoagulant)	
	b. Must be plastic (glass activates clo	otting)
	2. Syringe:	
	a. Plain (no anticoaguiant)	stting)
	D. Must be plastic (glass activates cio	itting)
	4 Indwelling line: flushed with 5 mL of saline :	and the first 5 mL of blood or six dead space volumes of the
	catheter should be discarded	and the mat sine of blood of six dead space volumes of the
	H. Verify the patient sample is being handled correctly	
	1. Transfer devices must be plastic and free of	anticoagulant
	I. Verify test limitations per CTI sheet	C C C C C C C C C C C C C C C C C C C
	Note: Analyzer is suspected only when multiple unexpected	ed results are generated on a specific serial number compared
	to different analyzer(s) that generate expected results for t	he specific patient sample(s).
	Resolution	
	IF incorrect sample type is used for i-STAT cartridge	THEN the incident is resolved
	testing	Classification is Complaint 1
		<u>C1066</u> will be added as supplemental code
	IF the sample is collected with an incorrect anticoagulant	THEN the incident is resolved
		Classification is Complaint 1
	IF the sample is not tested within the required time after	THEN the suspect cartridge lot(s) should be investigated
	collection per APOC literature	Classification is Complaint 2
	IF patient is not receiving heparin for ACT unexpected	THEN the suspect cartridge lot(s) should be investigated
	patient results	Classification is Complaint 2
		C1066 will be added as supplemental code
	IF the patient results or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated
	unknown after due diligence, PQA/TS will determine	Classification is Complaint 2
	cartridge lot number via internal systems	
	IF unexpected patient results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated
	sample type and anticoagulant use is ruled out	Classification is Complaint 2
		•

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Complaint	Description
Lactate (Lac)	Patient's lactate results from the i-STAT system are not what the customer was expecting. i-STAT results do not match
Unexpected Patient	the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT
Results	retest results
Answer pRE	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
questions!	Prompts for Meaningful Data Collection
	Cartridge type and lot number used:
RW Code: C1520	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	Unexpected Results Table
rsults - high, low,	
discrepant, not	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	
	Name of the comparative lab instrument (if applicable):
	Cartridge storage information:
	Cartridge nandling information: Are cartridges available to be returned for investigation:
	Ale califinges available to be returned for investigation.
	Controls tested on the i-STAT cartridges and accentable:
	Patient sample type used:
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Current Medications:
	Results from other tests (procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to nation?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT Lactate results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)
	D. Verify sample type used
	1. Must be whole blood
	2. If something other than whole blood is used for testing, advise customer of correct sample type and
	review intended use per Cartridge IFU (add <u>C1066</u>)

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E Verify anticoagula	ant used for sample collection	
E. Verify anticodgue	sample is being tested immediately	after collection (delayed testing will cause elevated lactate
results)		
G. Verify that the pa	itient sample is being collected correc	tlv
1. Evacuat	ted Tubes:	,
	a. Plain (no anticoagulant) or lithium	heparin (green top tube)
	i. Blue CG4+ cartridge: Us	e of a sample collected without an anticoagulant is not
	supported in US	
	b. Fill tubes to labeled capacity. Inco	rrect filling leads to higher heparin-to-blood ratios
2. Syringe	:	
	a. Plain (no anticoagulant) or lithium	heparin or balanced heparin
	i. Blue CG4+ cartridge: Use	e of a sample collected without an anticoagulant is not
	supported in US	· · · · · · · · · · · · · · · · · · ·
	b. Fill heparin syringes to labeled capa	acity. Incorrect filling leads to higher heparin-to-blood ratios
3. Capillar	y lube:	n lakalad fan alastuskuta maaanunamant
	a. Balanced neparin or litnium nepari	n labeled for electrolyte measurement
	i. Blue CG4+ cartridge: Use of a capillary sample is not supported	
4 Indwell	ing line: back flush line 5-6 times the	volume of catheter, connectors and needle to avoid
	ination	volume of eatherer, connectors and needle to avoid
H. Verify the patient	sample is being handled correctly	
1. Mixed v	well to avoid clotting	
I. Verify medication	ns/treatments patient is receiving are	not known to interfere per Cartridge IFU
	, , , , , , , , , , , , , , , , , , , ,	
Note: Analyzer is susp	pected only when multiple unexpected	d results are generated on a specific serial number compared
to different analyzer(s)) that generate expected results for the second s	ne specific patient sample(s).
Resolution		
IF incorrect sample typ	be is used for i-STAT cartridge	THEN the incident is resolved
testing		Classification is Complaint 1
		C1066 will be added as supplemental code
IF the sample is collect	ted with an incorrect anticoagulant	THEN the incident is resolved
		Classification is Complaint 1
IF the sample is not to	sted within the required time after	THEN the suspect cartridge lot(s) should be investigated
collection per APOC lit	rerature	Classification is Complaint 2
IF the patient results o	or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated
unknown after due dill	igence, PQA/IS WIII determine	Classification is Complaint 2
cartridge lot number v		
IF unexpected patient	results are reported and incorrect	THEN the suspect cartridge lot(s) should be investigated
sample type and antico	oagulant use is ruled out	 Classification is Complaint 2

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Complaint	Description
Troponin (cTnl)	Patient's cardiac troponin I (cTnI) results from the i-STAT system are not what the customer was expecting. i-STAT
Unexpected Patient	results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-
Results	STAT results or i-STAT retest results
Answer pRE questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1522	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	Positive cut-off value for i-STAT Troponin test:
	Name of the comparative lab instrument (if applicable):
	Troponin type (i.e. cTnT, high sensitive) being tested (if applicable):
	Positive cut-off value for comparative instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used (WB/Plasma):
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information (very important):
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	Results of Catheterization:
	Results of EKG:
	Final Patient Diagnosis:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT Troponin I (cTnI) results to be unexpected/different
	B. Verify if the i-STAT test was repeated

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	C. Verify comparat	ive instrument troponin (cTnT, high s	sensitivity cTnl or	high sensitivity cTnT) being tested (if
	applicable)			
	Note: The	results of different troponin assays a	re not generally c	omparable: cTnI and cTnT are distinct
	molecules a	ind results are not interchangeable,	nor comparable. I	n addition, significant variation in absolute
	troponin va	lues may be observed for a given pa	tient specimen wi	th different analytic methods.
	D. Collect informat	ion for the results table (<u>Appendix F</u>)		
	E. Verify sample ty	peused		
	1. Whole	blood or plasma		
	2. If som	ething other than whole blood or pla	isma is used for te	esting, advise customer of correct sample
	type a	nd review intended use per CTT shee	t (add <u>C1066</u>)	
	F. Verify anticoagu	lant used for sample collection		
	a. Sample	es must be collected in sodium of lite	nium neparin	so decreased results
	D. Testing	t sample is being tosted within 20 m	viputos of colloctic	se decreased results
	immediately if to	asting samples collected without ant	indles of conectic	on in testing anticoagulated samples of
	H Verify that the n	atient sample is being collected corr	octly	
	1 Evacua	ated Tubes:	certy	
	a. Evacad	Plain (no anticoagulant) or lithiu	n heparin (green t	top tube)
	b	Fill tubes to labeled capacity. Inc	orrect filling leads	s to higher heparin-to-blood ratios
	2. Syring	2:		
	, e	Plain (no anticoagulant) or lithiu	n heparin or balar	nced heparin
	b	Fill heparin syringes to labeled ca ratios	pacity. Incorrect	filling leads to higher heparin-to-blood
	3. Capilla	ry Tube: not recommended		
	4. Indwe	ling line: back flush line 5-6 times th	ne volume of cathe	eter, connectors and needle to avoid
	contar	nination		
	 Verify the patier 	t sample is being handled correctly		
	1. Mixed	well to avoid clotting		
	J. Verify test limita	tions per CTI sheet		
	Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number			nerated on a specific serial number
	compared to differen	t analyzer(s) that generate expected	results for the sp	ecific patient sample(s).
-	Resolution	une is used for i CTAT southides	THEN the incide	ut is used to d
	testing	pe is used for i-STAT cartridge		
	testing		• Classif	Idation is complaint 1
	IF the completic college	tod with an incorrect	<u>CIUGO</u> WIII DE ac	nt is resolved
	anticoogulant	Led with an incorrect		fication is Complaint 1
	anticoaguidill		Classif	
	IF the sample is not to	ested within the required time	THEN the suspe	ct cartridge lot(s) should be investigated
	after collection per A	POC literature	 Classif 	fication is Complaint 2
	IF the patient results	or cartridge type/ lot number is	THEN the cartrid	dge lot(s) should be investigated
	still unknown after du	le diligence, PQA/TS will	Classif	fication is Complaint 2
	determine cartridge l	ot number via internal systems		·
	IF unexpected nation	t results are reported and	THEN the susper	ct cartridge lot(s) should be investigated
	incorrect sample type	and anticoagulant use is ruled	Classif	fication is Complaint 2
	out		Clussifi	

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Complaint	Description
Prothrombin	Patient's PT/INR results from the i-STAT system are not what the customer was expecting. i-STAT results do not match
Time/INR (PT/INR)	the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT
Unexpected Patient	retest results
Results	
	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
Answer pRE	Prompts for Meaningful Data Collection
questions!	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
RW Code: C1523	
	Unexpected Results Table
Synonyms: i-STAT	
results - high, low,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
discrepant, not	Was the patient sample retested on a new i-STAT cartridge?
reliable, different,	
cannot trust	Was the patient on Coumadin or Warfarin:
	Why is the patient receiving Coumadin or Warfarin:
	Name of the comparative lab instrument (if applicable):
	Comparative instrument reagent ISI (if applicable):
	Comparative instrument thromboplastin source (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Council a tractor of for one of the second for
	Sample tested from a fingerstick:
	Patient sample type used
	Patient sample type used.
	Collection device (avringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled canacity:
	Sample mixed thoroughly:
	Sample hmcd therebaginy.
	Sample clotting detected:
	Transfer device used for loading the natient sample to the cartridge.
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT PT/INR results to be unexpected/different
	B. Verify if the i-STAT test was repeated

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	C. Collect informati	on for the results table (<u>Appendix F</u>)	have taking 0		
	a. If INR r	esult is <0.9, asked if patient is or has	been taking Coumadin/\	Wartarın	
	 	This result may occur if patient is	ot or has never been on	oral anticoagulant therapy (off label	
		use, add C1066)			
	D. Verify intended u	use of the cartridge			
	1. i-STAT	PT/INR monitors oral anticoagulant (Coumadin, warfarin) testi	ng	
	2. If testin	ng cartridge for any other reason, adv	ise customer of intended	use and review per CTI sheet (add	
	<u>C1066</u>)				
	E. Verify sample typ	Je used (WNOIE DIOOD) t sample is being tested immediately	after collection		
	G. Verify that the patient	atient sample is being collected corre	ctly		
	1. Evacua	ted Tubes:	ed Tubes:		
	a.	Plain (no anticoagulant)			
	b.	Must be plastic (glass activates clo	tting)		
	2. Syringe	2: Diaine (margareting a subject)			
	a.	Must be plastic (glass activates clo	tting)		
	3. Capilla	rv Tube: not recommended	(ting)		
	4. Skin Pu	incture:			
	a.	Test first drop of blood (do not wi	be off)		
	b.	Chlorhexidine gluconate (skin clea	nser) contaminated same	oles will prolong PT and elevate INR	
	5. Indwel	ling line: flushed with 5 mL of saline	and the first 5 mL of bloo	d or six dead space volumes of the	
	Cathete H Verify the nation	t sample is being handled correctly	l correctly and free of anticoagulant		
	1. Transfe	er devices must be plastic and free of			
	I. Verify test limita	tions per CTI sheet			
	Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number			on a specific serial number	
	compared to different	t analyzer(s) that generate expected i	esults for the specific pat	cient sample(s).	
	IE incorrect sample ty	ne is used for i-STAT cartridge	THEN the incident is rea	solved	
	testing	pe is used for i-stAT califinge	Classification	is Complaint 1	
			C1066 will be added as	supplemental code	
	IF the sample is collect	ted with an incorrect anticoagulant	THEN the incident is re-	solved	
			Classification	is Complaint 1	
	IF the patient is not o	n Coumadin/warfarin and the	THEN the suspect cartri	dge lot(s) should be investigated	
	PT/INR result is unexp	pected	Classification	is Complaint 2	
	IF the sample is not te	ested within the required time after	THEN the suspect cartri	dge lot(s) should be investigated	
	collection per APOC li	terature	Classification	is Complaint 2	
	IF the patient results	or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated	
	unknown after due di	ligence, PQA/TS will determine	 Classification 	is Complaint 2	
	cartridge lot number	via internal systems			
	IF unexpected patient	results are reported and incorrect	THEN the suspect cartri	dge lot(s) should be investigated	
	sample type and antic	coagulant use is ruled out	Classification	is Complaint 2	

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Complaint	Description	
CK-MB Unexpected	Patient's CK-MB results from the i-STAT system are not what the customer was expecting. i-STAT results do not match	
Patient Results	the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT	
	retest results	
Answer pRE		
questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint	
	Prompts for Meaningful Data Collection	
RW Code: C1524	Cartridge type and lot number used:	
Currenumer i CTAT	Why is the i-STAT result considered to be discrepant/unexpected:	
synonyms: 1-stat	Unaversitian Depute Table	
discrepant not	<u>Unexpected Results Table</u>	
reliable, different.	Was the natient sample retested on a new i-STAT cartridge?	
cannot trust		
	Name of the comparative lab instrument (if applicable):	
	Cartridge storage information:	
	Cartridge handling information:	
	Are cartridges available to be returned for investigation:	
	Controls tested on the i-STAT cartridges and acceptable:	
	Patient sample collected?	
	How is sample collected?	
	Type of anticoagulant used in the collection device:	
	Collection device filled to labeled capacity:	
	Sample mixed thoroughly:	
	Sample hemolysis detected:	
	Sample clotting detected:	
	Transfer device used for loading the patient sample to the cartridge:	
	i-STAT Analyzer Serial Number(s):	
	Patient information:	
	Age and gender:	
	Current Diagnosis:	
	Current Medications:	
	Results from other tests/procedures performed:	
	Date and time admitted:	
	Date and time discharged: What was impact to patient?	
	If patient treatment was based on lab results, what was the treatment?	
	Troubleshooting	
	A. Verify reason for considering the i-STAT CK-MB results to be unexpected/different	
	B. Verify if the i-STAT test was repeated	
	C. Collect information for the results table (Appendix F)	
	D. Verify sample type used	
	1. Whole blood or plasma	
	2. If something other than whole blood or plasma is used for testing, advised customer of correct sample	
	type and review intended use per CTI sheet (add <u>C1066</u>)	
	E. Verify anticoagulant used for sample collection	

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Samples must be collected in sodium or lithium heparin a. Testing samples collected with other anticoagulants will cause decreased results b. F. Verify the patient sample is being tested within 30 minutes of collection if testing anticoagulated samples or immediately if testing samples collected without anticoagulant G. Verify that the patient sample is being collected correctly 1. Evacuated Tubes: a. Plain (no anticoagulant) or lithium heparin (green top tube) b. Fill tubes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios. 2. Syringe: Plain (no anticoagulant) or lithium heparin or balanced heparin a. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios b. 3. Capillary Tube: not acceptable 4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid contamination H. Verify the patient sample is being handled correctly 1. Mixed well to avoid clotting Verify test limitations per CTI sheet 1. Note: Analyzer is suspected only when multiple unexpected results are generated on a specific serial number compared to different analyzer(s) that generate expected results for the specific patient sample(s). Resolution THEN the incident is resolved IF incorrect sample type is used for i-STAT cartridge testing • Classification is Complaint 1 C1066 will be added as supplemental code IF the sample is collected with an incorrect anticoagulant **THEN** the incident is resolved Classification is Complaint 1 IF the sample is not tested within the required time after **THEN** the suspect cartridge lot(s) should be investigated collection per APOC literature Classification is Complaint 2 IF the patient results or cartridge type/ lot number is still **THEN** the cartridge lot(s) should be investigated unknown after due diligence, PQA/TS will determine Classification is Complaint 2 cartridge lot number via internal systems IF unexpected patient results are reported and incorrect **THEN** the suspect cartridge lot(s) should be investigated sample type and anticoagulant use is ruled out Classification is Complaint 2 ٠ i-STAT Support Guide REF-1151C Section 8.0

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Complaint	Description		
BNP Unexpected	Patient's BNP results from the i-STAT system are not what the customer was expecting. i-STAT results do not match		
Patient Results	the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT		
	retest results		
Answer pRE questions!			
· · · · · · · · · · · · · · · · · · ·	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint		
RW Code: C1525	Prompts for Meaningful Data Collection		
	Cartridge type and lot number used:		
Synonyms: i-STAT	Why is the i-STAT result considered to be discrepant/unexpected:		
results - high, low,			
discrepant, not	Unexpected Results Table		
reliable, different,			
cannot trust	Was the patient sample retested on a new i-STAT cartrige?		
	Name of the comparative lab instrument (if applicable):		
	Cartridge storage information:		
	Cartridge handling information:		
	Are cartridges available to be returned for investigation:		
	Controls tested on the i-STAT cartridges and acceptable:		
	Patient sample type used (WB/Plasma):		
	How is sample collected?		
	Collection device (syringe, evacuated tube, capillary):		
	Type of anticoagulant used in the collection device:		
	Collection device filled to labeled capacity:		
	Sample mixed thoroughly:		
	Sample hemolysis detected:		
	Sample clotting detected:		
	Transfer device used for loading the patient sample to the cartridge:		
	I-STAT Analyzer Serial Number(s):		
	Detient information.		
	Patient information:		
	Age and gender:		
	Clinical symptoms at procentation:		
	Current Medications:		
	Results from other tests/procedures performed:		
	Date and time admitted:		
	Date and time discharged:		
	What was impact to natient?		
	If patient treatment was based on lab results, what was the treatment?		
	Troubleshooting		
	A. Verify reason for considering the i-STAT BNP results to be unexpected/different		
	B. Verify if the i-STAT test was repeated		
	C. Collect information for the results table (Appendix F)		
	D. Verify sample type used		
	1. Whole blood or plasma		
	2. If something other than whole blood or plasma is used for testing, advised customer of correct sample		
	type and review intended use per CTI sheet (add <u>C1066</u>)		
	E. Verify anticoagulant used for sample collection (must be collected with EDTA)		
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F. Verify the patier	nt sample is being tested within 30 m	inutes of collection if testing anticoagulated samples	
G. Verify that the p	atient sample is being collected corr	ectly	
1. Evacua	ated Tubes:		
а	. EDTA (purple/lavender top tube)		
b	. Fill tubes to labeled capacity. Inc	orrect filling leads to higher anticoagulant-to-blood ratios	
2. Syring	e:		
a	. EDIA Filler mineres to labola de sus situad	a second fills a local to bisk a second second set to block a second	
	Fill syringes to labeled capacity. Incorrect filling leads to higher anticoagulant-to-blood ratios		
3. Capilla 4. Induce	ling line: back fluch line 5.6 times th	a valume of estheter, connectors and needle to avoid	
4. Indue	ming line. back hush line 5-0 times the	ig line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid	
H Verify the patier	Contamination H Verify the patient sample is being handled correctly		
1. Mixed	 n. verify the patient sample is being handled correctly 1 Mixed well to avoid clotting (clotted samples will cause increased results) 		
2. Avoid	 Avoid hemolysis (gross hemolysis will cause decreased results) 		
I. Verify test limita	I. Verify test limitations per CTI sheet		
Note: Analyzer is sus	spected only when multiple unexpect	ed results are generated on a specific serial number	
compared to differen	t analyzer(s) that generate expected	results for the specific patient sample(s).	
Resolution			
IF incorrect sample ty	/pe is used for i-STAT cartridge	THEN the incident is resolved	
testing		Classification is Complaint 1	
		C1066 will be added as supplemental code	
IF the sample is colle	cted with an incorrect	THEN the incident is resolved	
anticoagulant		 Classification is Complaint 1 	
IF the sample is not t	ested within the required time	THEN the suspect cartridge lot(s) should be investigated	
after collection per A	POCIIterature	Classification is Complaint 2	
IF the patient results	or cartridge type/ lot number is	THEN the cartridge lot(s) should be investigated	
still unknown after d	ue diligence, PQA/TS will	Classification is Complaint 2	
determine cartridge	ot number via internal systems		
IF unexpected patien	t results are reported and	THEN the suspect cartridge lot(s) should be investigated	
incorrect sample type	e and anticoagulant use is ruled	Classification is Complaint 2	
out	0		

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Complaint	Description
Total B-hCG	Patient's B-hCG results from the i-STAT system are not what the customer was expecting i-STAT results do not match
Unexpected Patient	the patient's clinical nicture or are different when compared to lab instrument results, other i-STAT results or i-STAT
Results	refest results
nesuns	
Answer pRE questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1526	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Svnonvms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	Was the patient sample retested on a new i-STAT cartridge?
cannot trust	Positive cut-off value for i-STAT:
	Name of the comparative lab instrument (if applicable):
	Positive cut-off value for lab instrument (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Patient sample type used (WB/Plasma):
	How is sample collected?
	Collection device (syringe, evacuated tube, capillary):
	Type of anticoagulant used in the collection device:
	Collection device filled to labeled capacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Is patient pregnant?
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT Total β-hCG results to be unexpected/different
	B. Verify intended use of the cartridge
	1. Total β -hCG is intended to be used as an aid in the early detection of pregnancy
	2. If testing cartridge for any other reason, advise customer of intended use and review per CTI sheet (add
	<u>C1066</u>)

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C. Verify if the i-STAT test was repeated		
 Collect information for the results table (<u>Appendix F</u>) 		
E. Verify sample type used		
1. Must be whole blood or plasma		
2. If something other than whole blood or plasma is used for testing, advised customer of correct sample		
type and review intended use per CTI shee	t (add <u>C1066</u>)	
F. Verify anticoagulant used for sample collection		
1. Must be sodium or lithium heparin		
2. Samples collected in other anticoagulants	will cause decreased β-hCG results	
G. Verify the patient sample is being tested within 30 m	inutes of collection if testing anticoagulated samples	
H. Verify that the patient sample is being collected corr	ectly	
1. Evacuated Tubes:	,	
a. Sodium or lithium heparin (greer	n top tube)	
b. Fill tubes to labeled capacity. Inc	correct filling leads to higher heparin-to-blood ratios	
2 Svringe		
a Sodium or lithium henarin		
b Fill benarin syringes to labeled ca	inacity Incorrect filling leads to higher benarin-to-blood	
ratios	puerty. meetreet ming leads to inglier neparit to blood	
c Syringes must be plastic		
3 Canillary Tube: not accentable		
4 Indwelling line: back flush line 5-6 times th	a volume of catheter, connectors and needle to avoid	
4. Indivening line. back hush line 5-0 times to	le volume of catheter, connectors and needle to avoid	
Verify the estiont cample is being handled correctly	contamination	
 Verify the patient sample is being handled correctly Mixed well to avoid eletting (eletted complex will cause increased results) 		
I. Wixed well to avoid clotting (clotted samples will cause increased results)		
2. Avoid hemolysis (gross hemolysis will caus	2. Avoid hemolysis (gross hemolysis will cause decreased results)	
J. Verny test initiations per CT sheet	J. Verify test limitations per CTI sheet	
Nete: Analyzor is suspected only when multiple uneverse	tod results are generated on a specific serial number	
Note: Analyzer is suspected only when multiple unexpected on the provide only when multiple on the provide on	requite for the specific patient sample(s)	
compared to different analyzer(s) that generate expected	results for the specific patient sample(s).	
Resolution		
IF incorrect sample type is used for I-STAT cartridge	THEN the incident is resolved	
testing	Classification is Complaint 1	
	<u>C1066</u> will be added as supplemental code	
IF the sample is collected with an incorrect	THEN the incident is resolved	
anticoagulant Classification is Complaint 1		
IF the sample is not tested within the required time THEN the suspect cartridge lot(s) should be investigated		
after collection per APOC literature• Classification is Complaint 2		
IF the patient results or cartridge type/ lot number is	THEN the cartridge lot(s) should be investigated	
still unknown after due diligence, PQA/TS will	Classification is Complaint 2	
determine cartridge lot number via internal systems		
IF unexpected patient results are reported and	THEN the suspect cartridge lot(s) should be investigated	
incorrect sample type and anticoagulant use is ruled	Classification is Complaint 2	
out		

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Complaint	Description
PT ^{plus} Unexpected	Patient's PT/INR results from the i-STAT system are not what the customer was expecting. i-STAT results do not match
Patient Results	the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT
	retest results
Answer pRE	
questions!	Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
RW Code: C1527	Cartridge type and lot number used:
	Why is the i-STAT result considered to be discrepant/unexpected:
Synonyms: i-STAT	
results - high, low,	Unexpected Results Table
discrepant, not	
reliable, different,	All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results):
cannot trust	Was the patient sample retested on a new i-STAT cartridge?
	Is the patient on anticoagulant therapy?
	Why is the patient on anticoagulant therapy?
	Name of the comparative lab instrument (if applicable):
	Comparative instrument reagent ISI (if applicable):
	Comparative instrument thromboplastin source (if applicable):
	Cartridge storage information:
	Cartridge handling information:
	Are cartridges available to be returned for investigation:
	Controls tested on the i-STAT cartridges and acceptable:
	Datiant cample tune used:
	How is sample collected?
	Collection device (svringe, evacuated tube, capillary):
	Collection device filled to labeled canacity:
	Sample mixed thoroughly:
	Sample hemolysis detected:
	Sample clotting detected:
	Transfer device used for loading the patient sample to the cartridge:
	i-STAT Analyzer Serial Number(s):
	Patient information:
	Age and gender:
	Current Diagnosis:
	Clinical symptoms at presentation:
	Current Medications:
	Results from other tests/procedures performed:
	Date and time admitted:
	Date and time discharged:
	What was impact to patient?
	If patient treatment was based on lab results, what was the treatment?
	Troubleshooting
	A. Verify reason for considering the i-STAT Sodium results to be unexpected/different
	B. Verify if the i-STAT test was repeated
	C. Collect information for the results table (<u>Appendix F</u>)

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D. Verify intended use of the cartridge	
a. Monitor patients receiving anticoagulant the	erapy with coumarin derivatives.
b. If testing cartridge for any other reason, adv	ise customer of intended use and review per CTI sheet (add
<u>C1066</u>)	
E. Verify sample type used (whole blood)	
F. Verify that the patient sample is being collected corre	ctly
 Evacuated Tubes: 	
a. Plain (no anticoagulant)	
 Must be plastic (glass activates closed) 	tting)
2. Syringe:	
a. Plain (no anticoagulant)	
b. Must be plastic (glass activates closed)	itting)
Capillary Tube: not recommended	
4. Skin Puncture:	
a. Test first drop of blood (do not wi	pe off)
b. Chlorhexidine gluconate (skin clea	nser) contaminated samples will prolong PT and elevate INR
5. Indwelling line: flushed with 5 mL of saline	and the first 5 mL of blood or six dead space volumes of the
catheter should be discarded	
G. Verify the patient sample is being handled correctly	
 Transfer devices must be plastic and free of 	anticoagulant
H. Verify the patient sample is being tested immediately	after collection
I. Verify test limitations per CTI sheet	
Note: Analyzer is suspected only when multiple unexpected	ed results are generated on a specific serial number
compared to different analyzer(s) that generate expected results for the specific patient sample(s).	
Resolution	
IF incorrect sample type is used for i-STAT cartridge	THEN the incident is resolved
testing	 Classification is Complaint 1
	C1066 will be added as supplemental code
IF the sample is collected with an incorrect anticoagulant	THEN the incident is resolved
In the sample is confected with an incorrect anticoagulant	Classification is Complaint 1
IF the natient is not on anticoagulant therapy and the	THEN the suspect cartridge lot(s) should be investigated
In the patient is not on anticoagaiant therapy and the	
PT/INR result is unexpected	Classification is Complaint 2
PT/INR result is unexpected	Classification is Complaint 2
PT/INR result is unexpected IF the sample is not tested within the required time after	Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated
PT/INR result is unexpected IF the sample is not tested within the required time after collection per APOC literature	Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2
PT/INR result is unexpected IF the sample is not tested within the required time after collection per APOC literature	 Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2
PT/INR result is unexpected IF the sample is not tested within the required time after collection per APOC literature IF the national results or cartridge type/ lot number is still	Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated
 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence. POA/TS will determine 	Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated Classification is Complaint 2
 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine cartridge lot number via internal systems 	 Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated Classification is Complaint 2
 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine cartridge lot number via internal systems 	 Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated Classification is Complaint 2
 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine cartridge lot number via internal systems IF unexpected patient results are reported and incorrect 	 Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated
 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine cartridge lot number via internal systems IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out 	 Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2
 IF the sample is not tested within the required time after collection per APOC literature IF the patient results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine cartridge lot number via internal systems IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out 	 Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2 THEN the cartridge lot(s) should be investigated Classification is Complaint 2 THEN the suspect cartridge lot(s) should be investigated Classification is Complaint 2

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Complai	Complaint Description	
Star Out	Star OutsWhen a sensor does not pass internal quality checks, the *** symbols are displayed instead of results.	
Prompts for Meaningful Data Collection		Prompts for Meaningful Data Collection
1. What cartridge type, lot number(s) and box number(s) (if applicable) is the star-out occurring?		1. What cartridge type, lot number(s) and box number(s) (if applicable) is the star-out occurring?
RW Codes for star outs		2. Which analyte(s) starred out?
(red indi	(red indicates pRE): 3. How many star-outs have occurred? How many total cartridges have been tested?	
C1299	β-hCG	Note: Request approximate cartridge numbers tested so far when exact numbers are not known
C1201	Na (K, Cl,	4. If multiple star-outs occurred with ACT cartridges:
C1301	Hct)	a. What are the times the star-out occurred?
C1302	K (anion	b. Did ACT cartridge produce a result?
C1302	gap)	i. If yes, what was result?
C1303	Cl (anion	ii. If no, was sample testing on a different instrument? What instrument and what was
01505	gap)	result?
C1304	BUN (eGFR)	c. Was patient being administered heparin?
C1305	iCa	5. How many analyzers are showing star-outs?
C1306	рΗ	6. What is being tested on the cartridge? Patient sample, QC material or proficiency material?
01000	pH + PCO2	7. Was patient sample/QC material/proficiency material retested after star-out result?
	(TCO2	a. Did the retest give successful results?
C1307	anion gan	b. Was repeat testing on same sample?
	BE, sO2)	8. If star out occurred while testing patient sample:
C1308	PO2(sO2)	a. How was patient sample collected:
C1200	Chucoso	9 Star-outs occurring with one or multiple patients?
C1509	Glucose	10 If star-out occurred while testing OC material what is OC material lot number?
	Hematocrit	11. If star-out occurred while testing proficiency survey, what is the name and number of the survey?
C1210		12. How are cartridges stored and handled?
C1510	PUZ,	13. Have star-outs occurred with one operator or multiple operators?
	s(12)	Troubleshooting
	Creatinine	A. If one star out occurred on a patient or QC fluid, test a fresh sample/QC fluid on a new i-STAT cartridge
C1311	(eGFR)	B. If star-outs persist on patient sample
C1312		1. Determine the star-out rate (number of cartridges which starred-out versus the total number of
C1212		cartridges tested)
C1313	ACT Cellte	2. Verify patient sample type tested and anticoagulant used to collect patient sample
C1314	Prothrombin	3. Verify if star out results are occurring on single patient or multiple patients
	Time	4. Verify if star-outs are occurring on a specific cartridge lot number
C1315	Troponin	5. Verify if star-outs are from one box or different boxes of the cartridge lot number
C1316	ACT Kaolin	6. Verify number of star-outs from one box (<i>Is it more than 3 from one individual box?</i>)
C1317	TCO2	7. If star-outs occurred with ACT cartridge, confirm patient was administered heparin.
C1318	CK-MB	i. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants
C1319	BNP	ii. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU
C1206	PT pluc	(add <u>C1066</u>)
C1290	r i pius	C. If star-outs persist on QC material, verify if star-outs are isolated to a specific APOC QC material lot number
		1. Determine the star-out rate (number of cartridges which starred out versus the total number of
		Cartridges tested)
		 verify carcinges storage, handling and expiration date Verify storage (high temperature may cause PUN/Urea stor oute)
		1. Verify storage (ingli temperature may cause DUIV) of a star outs) 2. Verify handling (prolonged exposure of cartridge to air may cause $n \parallel /n \cap 2$ star outs)
		 Verify expiration data (expired cartridges may cause ctar oute) Verify expiration data (expired cartridges may cause ctar oute)
		5. Verify expiration date (expired to a specific analyzer serial number
	If ONLY Hematocrit analyte star-outs (no other analytes) are occurring on a specific analyzer. Perform caramic	
		conditioning cartridge

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 Proficiency Material star-out Verify validated proficiency material is being tested (<i>i-STAT 1 System Manual, Section 16: Proficiency or External QC Testing Art: 714378</i>) Note: Star-outs can occur due to an occasional sensor not passing QC checks and may occur at a rate of 2 to 3% or no more than 3 out of one individual box. 	
Resolution	
IF after running a new cartridge with fresh patient	THEN complaint is resolved
sample or new ampule/vial of QC material or	Classification is Complaint 1
proficiency sample the star-out is not reproducible	
IF the star out rate is less than 3% and there were no	THEN complaint is resolved
more than 3 star-out cartridges per box	Classification is Complaint 1
IF star-out is persistent on specific cartridge lot	THEN the suspect cartridge lot should be investigated
number at a rate of greater than 3% or more than 3	Classification is Complaint 2
cartridges starred out in an individual box	
	Request cartridges be returned for investigation and document request(s)
IF the star-out is persistent on multiple i-STAT	THEN the suspect cartridge and QC material lot(s) should
analyzers after troubleshooting but only on specific	be investigated
cartridge lot(s) and specific QC material lot(s) AND	Classification is Complaint 2
other cartridge lots and other QC material lot(s) run	
without issue on the same i-STAT analyzers	Request cartridges and QC material be returned for
	investigation and document request(s)
IF running the ceramic conditioning cartridge resolves	THEN complaint is resolved
the hematocrit star-out	Classification is Complaint 1
IF the star-out results persist on a specific analyzer	THEN the i-STAT analyzer should be replaced or repaired
and other analyzers do not show star outs on the	Classification is Repair
same cartridge lot number	

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Complaint	Description		
Results Suppressed	The i-STAT analyzer displays < or > when the result is below or above the reportable range of the test. Results that are		
(< >) or Outside of	dependent on a result that is flagged with a (< or >) will display a (< >) symbol.		
Reportable Ranges	Prompts for Meaningful Data Collection		
	1. What are the flags displayed - < or > or <>?		
	2. What analytes are showing the flags?		
RW Code: C3214	3. What was tested on the cartridge - patient or QC material or proficiency survey?		
	4. What is the cartridge type and lot number of the impacted cartridge(s)?		
Synonyms: carrots	5. What are all the test results on cartridge? Request screen shots or pictures of the results from analyzer and/or DMS		
or brackets instead	6. What is the name and lot number of the QC material, if cal ver or control is tested?		
of results	What testing pathway was used for testing QC or cal ver?		
	Note: If the issue is with Calibration Verification, it should be tested in the cal ver pathway on the analyzer. The (< or >)		
	symbols should not be displayed when testing in the cal ver pathway		
	8. Is the analyzer customized in DMS (DE customization workspace) for custom reportable ranges that are different		
	than the default reportable ranges?		
	9. How are all the control results displayed, numeric or suppressed?		
	AQF Note: If "Control Results Display Format" is set to suppress, all QC results will be flagged as <>.		
	Troubleshooting		
	A. Verify the flag that is displayed with results		
	B. Verify the analytes that show flags, review the reason for the flags and <u>sensor dependencies</u>		
	C. If the issue is occurring on a patient sample:		
	1. Verify results are expected and match the clinical condition of the patient (e.g. was the customer		
	expecting a high of low result for analyte)		
	2. If the results do not match the patient condition (OK)		
	 verify user has recested freshly drawn sample Confirm results (are the results the same or different upon retect?) 		
	iii Note: This is an unexpected result (IIR) issue. Use unexpected results complaint code follow		
	the steps/process for LIR		
	D If the issue is occurring with control material or proficiency survey material		
	1. Check if customized reportable ranges are used in the DMS (<i>Technical Bulletin: Reportable Range</i>		
	Customization on the i-STAT 1 Handheld Art: 730009)		
	i. Explain reportable ranges are applied to control and proficiency testing pathways		
	ii. Ask user if default i-STAT reportable ranges can be used for retesting control or proficiency		
	material (i.e. reset to factory default settings)		
	2. If the issue is occurring with control material or proficiency survey when using default reportable ranges,		
	ask the user to retest with a new ampule/vial following proper procedure		
	E. If <> is displayed for TCO2 results on CHEM8+ cartridges:		
	1. Inform customer that TCO2 result is obtained using an algorithm which includes pH and PCO2 results		
	(refer to CHEM8+ IFU Art: 765874)		
	2. Explain if pH or PCO2 results are outside the reportable ranges, whether factory default or customized,		
	the TCO2 result will appear as <>		
	3. Verify pH and pCO2 customization settings for reportable range in DE customization workspace		
	F. If the issue is occurring with cal ver materials:		
	1. Confirm testing pathway used		
	2. If not tested in cal ver pathway, ask user to retest using the cal ver pathway		
	3. It <> is displayed for results when testing in the cal ver path, ask user to retest following proper procedure		
	i. It issue persists after retesting provide a different lot number of the cal ver material		
	G. It <u>all</u> control results are displayed with suppressed symbols (<>) instead of results:		
	1. Verity customization settings for "Control Results Display Format" (Technical Bulletin: Liquid Quality		
1	Control Schedule and Lockout Art: 730077)		

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	Advise to change to numeric if results are req	uired
	Resolution	
	IF the patient results match the clinical condition of the	THEN the issue is resolved
	patient AND user understands reason for the	Classification is Complaint 1
	flags/symbols displayed with result (<, > or < >)	
	IF the patient results do not match the clinical condition	THEN the issue is to be investigated as Unexpected patient
	and/or lab results or retest results on next i-STAT	results complaint
	cartridge	Classification is Complaint 2
	IF control or proficiency results are obtained with no	THEN the issue is resolved
	flags/symbols (<, > or < >) after retesting and/or restoring	Classification is Complaint 1
	to factory settings on the analyzer (to apply default	
	reportable ranges)	
	IF correct testing pathway (cal ver pathway) is used for	THEN the issue is resolved
	retesting calibration verification material AND correct	Classification is Complaint 1
	results with no flags/symbols (<, > or < >) are obtained	
	IF correct testing pathway (cal ver pathway) was used for	THEN the issue should be investigated
	retesting calibration verification material AND the	Classification is Complaint 2
	suppressed symbols (< >) symbols are still displayed with a	
	specific cal ver lot number	
	IF all control results are suppressed and in customization	THEN the issue is resolved
	"Control Results Display Format" is set to suppress	Classification is Complaint 1
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Complain	a t	Description
Unaccon	ni table Method	Description Method Comparison study is done for an assessment of the bias /difference between two methods or to compare i
Compari		STAT results to apother instrument used as a reference method. The results between two methods of to compare i-
Compani	5011	instrument must be within a predetermined accuracy limit. 20-50 different patient samples may be included in the
Answer nPE questions l study: however, sustemars may perform mathed comparison studies with a s		study: however, customers may perform method comparison studies with a small sample size (2-5 samples)
Answerp	The questions:	study, nowever, customers may perform method comparison studies with a small sample size (2-5 samples).
RW Code	26.	Correlation study or comparison study results are high low discrepant do not match comparative instrument are
C1850	Na	not within the allowable difference between methodologies.
C1050	ING IV	
01051	N.	Results are not used to diagnose patients.
C1852	CI	Prompts for Meaningful Data Collection
C1853	iCa	1. What is cartridge type/lot number?
C1854	Glucose	2. Which analyte results for method comparison are unacceptable?
C1855	BUN/Urea	3. What are the results for the comparison study (with units of measure)?
C1856	рН	4. What is the patient sample type tested on the i-STAT 1 system?
C1857	PCO2	5. Was the same sample draw tested on i-STAT system and lab instrument?
C1858		6. What is the anticoagulant used for i-STAT samples?
C1050	F 02	7. What is the collection and test date/time for i-STAT and the lab instrument?
C1859	Hematocrit	8. How is the cartridge handled?
C1860	Hemoglobin	9. How is the sample collected and handled?
C1861	TCO2	10. What is the facility's acceptable accuracy limit for analyte?
C1862	Anion Gap	a What is the troponin type (i.e. cTnl. high sensitivity, cTnT) being tested on comparative
C1863	BE	instrument?
C1864	sO2	12. If Hct or Hb method comparison results are unacceptable:
C1865	НСОЗ	a. What is the EDTA (K2/K3) customization on the i-STAT analyzer?
C1866	Creatinine	b. What is the microhematocrit (MH) method calibration (K2/K3 EDTA) on the lab instrument? (All
C1067		instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference
01007	ACT Cente	method)
C1868	Lactate	c. Was CPB mode used for the testing on the i-STAT system?
C1869	ACT Kaolin	d. Was the sample tested immediately or was there a delay in testing?
C1870	Troponin	13. If ACT method comparison results are unacceptable:
C1871	PT/INR	a. What is the comparative instrument ((nrowerm or nonverm)?)
C1872	CK-MB	b. What is the comparative instrument ((prewarm or nonwarm)?
C1873	BNP	14. If Dase Excess method comparison results are unacceptable.
C1874	ß-hCG	b. What Base Excess is the comparative instrument using?
C1661	DTplus	15. If Anion Gap method comparison results are unacceptable:
01001	1.1.	a. What calculation is used on comparative method?
		16. Was the sample mixed before testing? How many times was it mixed?
Synonym	s: i-STAT	Troubleshooting
results –	correlation	A. Confirm with customer that i-STAT results were NOT used in diagnosing patients
study, hid	gh, low,	B. Verify one specific cartridge lot number is used for the study
different	, does not	C. Verify sample type used on the i-STAT 1 system
match		D. Verify if same sample draw was used for testing on both methods
		E. Verify anticoagulant used for sample collection
		F. Verify cartridge handling
		G. Verify that the patient sample is being collected, handled and tested correctly for each analyte/cartridge type
		H. Verify the table for <u>accuracy limits</u> for each analyte
		I. Document method comparison results in question in the incident summary (do not state "see attachment")
		J. If cTnI method comparison results are unacceptable:

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1. Verify comparative instrument troponin (cTnT, high sensitivity cTnI or high sensitivity cTnT) being
tested (if applicable)	
2. The results of different troponin assays ar	e not generally comparable: cTnl and cTnT are distinct
molecules and results are not interchangeable, nor comparable. In addition, significant variation in	
absolute troponin values may be observed for a given patient specimen with different analytic	
methods	
1. Vorify sample was collected without antic	agulant
2 Verify sample was tested immediately after	er draw
3 Verify calibration mode used for testing of	n i-STAT analyzer (prewarm or popwarm) and comparative
method are the same	
L. If Base Excess method comparison results are unacc	ceptable:
1. Verify calculation used (BEecf or BEb) on i	-STAT analyzer and comparative method are the same
M. If Anion Gap method comparison results are unacce	eptable:
1. Verify calculation used on comparative me	ethod is the same as the i-STAT cartridge
N. If Hct or Hb method comparison results are unaccept	otable:
1. Verify the EDTA (K2/K3) setting on the i-S	TAT analyzer and comparative method are the same
2. Verify if CPB mode was turned on for the	i-STAT tests
3. Verify if sample was tested immediately a	fter draw or if there was any delay
4. Verity it sample was mixed properly befor	e testing
Nete: Analyzer is suspected only when multiple uncome	stable method comparison results are concreted on a
specific i-STAT analyzer serial number compared to differ	rent analyzer(s) that generate accentable results for the
same sample(s)	
Same sample(s).	
IF incorrect sample type is used for i-STAT cartridge	THEN the incident is resolved
testing	Classification is Complaint 1
	C1066 will be added as supplemental code
IF the sample is collected with an incorrect	THEN the incident is resolved
anticoagulant	Classification is Complaint 1
IF the results for the 2 methods when compared are	THEN the incident is resolved
within the accuracy limits	Classification is Complaint 1
IF the results for the 2 methods when compared are	THEN the incident is resolved
within the accuracy limits but are outside the facility's	Classification is Complaint 1
acceptable limits	
IF unacceptable method comparison results are	THEN the suspect cartridge lot(s) should be investigated
reported and none of the above is true	Classification is Complaint 2
	Ask customer if cartridges are available to be returned
	for investigation and document request(s)
IF sample is tested outside the test timing for i-STAT	THEN the suspect cartridge lot(s) should be investigated
system	Classification is Complaint 2
	Ask sustainers if southings are susible to be returned
	for investigation and document request(s)
IF the method comparison results or cartridge type/ lot	THEN the cartridge lot(s) should be investigated
number is still unknown after due diligence $PO\Delta/TS$	Classification is Complaint 2
will determine lot number via internal systems	
	Ask customer if cartridges are available to be returned
	for investigation and document request(s)

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Complair	nt	Description		
Unaccept	table	i-STAT to i-STAT results do not compare. The results are not used to help diagnose a patient. Includes split sample		
Comparis	son -	testing and lot-to-lot comparison testing. Testing must be performed on patient samples and not control material.		
Regulato	ry	Prompts for Meaningful Data Collection		
_		1. What is cartridge type/lot number?		
Answer p	RE questions!	2. Which analyte results are unacceptable?		
DW/Codo		3. What are the results for the comparison study (with units of measure)?		
RW Code	IS.	 what is the patient sample type tested on the i-STAT system? What is the collection and test date/time? 		
01.005	INd	6 How is the cartridge handled?		
C1605	К	7 How is the sample collected and handled? What is th	e anticoagulant used for i-STAT samples?	
C1606	Cl	8. What is the facility's acceptable accuracy limit for ana	alvte?	
C1607	iCa	9. Was the sample tested immediately or was there a de	elay in testing?	
C1608	Glucose	10. Was the sample mixed before testing? How many tim	nes was it mixed?	
C1609	BUN/Urea	11. What is analyzer serial number?		
C1612	рН	Troubleshooting		
C1613	PCO2	A. Confirm testing performed on patient samples and no	ot control material	
C1614	PO2	B. Verify one specific cartridge lot number is used for th	e study	
C1615	Hematocrit	C. Verify anticoagulant used for sample collection		
C1616	Hemoglobin	D. Verify cartridge nandling		
C1010	теподобі	E. Verify that the patient sample is being collected, hand	died and tested correctly for each analyte/cartridge type	
01017		G Document comparison results in question in the incid	ent summary (do not state "see attachment")	
C1618	Anion Gap	H. If more than one analyzer was used for study, verify settings are the same for both analyzers		
C1619	BE	 ACT: prewarm or nonwarm Base Excess: BEecf or BEb 		
C1631	sO2			
C1632	HCO3	3. Hct/Hb: K3EDTA or K2EDTA, CPB-mode: yes or no		
C1633	Creatinine	Note: Analyzer is suspected only when multiple unacceptable comparison results are generated on a specific i-STAT		
C1634	Lactate	analyzer serial number compared to different analyzer(s) t	hat generate acceptable results for the sample(s).	
C1635	ACT Kaolin	Resolution		
C1636	PT/INR	IF Incorrect sample type is used for I-STAT cartridge testing	IHEN the incluent is resolved Classification is Complaint 1	
C1637	BNP		<u>C1066</u> will be added as supplemental code	
C1638	ß-hCG	IF the sample is collected with an incorrect anticoagulant	THEN the incident is resolved	
C1641		······································	Classification is Complaint 1	
C1642	Tropopin	IF the compared results are within the accuracy limits	THEN the incident is resolved	
C1042			Classification is Complaint 1	
C1643	CK-IVIB	IF the compared results are within the accuracy limits but are	THEN the incident is resolved	
		IF unacceptable comparison results are reported and none of	THEN the suspect cartridge lot(s) should be investigated	
Synonyms: i-STAT results – correlation		the above is true	 Classification is Complaint 2 	
			Ask customer if cartridges are available to be returned for	
study, high, low.			investigation and document request(s)	
different,	does not	IF sample is tested outside the test timing for i-STAT system THEN the suspect cartridge lot(s) should be investigated		
match			Classification is complaint 2 Ask customer if cartridges are available to be returned for	
			investigation and document request(s)	
		IF the comparison results or cartridge type/ lot number is still	THEN the cartridge lot(s) should be investigated	
		unknown after due diligence, PQA/TS will determine lot number	Classification is Complaint 2	
		via internal systems	Ask customer if cartridges are available to be returned for	
			investigation and document request(s)	

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Complair	•+	Decription			
		Description			
Droficion		Proficiency survey results are not considered acceptable.			
Results		Results are acceptable but snow a positive of negative bias compared to mean values.			
Results		Results are acceptable but are not within specific established SD or SDI limits on the survey report.			
Synonym	s: failed hias –	Survey exemples			
nositive o	or negative	Survey examples.			
poortire		CAP Critical Care/Aqueous Blood Survey (AQLAQ3, AQLAQ4)			
RW Code	25	Quality cross check (AQIQ)			
C1701	Na	API I-STAT Chemistry (including Blood Gas)			
C1702	к	WELL Plead Cas/Electrolytes/Matabalites (PT010E0)			
C1702		OF (Quality Evaluation) Product			
C1703		Description for Meaning for Data Callestica			
01704	iCa	Prompts for Meaningful Data Collection			
C1705	рН	1. Which analyte(s) is unacceptable?			
C1706	PCO2	2. What is the proficiency (external guality control) provider?			
C1707	PO2	4 What is proficiency survey name and sample identifier?			
C1708	Glucose	5. Why are results considered unaccentable (e.g. out of range, higher than expected SDL bias, etc.)?			
C1709	Urea/BUN	6. What are the unacceptable results (with units of measure) for each sample in the survey and the acceptable			
C1710	Hematocrit	peer range for each sample?			
C1711	Creatinine	7. Request a copy of the survey results report and the handling instructions.			
C1712		8. What is the CLEW version on analyzer?			
01712	ACT Cente	9. When were controls last tested? Were results acceptable?			
C1/13	PI/INR	10. How are cartridges stored and handled?			
C1714	ACT Kaolin	11. What analyzer serial number(s) are impacted?			
C1715	Hemoglobin	12. What testing pathway was used?			
C1716	TCO2	 Was analyzer on level surface during testing of Hct/Hb, ACT, PT/INR and immunoassay (cTnl, BNP, CK-MB, β- bCC) castridges2 			
C1717	Troponin	14 How are survey samples handled? Request conv of handling instructions			
C1718	CK-MB	Traubleshooting			
C1719	BNP	A Verify the analyte that has unaccentable proficiency results			
C1720	Lactate	 B. Verify validated proficiency material is being tested for the cartridge type tested (refer to i-STAT 1 System 			
C1721	B bCC	Manual, Section 16: Proficiency or External QC Testing (Art: 714378))			
C1721	p-neg	C. Verify why the results are considered unacceptable (e.g. out of range, higher than expected SDI, bias, etc.)			
C1/22	PT plus	D. Document the unacceptable results (with units of measure) for each sample in the survey and the acceptable			
		peer range for each sample			
		E. Request copy of survey results and attach to incident			
		F. Verify samples were handled per instructions. Request a copy of handling instructions and attach to incident			
		G. Request copy of results print outs from analyzer or data manager			
		H. Verify cartridges storage and handling			
		I. Verify last date of control testing and if results were acceptable			
		J. verify survey samples were nandled per survey instructions			
		K. Exposure of the survey samples to air could affect pH, PCO2, PO2, TCO2 and ionized calcium results – Do not			
		Use transfer pipelle to transfer sample to cartridge			
		Verify testing was performed on analyzer in proficiency pathway Proficiency Test nathway uses K3EDTA standardization and disables CPB mode for Hematocrit			
I. Fronciency rest pathway uses the DPEW/APM mode for ACT Proficiency Test pathway uses the DPEW/APM mode for ACT		 Proficiency Test pathway uses the PREWARM mode for ACT 			
		M. Verify results were reported with correct units of measure			
		N. Verify results were transcribed correctly on the survey form			
		O Verify coding for cartridges and instrument on survey form			

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Note: Acceptable ranges for the calculate these ranges. Variability reminder of the importance of fo		Note: Acceptable ranges for the survey were generated am calculate these ranges. Variability of operator technique con reminder of the importance of following testing instructions	ongst peer to peer testing with the group mean used to uld contribute to differences in results and serves as a s.
		Resolution	
		IF determined proficiency survey handling instructions	THEN complaint is resolved
		were not followed AND retesting produced acceptable	Classification is Complaint 1
		results	
		IF determined the results were transcribed incorrectly or	THEN the incident is resolved
		incorrect units of measure or incorrect coding	Classification is Complaint 1
		IF proficiency survey results are in range and user reports	THEN complaint is resolved
		bias in results or results are not on the mean. The results	Classification is Complaint 1
		are within the established SD or SDI limits per survey	
		report	
		IF proficiency survey results are in range and user reports	THEN cartridges require investigation
		results are NOT within the established SD or SDI limits per	 Classification is Complaint 2
		survey report	Ask customer if cartridges are available to be
			returned for investigation and document request(s)
		IF determined that correct proficiency survey handling	THEN cartridges require investigation
		instructions and testing procedure was followed and the	Classification is Complaint 2
		results were unacceptable per survey report	Ask customer if cartridges are available to be
			returned for investigation and document request(s)

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Complaint	Description		
Off Label Use of	APOC i-STAT Cartridge is used for testing outside of the intended use statement in the individual cartridge Instructions		
Product	For Use (IFU) or Cartridge and Test Information (CTI) sheet.		
	Examples:		
	Serum, urine, body materials or culture media samp	oles tested.	
RW Code: C1066	 ACT cartridges used for monitoring Angiomax 		
	 PT/INR cartridges used as screening test prior to sur 	gery or in stroke patients	
Answer pRE	 Total β-hCG is intended to be used as an aid in the example. 	arly detection of pregnancy	
Questions!	Prompts for Meaningful Data Collection		
	1. What is the lot number of the cartridge(s)?		
Synonyms: N/A	2. Was the product used outside the intended use for patient testing?		
	3. Was there any impact to patient?		
	4. Have internal studies been performed by customer for using the product outside the intended use?		
	Troubleshooting		
	A. Verify and document the details around the unintended use of the i-STAT cartridges		
	B. Determine and document if the customer has performed internal studies for using the product or specimen type		
outside of intended use			
	C. Determine and document if the product or specimen typ	e is being used for human diagnostic testing	
	D. Determine and document if there is any impact to patien	it care	
	E. Inform the customer that the use is Off-Label and docum	ent in the incident the reference used by TSS to provide	
	the customer with the intended use information		
	ResolutionIF the APOC cartridge is used outside of the intended use and proper intended use was discussed with customerTHEN complaint code C1066 should be added to product		
	Classification is determined based on		
	customer complaint (Complaint level 1 or		
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9.0 Advanced Quality Feature (AQF) Issues

Complaint	Description		
Advanced Quality	The i-STAT 1 Analyzer can be customized to utilize various advanced quality features with the release of JAMS132, and		
Feature not	DE version 2.3.		
functioning as			
expected	Advanced Quality Features include:		
	Quality Control Pass/Fail Determination (eVAS)		
RW Code: C3222	Ouality Control Scheduling and Lockout		
	Positive Patient Identification (PPID)		
Synonyms: eVAS, PPID.	Operator Competency Notification		
OC Schedule.	Benertable Bange Customization		
Reportable range	Reportable Range Customization		
customization	Prompts for Meaningful Data Collection		
operator competency	1. What is occurring that is different than expected?		
not working	2. Were any changes made to the customization settings recently?		
not working	3. Does the customization profile number on the analyzer match the customization profile for the specific location		
	in DMS customization workspace?		
	4. Is the issue occurring in the data management system (DMS) or the analyzer?		
	5. If on the analyzer, what is the serial number of the impacted analyzer(s)?		
	a. Are pictures of the analyzer menu screens or screenshots of the customization settings in DMS		
	customization workspace or the results/flags from DMS available?		
	6. If in the DMS, what DMS is being used? What DE version is being used (if applicable)?		
	a. Are pictures or screenshots of the QC results or result flags from DMS available?		
	b. Are pictures of the analyzer menu screens or screenshots of the customization settings in DMS		
	customization workspace available?		
	Troubleshooting		
	A. Verify if this is expected behavior per customization settings or due to user error		
	B. To determine root cause, have the customer follow the menu options on the analyzer to verify which options are		
	available and not available		
	For example: If QC schedule appears to still be due on the analyzer and user states they have already tested		
	controls, follow the analyzer menu options to see if Schedule QC path > APOC control >QC levels are available or		
	unavailable. If Scheduled OC path/APOC control options are still available: it indicates the controls were tested as		
	"Unscheduled QC" or as non-APOC controls.		
	C. Review the pictures of the analyzer menu screens, screenshots of the customization settings in DMS		
	customization workspace and/or screen shots of results/flags from DMS.		
	Examples:		
	1. If OC ranges are not displayed for the control results in DMS, verify the control pass/fail determination		
	settings in customization workspace of the DMS – None/Automatic via eVAS/Manual		
	 eVAS ranges are only displayed when testing occurred while using "Automatic via eVAS" P/F and APOC 		
	control options.		
	3. When using non-APOC control option, the eVAS ranges do not apply and OC P/E determination is		
	manual		
	4 Pass is displayed for a failed OC results or vice versa – If the control was tested as non-APOC control and		
	the OC P/E determination was performed manually by the user		
	If an end-user does not select PASS or FAIL upon completion of test, then the result determination will		
	diana se blank for the test result		
	display as blank for the test result.		
	6. If customer does not fulfill QC schedule for the previous month, when due the next month, there is no		
	grace period		
	D. Flags/errors in DMS for QC results from AQF settings – check that the analyzer is working per customization		
	settings.		
	1. If analyzer is working as expected refer to DMS vendor for troubleshooting		
	2. If analyzer is not working as expected troubleshoot per above or AOF literature below		
L			

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	E. Verify customization settings to see if analyzer has the same customization profile as the location preference in		
	DMS customization workspace if behavior is not exped	cted.	
	F. Verify the customization preference profile number to determine the date when changes were made to the		
	customization and see if this change caused the behavior.		
	1. Changes to customization settings may be needed to see the expected behavior in some instances		
	G. Ensure that customization is enabled in the customiza	tion workspace to allow the latest information to update in	
	the i-STAT 1 Analyzer when placed in a downloader		
	H. For information on how the different AQF settings wo	rk, review the technical bulletins	
	1. Reportable Range Customization (Art: 73000	09)	
	2. Liquid Quality Control Schedule and Lockout	(Art: 730077)	
	3. Liquid Quality Control Pass/Fail Customization (Art: 730078)		
	4. Positive Patient Identification (PPID) Customization (Art: 730211)		
	5. Operator Competency Notification (Art: 730292)		
	Note: Only analytes that are customized "enabled" are tested and used to qualify eVAS controls as pass or fail		
	Resolution		
	IF the advanced quality feature is verified to be	THEN the issue is resolved	
	functioning to specification after reviewing the	Classification is Complaint 1	
	instructions		
	IF the advanced quality feature is functioning to	THEN the issue is resolved	
	specification after choosing the correct settings	Classification is Complaint 1	
	IF the advanced quality feature is functioning to THEN the issue is resolved		
	specification and user error was determined to be causeClassification is Complaint 1IF the advanced quality feature is functioning to specification on the analyzer and the results in thirdTHEN the issue is resolved• Classification is Complaint 1		
	party DMS have flagged messages; refer to Vendor		
	support		

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Complaint	Description		
Analyzer message	The i-STAT 1 Analyzer displays message "certification expired" when scanning or entering an operator ID.		
"Certification	Prompts for Meaningful Data Collection		
expired"	1. How many analyzers are displaying message when scanning/entering operator ID?		
	a. What are the analyzer serial numbers?		
RW Code: C2566	b. Is user scanning the operator IDs or entering the ID manually on the analyzer?		
	2. Is the message with one operator ID or multiple IDs?		
Synonyms: Not	a. When did the analyzer last successfully communicate with the data manager?		
certified, ID not	3. Is the operator in question included in the operator list in the data management system?		
working	a. What is the certification date of the operator in the DMS?		
	4. Is the operator in question located in the DE System page (if applicable)?		
	a. What is the certification date of the operator in DE?		
	5. Request pictures of the message or menus on the analyzer (if appropriate).		
	Troubleshooting		
	A. Verify if the issue is with one analyzer or multiple analyzers		
	B. Verify if the issue is with one operator ID or multiple IDs		
	C. Verify if an operator list is in use for the analyzer		
	D. Verify if any changes were made to the operator ID(s) in question recently		
	E. Verify if the certification date of ID is entered correctly in DMS operator list and DE system		
	F. Review pictures and/or screenshots provided (if appropriate)		
G. Verify that the i-STAT 1 Analyzer has recently communicated with the data management system to			
	latest operator list has been uploaded		
	H. Verify the operator ID and certification are current in the data management system and the DE system (if		
	I. Reset the analyzer to factory settings and place in a downloader, ensure that communication is successful; verify		
	that the customization profile and current operator list updates in the analyzer and scan/enter the operator ID		
	dgdin		
	J. Ensure that customization is enabled in the customization workspace to allow the latest operator list to update in		
	the I-STAT I Analyzer when placed in a downloader		
	NOTE: If the issue accurs on multiple i STAT analyzers or multiple operator IDs suspect on issue with the DE (DMS; if		
	the issue occurs on only one i-STAT 1 Analyzer suspect that the analyzer has not undated its operator list information		
	Resolution		
	IF the message does not persist after placing the i-STAT 1 THEN the issue is resolved		
	Analyzer in the downloader or restoring to factory setting • Classification is Complaint 1		
	then docking the analyzer to pick up the current operator		
	list from DMS		
	IF the message does not persist after enabling THEN the issue is resolved		
	customization in the customization workspace and placing • Classification is Complaint 1		
	the analyzer in the downloader		
	IF the message does not persist after troubleshooting the THEN the issue is resolved		
	DE/DMS system to update with the latest operator • Classification is Complaint 1		
	information and placing the analyzer in the downloader		

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Complaint	Description		
Analyzer message	The i-STAT 1 Analyzer displays message "does not match selected level" when attempting to run controls to meet QC		
"Does not match	schedule.		
selected level"	Prompts for Meaningful Data Collection		
	1. Did the message appear when scanning the cartridges or the controls?		
RW Code: C3217	a. What are the lot number(s) of the product(s) not	t scanning?	
	b. Does the product being scanned match the prod	luct specified in the customization profile QC schedule?	
Synonyms: eVAS	c. What eVAS file is downloaded in the analyzer?		
not working, not	2. What is the analyzer serial number(s)?		
scanning, eVAS	3. Request printouts of the results from analyzer or pictures	of the message or menus on the analyzer (if appropriate).	
error	The results printout contains additional information that is	s not shown on the analyzer screen for that result.	
	Troubleshooting		
	A. Verify the product type, lot number and level that was sca	nned on the analyzer	
	B. Verify that the product being scanned matches the product specified in the customization profile for the QC schedule		
	(e.g. customer is scanning i-STAT Control when the schedule specified TriControl)		
	C. Review result printouts or pictures if requested		
	D. If the control specified in the customization setting does not match the control product scanned		
	1. Verify with customer if the control product(s) in the customization can be updated to the control product(s)		
	that is scanned/used on the analyzer		
	2. Verify user can scan the correct product per the customization settings		
	E. Ensure that customization is enabled in the customization	workspace to allow the latest information to update in the	
	i-STAT 1 Analyzer when placed in a downloader and scan t	the product again	
	F. If appropriate reset the analyzer to factory settings and pla	ace in a downloader, ensure that communication is	
	successful; verify that the customization profile updates in	n the analyzer status screen and scan the products again	
	Resolution		
	IF the error does not persist after scanning the correct	THEN the issue is resolved	
	product specified in the customization OR the • Classification is Complaint 1		
	customization was changed to match the product being		
	scanned		
	IF the error does not persist after enabling customization in	THEN THE ISSUE IS RESOLVED	
	the customization workspace and placing the analyzer in Classification is Complaint 1		
	the downloader		

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Complaint	Description	
eVAS not loading	The eVAS file is not uploading or updating successfully in the i-STAT 1 Analyzer or the DE Customization Workspace.	
into Device/DMS	Prompts for Meaningful Data Collection	
	1. Is the eVAS file not uploading to analyzer(s) or the DE Customization Workspace?	
RW Code: C3221	2. What data management system is being used?	
	a. What DE version is being used (if applicable)?	
Synonyms: No	b. Is the current eVAS file visible in the Customization Workspace?	
eVAS, not	c. What is the analyzer serial number(s)?	
working	d. When did the analyzer last successfully communicate with the data manager?	
	3. How was the eVAS upload performed?	
	4. Is issue occurring with one or multiple i-STAT Downloaders?	
	a. What is serial number of downloader?	
	5. Is it possible to access VAS log?	
	Troubleshooting	
	A. Verify if the eVAS not uploading to analyzer or DE/DMS or both; verify DMS used and version (if appropriate); verify DE	
	version	
	1. Cannot reinstall or revert to a lower eVAS than what is currently installed	
	B. If the eVAS is not uploading to the DE Customization Workspace, verify that correct eVAS upload instructions were	
	followed per Technical Bulletin: Quality Control Pass/Fail Determination Art: 730078.	
	1. If the instructions followed are correct, verify if customer had administrative rights or permission to upload	
	files to DE Customization Workspace	
	2. Ensure that the customer has full administrative rights to the system	
	3. Ensure all DE services (if applicable) are running on the DE System Main/Status page	
	4. If applicable, restart the eVAS service for info HQ customers	
	5. If eVAS does not upload after following the correct instructions refer to DMS vendor for a help with DE	
	permissions or restarting the DE Data Processor Service, DE Com Serv and eVAS service in DE	
	a. Verify that the file name matches the current file available on APOC website and the name has not	
	been changed	
	b. Download the eVAS file from the APOC website on your computer, right click on file and note file	
	size. Ask customer to download eVAS file and note file size. If the customer's file size is greater	
	than yours, the customer has browser settings that are modifying the eVAS file.	
	c. Request customer work with IT to confirm that there are no folder restrictions on the i-STAT/DE	
	software folders.	
	C. If the eVAS is not uploading to analyzer(s) and the eVAS has been successfully uploaded to DE Customization	
	Workspace, verify that the i-STAT 1 Analyzer has recently communicated with the data management system to ensure	
	that any available eVAS has been uploaded	
	1. Verify customization settings in DE Customization Workspace	
	2. Ensure that customization is enabled globally and for the location in the customization workspace to allow	
	the latest information to update in the i-STAT 1 Analyzer when placed in a downloader	
	3. Reset the analyzer to factory settings and place analyzer in a downloader, ensure that communication is	
	successful; verify that the customization profile updates in the Analyzer Status screen	
	4. Try a different downloader to rule out downloader specific issue	
	Note: The following steps may be provided to facility IT or the DMS vendor support to perform.	
	 eVAS version not updating in the DE customization workspace after uploading eVAS file (message states the file has been uploaded) 	
	1. On the DE server:	
	a. Stop the i-STAT/DE Data Processor Service	
	b. Stop the istatdeComsrv service.	
	c. Move the eVAS file to C:\Istat32\VAS folder	
	d. Confirm the correct eVAS file is displayed in the DE customization workspace	
	e. Restart the i-STAT/DE Data Processor Service and the istatdeComsrv service	

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2. The error "banker error" may appear in the VA	SLOG.txt file located in the C:\Istat32\Log folder
Resolution	
IF the eVAS uploads successfully to DMS customization workspace or analyzer after following correct instructions in <i>Technical Bulletin: Liquid Quality Control Pass/Fail</i> <i>Customization Art: 730078</i>	 THEN the issue is resolved Classification is Complaint 1
IF the eVAS uploads to analyzer successfully after enabling customization in the customization workspace and placing the analyzer in the downloader	 THEN the issue is resolved Classification is Complaint 1
IF the eVAS updates successfully after restarting DE eVAS service for Info HQ	 THEN the issue is resolved Classification is Complaint 1
IF the eVAS upload is resolved by IT or third-party DMS vendor support	 THEN the issue is resolved Classification is Complaint 1
IF only specific downloader(s) are not sending the eVAS	THEN refer to downloader transmission troubleshooting

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Complaint	Description		
Incorrect	When using the Positive Patient ID (PPID) feature the operator will see the patient ID number, patient name, patient		
information	gender, and (optional) patient date of birth. If any of this information is incorrect in the i-STAT 1 Analyzer per the		
displayed for PPID	customer's expectation, given the data in their ADT feed, the	en further troubleshooting should be performed. The operator	
	may also see incorrect patient information in DE System or t	he data management software, such as Info HQ.	
RW Code: C2565	Prompts for Meaningful Data Collection		
Synonyms: Year of birth incorrect, does not match, patient name incorrect, patient gender incorrect, patient ID does not match	 What patient information is incorrect or does not match? Is the incorrect PPID information showing on i-STAT 1 Analyzer(s), or in DE System/data management system/LIS/HIS/EMR/etc.? Is a patient list in use on the analyzer and DMS? What is the data management system used? What is version of DMS (if appropriate)? If analyzers are impacted, what is the analyzer serial number(s)? When did the analyzer last successfully communicate with the data management software, ADT feed, etc.)? Does the information show correctly in a different system (e.g. DE system, data management software, ADT feed, etc.)? 		
	9. Request printouts of the results from analyzer or pictur	es of the message or menus on the analyzer (as appropriate)	
	and or screenshots of the data manager results/errors.	The results printout contains additional information that is	
	not shown on the analyzer screen for that result.		
	Troubleshooting		
	A. Verify what patent information is incorrect or mismatch	ned	
	B. Verify use of patient list in DMS and on analyzer		
	C. Verify where this information is mismatched – analyzer	/DE/DMS/LIS/HIS/EMR	
	D. Verify that the i-STAT 1 Analyzer has recently communicated with the data management system to ensure that the latest patient list has been uploaded		
	E. Review printouts, photos and/or screenshots if provide	d	
	F. For incorrect patient date of birth, verify that the patier	nt's date of birth is correct on the ADT feed; if the customer is	
	using DE version <2.8, they can verify on the DE System	page	
	G. If possible, have the customer verify the patient list data in the data management system, such as Info HQ		
	H. If the information in the ADT feed is correct, but is not s	showing correctly in DE or the data management system, then	
	the services for the respective system may need to be restarted		
	I. APOC TS can restart the services for Info HQ		
	J. I nird-party data management vendor support will restart services for third-party DMS/LIS		
	Resolution	THEN the issue is received	
	Analyzer after placing in downloader	Classification is Complaint 1	
	Is the nation information is corrected in DE or the data	Classification is complaint 1	
	management system after allowing the systems to refresh	Classification is Complaint 1	
	or restart		

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The i-STAT 1 Analyzer is showing a message "Invalid eVAS" when powering on or attempting to run controls.		
Prompts for Meaningful Data Collection		
1. What is the analyzer serial number(s) displaying message?		
manager		
that the		
in error		
ll occur.		
set to		
F. Review printout, picture and/or screenshots provided		
pdate in the		
verify that		
the customization profile updates in the analyzer status screen		
ov oithor		
ay entiter		

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Complaint	Description		
Analyzer message	The i-STAT 1 Analyzer is showing a message "Lot Expired" when scanning cartridge pouch barcode.		
"Lot Expired"	The i-STAT 1 Analyzer is showing a message "Lot Expired" when scanning control vial during testing when analyzer is		
	customized for automatic pass/fail determination.		
RW Code: C3219	Prompts for Meaningful Data Collection		
	1. What is the lot number of the cartridge or control in question?		
Synonyms: eVAS	2. Did the message show when scanning the cartridges or the controls?		
not working, not	a. What is the expiration date of the product?		
scanning, eVAS	b. What is the lot number displayed by holding down on the scan key when scanning the product barcode?		
error	3. What is analyzer serial number(s)?		
	4. What is the date/time in the analyzer?		
	a. When did the analyzer last successfully communicate with the data manager?		
	b. Is the analyzer customized to synchronize clock with the data manager?		
	5. Request pictures of the message or menus on the analyzer (as appropriate).		
	Troubleshooting		
	A. Verify that the product being scanned is not expired		
	B. Confirm the lot number being scanned by asking customer to read the lot number from the analyzer screen by		
	holding down on the scan key when scanning the product barcode		
	C. Verify that the date/time in the i-STAT analyzer is accurate		
	D. Review printouts or pictures if provided		
	Resolution		
	IF the message does not persist after correcting the THEN the issue is resolved		
	date/time in the analyzer		
	IF the cartridge or control product is verified to be expired THEN the issue is resolved		
	Classification is Complaint 1		

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Complaint	Description		
Analyzer message	The i-STAT 1 Analyzer is displaying message "Lot not in eVAS" when attempting to scan controls or cartridge.		
"Lot not in eVAS"	Prompts for Meaningful Data Collection		
	1. When is the message occurring – during scanning of control or cartridge?		
RW Code: C3216	2. What is the lot number(s) of the cartridges and controls scanned?		
	3. What is the analyzer serial number(s)?		
Synonyms: invalid	4. Does the analyzer have the current eVAS file number?		
lot, no eVAS, not	5. Has the current eVAS file been successfully uploaded to Customization Workspace?		
working	6. If the eVAS file on the analyzer is current, did the message display when scanning the cartridges or the controls?		
	a. At what prompt is the cartridge and control being scanned?		
	Troubleshooting		
	A. Verify when the message is occurring – with control or cartridge		
	B. Verify that the i-STAT 1 Analyzer has the current eVAS uploaded on it		
	C. If the analyzer does not have the current eVAS, verify that the current eVAS file has been uploaded successfully to		
	the DMS customization workspace.		
	D. Ensure that customization is enabled in the customization workspace to allow the current information to update in		
	the i-STAT 1 Analyzer when placed in a downloader		
	E. Reset the analyzer to factory settings and place in a downloader, ensure communication is successful; verify that		
	the eVAS file and customization profile updates on the analyzer status screen. Repeat testing, verifying scanning of		
	the product is successful.		
	F. If the eVAS file is current on the analyzer; verify that the user is scanning the correct product for the appropriate		
	prompt displayed on the analyzer.		
	 Verify that user is scanning the barcode on the control vial/ampule Verify user is scanning the correct cortridge type when promoted to scan the cortridge barcode based on 		
	 verify user is scanning the correct cartridge type when prompted to scan the cartridge barcode based on the control product already scanned. 		
	the control product already scanned		
	3. Verify that a user is not scanning control barcode in place of cartridge barcode and vice versa		
	4. Ask the user to repeat the scanning steps to fulle out user entri		
	Note: In the case where the eVAS file is current and not compatible with the CLEW software, the customer may either		
	update the analyzers to current CLEW or disable eVAS until CLEW software is current.		
	Resolution		
	IF the message does not persist after updating to correct THEN the issue is resolved		
	eVAS file on the analyzer/DMS • Classification is Complaint 1		
	IF the message does not persist after scanning the correct THEN the issue is resolved		
	product for the prompt displayed on the analyzer • Classification is Complaint 1		
	IF the message does not persist after scanning the correct THEN the issue is resolved		
	cartridge for the control lot number scanned • Classification is Complaint 1		
	IF the message persists AND correct eVAS is downloaded THEN issue requires investigation		
	AND issue is not resolved after the above troubleshooting • Classification is Complaint 2		

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Complaint	Description				
Analyzer	When using the Positive Patient ID (PPID) feature the operator has the option (through customization) to verify the patient				
message "Year of	information by entering the patient's year of birth. If the year of birth does not match the information on the patient list				
birth invalid	currently in the i-STAT 1 analyzer, then the message "Year of birth invalid number" will appear.				
number"					
	Positive Patient Identification (PPID) Customization (Art: 73021	1)			
RW Code: C2564	Prompts for Meaningful Data Collection				
	1. When is the message appearing on the analyzer?				
Synonyms: Year	2. What is the analyzer serial number(s)?				
of birth incorrect,	3. What is the Data Management System in use?				
does not match	4. Is a patient list in use on the analyzer and DMS?				
	5. Is this occurring for one patient ID or multiple IDs?				
	6. What is the Year of Birth entered on the analyzer?				
	7. Does the year of Birth entered, match the information in t	he patient list in DE system and DMS?			
	8. What is the patient Date of Birth (DOB) in the patient list i	n DE system and ADT feed in DMS?			
	9. When did the analyzer last successfully communicate with	n the data manager?			
	10. Request printouts of the results from analyzer or pictures	of the message or menus on the analyzer (as appropriate)			
	and or screenshots of the data manager results/errors. Th	e results printout contains additional information that is not			
	shown on the analyzer screen for that result.				
	Troubleshooting				
	A. Verify that user is entering the correct year of birth and a four-digit year of birth on the analyzer				
	B. Review printouts, pictures and/or screenshots provided				
	C. Verify that the i-STAT 1 Analyzer has recently communicated with the data management system to ensure that the				
	current patient list has been uploaded				
	D. Verify that the patient's Year of Birth and date of birth (DOB) is correct on the ADT feed in DMS; if the customer is				
	using DE version <2.8, they can verify on the DE System pa	age			
	E. If the year of birth or DOB is incorrect in the ADT feed in D	MS, please have the user correct it			
	F. If using the PPID customization setting to "enter" year of k	pirth, it may be necessary to change the setting to "confirm"			
	or "replicate" the DOB; this will show the DOB that the i-S	TAT 1 Analyzer has stored in the current patient list when			
	scanning the patient ID				
	Resolution				
	IF the message does not persist and the year of birth is	THEN the issue is resolved			
	accepted after entering correct year of birth	Classification is Complaint 1			
	IF the message does not persist and the year of birth is	THEN the issue is resolved			
	accepted after placing the i-STAT 1 Analyzer in a downloader	Classification is Complaint 1			
	IF the message does not persist and the year of birth is	THEN the issue is resolved			
	accepted after the customer corrects the patient • Classification is Complaint 1				
	information in the ADT feed				

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10.0 Printer Issues

Complaint	Description			
Printer printing	Printer powers on but is printing slowly or has stopped printing			
slow/stopped	If printer does not power on, refer to <u>C2510</u>			
	Prompts for Meaningful Data Collection			
	1. What is printer serial number(s)?			
RW Code: C5472	2 What is the color of the Status and Power light on the printer?			
	3. Is printing occurring directly from analyzer or via downloader?			
Svnonvms: Unable	4 Is the printer plugged into AC power?			
to Print. Will not	5 If the issue occurs with i-STAT Printer, will i-STAT Printer successfully print while connected to AC power?			
Print Won't Print	6. If the issue occurs with Martal Printer, does the Martal printer baye a removable battery door?			
Cannot Print Can't	0. If the issue of card of a contract, in the printer waiter printer have a removable battery door:			
Print is not	7. Is the paper loaded confectly in the printer:			
Print, 15 HOL Printing Icn't	o. Is the confect FSTAT supplied paper used in the printer?			
Printing, ISH t	9. In the printer does not print when the analyzer is in the downloader, thete the printer to downloader cable			
Print Decen't Drint	connections			
Print, Doesn't Print	a. Is the printer connected to the downloader using correct cables?			
	b. Is the printer in a room with bright fluorescent lights above it?			
	c. Is the IR window on printer and analyzer clean?			
	Troubleshooting			
	A. Verify correct printing procedure is followed (result to be printed is displayed on the analyzer screen, distance			
	between analyzer and printer is appropriate)			
	B. Verify the color of the Status and Power lights			
	1. i-STAT Printer Status Light : Green is Ready, Orange is Out of Paper, and Red indicates Print head			
	temperature is out of range			
	2. i-STAT Printer Power Light : Green is OK, Orange is Battery Low, and Red or does not turn on indicates			
	Battery exhausted			
	3. Martel Printer Status Light: Solid light indicates the battery is exhausted, Flashing indicates out of Paper			
	C. Recharge the battery in the printer if the lights indicate exhausted battery			
	1. Martel Printer serial numbers below 240223657, must charge for 16 hours			
	2. Martel Printer serial numbers above 240223657, must charge for 9 hours			
	3. i-STAT Printer, charge for 3 hours			
	D. If recharging the battery does not or temporarily resolves printing issues, and all listed troubleshooting has been			
	exhausted, expect the battery to be the root cause of the experienced issues and it is necessary for customer to			
	replace the rechargeable battery, which is ordered via APOC, to resolve the printing issue. (i-STAT Printers and Martel			
	Printers with access to battery compartment)			
	Finiters with access to battery compartment,			
	E. Verify printer has the correct i-STAT symplied paper and is correctly installed (paper feeds from under the roll)			
	G Derform the Self-Test on the printer (i-STAT 1 System Manual Section 7: Portable Printer (Martel and i-STAT 1			
	Drinter) Art: 71/360) If "charging disabled" indicated for i-STAT Printer, battery requires replacement			
	Close IP window on the sectors and printer			
	I. Clean is window on the analyzer and printer			
	1. If printer is not printing from analyzer in the downloader			
	1. Verny i analyzer prints uneculy aligned to the analyzer			
	a. If yes, shield IR Window on I-STAT Printer from fluorescent lights or turn off the lights and print			
	2. Check cable connections between downloader and printer			
	3. I ry a different printer interface cable if available			
	Note: Thermal difference (thermal probe check results) is not a printable result			
	Resolution			
	IF recharging OR replacing the battery to the printer THEN the incident is resolved			
	allows printing			
<u> </u>	elassituation is company 1			

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IF the printer does not have a removable battery	THEN the printer should be replaced
compartment AND recharging the battery does not allow	 Classification is Repair
printing	
	Note: Martel printers will be replaced with i-STAT Printer kit
IF cleaning the IR window or shielding IR window from	THEN the incident is resolved
fluorescent light allows printing	Classification is Complaint 1
IF printer will print after loading the correct paper roll or	THEN the incident is resolved
loading the paper roll correctly	Classification is Complaint 1
IF analyzer will print directly from printer but not when	THEN the incident is resolved
connected to downloader and replacing the printer	Classification is Complaint 1
interface cable resolves the printing issue	
IF the printer Status or Power lights do not indicate	THEN the printer should be replaced
acceptable operating conditions AND the above	Classification is Repair
troubleshooting does not allow printing	Note: Martel printers will be replaced with i-STAT Printer kit
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Complaint	Description				
Paper Error (Jam,	Paper is not feeding or is stuck or jammed in printer.				
Load, Eject)	Prompts for Meaningful Data Collection				
	1. What is printer serial number(s)?				
	Troubleshooting				
RW Code: C5474	A. Turn the printer off, clear the jam, and re-insert the	e printer paper			
	B. Press the paper feed button				
Synonyms: Jammed,	C. Perform a Self-Test (<i>i-STAT 1 System Manual, Section 7: Portable Printer (Martel and i-STAT 1 Printer) Art: 714369</i>)				
Stuck, Blocked,	Resolution				
Obstructed	THEN the incident is resolved				
	Classification is Complaint 1				
	THEN the printer should be replaced				
	paper does not feed • Classification is Repair				
	Note: Martel printers will be replaced with i-STAT Printe				
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Complaint	Description			
Thermal Printhead	Thermal print head melted			
Melted	Prompts for Meaningful Data Collection			
	1. What is the printer serial number(s)?			
	2. What power cables were being used with the	printer at the time of the event?		
RW Code: C5242	3. What batteries were being used with the prin	iter?		
	Troubleshooting			
Answer pRE	A. Verify with the customer the melted component(s); specifically, the print head			
Questions!	Resolution			
	IF the print head is melted	THEN the printer and accessories should be replaced and investigated		
		Classification is Complaint 2		
Synonyms:				
Deformed, warped		Ask customer if the power cables and batteries that were in use at		
		the time of the event are available to return for investigation		
		Note: Martel printers will be replaced with i-STAT Printer kit		
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Complaint	Description				
Printout - Info not	The print out is faint, blurry, or misaligned or partial results are printed. The information printed does not match the				
as Expected	information displayed on the i-STAT 1 Analyzer.				
	Prompts for Meaningful Data Collection				
	1. Why is printout not as expected?				
RW Code: C5241	2. What is printer serial number (s) with the issue?				
	3. What is analyzer serial number(s) with the issue?				
Answer pRE	4. Is the information to be printed, displayed on the i-S	TAT 1 Analyzer?			
Questions!	5. Does the information on the print out match the res	ults in the i-STAT 1 Analyzer?			
	6. Are pictures or screen shots of the printouts in quest	ion and the complete results available?			
	Troubleshooting				
Synonyms:	A. Charge or change battery on the printer in question				
Crooked, pixelated,	B. Perform the printer Self-Test (i-STAT 1 System Manu	al, Section 7: Portable Printer (Martel and i-STAT 1 Printer) Art:			
smeared, smudged,	714369)				
incorrect results,	C. Reprint specific results				
missing					
information/results, faded, illegible	Note: Thermal difference (thermal probe check results) is not a printable result				
	If printed results appear inconsistent with a patient's clini	cal assessment, verify that the printed results match the data in			
	the analyzer.				
	• If the results in the analyzer match those on the print out, the patient sample should be retested using another				
	cartridge.				
	• If results on the analyzer do not match those on the print out, reprint the results.				
	• If the reprint still does not match the analyzer data, the printer requires replacement and the printed				
	results must not be used.				
	Resolution				
	IF after battery recharge/replacement the Self-Test	THEN the issue is resolved			
	and/or reprint is successfully (not faint, blurred or	Classification is Complaint 1			
	misaligned, incomplete/partial)				
	IF after battery recharge/replacement the Self-Test	THEN the printer should be replaced			
	does not print OR reprint is faint, blurred or misaligned	Classification is Repair			
	or incomplete/partial				
	Note: Martel printers will be replaced with i-STAT Printer kit				
	IF the results on the print out do not match the THEN the printer should be replaced				
	analyzer data • Classification is Repair				
		Note: Martel printers will be replaced with i-STAT Printer kit			
	IF the results on the print out match the analyzer data	THEN repeat sample testing on new cartridge and refer to			
	but do not match patient's clinical assessment	Unexpected Results troubleshooting			

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11.0 Wireless Issues

If customer reports wireless analyzer is not working or producing unknown code, confirm code displayed by assisting the customer with the following procedure:

- A. Power on analyzer
- B. Press Menu to access Administration menu
- C. Press 8 Wireless
- D. Press 1 Cancel to cancel "Initializing Wireless Module"
- E. Wait for Status to indicate State: Not Assoc.
- F. Press 4 Reset
 - a. If code is displayed, proceed to troubleshooting specific code
 - b. If analyzer displays message "Reset Successful", press 1 to continue
 - i. The analyzer status will display booting / joining / associating
 - ii. If the analyzer associates, press 3-Test Server
 - 1. If the analyzer displays "connection successful" analyzer will transmit
 - 2. If code is displayed, proceed to troubleshooting specific code

<u>GS000</u>	<u>GS001</u>	<u>GS002/GS010</u>	<u>GS003</u>	<u>GS020/GS021</u>	<u>GS022/GS023</u>	<u>GS024/GS025</u>
<u>GS030</u>	<u>iE53(x)</u>	<u>S/E200</u>	<u>S/E213</u>	Other Codes	WiFi Slow	<u>30000</u>
				Unable to Configur	e Wireless Analyzer	<u>Code 14</u>

If analyzer times out while performing above, proceed to troubleshooting other wireless codes.

If customer reports the wireless analyzer will not transmit, proceed to troubleshooting transmission issue.

If customer reports the wireless analyzer is losing settings, proceed to troubleshooting analyzer not functioning as expected.

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Complaint	Description		
GS000 Wireless	The wireless module on the i-STAT 1 Wireless Analyzer is not configured and should be programmed.		
Module is not	Prompts for Meaningful Data Collection		
configured	1. What is analyzer serial number(s)?		
	2. What type of wireless module is installed?		
	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
RW Code: C3229	b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256		
Supervised N/A	support)		
Synonyms. N/A	c. One black triangle on the upper right corner of the Mfg Label on the back = 5 GHz (2AAEX-SDMAC)		
	3. When is the code occurring on the analyzer(s)?		
	4. Were the analyzers successfully configured in the past or are they new to the facility?		
	5. Is the wireless feature presently being used in the facility?		
	Troubleshooting Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Walt for Status to Indicate State: Not Assoc.		
	1. If code is displayed proceed to troublesbooting specific code		
	2. If analyzer displays message "Reset Successful", press 1 to continue		
	a. The analyzer status will display booting / joining / associating		
	b. If the analyzer associates, press 3-Test Server		
	i. If the analyzer displays "connection successful" analyzer will transmit		
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	G\$000:		
	A. Program the wireless analyzer as per appropriate instructions:		
	1. GainSpan: Technical Bulletin: Configuring Wireless Settings Art: 726066		
	i. Ensure that the Reset wheless Module to Factory Defaults option is not checked in the		
	2 5 GHz: Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 200FX-SDMAC Art: 761424		
	B. Ensure that the analyzer successfully receives setup and connects to the network: if other wireless codes are		
	generated refer to appropriate troubleshooting		
	C. If the wireless feature is not being used in the facility, disable the wireless feature in the customization settings of the		
	analyzer or in the DE customization workspace		
	Resolution		
	IF the code GS000 does not persist after programming the THEN the issue is resolved		
	wireless settings on the i-STAT 1 Analyzer or disabling • Classification is Complaint 1		
	wireless teature		
	IF the code GSUUU persists after reprogramming THEN the analyzer should be replaced or repaired		
	Classification is Repair		

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Complaint	Description		
GS001 DHCP	The i-STAT 1 Wireless Analyzer cannot obtain an IP address from the DHCP server; there is no IP address present in		
process time out	analyzer		
	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
RW Code: C3233	2. What type of wireless module is installed?		
	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
Synonyms: N/A	h Two orange/gold triangles on the corners of the Mfg Label on the back = GainSpan V02 (w SHA256		
	support		
	Support)		
	c. One black triangle on the upper right corner of the Mig Label on the back = 5 GHz (ZAAEX-SDIMAC)		
	3. When is the code occurring on the analyzer(s)?		
	4. Have the analyzer(s) successfully associated with the network in the past or are they new to the facility?		
	5. Are the analyzer(s) being programmed with static IP addresses or DHCP (obtain IP address automatically)?		
	Troubleshooting		
	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to Cancel Initializing wheless would E. Wait for Status to indicate State: Not Assoc		
	E. Wait for Status to indicate State. Not Assoc. E. $Proce A = Rocot$		
	1. If code is displayed, proceed to trouble chaoting specific code		
	 If analyzer displayed, proceed to troubleshooting specific code If analyzer displayer message "Reset Successful" press 1 to continue 		
	a The analyzer status will display booting / joining / associating		
	 a. The analyzer status will display booting / joining / associating b. If the analyzer associates, press 3-Test Server i. If the analyzer displays "connection successful" analyzer will transmit 		
	ii. If code is displayed, proceed to troubleshooting specific code		
	ii. If code is displayed, proceed to troubleshooting specific code		
	G\$001:		
	A. Verify if the analyzer is intended to associate with the network via static IP addresses or DHCP (per the facility's IT		
	department)		
	B. If the analyzer needs to be reprogrammed for DHCP, program the wireless analyzer as per appropriate instructions:		
	1. GainSpan: Technical Bulletin: Configuring Wireless Settings Art: 726066		
	2. 5 GHz: Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 2AAEX-SDMAC Art: 761424		
	C. If the analyzer is successfully configured with the correct settings and the code GS001 persists, instruct the customer		
	to advise facility IT department that the analyzer is not able to acquire an IP address from the DHCP server (the MAC		
	address of the analyzer may not be correctly reserved on the network)		
	D. Ensure that the analyzer successfully receives setup and connects to the network; if other wireless codes are		
	generated refer to appropriate troubleshooting		
	Resolution		
	IF the code GS001 does not persist and the analyzer is able THEN the issue is resolved		
	to successfully associate with the network after • Classification is Complaint 1		
	troubleshooting		
	IF the code GS001 does not persist and the analyzer THEN the issue is resolved		
	• Classification is Complaint 1		
	facility's IT department		
	IF the code GSUU1 persists on specific analyzer(s) after the THEN the analyzer should be replaced or repaired		
	above troubleshooting and other analyzers are working as		
1	expected		

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Complaint	Description		
GS002/GS010	The i-STAT 1 Wireless Analyzer is not able to associate with the access point; the access point rejected the association		
Connection to	request.		
AP has failed	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
	2. What type of wireless module is installed?		
RW Code:	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
C3231	b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256 support)		
Synonyms: N/A	c. One black triangle on the upper right corner of the Mfg Label on the back = 5 GHz (2AAEX-SDMAC)		
	3. when is the code occurring on the analyzer(s)?		
	4. Have the analyzers successfully associated with the network in the past or are they new to the facility?		
	5. Is this issue occurring in one location in the facility or all locations?		
	a. Is the analyzer being used in a location with strong wireless signal?		
	6. Have the analyzer(s) been programmed with the correct SSID and security information/password (typos or case sensitive)?		
	7. What type of encryption is the analyzer programmed to use (Pre-Shared Key, EAP-TLS, EAP-TTLS/ MSCHAPv2,		
	PEAPv0/EAP – MSCHAPv2)?		
	a. Have certificates been update?		
	b. When was the analyzer last configured with wireless settings? Was it within the dates of the certificate?		
	c. Are SHA-256 type certificates being used?		
	Troubleshooting		
	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Keset		
	1. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	2. If analyzer displays message reset successful, press 1 to continue		
	a. The dialyzer status will display booting / joining / associating		
	b. If the analyzer displays 5-rest server		
	ii. If code is displayed, proceed to troubleshooting specific code		
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	GS002/GS010:		
	A. If only one wireless analyzer is generating code and all others are working, then reconfigure the analyzer as per		
	appropriate instructions.		
	2 5 GHz: Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 200FX-SDMAC Art: 761424		
	B Ensure that the analyzer is programmed with the correct settings		
	1. Confirm SSID (case sensitive) on analyzer under view set-up		
	2. Confirm the following via WCU or IT department		
	a. If PSK – check security key (recheck all characters)		
	b. If PEAPv0 / EAP – MS-CHAP check username & password.		
	c. If an IP address was entered in the analyzer, try DHCP option instead		
	C. Ensure that the wireless signal is strong (not <65dbm); move the analyzer to an area with strong wireless signal		
	D. If all wireless analyzers are generating code, request authentication / encryption being used		
	1. If EAP-TLS, AP-TTLS, and PEAP-MSCHAP (not PSK) authentication		
	a. Has the customer updated the certificates on the Wireless LAN Controller?		

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	 i. If certificates have been upor Gainspan analyzer configura of the certificates) ii. Reset the wireless module t correct network settings b. Has the customer updated the certific i. If the i-STAT 1 Wireless anal on the back) and site is usin replaced to a with an analyz Note: will not support SHA- 2. If PSK authentication a. Advise customer to have IT check the E. If above troubleshooting does not resolve 1. Confirm firewalls are off 	dated, all the analyzers will need to be reconfigured (the ation date of must be within the start date and expiration date o factory settings then reprogram the analyzer with the cates on the Wireless LAN Controller to SHA-256? lyzer has the old Gainspan wireless module (two blue corners g SHA-256 type certificates, then the analyzer should be ter with the new Gainspan module (two orange/gold corners) -3 wireless network
	Note: It may take several attempts to configure the analyzer Recolution	<u>s</u>
-	IF the code GS002 and/or GS010 does not persist and the	THEN the issue is resolved
	analyzer successfully associates with the wireless network	Classification is Complaint 1
	after programming with the correct SSID or security	
	information OR resetting the wireless module to factory	
	defaults and then reprogramming	
	IF the code GS002 and/or GS010 does not persist and the	THEN the issue is resolved
	analyzer successfully associates with the wireless network	Classification is Complaint 1
	after moving to an area with strong wireless signal	
	IF the code GS002 and/or GS010 is not resolved on an i-STAT	THEN the analyzer should be replaced or repaired
	1 analyzer using the old Gainspan module (two blue corners)	Classification is Repair
	and the customer is using SHA-256 certificates	Analyzer will be replaced with a wireless module that is SHA-
		256 capable

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Complaint	Description		
GS003 Error	The i-STAT 1 Wireless Analyzer failed to make a connection to the i-STAT DE server port 6004; unable to connect to the i-		
creating TCP	STAT DE server.		
connection to	Prompts for Meaningful Data Collection		
port	1. What is analyzer serial number(s)?		
	2. What type of wireless module is installed?		
DW Code: C2222	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
RW Code: C3232	b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256 support)		
Suponyms: N/A	c. One black triangle on the upper right corner of the Mfg Label on the back = 5 GHz (2AAEX-SDMAC)		
Synonyms. N/A	3. When is the code occurring on the analyzer(s)?		
	4. Have the analyzers successfully transmitted results in the past or are they newly configured?		
	5. What are the IP address settings (analyzer IP, subnet, gateway) for the i-STAT 1 Wireless Analyzers generating the code		
	G\$003?		
	6. What data manager program is being used?		
	a. What is the i-STAT DE server IP address and port number?		
	Troubleshooting		
	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	1. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	 If analyzer displays message "Reset Successful", press 1 to continue The analyzer status will display booting / joining / associating 		
	D. If the analyzer disoluties, press 3-rest server		
	 i. If the analyzer displays "connection successful" analyzer will transmit ii. If code is displayed, proceed to troubleshooting specific <u>code</u> 		
	G\$003:		
	A. Ensure that the analyzer is programmed with the correct network settings; if the analyzer needs to be reconfigured		
	program the wireless analyzer as per appropriate instructions:		
	1. GainSpan: Technical Bulletin: Configuring Wireless Settings Art: 726066		
	2. 5 GHz: Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 2AAEX-SDMAC Art: 761424		
	B. Verify server IP address in the analyzer's Wireless Setup page is the IP address of the i-STAT DE server (DE server IP can		
	be confirmed on DE systems page link http://servername/istatdesystem)		
	C. Verify server port is 6004		
	D. Verify the data manager running		
	E. Verify that the i-STAT DE services are running		
	F. If the server IP address and port are correct, have IT check the validity of the IP address assigned to the analyzer		
	G. If the code GS003 occurs on specific i-STAT analyzers but not on others, then compare the IP address settings between		
	the functioning and non-functioning analyzers; refer customer to facility IT department to discuss why the settings on		
	the non-functioning analyzer cannot connect to the DE server		
	H. If the code GS003 occurs on all I-STAT analyzers, refer customer to facility IT department to check if there are any		
	security/firewall policies that are blocking network traffic to the I-STAT DE server, specifically port 6004		
	Kesolution		
	IF the code doors does not persist and the analyzer IHEN the issue is resolved		
	correct i-STAT DE server IP address and port number		

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IF the code GS003 does not persist and the analyzer successfully transmits results after reprogramming with a different set of IP addresses (subnet, gateway)	 THEN the issue is resolved Classification is Complaint 1
IF the code GS003 does not persist and the analyzer successfully transmits results after troubleshooting by the facility's IT department	 THEN the issue is resolved Classification is Complaint 1
IF the code GS003 persists on specific analyzer(s) after the above troubleshooting and other analyzers are working as expected	 THEN the analyzer should be replaced or repaired Classification is Repair

Complaint	Description		
GS020/GS021	i-STAT 1 Wireless Analyzer (GainSpan) cannot connect to the ad hoc network during the wireless configuration process;		
Unable to receive	analyzer is unable to successfully receive setup.		
setup ad hoc	i-STAT 1 Wireless Analyzer (5 GHz) failed to complete configuration file load process.		
	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
RW Code: C3234	2. What type of wireless module is installed?		
	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
Synonyms: N/A	b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256		
	support)		
	c One black triangle on the upper right corner of the Mfg Label on the back = 5 GHz (2AAEX-SDMAC)		
	If occurring on GainSpan Analyzer:		
	1. When is the code occurring on the analyzer(s)?		
	2. Have all the wireless setup steps been properly completed per <i>Technical Bulletin: Configuring Wireless Settings Art:</i> 726066?		
	a. Is WLAN Autoconfig started and set to automatic?		
	b. What IP addresses are entered in the wireless network adapter (Internet Protocol Version 4 (TCP/IPv4) on the computer?		
	c. Is the ad-hoc network "Abbott-Configuration" set up?		
	3. Are there any firewalls or security settings blocking the connection of the i-STAT to the ad-hoc network?		
	 Is the correct JAVA version (1.6+) being used with the Wireless Setup Utility? Do the user's Windows login credentials have read AND write access to location "C:\Abbott\i-STAT1 Wireless Setup Utility"? 		
	 If occurring on 5 GHz Analyzer: 1. When is the code occurring on the analyzer(s)? 2. Have all the steps loading network configuration file been properly completed per Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 2AAEX-SDMAC Art: 761424 		
	a. What web browser was used?		
	b. Was analyzer set to "Receive Setup: prior to loading file?		
	c. Was wireless interface enabled on computer?		
	d. Was correct password entered when selecting network? 'istatYYYYYXXXXX' where 'YYYYYXXXXXX' is the		
	wireless module MAC address (excluding the ':' delimiter between bytes) using numbers and capital letters		
	and 'istat' is in lower case letters.		
	e. Was correct file selected?		
	Troubleshooting		

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Confirm code displayed:

- A. Power on analyzer
- B. Press Menu to access Administration menu
- C. Press 8 Wireless
- D. Press 1 Cancel to cancel "Initializing Wireless Module"
- E. Wait for Status to indicate State: Not Assoc.
- F. Press 4 Reset

2.

- 1. If code is displayed, proceed to troubleshooting specific <u>code</u>
 - If analyzer displays message "Reset Successful", press 1 to continue
 - a. The analyzer status will display booting / joining / associating
 - b. If the analyzer associates, press 3-Test Server
 - i. If the analyzer displays "connection successful" analyzer will transmit
 - ii. If code is displayed, proceed to troubleshooting specific code

GS020/GS021

If occurring on GainSpan Analyzer:

- A. Verify that the computer is set up correctly as per Technical Bulletin: Configuring Wireless Settings Art: 726066
 - 1. Set wireless network adapter TCP/IPv4 is set to 192.168.3.100
 - (The wireless analyzer is preprogrammed to talk on Abbott-Configuration when 5- receive setup is pressed in the wireless menu.)
 - Setup ad hoc network "Abbott-Configuration" with security type: No authentication (Open) (The wireless analyzer is preprogrammed to look for the address 192.1683.100 when 5- receive setup is pressed in the wireless menu)
- B. Instruct the customer to disable any firewalls or antivirus software that may be blocking the connection to the ad-hoc network, WCU, or JAVA
- C. If code still occurs, the customer may need to use a computer that is not on their local domain to avoid their network security policies or try a different computer
- D. If several analyzers have been configured successfully using the computer but now code occurs, advise customer to restart the computer

Note: It may take several attempts to configure the analyzers

- E. If the JAVA version is suspect, uninstall all current JAVA versions and reinstall the Wireless Setup Utility, installing the JAVA bundled with the installer
- F. Verify that customer's Windows login credentials have read AND write access to location "C:\Abbott\i-STAT1 Wireless Setup Utility"

If occurring on 5 GHz Analyzer:

- A. Attempt to load the network configuration file again:
 - 1. Verify that the correct programming steps are being performed as per Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 2AAEX-SDMAC Art: 761424
 - 2. If wireless network is not a choice in the list of available networks on the laptop, check the MAC address on the analyzer to confirm the correct MAC address.
 - i. The network displayed for the analyzer is 'iSTATXXXXXX' where 'XXXXXX' is the last 3 bytes of the wireless module MAC address. (e.g. iSTAT55E09B).
 - 3. If the network password does not work, check the MAC address on the analyzer to confirm the correct MAC address.
 - i. The network password for the wireless analyzer is 'istatYYYYYXXXXX' where 'YYYYYXXXXXX' is the wireless module MAC address. (e.g. istat84253F55E09B)
 - 4. If the login page for the wireless analyzer does not appear, check the wireless adapter on the laptop and confirm it is set to obtain an IP address automatically.
- B. After a successful configuration (setup successful displays on the analyzer) press 4 for reset, if an error code displays refer to appropriate troubleshooting.
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Resolution	
IF the code GS020 and/or GS021 does not persist and the	THEN the issue is resolved
analyzer successfully receives setup after following the	 Classification is Complaint 1
configuration instructions	
IF the code GS020 and/or GS021 does not persist and the	THEN the issue is resolved
analyzer successfully receives setup after disabling any	 Classification is Complaint 1
firewalls or antivirus software	
IF the code GS020 and/or GS021 does not persist and the	THEN the issue is resolved
analyzer successfully receives setup after installing the	 Classification is Complaint 1
correct JAVA version	
IF the code GS020 and/or GS021 does not persist and the	THEN the issue is resolved
analyzer successfully receives setup after customer uses	 Classification is Complaint 1
Windows login credentials that have read AND write access	
to location "C:\Abbott\i-STAT1 Wireless Setup Utility"	
IF the code GS020 and/or GS021 does not persist and the	THEN the issue is resolved
analyzer successfully receives setup after disabling/shutting	 Classification is Complaint 1
off other wireless devices that are broadcasting a duplicate	
SSID" Abbott-Configuration"	
IF the code GS020 and/or GS021 does not persist and the 5	THEN the issue is resolved
GHz analyzer successfully receives network configuration	Classification is Complaint 1
file after repeating procedure	
IF the code GS020 and/or GS021 persists on specific	THEN the analyzer should be replaced or repaired
analyzer(s) after the above troubleshooting and other	Classification is Repair
analyzers are working as expected	

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GS022, GS023 –	The i-STAT 1 Wireless Analyzer failed to erase/write the configuration to flash; configuration not successful.		
config storage	Prompts for Meaningful Data Collection		
failed to	1. What is analyzer serial number(s)?		
erase/write to	2. What type of wireless module is installed?		
flash	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
	b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256		
	support)		
RW Code: C3226	$\frac{3}{3}$ When is the code occurring on the analyzer(s)?		
	5. When is the code occurring on the analyzer(s):		
Synonyms: N/A	4. Have the analyzer(s) successfully been programmed in the past of are they new analyzers?		
	S. Is the customer attempting to compute the wireless Analyzer using EAF-TLS, EAF-TLS/WISCHARVZ, OF PEAFVO/EAF-		
	INISCHAPVZ EICLYPTION via the WCO:		
	a. If yes, is the customer attempting to load a client of CA certificate file to the wheless Analyzer via the will be write as a second s		
	Confirm code displayed:		
	A Power on analyzer		
	B Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	1. If code is displayed, proceed to troubleshooting specific code		
	2. If analyzer displays message "Reset Successful", press 1 to continue		
	a. The analyzer status will display booting / joining / associating		
	b. If the analyzer associates, press 3-Test Server		
	i. If the analyzer displays "connection successful" analyzer will transmit		
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	G\$022/G\$023:		
	A. Reset the Wireless Module to Factory Defaults via the Wireless Setup Utility. Reboot the Wireless Module (GS000		
	should appear during initialization) and verify that SSID = NOT-CONFIGURED in the Wireless Setup page.		
	B. Attempt to reprogram the wireless analyzer as per <i>Technical Bulletin: Configuring Wireless Settings Art: 726066</i>		
	C. If attempting to load a Client or CA Certificate file to the Wireless Analyzer via the WCU, refer customer to their II		
	department to discuss if correct certificate files are being used; wCU accepts .pem, .cer, .crt, .der, .p12, and .ptx		
	Certificate files		
	generated refer to appropriate troublesbooting		
	Percentice to appropriate troubleshooting		
	IF the code GS022 and/or GS023 does not persist and the THEN the issue is resolved		
	analyzer is successfully configured after reprogramming		
	IF the code GS022 and/or GS023 does not persist and the THEN the issue is resolved		
	analyzer is successfully configured after loading correct		
	Client or CA certificates		
	IF the code GS022 and/or GS023 persists on the specific THEN the analyzer should be replaced or renaired		
	analyzer after reprogramming and all other analyzers have • Classification is Repair		
	been programmed successfully		
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Complaint	Description			
GS024, GS025 –	The i-STAT 1 Wireless Analyzer configuration file is corrupt or empty; configuration not successful.			
Wireless config file	Prompts for Meaningful Data Collection			
corrupt/empty	1. What is analyzer serial number(s)?			
	2. What type of wireless module is installed?			
	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01			
RW Code: C3227	b Two orange/gold triangles on the corners of the Mfg. Label on the back – GainSpan V02 (w SHA256			
	b. Two orange/gold thangles on the corners of the wirg. Laber on the back – Gamppan voz (w ShAz50			
Synonyms: N/A	support)			
	3. When is the code occurring on the analyzer(s)?			
	4. Have the analyzer(s) successfully been programmed in the past or are they new analyzers?			
	5. Is the customer attempting to configure the Wireless Analyzer using EAP-TLS, EAP-TTLS/MSCHAPv2, or PEAPv0/EAP-			
	MSCHAPv2 encryption via the WCU?			
	a. If yes, is the customer attempting to load a Client or CA Certificate file to the Wireless Analyzer via the			
	WCU?			
	Troubleshooting			
	Confirm code displayed:			
	A. Power on analyzer			
	B. Press Menu to access Administration menu			
	C. Press 8 - Wireless			
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"			
	E. Wait for Status to indicate State: Not Assoc.			
	F. Press 4 - Reset			
	1. If code is displayed, proceed to troubleshooting specific <u>code</u>			
	2. If analyzer displays message "Reset Successful", press 1 to continue			
	a. The analyzer status will display booting / joining / associating			
	b. If the analyzer associates, press 3-Test Server			
	i. If the analyzer displays "connection successful" analyzer will transmit			
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>			
	GS024/GS025:			
	A. Reset the Wireless Module to Factory Defaults via the Wireless Setup Utility. Reboot the Wireless Module (GS000			
	should appear at initialization) and verify that SSID = NOT-CONFIGURED in the Wireless Setup page.			
	B. Attempt to reprogram the wireless analyzer as per Technical Bulletin: Configuring Wireless Settings Art: 726066			
	C. If attempting to load a Client or CA Certificate file to the Wireless Analyzer via the WCU, refer customer to their IT			
	department to discuss if correct certificate files are being used; WCU accepts .pem, .cer, .crt, .der, .p12 and .pfx			
	certificate files			
	D. Ensure that the analyzer successfully receives setup and connects to the network; if other wireless codes are			
	generated refer to appropriate troubleshooting			
	Resolution			
	IF the code GS024 and/or GS025 does not persist and the THEN the issue is resolved			
	analyzer is successfully configured after reprogramming • Classification is Complaint 1			
	IF the code GS024 and/or GS025 does not persist and the THEN the issue is resolved			
	analyzer is successfully configured after loading correct • Classification is Complaint 1			
	Client or CA certificates			
	IF the code GS024 and/or GS025 persists after THEN the analyzer should be replaced or repaired			
	reprogramming on a specific analyzer and other • Classification is Repair			
	analyzers have been programmed successfully			

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Complaint	Description		
GS030 Device	The i-STAT 1 Wireless Analyzer customization failed to enable wireless module; analyzer did not reboot the wireless		
software failed to	module after updating firmware		
enable module	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
DW/ Code: C2220	2. What type of wireless module is installed?		
RW Code: C3230	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
Synonyms: N/A	 Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256 support) 		
	c. One black triangle on the upper right corner of the Mfg Label on the back = 5 GHz (2AAEX-SDMAC)		
	3. When is the code occurring on the analyzer(s)?		
	4. Have the analyzer(s) successfully been functioning wirelessly in the past or are they new analyzers?		
	Troubleshooting		
	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	 If code is displayed, proceed to troubleshooting specific code If applying displayed proceed to troubleshooting specific code 		
	2. If analyzer displays message reset succession, press 1 to continue		
	a. The analyzer status will display booling / joining / associating		
	D. II the analyzer displays "connection successful" analyzer will transmit		
	ii. If code is displayed, proceed to troubleshooting specific code		
	G\$030:		
	A. Ensure that the analyzer is programmed with the correct network settings; if the analyzer needs to be reconfigured		
	program the wireless analyzer as per appropriate instructions:		
	1. GainSpan: Technical Bulletin: Configuring Wireless Settings Art: 726066		
	i. May need to reset wireless module to factory settings, ensure that "Reset Wireless Module to Factory Defaults" is checked in the Wireless Setup Utility		
	2. 5 GHz: Technical Bulletin For the i-STAT 1 Wireless Analyzer FCC ID: 2AAEX-SDMAC Art: 761424		
	B. Ensure that the analyzer connects to the network; if other wireless codes are generated refer to appropriate		
	Resolution		
	IF the code GS030 does not persist and the analyzer THEN the issue is resolved		
	successfully connects to the network after resetting the		
	wireless module		
	IF the code GS030 persists after resetting THEN the analyzer should be replaced or repaired		
	Classification is Repair		
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Complaint	Description			
iE53(x) Unable to	The i-STAT 1 Wireless Analyzer cannot connect to the ad hoc network during the wireless configuration process; analyzer			
receive setup ad	is unable to successfully receive setup.			
hoc	Code iE53C or iE53D			
	Prompts for Meaningful Data Collection			
	1. What is analyzer serial number(s)?			
RW Code: C3208	2. When is the code occurring on the analyzer(s)?			
	3. Have all the wireless setup steps been properly completed per <i>Technical Bulletin: Configuring Wireless Settings Art:</i>			
Synonyms: N/A	726066?			
	a Is WI AN Autoconfig started and set to automatics?			
	 b. What IP addresses are entered in the wireless network adapter (Internet Protocol Version 4 (TCP/IPv4) on 			
	the computer?			
	c Is the ad-hoc network "Abbott-Configuration" set un?			
	4 Are there any firewalls or security settings blocking the connection of the i-STAT to the ad-hoc network?			
	5. Is the correct IAVA version (1.6+) being used with the Wireless Setup Utility?			
	 Do the customer's Windows login credentials have read AND write access to location "C:\Abbott\i-STAT1 Wireless 			
	Setup Utility"?			
	Troubleshooting			
	Confirm code displayed:			
	A. Power on analyzer			
	B. Press Menu to access Administration menu			
	C. Press 8 - Wireless			
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"			
	E. Wait for Status to indicate State: Not Assoc.			
	F. Press 4 - Reset			
	1. If code is displayed, proceed to troubleshooting specific <u>code</u>			
	2. If analyzer displays message "Reset Successful", press 1 to continue			
	a. The analyzer status will display booting / joining / associating			
	b. If the analyzer associates, press 3-Test Server			
	i. If the analyzer displays "connection successful" analyzer will transmit			
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>			
	iE53(x):			
	A. Verify that the computer is set up correctly as per <i>Technical Bulletin: Configuring Wireless Settings Art:</i> 726066			
	(specifically, ad-hoc SSID is "Abbott-Configuration" and wireless network adapter TCP/IPv4 is set to 192.168.3.100)			
	B. Verify that there are no other wireless devices in the vicinity that are broadcasting the SSID "Abbott-Configuration";			
	only the WCU PC should be broadcasting SSID "Abbott-Configuration"			
	c. Instruct the customer to disable any firewalls of antivirus software that may be blocking the connection to the ad-no			
	network, wco, or JAVA; the customer may need to use a computer that is not on their local domain to avoid their			
	D If the IAVA version is suspect, uninstall all surrent IAVA versions and reinstall the Wireless Setup Utility, installing the			
	10. In the JAVA version is suspect, uninstantial current JAVA versions and remistant the wheless setup othicy, instanting the			
	F Verify that customer's Windows login credentials have read AND write access to location "C:\Abbott\i-STAT1			
	Wireless Setun Hitility"			
	Resolution			
	IF the code iE53C and/or iE53D does not persist and the THEN the issue is resolved			
	analyzer successfully receives setup after following the • Classification is Complaint 1			
	configuration instructions			
	IF the code iE53C and/or iE53D does not persist and the THEN the issue is resolved			
	analyzer successfully receives setup after disabling any • Classification is Complaint 1			
	firewalls or antivirus software			

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IF the code iE53C and/or iE53D does not persist and the analyzer successfully receives setup after installing the correct JAVA version	 THEN the issue is resolved Classification is Complaint 1
IF the code iE53C and/or iE53D does not persist and the analyzer successfully receives setup after customer uses Windows login credentials that have read AND write access to location "C:\Abbott\i-STAT1 Wireless Setup Utility"	 THEN the issue is resolved Classification is Complaint 1
IF the code iE53C and/or iE53D does not persist and the analyzer successfully receives setup after disabling/shutting off other wireless devices that are broadcasting a duplicate SSID "Abbott-Configuration"	 THEN the issue is resolved Classification is Complaint 1
IF the code iE53C and/or iE53D persists on specific analyzer(s) after the above troubleshooting and other analyzers are working as expected	THEN analyzer should be replaced or repairedClassification is Repair

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Complaint	Description		
S/E200 Wireless	The wireless module on the i-TAT 1 Wireless Analyzer is not configured and should be programmed.		
Module is not	Prompts for Meaningful Data Collection		
configured	1. What is analyzer serial number(s)?		
	2. When is the code occurring on the analyzer(s)?		
	3. Were the analyzers successfully configured in the past or are they new to the facility?		
RW Code: C3224	4. Is the wireless feature presently being used in the facility?		
Supersume: N/A	Troubleshooting		
Synonymis. N/A	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	 If code is displayed, proceed to troubleshooting specific <u>code</u> If analyzer displays massage "Baset Suscessful" proce 1 to continue 		
	 If analyzer displays message "Reset Successful", press 1 to continue The analyzer status will display beating (isolary description) 		
	a. The analyzer status will display booting / joining / associating h If the analyzer associates press 3-Test Server		
	i. If the analyzer displays "connection successful" analyzer will transmit ii. If code is displayed, proceed to troubleshooting specific code		
	S/E200:		
	A. Program the wireless analyzer as per Technical Bulletin: Configuring Wireless Settings Art: 726066		
	1. Ensure that the "Reset Wireless Module to Factory Defaults" option is not checked in the Wireless Setup		
	Utility		
	B. Ensure that the analyzer successfully receives setup and connects to the network; if other wireless codes are		
	generated refer to appropriate troubleshooting C. If the wireless feature is not being used in the facility, disable the wireless feature in the customization settings of the analyzer or in DMS customization workspace Resolution IF the code S/E200 does not persist after programming the wireless settings on the analyzer or disabling wireless feature THEN the issue is resolved • Classification is Complaint 1		
	IF the code S/E200 persists on specific analyzer(s) after THEN the analyzer should be replaced or repaired		
	programming the wireless settings on the analyzer Classification is Repair		

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Complaint	Description		
S/E213 – No WLAN	The i-STAT 1 Wireless Analyzer doe not detect an available WLAN connection.		
connection avail.	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
	2. When is the code occurring on the analyzer(s)?		
RW Code: C3228	3. Have the analyzer(s) successfully transmitting results wirelessly in the past or are they new analyzers?		
a	Troubleshooting		
Synonyms: N/A	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	1. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	2. If analyzer displays message "Reset Successful", press 1 to continue		
	a. The analyzer status will display booting / joining / associating		
	b. If the analyzer associates, press 3-Test Server		
	i. If the analyzer displays "connection successful" analyzer will transmit		
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	S/F213·		
	3/E213:		
	A. Verify with the customer (if department) that a what connection is available B. Reset the wireless module to factory settings (program the wireless analyzer as per <i>Technical Bulletin: Configuring</i>		
	Wireless Settings Art: 726066 and ensure that "Reset Wireless Module to Factory Defaults" is checked in the		
	Wireless Setun Utility) then reprogram the analyzer with the correct network settings		
	C Ensure that the analyzer successfully receives setup and connects to the network settings		
	generated refer to appropriate troubleshooting		
	Resolution IF the code S/E213 does not persist and the analyzer successfully associates with the network THEN the issue is resolved • Classification is Complaint 1		
	IF the code S/E213 persists on specific analyzer(s) and the THEN the analyzer should be replaced or repaired		
	other analyzer(s) are working as expected • Classification is Repair		

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Complaint	Description		
Other wireless	The i-STAT 1 Wireless Analyzer displays an error code associated with the wireless functionality that is not currently		
code displayed	defined in a specific complaint code.		
	Wireless analyzer displays "Time Out" after pressing 4-Reset and no other codes occur		
RW Code: C3212	Prompts for Meaningful Data Collection		
c	1. What is analyzer serial number(s)?		
Synonyms: N/A	2. What type of wireless module is installed?		
	a. Two blue triangles on the corners of Mfg. Label on the back = GainSpan V01		
	b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256		
	support)		
	c. One black triangle on the upper right corner of the Mfg Label on the back = 5 GHz (2AAEX-SDMAC)		
	3. What is the error code/message displayed on the analyzer(s)?		
	4. When is the error code occurring?		
	a. During configuration of the wireless settings?		
	b. During association to the network?		
	c. During ping server? (option 2-Ping Server in Wireless Menu)		
	d. During test server? (option 3-Test Server in Wireless Menu)		
	e. Does the analyzer fail to maintain a connection? (connection status goes from associated to not associated)		
	5. What data manager program is being used?		
	6. Are the IP address settings being set automatically via DHCP or manually via Static IP settings entered in the WCU?		
	7. What type of encryption is the analyzer programmed to use (Pre-Shared Key, EAP-TLS, EAP-TTLS/ MSCHAPv2,		
	PEAPVU/EAP - MSCHAPV2)?		
	Confirm code dienlaued		
	Commin code displayed.		
	A. POwer off dialyzer		
	C Press 8 - Wireless		
	D Press 1 - Cancel to cancel "Initializing Wireless Module"		
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	1. If code is displayed, proceed to troubleshooting specific code		
	2. If analyzer displays message "Reset Successful", press 1 to continue		
	a. The analyzer status will display booting / joining / associating		
	b. If the analyzer associates, press 3-Test Server		
	i. If the analyzer displays "connection successful" analyzer will transmit		
	ii. If code is displayed, proceed to troubleshooting specific <u>code</u>		
	Unier Codes/Issues		
	A. verify the stars when the error code/message is occurring		
	C Ensure that the analyzer is programmed with the correct network settings		
	D Ensure that the analyzer successfully receives setup and connects to the network if specific defined wireless codes		
	are generated see the relevant articles in this guide		
	E. If customer is reporting a code GS004 (Handheld is unable to ping the data management system (failed Ping request))		
	1. Verify that the DMS is open and running		
	2. Verify DE IP address is correctly entered in the analyzer		
	F. If customer is reporting "Time Out" message after pressing 4-Reset and no other codes occur, repair or replace		
	analyzer		
	G. If customer is reporting S/E20B/E220 and is using SHA-256 type certificates, then the analyzer should be replaced		
	(upgraded to a new Gainspan with two orange/gold corners)		

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H. Ensure there are no security/firewall policies that are blocking network traffic to the i-STAT DE server, specifically port 6004	
Resolution	
IF the error code/message does not persist after	THEN the issue is resolved
troubleshooting and the analyzer successfully associates	Classification is Complaint 1
with the network and transmits results	
IF "Time Out" message after pressing 4-Reset and no other	THEN the analyzer should be replaced or repaired
codes occur	Classification is Repair
IF the error code/message persist on specific analyzer(s)	THEN the analyzer should be replaced or repaired
after all the troubleshooting above	Classification is Repair

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Complaint	Description		
WiFi connection	The customer reports that the wireless network connection is slow.		
slow	Prompts for Meaningful Data Collection		
	1. Is the slow wireless connection impacting the transmission of the i-STAT 1 Wireless Analyzers?		
	2. What is analyzer serial number(s)?		
RW Code: C4701	3. How was the wireless network determined to be slow?		
	4. How are wireless transmission being initiated?		
Synonyms: Wireless	a. Manually by selecting transmit on the analyzer?		
not strong,	b. Automatically by relying on the auto-transmit feature before the analyzer times out?		
successful, reliable	Troubleshooting		
	A. Verify why the network is determined to be slow		
	B. Access the wireless menu on an i-STAT 1 Wireless Analyzer that is configured for wireless communication and verify		
	that the analyzer associates with the network and has a strong or medium signal		
	1. Wireless transmission should be made at a signal strength of -65dBm or greater (i.e60dBm, -50dBm,		
	etc.).		
	2. The wireless analyzer does not support roaming, and so the wireless analyzer must not be moved from		
	one location to another during wireless transmission.		
	C. If relying on the auto-transmit feature before the analyzer times out:		
	1. Check analyzer customization for unusually long time out setting (default is 2 minutes).		
	2. Check analyzer customization if "Auto- Chart Presentation" is enabled. If this option is enabled and there		
	are no mandatory fields, then the analyzer will automatically display the Chart Page during the cartridge		
	test. The Chart Page will be visible for up to 15 minutes before the analyzer times out, unless user input is		
	made on the page or the right arrow key is used to skip the chart page.		
	D. Advise the customer to work with facility II department to troubleshoot		
	Resolution		
	IF the I-STAT 1 Wireless Analyzer is found to associate THEN the issue is resolved		
	• Classification is Complaint 1		
	IF the wireless network is determined to be weak or THEN the issue is resolved		
	 difficult to connect to reliably and is resolved after help Classification is Complaint 1 		
	from facility's IT department.		

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Complaint	Description		
30000 Device	The i-STAT 1 Wireless Analyzer customization failed to enable wireless module; analyzer did not reboot the wireless		
software failed to	module after updating firmware		
enable module	Prompts for Meaningful Data Collection		
	1. What is analyzer serial number(s)?		
	2. What type of wireless module is installed?		
RW Code: C3225	a. Two blue triangles on the corners of Mfg. Lal	pel on the back = GainSpan V01	
a	b. Two orange/gold triangles on the corners of	the Mfg. Label on the back = GainSpan V02 (w SHA256	
Synonyms: N/A	support)		
	3. Have the analyzer(s) successfully been functioning wire	elessly in the past or are they new analyzers?	
	4. When did the error start occurring?	,	
	5. What is the analyzer battery voltage as shown in the a	nalyzer status page?	
	Troubleshooting		
	Confirm code displayed:		
	A. Power on analyzer		
	B. Press Menu to access Administration menu		
	C. Press 8 - Wireless		
	D. Press 1 - Cancel to cancel "Initializing Wireless Module	"	
	E. Wait for Status to indicate State: Not Assoc.		
	F. Press 4 - Reset		
	 If code is displayed, proceed to troubleshoot 	ing specific <u>code</u>	
	2. If analyzer displays message "Reset Successf	l", press 1 to continue	
	a. The analyzer status will display boo	oting / joining / associating	
	b. If the analyzer associates, press 3-1	est Server	
	i. If the analyzer displays d	connection successful analyzer will transmit	
	li. li code is displayed, proc	eed to troubleshooting specific <u>code</u>	
	20000-		
	A. If analyzer battery voltage is low (~ 7V or less), charge	or replace analyzer battery (~8V or more)	
	 B. Reset the wireless module (select 4-Reset in the Wireless Menu of the analyzer) C. Ensure that the analyzer connects to the network; if other wireless codes are generated refer to appropriate troubleshooting Resolution 		
	IF the code 30000 does not persist and the analyzer	THEN the issue is resolved	
	successfully connects to the network after resetting the	Classification is Complaint 1	
wireless module			

IF the code 30000 persists after resetting

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THEN the analyzer should be replaced or repaired Classification is Repair

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Complaint	Description		
Unable to configure	The customer reports that the i-STAT downloader or downloader/recharger, i-STAT 1 Wireless Analyzer, or the i-STAT		
downloader/	Alinity Instrument cannot be configured successfully. If the customer reports a specific error code or message during		
wireless analyzer/	configuring, see the appropriate complaint code.		
Alinity	Prompts for Meaningful Data Collection		
	1. What is the serial number of the product that cannot be configured?		
	What steps have been performed to attempt to configure the hardware?		
RW Code: C1023	3. What step of configuration process is the user stuck at or cannot proceed past?		
	4. Does user have full admin rights to the laptop/PC?		
Synonyms:	5. Has the user configured another downloader/wireless analyzer successfully using the same laptop/PC recently?		
Downloader, Bas,	6. Is this new hardware or has it been in use without issue at an earlier date?		
cradie, I-STAT, dock,	Troubleshooting		
not working, cannot	Verify the following information is available and has been provided by facility IT department:		
be configured,	A. IP address		
cannot program	B. Gateway IP address		
	C. Subnet mask		
	D. DE server IP address		
	If are growning on i CTAT 1 Developeder		
	n programming an <u>i-STAT I Downoader</u> .		
	B If programming network downloader or network downloader recharger (DN-300/DRN-300) verify the correct		
	nrogramming steps are being performed as per i-STAT 1 System Manual Section 21: Downloader Programming		
	and Wiring (DN/DRN) Art: 714383		
	Note: For PUTTY assistance, refer to Appendix B: Additional Transmission Troubleshooting		
	C. If programming DRC-300 downloader recharger, verify that the correct programming steps are being performed as		
	per Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690.		
	D. Verify that correct cables are used and connected properly per instructions		
	E. Verify that the user has full administrative rights to the computer being used and that there are no firewalls or		
	security software in use blocking the configuration		
	F. Verify if the unit has been successfully configured in the past or if this is a new product to the facility (not previously		
	configured).		
	1. If previously configured, verify with facility IT department there have been no changes to network		
	If programming an <u>i-STAT 1 Wireless Analyzer</u> :		
	A. Verify serial number is wireless analyzer		
	B. Check the color of the corners of the label on the back of the wireless analyzer		
	1. If blue or orange, 2.4 GHz analyzer		
	2. If black, 2.4 or 5 GHz analyzer		
	If programming 2 4 GHz Wireless Analyzer :		
	A Verify that the correct programming steps are being performed as per Technical Bulletin: Configuring Wireless		
	Settings Art: 726066		
	1. Refer to Appendix B: Additional Transmission Troubleshooting for programming on Windows 8 and above		
	onerating systems		
	2 Refer to appropriate traublachapting for codes 65020/65021 and iE52y		
	2. Notify that the user has full administrative rights to the computer being used and that there are to first the re-		
	b. verify that the user has full auministrative rights to the computer being used and that there are no fireWalls or security software in use blocking the configuration.		
	security software in use blocking the configuration.		
	configured)		
	1. If previously configured, verify with facility IT department there have been no changes to network		
	D. Use laptop with wireless connection and, if possible, a dedicated laptop for configuring wireless		
	E. Verify that WCU version 2.0 is used		

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	F. Verify that JAVA version is 1.6 or higher (2 different JAVA versions installed on the laptop can cause issues)		
	G. Is only 1 wireless nanoneid/configuration utility being s	etup at a time?	
	H. Was the correct SSID, Authentication type, Encryption type, Security Key, entered?		
	 Except for Preshared key encryption, all other encryptions certifications can expire (only facility IT would have certification information) 		
	J. If message "Error Message Assertion Failed" occurs in WCU, set Windows display setting to 100% (default) in		
	control panel		
	If programming 2.4 or 5 GHz wireless analyzer :		
	A. Verify that the correct programming steps are being pe	rformed as per Technical Bulletin For the i-STAT 1 Wireless	
	Analyzer FCC ID: 2AAEX-SDMAC Art: 761424		
	B. If wireless network is not a choice in the list of available	e networks on the laptop, check the MAC address on the	
	analyzer to confirm the correct MAC address.		
	1. The network displayed for the analyzer is 'iST	ATXXXXXX' where 'XXXXXX' is the last 3 bytes of the wireless	
	module MAC address. (e.g. iSTAT55E09B).		
	C. If the network password does not work, check the MAC	Caddress on the analyzer to confirm the correct MAC	
	address.		
	 The network password for the wireless analyzed 	zer is 'istatYYYYYYXXXXXX' where 'YYYYYYXXXXXX' is the	
	wireless module MAC address. (e.g. istat8425	3F55E09B)	
	D. If the login page for the wireless analyzer does not app	ear, check the wireless adapter on the laptop and confirm it	
	is set to obtain an IP address automatically.		
	E. After a successful configuration (setup successful displa	ays on the analyzer) press 4 for reset, if an error code displays	
	refer to appropriate troubleshooting.		
	Resolution		
	IF the i-STAT downloader or wireless analyzer is	THEN the issue is resolved	
	successfully configured after programming per the	 Classification is Complaint 1 	
	instructions		
	IF the i-STAT 1 Wireless Analyzer is successfully configured	THEN the issue is resolved	
	after obtaining administrative rights to the computer	Classification is Complaint 1	
	IF the i-STAT downloader cannot be successfully	THEN the downloader should be replaced	
	configured AND other downloaders are able to be	Classification is Repair	
	successfully configured using the same computer setup in		
	the same time interval		
	IF the i-STAT wireless analyzer cannot be successfully	THEN the wireless analyzer should be replaced or repaired	
	configured AND other wireless analyzers are able to be	Classification is Repair	
	successfully configured using the same computer setup in	-	
	the same time interval		
I			

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12.0 Transmission Issues

complaint	Description		
Unsuccessful/Slow	Data is not transmitting from the i-STAT 1 analyzer to the Third-Party Data Management System (DMS) using the DE		
transmission i-STAT	system or the transmission is slow. Transmission may be occurring through a hardwired i-STAT downloader or		
1>DE>Third Party	wirelessly through the i-STAT 1 Wireless Analyzer.		
Data Management			
System (DMS)	This code is used:		
	When the i-STAT analyzer is not transmitting to the Third-Party Data Management System (DMS) such as		
	RALS, PWEB, Telcor, Radiometer, etc.		
RW Code: C4133	 When the i-STAT analyzers have 0 unsent records and the results are not seen in Third-Party DMS. 		
	 For slow transmission issues from analyzer to Third-Party DMS 		
	Prompts for Meaningful Data Collection		
Synonyms: Results no	1. What is analyzer serial number(s) with transmission issue?		
crossing	2. Are there unsent results on the analyzer status page?		
	3. Is the transmission unsuccessful or slow?		
	4. What version of DE is being used?		
	5. What data management system is being used?		
	6. When was the last successful i-STAT results communication in the date management system?		
	7. How many records have not transmitted?		
	a. Have all records stopped transmitting past a specific date/time or are only particular records impacted?		
	8. Exactly when did the communication stop and how long has it been down?		
	a. Is the transmission issue intermittent or consistent (completely stopped)?		
	b. Have there been any changes or service on the network?		
	c. Have there been any updates to the DE server?		
	9. Are there any pending or unsent records in the Data Manager Interface (DMI) on the DE System page?		
	a. How many records are Pending or Unsent?		
	10. Does the i-STAT 1 Wireless Analyzer transmit results wirelessly?		
	11. If using i-STAT 1 Wireless Analyzer, does the analyzer transmit results when placed in a hardwired i-STAT		
	downloader?		
	12. Is one downloader having a transmission issue or multiple downloaders?		
	13 What is the serial number of any downloader(s) not transmitting?		
	14 Was the i-STAT 1 Wireless Analyzer /downloader recently reconfigured?		
	a Did the IP address of DE server change?		
	For slow transmission issues:		
	1 If slow transmission, what is the amount of time delay?		
	2 What are the details of the delayed transmission, cartridge type used time of the test, etc.? Request		
	screenshots/nictures from data manager when annronriate		
	3 Is the delay in transmission from analyzer to DE or DE to DMS?		
	Troubleshooting		
	A Verify if the transmission issues are impacting only one specific i-STAT downloader or wireless analyzer or multiple		
	B If multiple downloaders/analyzers are not transmitting is entire facility impacted or just specific locations		
	C Verify that the analyzer(s) have zero unsent results on the analyzer status screen		
	1 If zero unsent results on analyzer, check Data Manager Interface (DMI) on the DE System nage		
	2. If no uncent or nonding results, contact the DMS wonder to restart the i STAT Client services		
	a. In the unsent of pending results, contact the Divis vendor to restart the r-start Chefft services		
	D. II error displayed, restart the following services:		
	1. World Wide Web Publishing Service (IIS)		
	SQLAnywhere – iSTATDEDB service.		
	c. If "-1" appears, restart SQLAnywhere – iSTATDEDB service.		
	2. If there are unsent results on analyzer		
	a. Verify in the Main/Status page on the DE System page that all services are "running"		
	b. If all analyzers are not transmitting, restart the IstatDeComSrv service.		

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		a Varify in the View/Cat Configuration name on the I	DE System page that "anable patyuark	
		c. verify in the view/set computation page on the t	DE System page that enable network	
		communications is checked and i-STAT series sc	o (I-STAT I) Analyzer is checked and port	
	2 16 19 19	set to 5004		
	3. If none	e of the above resolutions are successful escalate to D	JNIS escalation team	
	D. Verify the date a	and time of last successful I-STAT results communicati	on to data manager	
	Note: The i-STAT 1 V	Vireless Analyzer will attempt to transmit wirelessly w	when placed in a downloader (if the wireless	
	feature is enabled). t	he wireless feature may need to be disabled on the i-	STAT to effectively troubleshoot downloader	
	transmission.	ne whereas reduire may need to be disabled on the r		
	If multiple download	lers/wireless analyzers/i-STAT 1 analyzers are not tra	ansmitting	
	A. Verify the data r	nanagement system is running	-	
	B. Verify no change	es to the DE server IP address or to the network		
	C. Verify if any reco	ent/current network issues at customer site		
	D. Verify that comp	outer or Server where data management software is in	nstalled is not powered off or down	
	E. Check if DE serv	E. Check if DE services are running in DE system		
	F. If services are ru	inning refer customer to facility IT department for tro	ubleshooting	
	G. If DE services are	e down or DE server is suspect; refer to DMS vendor s	support or facility IT support	
	If specific analyzer(s)	If specific analyzer(s) is not transmitting wirelessly or via multiple downloaders		
	A. Verify if auto transmit or wireless is enabled under customization settings and instrument			
	B. Clean the IK window on the analyzer			
	D Try to transmit i	C. Verify battery voltage is not low D. Try to transmit i-STAT 1 analyzer from different downloaders		
	E. Verify if the wire	 D. Try to transmit i-STAT I analyzer from uniferent downloaders F. Verify if the wireless analyzer has transmitted successfully before 		
	F. Verify if the wire	F Verify if the wireless analyzer has transmitted successfully before		
	G. Verify that the v	G. Verify that the wireless analyzer is configured correctly		
	H. Verify that the s	ignal strength of the wireless handheld > -65 dbm		
	I. Check if the IP a	ddresses, gateway, and subnet mask are setup correc	tly in the wireless handheld	
	1. Access	s wireless menu on analyzer – select 4-reset and if ana	alyzer wireless state is: "Associated", press 3-	
	test se	erver, if analyzer displays successful then the analyzer	is programmed correctly	
	2. After v	verifying the above to be successful, is it possible to tr	ansmit data?	
	If an a sift - showing -			
	IT specific downloade	er(s) is not transmitting results	ractly	
	B Switch cables fr	om a working downloader to rule out cable issue	iecuy.	
	C Verify the come	hort USB nort or network lack being used is active and	has not been disabled/inactivated	
	D. Verify proper lig	th configuration on the downloaders		
	E. Verify download	der IP address and configuration		
	F. Ping the IP addr	ess of the downloader (can obtain the IP address from	n facility IT department or DE system or	
	customization w	vorkspace):		
	1. Access	s command prompt		
	2. Type "	'ping <ip address="">", then press enter</ip>		
	3. If ther	e is a reply; then perform Tracert (or Telnet)		
	4. If ping	is not successful refer user to facility IT department t	o check the IP address of downloader.	
	G. Tracert the IP ac	ddress of the downloader:		
	1. Type "	'tracert <ip address="">" at command prompt, then pres</ip>	s enter	
	2. If the	downloader has a static IP address, the final reply will	display that IP address.	
	3. If the	final reply is a hostname instead of the IP address, ver	ify that the hostname is not for another	
	device	on the network such as a printer or a computer. If th	e hostname is for another device on the	
	netwo	ork, this explains why the IP address pings but the dow	/nloader does not transmit.	
	4. If the l	IP address is displayed, then perform Telnet (DN/DRN	-300 models only) or Web Browse (DRC-300	
	model			

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	H Telnet the IP add	Iress of the DN/DRN-300 downloader:	
	1. Type "1	relnet <ip address=""> 9999" at command prompt, then</ip>	press enter
	2. If Lanti	onix message and directions appear, press enter to c	open the device configuration. Verify
	setting	S:	,
	Ū	a. Server configuration displays the IP address of the	e downloader, subnet and gateway address of
		the network port	
		b. Channel 2 configuration displays the settings for c	communication to i-STAT DE server (the
		remote IP address should match the IP address of	f DE server).
		c. If the settings are incorrect or have appeared to h	nave reverted to default settings, reconfigure
		the downloader per i-STAT 1 System Manual, Sect	tion 21: Downloader Programming and
		Wiring (DN/DRN) Art: 714383.	
	I. Web Browse the	IP address of the DRC-300 by opening web browser	window; in address line enter HTTP://
	tollowed by the l	P address, then press enter.	nonu ontions quailable to varify the surrant
	1. If the A	COC DRC-300 login page displays, choose from the n	nenu options available to verify the current
	Art: 72	s of re-configure per recrimical bulletin. I-STAT I DOW	moader/Recharger (moder humber DRC-500)
	AIL. 72	8030.	
	For slow transmission	with i-STAT 1 Wireless Analyzer or i-STAT 1 Analyz	er with tests done in or outside of the
	downloader:	· · · · · · · · · · · · · · · · · · ·	
	A. Access the wirele	ess menu on an i-STAT 1 Wireless Analyzer that is cor	nfigured for wireless communication and
	verify that the ar	alyzer associates with the network and has a strong	or medium signal
	1. Wirele	ss transmission should be made at a signal strength o	of -65dBm or greater (i.e60dBm, -50dBm,
	etc.).		
	2. The wi	reless analyzer does not support roaming, so the wire	eless analyzer must not be moved from one
	locatio	n to another during wireless transmission.	
	B. If relying on the	auto-transmit feature before the analyzer times out:	
	1. Check	analyzer customization for unusually long inactivity I	ime Out setting (default is 2 minute),
	minimi 2 Chack	Im allowable inactivity timeout limit is 45 seconds	is anabled. If this antion is anabled and there
	Z. Check	mandatory fields then the Analyzer will automatical	Is enabled. If this option is enabled and there
	die no test T	he Chart Page will be visible for up to 15 minutes bef	fore the analyzer times out unless the user
	input is	s made on the page or the forward arrow is used on t	the keynad to advance screen to the next
	screen	to allow transmission.	
	3. Check	if there are any CHART page or STATNotes items set t	to "Required". If items are set to required,
	inform	user that mandatory requirements for chart page ite	ems are expected to cause 15-minute
	transm	ission delay to allow operator time to enter the requ	ired information. This 15 minutes time is not
	custom	nizable.	
	4. Check	f customer has comment codes set to "Required". If	Comment codes are required, inform user
	that th	ere is potential 15-minute transmission delay to allow	w operator to enter comment code.
	5. Check	It "Limit number of record in transmit all" is enabled.	I his option allows the customer to limit the
	numbe	r of test results that are retransmitted when an end	user selects "Iransmit All". The i-STAT
	Analyz	er will store 1000 test results. If this feature is not en	habled and user selects the "transmit all"
	option	, an results within the FSTAT Analyzer are re-transmit if "Operator Test Selection" option is applied. If this	ileu. is anahlad a 15-minuta transmission dalau
	o. Uneck	a operator rest selection option is enabled. If this	is enabled, a 13-minute transmission delay
		: expected. munnassay cartridge tests the time stamp for the res	ult will be at the beginning of the test cyclor
	7. FULITII Δσth	Troponin test is a 10-minute test with a time stamp	at the heginning of the test so may be
	c.g. the	yed as a 10-minute delay even when it is transmitted	to DMS soon after the test is complete
	8 If mult	inle simultaneous tests are done on the analyzer with	hout allowing the analyzer to power off then
	the tes	t results will only transmit after the final cartridge te	ist
	Resolution		

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IF a specific downloader(s) or analyzer(s) is suspect and issue	THEN the issue is resolved
is resolved through troubleshooting	Classification is Complaint 1
IF a specific downloader(s) is suspect and issue is NOT	THEN replace the downloader in question
resolved through troubleshooting	Classification is Repair
IF a specific analyzer(s) is suspect and issue is NOT resolved	THEN replace or repair the analyzer in question
through troubleshooting	Classification is Repair
IF the record(s)/result(s) transmit successfully after	THEN the issue is resolved
correcting the settings on the DE System page	Classification is Complaint 1
IF the record(s)/results(s) transmit successfully after	THEN the issue is resolved
restarting the DE server or services by facility IT or DMS	Classification is Complaint 1
vendor	
IF the record(s)/result(s) do not transmit after restarting the	THEN the issue should be referred to the Third-Party
DE server/services AND the settings in DE have been	DMS vendor for troubleshooting
confirmed to be correct and enabled	Classification is Complaint 1
IF the customer reports that the transmission is slow, and is	THEN the issue is resolved
resolved after the troubleshooting above	Classification is Complaint 1
IF the customer reports that the transmission is slow, and is	THEN the issue is NOT resolved and requires
NOT resolved after the troubleshooting above	investigation
	Classification is Complaint 2

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Complaint	Description		
Unsuccessful/Slow	Data is not transmitting from analyzer to DE to Info HQ Manager data management system successfully.		
transmission, i-	This code is also used for slow transmission issues from analyzer to Info HQ		
STAT 1>DE>Info	Prompts for Meaningful Data Collection		
HQ	1. What is analyzer serial number(s) with transmission issue?		
	2. Are there unsent results on the analyzer status page?		
	3. Is the transmission unsuccessful or slow?		
RW Code: C4132	4. What version of DE is being used?		
	5. Is Info HQ Manager or Info HQ Express being used?		
	a. What version of Info HQ is being used?		
	6. When was the last successful i-STAT results communication in the date management system?		
	7. How many records have not transmitted?		
Synonyms: Results	a. Have all records stopped transmitting past a specific date/time or are only particular records impacted?		
not crossing	8. Exactly when did the communication stop and how long has it been down?		
	a. Is the transmission issue intermittent or consistent (completely stopped)?		
	b. Have there been any changes or service on the network?		
	c. Have there been any updates to the DE server?		
	9. Are there any pending or unsent records in the Data Manager Interface (DMI) on the DE System page?		
	a. How many records are Pending or Unsent?		
	10. Does the i-STAT 1 Wireless Analyzer transmit results wirelessly?		
	 If using i-STAT 1 Wireless Analyzer, does the analyzer transmit results when placed in a hardwired i-STAT downloader? 		
	12. Is one downloader having a transmission issue or multiple downloaders?		
	13. What is the serial number of any downloader(s) not transmitting?		
	14. Was the i-STAT 1 Wireless Analyzer /downloader recently reconfigured?		
	a. Did the IP address of DE server change?		
	For slow transmission issues:		
	1. If slow transmission, what is the amount of time delay?		
	2. What are the exact details (time of test on the analyzer vs time of results transmission) of the delayed transmission?		
	Request screenshots/pictures when appropriate.		
	3. Is the delay in transmission from analyzer to DE or DE to Info HQ?		
	Troubleshooting		
	A. Verify if the transmission issues are impacting only one specific i-STAT downloader or wireless analyzer or multiple		
	B. If multiple downloaders/analyzers are not transmitting, is entire facility impacted or just specific locations.		
	C. Verify that the analyzer(s) have zero unsent results on the analyzer status screen		
	1. If zero unsent results on analyzer, check Data Manager Interface (DMI) on the DE System page		
	a. If no unsent or pending results, contact the DMS vendor to restart the i-STAT Client services		
	b. If error displayed, restart the following services:		
	1. World Wide Web Publishing Service (IIS)		
	SQLAnywhere – iSTATDEDB service.		
	c. If "-1" appears, restart SQLAnywhere – iSTATDEDB service.		
	2. If there are unsent results on analyzer		
	a. Verify in the Main/Status page on the DE System page that all services are "running"		
	b. If all analyzers are not transmitting, restart the IstatDeComSrv service.		
	c. Verify in the View/Set Configuration page on the DE System page that "enable network		
	communications" is checked and "i-STAT Series 300 (i-STAT 1) Analyzer" is checked and port set		
	to 6004		
	3. If none of the above resolutions are successful escalate to DMS escalation team		
	D. Verify the date and time of last successful i-STAT results communication to data manager		

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Note: The i-STAT 1 Wireless Analyzer will attempt to transmit wirelessly when placed in a downloader (if the wireless feature is enabled); the wireless feature may need to be disabled on the i-STAT to effectively troubleshoot downloader transmission.

If multiple downloaders/wireless analyzers/i-STAT 1 analyzers are not transmitting

- A. Verify the data management system is running
- B. Verify no changes to the DE server IP address or to the network
- C. Verify if any recent/current network issues at customer site
- D. Verify that computer or Server where data management software is installed is not powered off or down
- E. Check if DE services are running in DE system
- F. If services are running refer customer to facility IT department for troubleshooting
- G. If DE services are down or DE server is suspect; refer to DMS vendor support

If specific analyzer(s) is not transmitting wirelessly or via multiple downloaders

- A. Verify if auto transmit or wireless is enabled under customization settings and instrument
- B. Clean the IR window on the analyzer
- C. Verify battery voltage is not low

I.

- D. Try to transmit i-STAT 1 analyzer from different downloaders
- E. Verify if the wireless analyzer has transmitted successfully before
- F. Verify if the wireless handheld transmits data successfully when docked in the specific downloader
- G. Verify that the wireless analyzer is configured correctly
- H. Verify that the signal strength of the wireless handheld > -65 dbm
 - Check if the IP addresses, gateway, and subnet mask are setup correctly in the wireless handheld
 - 1. Access wireless menu on analyzer select 4-reset and if analyzer wireless state is: "Associated", press 3test server, if analyzer displays successful then the analyzer is programmed correctly
 - 2. After verifying the above to be successful, is it possible to transmit data?

If specific downloader(s) is not transmitting results

- A. Verify that correct cables are in use and the cables are connected correctly.
- B. Switch cables from a working downloader to rule out cable issue
- C. Verify the com port, USB port or network jack being used is active and has not been disabled/inactivated
- D. Verify proper light configuration on the downloaders
- E. Verify downloader IP address and configuration
- F. **Ping** the IP address of the downloader (can obtain the IP address from facility IT department or DE system or customization workspace):
 - 1. Access command prompt
 - 2. Type "ping <IP Address>", then press enter
 - 3. If there is a reply; then perform Tracert (or Telnet)
 - 4. If ping is not successful refer user to facility IT department to check the IP address of downloader.
- G. Tracert the IP address of the downloader:

2.

- 1. Type "tracert <IP Address>" at command prompt, then press enter
- 2. If the downloader has a static IP address, the final reply will display that IP address.
- 3. If the final reply is a hostname instead of the IP address, verify that the hostname is not for another device on the network such as a printer or a computer. If the hostname is for another device on the network, this explains why the IP address pings but the downloader does not transmit.
- 4. If the IP address is displayed, then perform Telnet (DN/DRN-300 models only) or Web Browse (DRC-300 model)
- H. Telnet the IP address of the DN/DRN-300 downloader:
 - 1. Type "telnet <IP Address> 9999" at command prompt, then press enter
 - If Lantronix message and directions appear, press enter to open the device configuration. Verify settings: a. Server configuration displays the IP address of the downloader, subnet and gateway address of the network port

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t	 Channel 2 configuration displays the s ID address ab audit match the ID address 	ettings for communication to I-STAT DE server (the set of DE server)	he remote
	IP address should match the IP addres	ss of DE server).	
	downloader per i-STAT 1 System Man	ual, Section 21: Downloader Programming and \	Wiring
	(DN/DRN) Art: 714383.		
I. Web Browse th	e IP address of the DRC-300 by opening w	eb browser window; in address line enter HTTP:/	/ followed
by the IP addres	ss, then press enter.		
1. If the	APOC DRC-300 login page displays, choose	e from the menu options available to verify the c	urrent
settin	gs or re-configure per Technical Bulletin: i	-STAT 1 Downloader/Recharger (model number I)RC-300)
Art: 7	28690.		
F		at a successful to the second s	
For slow transmissio	on with I-STAT I WIREless Analyzer or I-ST	AT I ANALYZER WITH TESTS DONE IN OR OUTSIDE OF TH	<u>e</u>
downloader:	loss monu on an i STAT 1 Wireless Analyze	or that is configured for wireless communication	and vorify
A. Access the whe	er associates with the network and has a s	trong or medium signal	and verify
1 Wirel	ess transmission should be made at a sign	al strength of -65dBm or greater (i.e60dBm -50)dBm etc.)
2 The w	vireless analyzer does not support roaming	so the wireless analyzer must not be moved fro	im one
locati	on to another during wireless transmission	n	in one
B. If relying on the	auto-transmit feature before the analyze	r times out:	
1. Check	canalyzer customization for unusually long	nactivity Time Out setting (default is 2 minute).	minimum
allow	allowable inactivity timeout limit is 45 seconds		
2. Check	 Check analyzer customization if "Auto- Chart Presentation" is enabled. If this option is enabled and there 		
are no mandatory fields, then the analyzer will automatically display the Chart Page during the cartride		artridge	
test. The Chart Page will be visible for up to 15 minutes before the analyzer times out unless the user in			e user input
is mad	is made on the page or the forward arrow is used on the keypad to advance screen to the next screen t		
allow	transmission.		
3. Check	if there are any CHART page or STATNote	s items set to "Required". If items are set to requ	uired,
inforr	n user that mandatory requirements for cl	chart page items are expected to cause 15-minute enter the required information. This 15 minutes time is not	
transı	mission delay to allow operator time to en		
custo	mizable.		
4. Check	c if customer has comment codes set to "R	equired". If Comment codes are required, inform	i user that
there	is potential 15-minute transmission delay	to allow operator to enter comment code.	
5. Check	c if "Limit number of record in transmit all"	' is enabled. This option allows the customer to li	mit the
numb	per of test results that are retransmitted w	hen an end user selects "Transmit All". The i-STA	T Analyzer
will store 1000 test results. If this feature is not enabled and user selects the "transmit all" option, a		n, all	
result	results within the i-STAT Analyzer are re-transm		
6. Check	if "Operator Test Selection" option is ena	bled. If this is enabled, a 15-minute transmission	delay may
be ex	pected.		
7. For in	nmunoassay cartridge tests the time stam	o for the result will be at the beginning of the tes	t cycle; e.g.
the Troponin test is a 10-minute test with a time stamp at the beginning of the test so may be perc		erceived as	
a 10-r	minute delay even when it is transmitted t	o DMS soon after the test is complete.	
8. If mul	8. If multiple simultaneous tests are done on the analyzer without allowing the analyzer to power off then the		
test r	test results will only transmit after the final cartridge test		
Resolution	Resolution		
IF a specific downloa	ader(s) or analyzer(s) is suspect and issue	THEN the issue is resolved	
is resolved through t	troubleshooting	Classification is Complaint 1	
IF a specific downloa	ader(s) is suspect and issue is NOT	THEN replace the downloader in question	
resolved through tro	oubleshooting	Classification is Repair	
IF a specific analyzer	(s) is suspect and issue is NOT resolved	THEN replace or repair the analyzer in question	1
through troubleshoo	oting	Classification is Repair	

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IF the record(s)/results(s) transmit successfully after correcting the settings on the DE System page or restarting DE server/services	 THEN the issue is resolved Classification is Complaint 1
IF results transmission issue is resolved by the facility IT department after fixing IP address/configuration/network settings/etc.	 THEN the issue is resolved Classification is Complaint 1
IF the record(s)/result(s) transmit after troubleshooting the Info HQ settings	 THEN the issue is resolved Classification is Complaint 1
IF the record(s)/result(s) still not transmitting after troubleshooting the Info HQ settings; not facility network related	 THEN the issue is NOT resolved and requires investigation Classification is Complaint 2
IF customer reports that the transmission is slow and is resolved after the troubleshooting above	 THEN the issue is resolved Classification is Complaint 1
IF the customer reports that the transmission is slow, and is NOT resolved after the troubleshooting above	 THEN the issue is NOT resolved and requires investigation Classification is Complaint 2

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Complaint	Description		
Unsuccessful/Slow	Data is not transmitting or is slow from Info HQ to the LIS/HIS successfully. The results have successfully transmitted to		
Transmission Info	Info HQ.		
HQ to Third Party	Prompts for Meaningful Data Collection		
Interface	1. What version of Info HQ is being used?		
	2. Is the transmission unsuccessful or slow?		
RW Code: C4141	3. What interface vendor is being used (e.g. APOC, Medited	ch, Conworx, Telcor, JResult Net, etc.)?	
	4. Has the interface transmitted successfully in the past or	is this a new installation?	
	5. How many records have not transmitted?		
Unsuccessful/Slow	 Have all records stopped transmitting past a sp 	pecific date/time or are only particular records impacted?	
transmission Info	6. Date/time when communication stopped (how long has	it been down)?	
HQ to APOC	a. Is the transmission issue intermittent or is it co	ompletely/consistently down?	
Interface	b. Was there any network outage recently?		
	7. Have there been any updates or modifications to the Info	o HQ server?	
RW Code: C4143	8. Are there any interface messages in Info HQ?		
	9. Is the Info HQ configured with correct LIS settings? Were	e any changes made to settings?	
Curren an une a Desulte	10. What is the interface "Sent" status in Info HQ for the imp	bacted records?	
synonyms: Results	11. Have the records been resent from into HQ?		
not crossing			
	For slow transmission	102 ///	
	1. Is there any delayed transmission from analyzer to info HQ? (if yes, see <u>C4132</u>)		
	2. Is there delayed transmission from info HQ to interface/	LIS/HIS?	
	3. What is the amount of delay?		
	4. Is it all results or some results?		
	I roubleshooting	the second and static the "Constant UC" however (should the	
	A. Attempt to resend the records in into HQ by highlighting	the record and clicking the "Send to LIS" button (check the	
	resend box if necessary)	a deal wat watch a conclust to DNAC conclusion to an	
	B. If using APOC Interface (Mirth), and resending the results	s does not resolve, escalate to Divis escalation team	
	c. Ensure that the interface has been successfully configure	ed for find HQ by the APOC implementation team if this is a	
	D Restart of Info HO server might be the option		
	1 Info HO team (APOC Princeton) will perform re	estart for Info HO	
	2 IResult Net Vendor (Data Innovations) will perform	form the restart of their servers	
	Resolution		
	IF the record(s) transmit successfully after resending the	THEN the issue is resolved	
	records	Classification is Complaint 1	
	IF the record(s) transmit successfully after correcting the	THEN the issue is resolved	
	interface settings	Classification is Complaint 1	
	IF the record(s) do not transmit after recending AND the	THEN the issue should be referred to the interface vendor	
	interface settings have been confirmed to be correct	for troubleshooting	
		Classification is Complaint 1	
	IF the customer reports that the transmission is slow from	THEN the issue should be referred to the interface/US/HIS	
	InfoHO to interface/US/HIS	vendor for troubleshooting	
		Classification is Complaint 1	
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13.0 Data Management System (DMS) Issues

Complaint	Description		
Data – Unable to	Results or data is unable to be found or is missing. This may apply to both the analyzer, data management systems, and		
find/lost	Hospital systems.		
	Prompts for Meaningful Data Collection		
	 Where is the data lost/unable to be found (DMS, analyzer, LIS/HIS)? 		
RW Code: C2590	2. What are the serial numbers of i-STAT 1 Analyzers?		
	a. What pathway was used for cartridge testing?		
Answer pRE	b. Are there any unsent results on Analyzer Status page?		
Questions!	What data management system is being used?		
	4. What is the version of Info HQ software?		
Synonyms: N/A	5. What is the version of DE software (if applicable)?		
	6. Which data viewer is being searched for the results?		
	7. What is the date or date range of missing data?		
	8. Were the results previously viewed in analyzer or DMS?		
	9. Were any system updates performed prior to the loss of results/data?		
	10. Request printouts of the results from analyzer or pictures of the message or menus on the analyzer (as appropriate)		
	and or screenshots of the data manager results/errors. The results printout contains additional information that is		
	not shown on the analyzer screen for that result.		
	Troubleshooting		
	A. Verify testing pathway used on i-STAT 1 Analyzer		
	B. Check if the results are under a different pathway on the analyzer		
	C. Verify date range of viewed results (in DMS) matches when testing was performed		
	D. Verify correct data viewer is being viewed in DMS		
	E. Assist customer with procedure to locate data in analyzer and/or DMS, as applicable		
	F. Review printouts, pictures and/or screenshots provided		
	G. If user reports zero unsent results on analyzer and there are missing results in DMS:		
	1. If the records are from the current month, manually transmit results from the analyzer "Transmit data >		
	This Month		
	2. If the records are from the previous month, manually transmit results from the analyzer "Transmit data >		
	Last Month		
	H. If user is unable to view location data in Info HQ, reset user permissions		
	1. Tools>User Admin>Highlight User>Edit User Information		
	2. Select location and save settings		
	I. If operator is not located under operator tab in Info HQ for location, check operator status		
	1. Operators>Search for Operator		
	2. If "inactive" status, select Operator tab and edit status Resolution		
	IF repeating the steps to view the data locates the missing THEN the issue is resolved		
	data on the analyzer or Into HQ • Classification is Complaint 1		
	IF unable to locate data in a third-party DMS THEN refer customer to DMS vendor		
	Classification is Complaint 1		
	IF results are missing/lost in Info HQ and results are on THEN the issue is investigated		
	the analyzer • Classification is Complaint 2		

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Complaint	Description		
Results changed	The records in the data management system (DMS) or Interface or LIS/HIS have incorrect or different information that		
or affected during	does not match the information in the i-STAT 1 Analyzer or DMS.		
transmission	Prompts for Meaningful Data Collection		
	1. What information is not correct or different in the DMS?		
	a. Is the information in the i-STAT 1 Analyzer corre	ect?	
RW Code: C4325	2. What version of DE is being used?		
	3. What data management system or version of Info HQ is b	eing used (if applicable)?	
Answer pRE	4. Request printouts of the results from analyzer or pictures	of the message or menus on the analyzer (as appropriate)	
Questions!	and or screenshots of the data manager results/errors. The	ne results printout contains additional information that is	
	not shown on the analyzer screen for that result.		
Synonyms: Data,	Troubleshooting		
results, records,	A. Verify that the results in the i-STAT 1 Analyzer are correct		
wrong incorrect	B. Verify what information appears to be incorrect or differe	ent in the DMS/LIS/HIS; get screenshots of any discrepancies	
	to aid in troubleshooting		
	C. Review printouts, pictures and/or screenshots provided		
	Examples:		
	1. β-hCG results are greater the 2,000 on the analyzer and DMS are going into Sunquest (LIS) as greater than 25		
	2. DMS/LIS report is flagging a result for iCa of 1.27 mmol/L as critically high, however, the result is not critically		
	high on the analyzer		
	3. i-STAT 1 analyzer and DMS indicates arterial sample	but result is transmitted to LIS as venous sample.	
	Customer states specific information displayed in DN	/IS for the i-STAT result records is not displayed in the site's	
	LIS.		
	5. i-STAT 1 Analyzers that are customized to disable all analytes except iCa for CHEM8+ cartridges are running the		
	tests and storing the records in DMS with only iCa, but the test result displayed in the LIS shows results for all		
	analytes on cartridge		
	6. Info HQ not sending LOINC code for BEect and Hb* w	while sending patient test results to LIS system	
	7. I-STAT results are flagged as critical on the analyzer a	ind when going into LIS they are no longer being flagged as	
	IF results in the DMS are verified to match the I-STAT 1	THEN the issue is resolved	
		Classification is Complaint 1	
	IF results in Info HQ do not match the I-STAT 1 Analyzer	THEN the issue is investigated	
		Classification is Complaint 2	
	IF results in the third party DMS do not match the i-STAT 1	THEN refer customer to DMS vendor for issue resolution	
	Analyzer, work with DMS vendor on issue resolution	Classification is Complaint 1	
	IF results in the Interface/LIS/HIS do not match the DMS and	THEN refer customer to Interface/LIS/HIS vendor for issue	
	i-STAT 1 Analyzer	resolution	
		Classification is Complaint 1	

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Complaint	Description		
Re-appearance of	Records have populated in the data management system, interface, or LIS from the i-STAT 1 analyzer that are not current		
aged data	(old records from an earlier date).		
	Prompts for Meaningful Data Collection		
	1. Where are the old records showing (e.g. DMS, interface, LIS)?		
RW Code: C4561	a. How many old records have populated?		
	b. What is the date/time stamp on the records for date performed and date transmitted?		
Synonyms: Old	2. Did the old records transmit at one time (one event), multiple times (multiple events), or is this an intermittent issue?		
records results	3. What version of DE is being used (if applicable)?		
transmitting	4. What data management system is being used?		
	5. Are the old records transmitting from one specific i-STAT 1 Analyzer or from one specific downloader or location?		
	a. What is the serial number(s) of the impacted hardware?		
	6. Did the operator manually transmit records from the i-STAT 1 Analyzer?		
	a. Was the option to transmit "last month" or transmit "all" records selected?		
	7. Request printouts of the results from analyzer or pictures of the message or menus on the analyzer (as appropriate)		
	and or screenshots of the data manager results/errors. The analyzer results printout contains additional information		
	that is not shown on the analyzer screen for that result.		
	Troubleshooting		
	A. Verity if the operator manually transmitted records from the i-STAT 1 Analyzer to DMS		
	B. Verify that the "limit the number of records in transmit all" is set to 14 days under instrument tab in DMS		
	customization workspace		
	C. Verify the date range for the results view screen in DMS		
	D. Verify if the operator manually transmitted records from the Info HQ.		
	E. Verify if the old records show in the Divis or if they only show in the interface/Lis		
	F. Review printout, pictures and/or screensnots provided		
	Resolution		
	IF the customer confirms that records were manually IFEN the issue is resolved		
	• Classification is Complaint 1		
	populate in the DIVIS/Interface/LIS		
	IF the customer commission that records were manually Inc. the issue is resolved		
	the interface/LIS		
	IF the sustamentations that the old records do not show in THEN refer the insident to the interface or HS yender for		
	the DMS but they do show in LIS/interface		
	Classification is Complaint 1		
: CTAT Cummont Cuida	Classification is complaint 1		

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Complaint	Description		
DMS Report info	The records in the data management system (DMS) have inco	rrect information that does not match the information in the	
is incorrect	i-STAT 1 Analyzer or does not match labeling for APOC products when generating a report.		
	Prompts for Meaningful Data Collection		
	1. What information is not correct in the DMS report?		
RW Code: C4585	a. Is the information in the i-STAT 1 Analyzer corr	ect?	
	b. Is the information in DE correct (if applicable)?		
Synonyms: Data,	c. Is the information in the DMS data viewer corr	ect (outside of the report)?	
results, records,	2. What version of DE is being used (if applicable)?		
wrong incorrect in	3. What data management system or version of Info HQ is	being used (if applicable)?	
report	4. What is the expected information on the report?		
	5. How is the information captured/displayed on the analyzed o	zer?	
	6. When appropriate, what are the customization settings i	n customization workspace?	
	7. Request printouts of the results from analyzer or picture	s of the message or menus on the analyzer (as appropriate)	
	and or screenshots of the data manager results/errors. T	he results printout contains additional information that is	
	not shown on the analyzer screen for that result.		
	Troubleshooting		
	A. Verify that the results or information in the i-STAT 1 Ana	lyzer are correct	
	B. Verify what information appears to be incorrect in the D	MS; get screenshots or pictures of any discrepancies to aid in	
	troubleshooting		
	C. Request specific details of report data		
	D. Determine if the information is correctly captured/displa	yed on the analyzer	
	E. If this is related to any of the customization settings, ver	ify the customization settings on the analyzer and	
	customization workspace		
	F. Review printouts, pictures and/or screenshots provided		
	Examples:		
	1. The control or cartridge lot number comes up as	expired in DMS report	
	 Internal simulator report in info HQ shows blank DWeb report does not have reference report for 	operator ID field	
	3. Pweb report does not have reference ranges for	some analytes	
	4. The reference ranges displayed in Divis report is	incorrect	
	5. The Qivil report indicates test not available , th		
	Resolution	TUEN the issue is received	
	1 Applyzer and the DMS	Classification is Complaint 1	
	I Analyzer and the Divis	Classification is complaint 1	
	The data available on the report is not what is expected by	THEN the issue is resolved	
	information input into other DMS fields	Classification is complaint 1	
	Information input into other DWS fields	THEN refer sustements third party DMS yender	
	narty DMS report is not matching the analyzer info	Classification is Complaint 1	
	IF the information on the analyzer is correct and the lafe	Classification is complaint 1	
	IF the information on the analyzer is correct and the info	Classification is Complaint 2	
		Classification is Complaint 2	

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Complaint	Description		
Alarm/Error	The customer reports that an alarm or error message is occurring on the data management system or webpage.		
message on DMS	Prompts for Meaningful Data Collection		
PC/Webpage	1. What data management system (DMS) is being used?		
	2. What is the error or alarm that is occurring?		
	a. Can a screenshot be provided?		
RW Code: C4332	3. Is the error preventing normal operation of the software or webpage?		
	4. When did the error start to occur?		
Synonyms: Flag,	5. Have there been any updates to the DE and/or DMS server?		
warning, alert,	6. When does the error message show (e.g. during start up, when accessing a specific window)?		
window, pop up	How frequently does the error or alarm appear?		
	8. Request printouts of the results from analyzer or pictures of the message or menus on the analyzer (as appropriate)		
	and or screenshots of the data manager results/errors. The results printout contains additional information that is		
	not shown on the analyzer screen for that result.		
	Troubleshooting		
	If occurring with i-STAT/DE:		
	A. If the error occurs when trying to open DE system or DE customization webpage, restart DE/DMS page		
	B. Verify with the customer if any firewalls or security software is potentially interfering with the operation of the		
	software		
	C. In case of alarms/errors in DMS related to i-STAT results, verify the analyzer results are as expected and do not		
	display any errors or flags.		
	D. If the alarms are related LIS settings not matching DE customization workspace or DMS settings refer customer to LIS		
	vendor for any appropriate changes		
	E. If every restart of computer resolves the issue, make sure appropriate services and folders are exempted from anti-		
	Virus scanning.		
	r. Review printout, pictures and/or screenshots (in provided)		
	If occurring with Info HO:		
	A From occurs when user attempts to login to Info HO		
	1. If "Server Error in / Data Manager Application" error displayed, restart the		
	APOC.datamanager.connectivitymanager service		
	2. If " RUN TIME " error displayed, restart the APOC.datamanager.connectivitymanager service		
	B. Error occurs when user attempts to access the Info HQ link.		
	1. If " 404 " error displayed, restart the World Wide Web Publishing service		
	2. If "can't reach this page" error displayed, restart the World Wide Web Publishing service		
	3. If the web page cannot be reached after trying the above resolutions, ask the customer to reboot the info		
	HQ server.		
	C. Error occurs when attempting to reach a DE web page. (System or customization)		
	 If "404" error displayed, restart the World Wide Web Publishing service 		
	2. If "can't reach this page" error displayed, restart the World Wide Web Publishing service		
	D. If the alarms are related LIS settings not matching DMS settings refer customer to LIS vendor for any appropriate		
	changes		
	E. If every restart of computer resolves the issue, make sure appropriate services and folders are exempted from anti-		
	virus scanning.		
	F. Review printout, pictures and/or screenshots (if provided)		
	If occurring with Third-Darty DMS:		
	Λ In case of alarms/errors in DMS related to i.STAT results, varify the analyzer results are as expected and do not		
	A. In case of alarms/errors in Divisire lated to FSTAT results, verify the dilaryzer results are as expected and do not display any errors or flags		
	B If the alarms are related US settings not matching DMS settings refer customer to US vendor for any appropriate		
	changes		
	C. If every restart of computer resolves the issue, make sure appropriate services and folders are exempted from anti-		
	virus scanning.		

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D. Review printout, pictures and/or screenshots (if provided)E. Refer to DMS vendor if DE is ruled out		
Resolution		
IF restarting the application or the computer/webpage	THEN the issue is resolved	
removes the error message	Classification is Complaint 1	
IF the error message is removed by disabling the firewall or security software on the DMS server/computer or restarting of the DE/DMS services or server	 THEN refer customer to third party DMS vendor Classification is Complaint 1 	
IF the error message is not resolved for APOC DMSTHEN the issue is NOT resolvedproducts after advanced troubleshooting• Classification is Complaint 2		

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Complaint	Description		
Customization –	The customer reports that the i-STAT 1 Analyzer is not receiving the correct customization settings from the data		
system won't	management system or the customization settings are not displaying correctly or updating in the customization		
update/incorrectly	workspace.		
displayed	Prompts for Meaningful Data Collection		
	1. What is the specific issue occurring?		
	2. Is the issue occurring on the analyzer or DE/DMS?		
RW Code: C4411	3. Are the customization settings updating and displaying correctly in the Customization Workspace?		
	a. What preference number is expected to display?		
Synonyms:	b. What customization settings are incorrect?		
Incorrect	4. Is the i-STAT 1 Analyzer receiving the incorrect customization settings?		
customization, not	a. What is analyzer serial number(s)?		
functioning	b. What customization preference number is on the i-STAT 1 Analyzer Status screen?		
correctly, as	c. What is the expected preference number?		
expected, settings	d. Was the i-STAT analyzer recently placed in a downloader?		
wrong	e. Is the analyzer an i-STAT 1 Wireless Analyzer (communicating wirelessly)?		
	f. Is the analyzer assigned to correct location?		
	g. Is the assigned location configured to use desired customization?		
	h. Is customization enabled globally and for the location in DE customization?		
	I. Are STAT Notes enabled for the location in the Customization Workspace?		
	5. Is the issue occurring with a specific downloader?		
	6. Is a different downloader with the same preference number available to dock the analyzer?		
	7. Request printouts of the results from analyzer or pictures of the message or menus on the analyzer (as appropriate)		
	and or screenshots of the data manager results/errors. The results printout contains additional information that is		
	A Collect details of the issue that is occurring		
	B Review printouts, pictures and/or screenshots provided		
	If customization workspace is not updating:		
	A. If the customization keeps changing to " Default0 " in the customization workspace, it may be due to activation of the		
	"Default Values" button in the preferences screen, which can be activated by hitting the Enter key on the keyboard		
	when changing preferences instead of clicking ok to accept the changes		
	B. If the customer is expecting a specific preference number, educate the customer on the way the preference number		
	update; use the "apply preferences" tool to assign preferences to specific locations		
	C. If customer cannot make changes to preferences, verify DE version.		
	1. DE 2.10 requires log in to access customization workspace		
	2. Users are granted "Full Access" or "Read-Only Access". Refer customer to administrator.		
	If the i-STAT 1 Analyzer is not picking up the desired preferences:		
	A. Ensure that the analyzer is being placed in a downloader in the location it is assigned to in the data management		
	system		
	B. Ensure that the analyzer serial number is assigned to the correct location in the data management system		
	C. If the analyzer communicates whelessly verify that the analyzer ip is assigned to the correct location		
	D. Verify Enabled Customization is checked globally		
	verify enabled is checked for an locations in the custoffil/ation workspace Reset the analyzer to factory settings then place in a downloader to communicate (or enable wireless and		
	communicate wirelesch) and check the preference chown in the Analyzer Status screen to verify if analyzer is nicking		
	un wrong customization or no customization		
	G Educate the customer on the difference between DMS download versus assignments locations: assignment (logical)		
	picks up the settings of the location the analyzer is assigned to while download (nhysical) nicks up the settings of the		
	location the analyzer is downloaded		
	If sample-type customization is not functioning:		

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	Α.	No DMS:	
		 Review feature and explain default setting is "Cart Based" 	
		2. View analyzer customization	
		3. Change customization to either "Cart Based" or "Custom" sample-type selection	
	To determine if analyzer is using STATNotes feature, view Customization > Patient Tests > Page over to 2 nd I		
		STATNotes (disabled or XXXXXXXX for profile)	
	В.	DMS (no STATNotes)	
		 Review feature and explain default setting is "Cart Based" 	
		2. Verify analyzer is manually customized to "Custom" sample-type selection	
		3. Verify in i-STAT/DE customization workspace that customization is enabled globally and enabled for the	
		location	
		4. Place analyzer in downloader to apply preference	
	Exa	mples:	
		1. If the critical/action range flags are not displaying with results on the analyzer/DMS, check the critical/action	
		ranges are correctly customized in the DE/DMS customization workspace	
		2. If analytes are disabled for the cartridge in customization workspace and the results for the analytes are still	
	reporting out on the cartridge test		
		3. Analyzer is not picking up the customization settings from DMS/DE customization workspace	
		4. Operator list is in use and invalid operator lock out feature is enabled; however, i-STAT 1 Analyzers are allowing	
		operators who are not the list to perform testing	
		5. Sample type is set as mandatory under chart page in DE/DMS customization workspace, but the prompt is not	
		coming up on the analyzer	
		6. The analyzer is customized to print reference ranges, but the printout does not print the reference ranges along	
		with results	
		7. Internal simulator is not being activated on the analyzer per internal simulator schedule customization	
	Res	olution	
	IF t	he customization updates successfully after THEN the issue is resolved	
	trou	ubleshooting steps above • Classification is Complaint 1	
	IF t	he customization settings are not displaying correctly or THEN the issue is NOT resolved	
	as e	expected in the analyzer or DMS even after all • Classification is Complaint 2	
	tro	ubleshooting	
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Complaint	Description		
Unable to access/	The customer is unable to login to or access the APOC website, DE/Data Management webpages or Info HQ Manager		
login to webpage	Prompts for Meaningful Data Collection		
	1. What webpage cannot be accessed?		
	a. Does the webpage not open at all?		
RW Code: C4581	b. Is login information being rejected?		
	c. Is there an error message showing when attempting to open the webpage? (refer to <u>C4332</u>)		
Synonyms: Can't	2. What version of DE is being used (if applicable)?		
login, get onto	3. What data management system or version of Info HQ is being used (if applicable)?		
website	4. What browser is used to access the webpage? – Internet Explorer, Chrome, etc.		
	Troubleshooting		
	If unable to log into the APOC website:		
	A. Verify that the correct username/email address is being used		
	B. Use the password reset tool if necessary		
	1. User must remember password		
	C. Set up account if new user		
	If using i-STAT/DE:		
	A. Verify Internet Explorer is used to access the webpage if the i-STAT/DE webpage components do not display properly		
	or are missing		
	1. i-STAT DE and its webpages are validated for use on Internet Explorer only		
	B. If unable to access the DE System page, verify the link being used: http:// iservername or IP		
	address1/ISTATDESYSTEM		
	C. If unable to access the DE Customization Workspace.		
	1. Verify the link being used: http:// [servername or IP		
	address]/ActiveX/custom.aspx?inst=[facilityname]&Option=1		
	2. If using DE 2.10 , verify user access has been created in Active Directory		
	i. Users will have either "Full Access" or "Read-Only Access"		
	D. If unable to access the DE webpages, verify that the server name and facility name are correct with the data		
	management vendor		
	E. If unable to access DE links from within a third party DMS refer customer to DMS vendor for support		
	If using Info HQ Manager or Info HQ Express:		
	A. Verify Internet Explorer is used to access the webpage if the Info HQ webpage components do not display properly or		
	are missing		
	1. Info HQ software and its webpages are validated for use on Internet Explorer only		
	B. If unable to access the Info HO, verify the link being used: http://[servername]/Data Manager		
	C. If unable to log into Info HO:		
	1. Try Admin Log in:		
	i. Username: "admin"		
	ii. Password: "admin123" or "Admin123"		
	2. Try to change the user's password using the "Change password" link		
	3. Ask an admin user to reset user's password		
	4. If the above does not resolve the issue, then escalate to escalations team.		
	D. If user selected "forget password" and did not receive email with temporary password, verify email set up in Info HQ		
	(Tools>InfoHQ Configuration>email)		
	1. If fields are blank, no email was set up		
	i. Info HQ must have email set up on same email exchange server as user's email		
	ii. Refer customer to IT to set up email		
	2. User will be locked out and should follow steps above to log in		
	Resolution		

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IF the user can access the DE System and/or Customizatio pages after using the correct hyperlinks or Internet Explorer	 THEN the issue is resolved Classification is Complaint 1
	If the DE link from within the third-party DMS do not work, then refer to the DMS vendor
IF the user is not able to access the DE System and/or Customization pages after using the correct hyperlinks	THEN refer to the DMS vendorClassification is Complaint 1
IF the user can access the APOC or Info HQ webpage after troubleshooting	 THEN the issue is resolved Classification is Complaint 1
IF the user can access the Info HQ webpage after another Info HQ administrator successfully logged in and reset the password	 THEN the issue is resolved Classification is Complaint 1
IF the user is not able to log into the APOC website and the reset password tool is not working	 THEN contact the APOC website vendor for further assistance Classification is Complaint 1

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Complaint	Description		
Unable to	The customer is unable to install DMS version/setup SW (applies to APOC DMS)		
install DMS	Prompts for Meaningful Data Collection		
version/setup	1. What is the name and version of DMS being installed?		
SW	a. At what step is the user stuck?		
	b. Is there an error message occurring during installation? (add/refer to <u>C4332</u>)		
	2. What is the operating system on the computer used for	DMS installation?	
RW Code:	3. What instructions is the user following for the installation steps?		
C4200	Troubleshooting		
	A. Verify name and version of DMS being installedB. Verify the operating system on the laptop or computer used for installation		
Synonyms:			
Cannot install	C. Request pictures or screenshots if any errors are occurring during installation		
	D. Verify if the appropriate instructions are used for the installation of the DMS		
	Resolution		
	IF the user can install DMS after using the correct	THEN the issue is resolved	
	instructions	Classification is Complaint 1	
	IF the user is using the incorrect operating system	THEN inform user to use proper operating system	
		Classification is Complaint 1	
	IF the user cannot install DMS after using the correct	THEN the issue is not resolved	
	installation instructions	Classification is Complaint 2	

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Complaint	Description		
DMS Functionality	The Data Management System (DMS) is not performing as expected and no specific error codes are being generated.		
not as Expected per	Note: C2569 should only be used when there is no other specific complaint code available.		
Customer	Prompts for Meaningful Data Collection		
	1. What is the version number of the DMS or product(s) in question?		
	2. What is occurring with the DMS?		
RW Code: C2569	3. Are any error codes or messages are being displayed by the DMS or product(s)?		
	4. Are there any issues with the functionality of the i-STAT analyzer?		
Synonyms: N/A	5. Request printouts of the results from analyzer or pictures of the message or menus on the analyzer (as appropriate)		
	and or screenshots of the data manager results/errors. The results printout contains additional information that is		
	not shown on the analyzer screen for that result.		
	Troubleshooting		
	A. Request specific details regarding complaint		
	B. Review testing procedures and performance specifications		
	C. Check or review the functionality of the i-STAT analyzer if the issue reported involves the analyzer.		
	D. Review printouts, pictures and/or screenshots provided		
	Examples:		
	1. Customer reports no i-STAT results are transmitting from third-party DMS to the LIS		
	2. The analyzer that are in the DMS are not being seen in DE system page		
	3. The devices, locations, operators, patients, etc. are not populating from DMS to DE		
	4. The control ranges are not printing from DMS for multiple analyzers		
	5. Unable to run the extended simulator report in Info HQ		
	6. Unable to update DMS with a new I-STAT cartridge lot number		
	7. The ACT-K Level 2 control range displaying in InfoHQ is same as ACT Level 1		
	8. I-STAT Control result is flagged out of range in DMS (RALS, PWeb, UniPOC, etc.) but passes on the i-STAT 1		
	Analyzer		
	Resolution		
	IF the complaint is resolved with discussion of performance		
	Specifications AND product is determined to be functioning as • Classification is Complaint 1		
	Expected		
	IF the Divis is not an Abbott Point of Care product and the IHEN advise the customer to contact DMS vendor		
	analyzer is functioning as expected support for issue resolution		

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14.0 Downloader Issues

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Complaint	Description		
Unable to configure	The customer reports that the i-STAT downloader or downloader/recharger, i-STAT 1 wireless analyzer, or the i-STAT		
downloader/	Alinity cannot be configured successfully. If the customer reports a specific error code or message during configuring, see		
wireless analyzer/	the appropriate complaint code		
Alimiter	Description of the company back collection		
Allnity	Prompts for Meaningful Data Collection		
	 Is the issue regarding configuration of an i-STAT downloader or wireless analyzer? 		
	a. Is one product impacted or multiple products?		
RW Code: C1023	b. What is the serial number of the impacted product(s)?		
	2. Is this new hardware or has it been in use without issue at an earlier date?		
Synonyms:	3 What steps have been performed to attempt to configure the hardware?		
Downloader Base	Translate to the first to the f		
	Troubleshooting		
сгабіе, і-STAT, боск,	Verify the following information is available and has been provided by customer IT:		
not working, cannot	A. IP address		
be configured,	B. Gateway IP address		
cannot program	C. Subnet mask		
	If programming an <u>I-STAT Downloader</u> :		
	A. Verify serial number		
	B. If programming network downloader or network downloader recharger (DN-300/DRN-300), verify the correct		
	programming steps are being performed as per i-STAT 1 System Manual, Section 21: Downloader Programming and		
	Wiring (DN/DRN) Art: 714383		
	Note: For PITTY assistance, refer to Appendix B. Additional Transmission Troubleshooting		
	In the reasonable of the second secon		
	c. In programming DRC-500 downloader recharger, verny that the correct programming steps are being performed as		
	per Technical Bulletin: I-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690		
	D. Verify that correct cables are used and connected properly per instructions		
	E. Verify that the user has full administrative rights to the computer being used and that there are no firewalls or		
	security software in use blocking the configuration		
	E Verify if the unit has been successfully configured in the past or if this is a new product to the facility (not previously		
	configured)		
	computed).		
	1. In previously compared, verify with it department there have been no changes to network		
	If programming an <u>i-STAT 1 Wireless Analyzer</u> :		
	A. Verify serial number is wireless analyzer		
	B. Check the color of the corners of the label on the back of the wireless analyzer		
	1. If blue or orange, 2.4 GHz analyzer		
	2 If black 2.4 or 5.6Hz analyzer		
	it programming <u>2.4 GHz Wireless Analyzer</u> :		
	A. Verify that the correct programming steps are being performed as per Technical Bulletin: Configuring Wireless		
	Settings Art: 726066		
	1. Refer to Appendix B: Additional Transmission Troubleshooting for programming on Windows 8 and above		
	operating system		
	z. Refer to appropriate troubleshooting for codes <u>GS020/GS021</u> and <u>IES3X</u> .		
	B. Verify that the user has full administrative rights to the computer being used and that there are no firewalls or		
	security software in use blocking the configuration		
	C. Verify if the unit has been successfully configured in the past or if this is a new product to the facility (not previously		
	configured)		
	1. If providually configured varify with IT department there have been as changed to active the		
	The previously compared with the uppartment there have been to changes to network		
	D. Use laptop with wireless connection and a dedicated laptop for configuring wireless		
	E. Verify that WCU version 2.0 is used		

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rr			
	F. Verify that Java version is 1.6 or higher (2 different Java versions installed on the laptop can cause issues)		
	H Was the correct SSID Authentication type Encryption type Security Key entered?		
	H. Was the correct SSID, Authentication type, Encryption type, Security Key, entered?		
	 Except for Preshared key encryption, all other encryptions certifications can expire (only facility IT would have certification information) 		
	If message "Error Message Assertion Failed" occurs in WCU, set Windows display setting to 100% (default) in		
	control panel	, , , , , , , , , , , , , , , , , , , ,	
	If programming 2.4 or 5 GHz wireless analyzer :		
	A. Verify that the correct programming steps are being pe	rformed as per Technical Bulletin For the i-STAT 1 Wireless	
	Analyzer FCC ID: 2AAEX-SDMAC Art: 761424		
	B. If wireless network is not a choice in the list of available	e networks on the laptop, check the MAC address on the	
	analyzer to confirm the correct MAC address.		
	1. The network displayed for the analyzer is 'iST	ATXXXXXX' where 'XXXXXX' is the last 3 bytes of the wireless	
	module MAC address. (e.g. ISTAT55EU9B).		
	C. If the network password does not work, check the MAC	address on the analyzer to confirm the correct MAC	
	address.		
	 The network password for the wireless analysis 	zer is 'istatYYYYYXXXXXX' where 'YYYYYXXXXXX' is the	
	wireless module MAC address. (e.g. istat8425	3F55E09B)	
	D. If the login page for the wireless analyzer does not app	ear, check the wireless adapter on the laptop and confirm it	
	is set to obtain an IP address automatically.		
	E. After a successful configuration (setup successful displa	ays on the analyzer) press 4 for reset, if an error code displays	
	refer to appropriate troubleshooting.		
	Resolution		
	IF the i-STAT downloader or wireless analyzer is	THEN the issue is resolved	
	successfully configured after programming per the	Classification is Complaint 1	
	instructions		
	IF the i-STAT 1 Wireless Analyzer is successfully configured	THEN the issue is resolved	
after obtaining administrative rights to the computer • Classification is Complaint 1		Classification is Complaint 1	
	IF the i-STAT downloader cannot be successfully THEN the downloader should be replaced		
	configured AND other downloaders are able to be	Classification is Repair	
	successfully configured using the same computer setup in		
	the same time interval		
	IF the i-STAT wireless analyzer cannot be successfully	THEN the wireless analyzer should be replaced or repaired	
configured AND other wireless analyzers are able to be		Classification is Repair	
	successfully configured using the same computer setup in		
	the same time interval		
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Complaint	Description			
Downloader/Base	The customer reports that the i-STAT downloader or downloader/recharger is not functioning as expected.			
Station not				
functioning as	Examples:	Examples:		
expected	 Proximity light does not light up when analyzer place 	ced in downloader however communication occurs		
	 Battery charging lights do not light up however bat 	tery charges		
RW Code: C1027	If the customer is reporting that the unit is not charging batteries, not printing or not transmitting, see other appropriate troubleshooting and complaint codes.			
Synonyms:	Prompts for Meaningful Data Collection			
Downloader, Base,	1. Is the unexpected behavior occurring on one i-STAT dow	vnloader or multiple downloaders?		
craale, I-STAT,	a. What is the serial number of the downloader(s)?		
blinking lights	b. If DRC-300 Downloader/Rechargers are involv	ed, what is the firmware version of DRC-300		
billiking lights	Downloader/Rechargers that are experiencing the issue?			
	I. I ne firmware version can be viewed on the DRC-300 configuration page.			
	3. How long has this behavior been occurring?			
	Troubleshooting			
	A. Verify the behavior of the downloader to be to specification			
	1. i-STAT 1 System Manual, Section 6: i-STAT Downloader Art: 714368			
	2. i-STAT 1 System Manual, Section 21: Downloader Programming and Wiring (DN/DRN) Art: 714383			
	3. Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690			
	B. Document firmware version for DRC-300 downloaders			
	C. If the downloader no longer recognizes an analyzer is docked (the proximity light does not turn on); clean the IR			
	windows in the downloader and on the analyzer			
	D. Verify if the behavior has been occurring for the entire ine of the product or if it started after the product was already			
	Resolution			
	IF the behavior of the downloader is confirmed to be to	THEN the issue is resolved		
	specification	Classification is Complaint 1		
	IF the behavior of the downloader is found to not be to	THEN the downloader should be replaced		
	specification AND the downloader was functioning as	Classification is Repair		
	expected at an earlier date			
	IF the behavior of the downloader is found not to be	THEN the downloader should be investigated		
	specification AND the downloader has been functioning	Classification is Complaint 2		
	out of specification since it was received			
		<u>C5555</u> may need to be added		
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Complaint	Description	
Damaged or missing	The i-STAT 1 Analyzer has damaged or missing charging pads/contacts or the i-STAT downloader/recharger has	
charging pins/	damaged or missing charging pins.	
contacts	Prompts for Meaningful Data Collection	
	1. What i-STAT hardware is being impacted?	
RW Code: C3213	a. What are the serial numbers of the impacted device(s)?	
	2. Are the charging pins/contacts damaged or missing?	
Synonyms: Pins, pads,	a. If damaged, what is the nature of the damage?	
contacts, broken,	Troubleshooting	
snapped, bent,	A. Verify that there is damage/compromise to the charging contacts; there should be four gold charging pins on the	
smasnea, sunk,	downloader/recharger and four corresponding gold charging pads/contacts on the i-STAT analyzer	
wedged, down	B. If the charging contacts are all in place, determine if the customer is having any other specific issues that require	
	troubleshooting; see codes <u>C2581</u> or <u>C2582</u>	
	Resolution	
	IF the gold charging pads/pins/contacts are damaged, THEN the hardware should be replaced	
	missing, or otherwise compromised • Classification is Repair	
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15.0 Cartridae Issues

Complaint	Description	
Closure Failure	The i-STAT Cartridge(s) snap/clip mechanism will not close or does not securely fasten to the cartridge (opens after closure or during testing)	
(Shap/ chp/	Prompts for Meaningful Data Collection	
RW Code: C1804	 What is the type and lot number of the impacted cartrid What is the box number of the impacted cartridge(s)? How many cartridges will not close? 	ge(s)?
Answer pRE	Troubleshooting	
Questions! Synonyms: Wll not	 A. Verify cartridge storage, filling, and handling conditions B. Verify that the cartridge was closed properly before inse C. If it is a new user, have the user test another cartridge fille 	erting into i-STAT analyzer rom the same box or lot number of cartridges
close, won't close,	Resolution	¥
does not snap, doesn't snap, will not stay closed, difficult/hard to close, pops open	IF the cartridge(s) snap/clip mechanism will not close or does not securely fasten on multiple cartridges AND cartridge storage, filling, and handling conditions are acceptable AND the cartridge was closed correctly	 THEN the cartridge(s) should be investigated Classification is Complaint 2 Ask customer if cartridges are available to be returned for investigation and document request(s)
	IF the cartridge(s) were stored/filled/handled/closed incorrectly AND the new cartridge test is successful by the new user	 THEN the incident is resolved Classification is Complaint 1

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Complaint	Description		
Cartridge won't Fill	The i-STAT Cartridge(s) does not fill with patient sample or QC material materials.		
as Expected	Prompts for Meaningful Data Collection		
	1. What is the lot number of the impacted cartridge(s)?		
	2. What is the box number of the impacted cartridge(s)?		
RW Code: C1805	3. What transfer device is used for filling cartridge?		
	4. How many cartridges will not fill?		
Answer pRE	5. Is the user new to i-STAT cartridge use?		
Questions!	6. Are other users able to fill the same cartridges properly?		
	Troubleshooting		
Synonyms: Will not	A. Verify transfer device used for filling cartridges		
fill, does not fill,	B. Verify cartridge filling and handling conditions		
sample pooling and	C. Review cartridge filling procedure with user		
not being drawn			
into cartridge,	Note: Burst calibrant packs causing calibrant material to enter the material path will prevent sample from reaching the		
sample is pulled	fill mark. Cartridges resting on padded surface while filling may cause blockage of air vent on underside of cartridge		
quickly in cartridge	preventing sample from flowing to fill mark.		
past fill line			
	D. Verify cartridge expiration date (cartridges reaching expiration date may become difficult to fill)		
	E. If new user or cartridge handling/filling is suspected, have user test another cartridge from the same box or lot of		
	cartridges		
	F. Request photo of cartridge(s) that will not fill		
	Resolution		
	IF the cartridge(s) do not fill with patient sample or QC THEN the cartridge(s) should be invest	stigated	
	material AND cartridge filling and handling conditions are • Classification is Complaint a	2	
	acceptable		
	Ask customer if cartridges are availa	ble to be returned for	
	investigation and document request	(s)	
	IF the cartridge(s) were filled or handled incorrectly AND THEN the incident is resolved		
	the retest of additional cartridges is successful • Classification is Complaint	1	
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Complaint Description **Cartridge Pouch** The i-STAT Cartridge(s) pouch is punctured or damaged upon removal from the cartridge box. Damaged **Prompts for Meaningful Data Collection** 1. What is the lot number of the impacted cartridge(s)? What is the box number of the impacted cartridge(s)? 2. RW Code: C1810 How many cartridges have damaged pouches? 3. Troubleshooting Answer pRE Verify cartridge storage and handling conditions Α. Questions! Verify shipping conditions Β. Advise user not to use the cartridge if pouch is damaged C. Synonyms: Ripped, Request photo of cartridge damage D. torn, slashed, Resolution punctured IF the cartridge pouches are damaged AND cartridge storage THEN the cartridge(s) should be investigated and handling conditions are acceptable Classification is Complaint 2 Ask customer if cartridges are available to be returned for investigation and document request(s) IF the cartridge pouches are stored or handled incorrectly THEN the incident is resolved Classification is Complaint 1 • IF cartridges pouches were damaged during shipping **THEN** the shipping process should be investigated Classification is Complaint 2 •

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Complaint	Description	
Incorrect Cartridge	The i-STAT Cartridge box includes incorrect quantity of cartridges.	
Count in Box	Prompts for Meaningful Data Collection	
	1. What is the lot number of the impacted cartridge(s)?	
	2. What is the box number of the impacted cartridge(s)?	
RW Code: C1811	3. Is this a newly opened box of cartridges?	
	Troubleshooting	
Synonyms: Not	A. Verify 25 cartridges are present in the box for all cartridge types except for PT/INR; only 24 cartridges are shipped	
enough, wrong,	per PT/INR box	
missing, too many	Resolution	
	IF the cartridge box has incorrect cartridge quantity AND	THEN the cartridge(s) should be investigated
	the quantity of expected cartridges have been verified	Classification is Complaint 2
		Ask customer if cartridges are available to be returned for
		investigation and document request(s)
	IF the cartridge box has the expected quantity of	THEN the incident is resolved
	cartridges	Classification is Complaint 1
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Complaint	Description	
Missing Cartridge in	The i-STAT Cartridge pouch or clear portion pack is missing a cartridge.	
Pouch/Portion Pack	Prompts for Meaningful Data Collection	
	1. What is the cartridge type and lot number of the impacted cartridge(s)?	
	2. What is the box number of the impacted cartridge(s)?	
RW Code: C1824	3. How many cartridge pouches/portion packs have missing cartridges?	
	Troubleshooting	
Synonyms: Empty	A. Verify that the cartridge is missing from the cartridge pouch/pack	
pouch	B. Request photo of pouch or return for investigation	
	Resolution	
	IF the cartridge is missing from the cartridge pouch/pack THEN the cartridge(s) should be investigated	
	Classification is Complaint 2	
	Ask customer if cartridges are available to be returned for	
	investigation and document request(s)	

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Complaint	Description		
Visible Leak	The i-STAT Cartridge(s) has a visible leak. Sample is seen outside the material path in the cartridge.		
	Prompts for Meaningful Data Collection		
	1. What is the type/lot number of the impacted cartridge(s)?		
RW Code: C1803	2. What is the box number of the impacted cartridge(s)?		
	3. How many cartridges with visible leak?		
Answer pRE	4. Did any quality check codes occur?		
Questions!	a. What quality check code(s) occurred (if applicable)?		
	Troubleshooting		
Synonyms: Leaking,	A. Verify cartridge storage conditions and handling		
Dripping	B. Request photo of the visible leak for the cartridge		
	Resolution		
	IF the cartridge(s) have a visible leak AND cartridge THEN the cartridge(s) should be investigated		
	storage and handling conditions are acceptable • Classification is Complaint 2		
	Ask customer if cartridges are available to be returned for		
	investigation and document request(s)		
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Complaint	Description	
Foreign Material	The i-STAT Cartridge(s) has foreign material (hair, extra sensor chip, red dot) in or on the cartridge.	
Found in Product	i-STAT QC material has foreign material within vial or ampule.	
	APOC hardware product has foreign material on outer cover or internally that is visible via the IR/Scanner windows	
	Prompts for Meaningful Data Collection	
RW Code: C1812	1. What is the lot number of the impacted cartridge(s)?	
	2. What is the box number of the impacted cartridge(s)?	
Answer pRE	3. What is the QC material lot number?	
Questions!	4. What is the serial number of APOC product?	
	Troubleshooting	
Synonyms: Debris,	A. Verify the foreign material in or on the i-STAT cartridge(s) or within QC material	
hair, dust, particles,	B. Request cartridge or QC material be returned for investigation, if available	
marks	C. Request photo of cartridge or QC material or APOC hardware if possible	
	Resolution	
	IF the i-STAT Cartridge(s) or QC material or APOC hardware THEN the product should be investigated	
	has foreign material • Classification is Complaint 2	
Synonyms: Debris, hair, dust, particles, marks	Troubleshooting A. Verify the foreign material in or on the i-STAT cartridge(s) or within QC material B. Request cartridge or QC material be returned for investigation, if available C. Request photo of cartridge or QC material or APOC hardware if possible Resolution IF the i-STAT Cartridge(s) or QC material or APOC hardware has foreign material Provide the state of	

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16 0 Miscellaneous

10:0 111500110005		
Complaint	Description	
No Charge Product for	Troubleshooting tools, feet, battery doors and carriers and cables can be sent at no charge when deemed necessary	
Troubleshooting	for troubleshooting of the issue reported.	
	Prompts for Meaningful Data Collection	
	1. What is the serial number of the impacted product(s)?	
RW Code: C1071	Troubleshooting A. Verify the customer is experiencing an issue that warrants the use of sending no charge product(s)	
Synonyms: N/A	Resolution	
	IF through troubleshooting it is determined that	Refer to initial complaint
	troubleshooting tools, feet, battery covers and carriers	
	and cables can be sent at no charge	
CTAT Comment Cuide DEE		Detune to the TOC

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Complaint	Description		
Dispensing Tip Use Issues	The dispensing tip(s) are leaking, difficult to use, or damaged or plugs fall off		
	Prompts for Meaningful Data Collection		
	1. What is lot number of the impacted dispensing tip(s)?		
RW Code: C5567	2. What is the specific issue with dispensing tip(s)?		
	Troubleshooting		
Synonyms: Difficult to pull, A. Verify the impacted dispensing tip(s) are manufactured by Abbott		red by Abbott	
cap is stuck, tight, hard	B. Identify the specific issue being experienced with the dispensing tip		
	Resolution		
	IF the dispensing tip(s) are verified to have an issue THEN the dispensing tip(s) should be replaced and		
	AND the dispensing tips are manufactured by Abbott	investigated	
Classification is Comp		Classification is Complaint 2	
	IF the dispensing tips are not manufactured by Abbott	THEN advise the customer to contact the manufacturer	
		of the dispensing tips for support	
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Product Labeling Customer facing literature is missing information, incomplete or incorrect. Product labeling is incomplete Incomplete/ missing or incorrect. Incorrect/ Prompts for Meaningful Data Collection Missing 1. What is the reference number or article number of the document(s) in guestion (if applicable)?
Incomplete/ missing or incorrect. Incorrect/ Prompts for Meaningful Data Collection Missing 1. What is the reference number or article number of the document(s) in question (if applicable)?
Incorrect/Prompts for Meaningful Data CollectionMissing1. What is the reference number or article number of the document(s) in question (if applicable)?
Missing 1. What is the reference number or article number of the document(s) in question (if applicable)?
2. What product has incorrect labeling (if applicable)?
RW Code: C1050 a. What is the lot number(s) or serial number(s) of products?
Troubleshooting
Answer pRE Questions! A. Document the specific details of what is incorrect, incomplete or missing
B. Request a photo to understand the issue if appropriate
Synonyms: N/A Resolution
IF the customer facing literature is missing information THEN the specific documents should be review
OR is incomplete OR is incorrect investigated
Classification is Complaint 2
IF product labeling is missing information OR is THEN the specific product should be investigated
incomplete OR is incorrect • Classification is Complaint 2

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Complaint	Description	
No/Limited Information Provided by Customer	APOC product other than i-STAT Analyzer is not functioning as expected. The customer is unable to provide pertinent information to the support specialist about the issue to be able use a specific complaint code or to assist in troubleshooting.	
RW Code: C2567	Examples for use in Rocketware Complaint System:	
Synonyms: N/A	 Customer reports discrepant/unexpected results without providing specific analyte, cartridge or results (i.e. "discrepant blood gas results") Use C2567 and select "Yes" for pRE screening question so MERC is aware Note: When information is received, add the new complaint code prior to deleting C2567 to save the pRE questions responses Customer reports unexpected analyte(s) without providing actual results Use complaint code for the unexpected analyte(s) and C2567 Once results are provided, remove C2567. Removing the code will trigger notification to MERC. 	
	Prompts for Meaningful Data Collection	
	 What is the serial number or lot number of the product(s) in question? What is the issue or describe what is wrong with the product(s)? 	
	Troubleshooting	
	A. Request and document specific details Note: Complaint code should be changed to appropriate complaint code once details are provided by customer Resolution	
	IF information is not provided	 THEN request additional information to assist in troubleshooting Classification is Complaint 1
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Complaint	Description	
General	International customer returned a loaner analyzer and it is sent for maintenance at repair center. International	
Maintenance/Loaner	customer requests maintenance on analyzer. No issues reported with analyzer.	
Return	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number?	
	Troubleshooting	
RW Code: C5600	A. Verify no issues reported with analyzer	
	Processing	
Synonyms: Loaner	IF this is a true maintenance and/or loaner	THEN use this code
		Classification is Repair

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Complaint	Description	
Quality Directive Support	Code is used when directed through a PQA approved Quality Directive.	
	Prompts for Meaningful Data Collection	
	1. As per Quality Directive	
RW Code: C1061	Troubleshooting	
	A. As per Quality Directive	
Synonyms: QD, Field Action,	Resolution	
customer Letter	IF the incident being documented aligns with an	THEN use code as directed by the quality directive
	approved active quality directive (not expired)	

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Complaint	Description	
Unable to return product -	Code is used in conjunction with a Quality Directive issued by PQA	
Directive	Prompts for Meaningful Data Collection	
	1. As per Quality Directive	
	Troubleshooting	
RW Code: C1064	A. As per Quality Directive	
	Resolution	
Synonyms: QD, Field Action,	IF the incident being documented aligns with an	THEN add code to product as directed by the quality
customer Letter	approved active quality directive (not expired)	directive

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17.0 Supplemental Codes

The following codes are used by APOC Technical Services when documenting in Rocketware Complaint System.

Complaint	Description		
Out of Box Failure	The i-STAT equipment (e.g. analyzer, printer, downloader) failed upon initial use.		
	Prompts for Meaningful Data Collection		
	1. What is the serial number of the impacted product(s)?		
RW Code: C5555	2. Was the product used for patient testing?		
Supplemental Code	3. When was the product received?		
	4. How many uses of the product have occurred?		
Answer pRE	5. What type of battery is being used (if applicable)?		
Questions!	a. What color is the battery holder (if applicable)?		
	b. What is the rechargeable battery BOD (if applicable)?		
Synonyms: First use	Note: C5555 is supplemental code used in addition to the complaint code used for the reported customer complaint.		
failure	Troubleshooting		
	A. Verify if the failure occurred during initial use or within the first week of use with less than or equal to 10 uses		
	Resolution		
	IF the i-STAT product(s) failed during initial use OR within	THEN the product(s) should be replaced and investigated	
	the first week of use AND with less than or equal to 10	Classification is Complaint 2	
	uses		
	IF the i-STAT product(s) did not fail during initial use OR	THEN troubleshoot the impacted product(s)	
	within the first week of use OR has greater than 10 uses		
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Complaint	Description	
Resolution not in Current	The issue was resolved with assistance or aid from sources that are not in current support literature. There is no	
Literature	product deficiency.	
	Note: C2573 supplemental code used in addition to the	complaint code used for the reported customer
	complaint	
RW Code: C2573	Prompts for Meaningful Data Collection	
Supplemental Code	1. Not Applicable	
	Troubleshooting	
Synonyms: N/A	A. Verify the information used to troubleshoot the issu	ie is not in current literature
	Resolution	
	IF the information used to troubleshoot and resolve	THEN the issue is resolved
	the issue is not in current literature and there is no	Classification is Complaint 1
	product deficiency	

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Complaint	Description		
Repair and Return	Code is added to analyzer repair incident when internati	onal distributor is sending analyzer directly to local repair	
	center for repair and returning analyzer directly to customer or distributor.		
	Prompts for Meaningful Data Collection		
RW Code: C5554	1. Not Applicable		
Supplemental Code	Troubleshooting		
	A. Verify with distributor the repair center where the analyzer will be returned for repair.		
	Resolution		
Synonyms: N/A	IF the i-STAT analyzer requires repair and will be sent	THEN add complaint code to product	
	to local repair center for repair and return		
	IF the i-STAT analyzer requires repair and will be sent	THEN add C5553 (Repair and Return-Direct to Flex)	
	to Flextronics Singapore directly for repair and return		
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Complaint	Description		
Repair and Return – Direct	Code is added to analyzer repair incident when international distributor or repair center is sending analyzer		
to Flex	directly to Flextronics Singapore for repair and Flextronics is returning repaired analyzer directly to distributor,		
	customer or repair center.		
	Prompts for Meaningful Data Collection		
RW Code: C5553	1. Not Applicable		
Supplemental Code	Troubleshooting		
	A. Verify with distributor or repair center that analyzer	r will be returned for repair directly to Flextronics	
Synonyms: N/A	Singapore		
	Resolution		
	IF the i-STAT analyzer requires repair and will be sent	THEN add complaint code to product	
	to Flextronics Singapore directly for repair and return		
	IF the i-STAT analyzer requires repair and will NOT be	THEN add C5554 (Repair and Return)	
	sent to Flextronics Singapore directly for repair and		
	return		

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Complaint	Description			
Unknown DMS Vendor	Supplemental Code is added when troubleshooting informatics complaint and the data management system			
	being used is from an unknown third-party ve	being used is from an unknown third-party vendor.		
RW Code: C5563	Third Party DMC Vandar			
Supplemental Code	AegisPOC	Abbot	Rapid Diagnostics	
	RALS	Abbott Rapid Diagnostics		
Synonyms: N/A	PrecisionWeb	Abbot	t Diabetes Care	
	AQURE Radiometer			
	Bio-ConnectBio-AsiaHarvest/TrellisOrchard			
	CobasIT 1000RochePOCceleratorSiemensUniPOCSiemens			
	QML	Telcor		
	relaymed Relaymed Prompts for Meaningful Data Collection 1. Not Applicable Troubleshooting A. Confirm the data management system is not from a known third-party vendor B. Troubleshoot per customer complaint			
	IF the data management system vendor is un	known	THEN add the code to product	
	IF the data management system vendor is known THEN do not add code to product			luct

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18.0 Shipping Issues

Complaint	Description		
Compromised	Compromised product. Box is warm, ice/gel packs are melted, temperature strip is colored.		
Product	Prompts for Meaningful Data Collection		
	1. What is the product type, lot number and quantity from the shipment?		
	2. Was the product(s) directly ordered from APOC or a third	d-party Distributor?	
RW Code: C1002	a. If APOC, what is the order number or the purch	nase order number (PO#)?	
	b. If third-party Distributor, who is the distributor? What is the PO#?		
Synonyms: box is	3. What is the appearance of the temperature strip? Which	h windows have color? (Note: May request image of the	
warm, temperature	temperature strip if unable to verify during customer cor	ntact)	
strip colored, ice packs	4. When was the product ordered and when was it delivered to the customer?		
are melted	5. Who received and unpacked the box?		
	6. If appropriate, was the shipment left on the dock/receiving area and delivered after several days?		
	7. If appropriate, did the customer package and ship the pr	oduct to a sister facility?	
	Troubleshooting		
	A. Verify the product type, lot number and quantity from the	ne shipment	
	B. Verify the temperature strip was activated		
	C. Verify if there is color in any windows on the temperatur	e strip – specifically if there is color in windows 3 or 4 or	
	both.		
	D. If the temperature strip indicates product is compromise	ed (color in windows 3 and/or 4), use the PO# to verify if	
	the product was shipped direct from APOC to customer?		
	If appropriate verify if the customer packaged and shipped product to their sister facility		
	F. Verify if there was any shipment delay		
	Refer to Appendix D for information regarding temperature strip and other shipment information		
	Resolution		
	IF the product was received warm and the product is not	THEN the issue is resolved	
	compromised based on the temperature strip status	Classification is Complaint 1	
	IF the product was received compromised based on the	THEN the issue is resolved	
	temperature strip status and customer shipped it on their	Classification is Complaint 1	
	own to a sister facility		
	IF the product was received a few days late by the customer	THEN the product should NOT be replaced as we	
	as it was left on the dock/receiving area and the product is	cannot confirm the temperature status of the	
	compromised based on the temperature strip status	shipment immediately after delivery and the shipment	
		error should be investigated	
		Classification is Complaint 2	
	IF the product was ordered from APOC AND the product is	THEN the product should be replaced and the	
	compromised based on the temperature strip status	shipment error investigated	
		Classification is Complaint 2	
	IF the product is compromised based on the temperature	THEN the product should be replaced and the	
	strip status (color in windows 3 and/or 4) AND was ordered	shipment error investigated	
	from a third-party Distributor and shipped direct to	Classification is Complaint 2	
	customer		
	IF the product is compromised based on the temperature	THEN refer customer to distributor for replacement	
	strip status (color in windows 3 and/or 4) AND was ordered	and investigate shipping complaint	
	from a third-party Distributor and NOT shipped direct to	Classification is Complaint 2	
	customer from APOC		
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Complaint	Description		
Shipment Error	Shipment sent to incorrect address or incorrect product shipped. Incomplete order shipped, items missing from		
	shipment, delayed shipment, damaged outer shipping boxes.		
	Prompts for Meaningful Data Collection		
RW Code: C1004	1. Was the product(s) directly ordered from APOC or a	a third-party Distributor?	
	a. If APOC, what is the order number or the purchase order number (PO#)?		
Synonyms: delayed,	b. If distributor, who is the distributor? What	t is the PO#?	
missing, incorrect shipment	2. Was the order shipped to the wrong address?		
	3. Was correct shipping information provided by custo	omer when placing the order? (Check with APOC	
	customer service on this to confirm)		
	4. What is the product type and lot number or serial n	umber or part number?	
	5. If incomplete order, what products/part numbers and	re missing?	
	a. What product(s) was ordered?		
	b. What product(s) was received?		
	6. If appropriate, what is the damage to the outer shipping box?		
	Troubleshooting		
	A. For delayed shipment, verify the order details (date	of order, ship date, the ship to address or any special	
	instructions) in ISS or with APOC Customer Service		
	B. For delivery to incorrect shipping address, verify with customer service if correct shipping address was		
	provided by customer when placing the order		
	C. Verify product type, serial number or lot number an	d quantity from the shipment	
	D. Verify if the product was shipped to customer direct	tly from APOC	
	E. In case of incorrect order, verify customer ordered of	correct product	
	F. Verify products or part numbers missing from the or	rder	
	Resolution		
	IF the product was ordered from APOC AND the	THEN the incident is resolved	
	Customer Service	Classification is Complaint 1	
	IF the product was ordered from APOC AND correct	THEN the incident is resolved	
	product was shipped based on customer's order	Classification is Complaint 1	
	IF the product was ordered from APOC AND was	THEN the product should be replaced and the	
	shipped to incorrect address	shipment error should be investigated	
		Classification is Complaint 2	
	IF the product was ordered from APOC AND customer	THEN the correct product or missing component of the	
	received incorrect product or incomplete order and is	order should be replaced and the shipment error	
	compromised due to this or the facility never received	should be investigated	
	the shipment	Classification is Complaint 2	
	IF the APOC shipment delivery to customer was	THEN the product should be replaced and the	
	delayed and product is compromised	shipment error should be investigated	
		Classification is Complaint 2	
	IF the product was ordered from a third-party	THEN refer customer to distributor for replacement	
	Distributor and was not shipped direct from APOC	and investigate shipping complaint	
		Classification is Complaint 2	
CTAT Comment Coulds DEE 445			

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Complaint	Description		
Missing Ice Pack	Shipment of APOC products was received without ice pack/gel pack.		
	Prompts for Meaningful Data Collection		
	1. Was the product(s) directly ordered from APOC or a	a third-party Distributor?	
RW Code: C1000	a. If APOC, what is the order number or the	purchase order number(PO#)?	
	b. If distributor, who is the distributor? What	t is the PO#?	
Synonyms: No Ice Pack	2. Who received and unpacked the box?		
	3. What is the product type and lot number from the s	hipment?	
	Troubleshooting		
	A. Verify product type, lot number and quantity from the shipment		
	B. Verify that the ice pack (gel pack) is missing		
	C. Verify PO# or order number		
	D. Verify PO# used with the distributor order if the order was shipped directly from APOC		
	Refer to Appendix D for information regarding temperature strip and other shipment information		
	Resolution		
	IF the product was ordered and shipped directly from	THEN the product should be replaced and the order	
	APOC AND the ice pack (gel pack) is missing	should be investigated	
		Classification is Complaint 2	
	IF the product was ordered from a third-party	THEN the product should be replaced and the order	
	Distributor AND shipped directly from APOC and the	should be investigated	
	ice pack (gel pack) is missing	Classification is Complaint 2	
	IF the product was ordered from a third-party	THEN refer customer to distributor for replacement	
	Distributor (not shipped direct from APOC) AND the ice	and investigate shipping complaint	
	pack (gel pack) is missing	Classification is Complaint 2	
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Complaint	Description		
Missing Temperature Strip	Shipment of APOC products was received without temperature strip		
	Prompts for Meaningful Data Collection		
	1. Was the product(s) directly ordered from APOC or a	third-party Distributor?	
RW Code: C1005	a. If APOC, what is the order number or the	purchase order number (PO#)?	
	b. Who is the distributor? What is the PO#?		
Synonyms: No Strip, No	2. What is the product type and lot number from shipr	nent?	
Temperature Strip	3. Who received and unpacked the box?		
	Troubleshooting		
	A. Verify product, type, lot number and quantity from the shipment		
	B. Verify that the temperature strip is missing by asking the customer is check the contents of the box		
	Refer to Appendix D for information regarding temperature strip and other shipment information		
	Resolution		
	IF the product was ordered from APOC AND the	THEN the product should be replaced and the order	
	Temperature Strip is missing	should be investigated	
	Classification is Complaint 2		
	IF the product was ordered from a third-party THEN the product should be replaced and the order		
	Distributor and shipped direct from APOC to customer should be investigated		
	Classification is Complaint 2		
	IF the product was ordered from a third-party THEN refer customer to distributor for replacement		
	Distributor and not shipped direct from APOC	and investigate shipping complaint	
		Classification is Complaint 2	

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Complaint	Description		
Product Received	Shipment of APOC product was received damaged, CLEW software CD was cracked when received, QC material		
Damaged	vials were broken		
	Prompts for Meaningful Data Collection		
	1. Was the product(s) directly ordered from APOC or a	a third-party Distributor?	
RW Code: C5560	a. If APOC, what is the order number or the	purchase order number (PO#)?	
	b. If distributor, who is the distributor? Wha	t is the PO#?	
Synonyms: Broken,	2. How is the product damaged?		
cracked, Squished,	3. What is the product type, lot number or serial numl	per of damaged product?	
Discolored	Troubleshooting		
	A. Verify product type, lot number and quantity from the shipment		
	B. Identify the nature of the damage		
	C. Verify if the product was shipped from APOC or distributor		
	Resolution		
	IF the product was ordered from APOC AND is	THEN the product should be replaced and the order	
	damaged	should be investigated	
		Classification is Complaint 2	
	IF the product was ordered from a third-party	THEN the product should be replaced and the order	
	Distributor and shipped direct to customer from APOC	should be investigated	
		Classification is Complaint 2	
	IF the product was ordered from a third-party	THEN refer customer to distributor for replacement	
	Distributor and NOT shipped direct to customer from	and investigate shipping complaint	
	APOC Classification is Complaint 2		
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Appendices

Appendix A: Accuracy Expectations

Note: The expected system difference between the i-STAT System and major laboratory systems such as Ortho Vitros, Beckman systems, Roche systems and blood gas systems from Siemens, Radiometer and Instrument Laboratories (IL) should not be medically significant based on data collected by i-STAT and its customers. There is no consensus for medically allowable differences. Expectations will differ from hospital to hospital. As a guideline, two different systems should agree within the following plus or minus range to avoid having to provide clinicians with two different reference ranges.

Measured Results	
Analyte	Accuracy Expectations
Sodium	4 mmol/L
Potassium	0.5 mmol/L
Chloride	6%
Ionized calcium	5% or 0.05 mmol/L Note: Normalized results should not be compared to results from the i-STAT System
рН	0.04 units
PCO2	8% or 0.67 kPa (5 mmHg)
PO2	10% or 0.67 kPa (5 mmHg)
Glucose	10% or 0.33 mmol/L (6 mg/dL)
Urea	9% or 0.71 mmol/L
BUN	9% or 2.0 mg/dL
Lactate	12% or 0.6 mmol/L
Creatinine	15% or 26.5 umol/L (0.3 mg/dL)
Hematocrit	6% Note: 6% of the results and NOT 6 %PCV
Hematocrit	Technical Bulletin: K2EDTA and K3EDTA Customization for Hematocrit on the i-STAT System Art: 716240
	 Average i-STAT hematocrit results over a group of samples should normally agree with those from the comparative method within ± 2 %PCV at 29 %PCV and below, ± 3 %PCV from 30 to 50 %PCV, and within 10 %PCV above 50 %PCV when the following conditions are met: i-STAT analyzer is customized correctly Comparative instrument is calibrated correctly Sample handling is optimal for both i-STAT and comparative methods Samples are unaffected by factors listed in the i-STAT Cartridge and Test Information sheet for Hematocrit or in the user documentation for the comparative method. Note: The choice of the K2EDTA or K3EDTA setting on the i-STAT analyzers depends on how the cell counter is calibrated and not on the EDTA type used to collect samples.
TCO2 [measured/calculated]	+/- 3 SD
PT/INR	Agreement within ± 0.4 is usually acceptable for INR
ACT	There is no global reference method or standard for the activated clotting time (ACT) test. The ITC Hemochron instrument is often considered to be the reference method due to its historic market presence. The i-STAT1 Analyzer ACT results can be customized to match results from the traditional Hemochron test tube-based instrument, which performs tests without a pre-warming cycle. The time to clot is longer without pre-warming.
cTnl, BNP, and CK-MB	Results from different instruments/methods can be disparate owing to differences in calibration and assay specificity. While considerable progress in standardizing cTnI assays has been made, differences in results from different methods are expected. Correlation slopes ranging from 0.5 to 1.5 are anticipated between troponin methods/assays. Though similar considerations apply to CK-MB, correlation slopes between methods are expected to be closer to 1. In the case of BNP, there is considerable difference in calibration from one manufacturer to another to the extent that correlation slopes are quite variable. The table below summarizes the expected ranges of correlation slopes for correlations i-STAT and other methods.

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cTnl 0.5 to 1.5
BNP 0.7 to 2.5
CK-MB 0.8 to 1.3
**Note that while the indicated ranges are anticipated for method correlation slopes, values for individual samples can vary widely from one method to another, e.g. though two methods may correlate with a slope of 1.00, it's expected that some individual results from such a correlation may vary by a factor of two or more.

Calculated Analyte Information

Anion Gan	A difference in the calculated anion gap may be due to the difference in equations:		
Amon Gup			
	I-STATEC8+: (Na + K) - (CT + HCO3)		
	i-STAT CHEM8+: (Na + K) - [Cl + (TCO2 - 1)]		
	Alternative: Na - (Cl + HCO3) or Na - (Cl + TCO2)		
Hemoglobin	Hemoglobin is estimated by multiplying the hematocrit as a decimal fraction by the average MCHC (mean		
	corpuscular hemoglobin concentration) of 34. The hemoglobin value will be inaccurate and should not be used		
	when the MCHC is outside the reference (normal) range of 32 to 36. When performing a method comparison,		
	the hematocrit used on the i-STAT system should be compared to the calculated hematocrit from an automated		
	cell counter or to the measured value from the spun microhematocrit method.		
Base Excess	BE _{ecf} (extracellular fluid) and BE _b (blood) are calculated differently and will differ in value in some conditions that		
	affect acid-base balance. When comparing BE results with another type of analyzer, use the same BE. The cause		
	of discrepant results is usually a difference in the pH and/or PCO2 and HCO3 results.		
	BEecf = HCO3 - 24.8 + 16.2(pH - 7.4)		
	BEb = (1 - 0.014*Hb) * [HCO3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)]		

Sensor Dependencies

Primary Sensor	Dependent Sensors	Dependent Calculated Values
Na	K, Cl, Hct, BUN	Anion Gap, Hb
pH and PCO2	PCO2 and pH	HCO3, BE, TCO2, anion gap, sO2
Hct		Hb
Hct	Cl, urea, glucose, PO2, lactate, creatinine	Anion Gap, sO2, Hb
(fluidics problem - movement or quality of		
calibrant or sample)		
PO2		sO2
K or Cl		Anion Gap

Sodium (Na)

The i-STAT software (all models of analyzer) leverages algorithms for the Potassium (K), Chloride (Cl) and BUN Assays which are dependent and adjusted for the sample's Sodium (Na) concentration (Ion-Selected Electrode measured sample fluid voltage). The i-STAT System automatically always adjusts the K, Cl and BUN displayed result depending upon the measured Na level.

Sodium is a significant determinant of blood's electrical conductivity. Hct displayed results are adjusted to the measured Na level.

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Appendix B: Additional Transmission Troubleshooting

Downloader Troubleshooting: DRC-300

4.

If the customer reports that a DRC-300 downloader is not transmitting results:

- 1. Verify that the downloader is plugged in and that the unit has power
 - a. Ensure that the power cable is not faulty and the outlet is working or try another outlet
- 2. Unplug the power cable from the downloader and plug it back in to "restart" the downloader
- 3. Check the light configuration on the back of the downloader when powering on and functioning
 - a. Initial power up (Boot Process)
 - i. Yellow (Data Activity) Will blink 1 time and stay on
 - ii. Green (Power) Will blink 1 time and stay on
 - b. During operation:
 - i. Yellow (Data Activity) Blinking
 - ii. Green (Power) On
 - Ping and Web Browse the downloader IP address to verify connectivity
 - a. Click the Windows Start button and open the Run tool; in the Run tool enter CMD to open the command.exe window
 - b. Enter "cd C:\" to go to the root letter drive
 - c. Type in "ping [IP of the downloader]" and press the Enter key
 - i. For example, if the downloader IP address is 192.168.47.77, then enter "ping 192.168.47.77"
 - ii. If the Ping is successful, try Web Browse
 - d. Open a web browser, such as Internet Explorer, and type the downloader IP address into the address bar at the top of the screen and press the Enter key
 - i. If the configuration login page opens, enter the password "i-STAT" and verify the settings on the Configuration page
 - ii. If the configuration login page fails to open, verify that the correct downloader IP address is being used
- 5. If Ping and Web Browse fail, advise the customer that the downloader is not accessible on the network
 - a. The downloader may need to be reprogrammed as per *Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690.*
 - b. The customer may need to investigate a potential networking issue with the IP address for that downloader
- 6. If Ping is successful but Web Browse is not, advise the customer that another device on their network may be using the IP address of the downloader

APOC has not validated use of virtual IP address with their products. Product connectivity functionality may or may not be affected.

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Downloader Troubleshooting: DRN-300 or DN-300

If the customer reports that a DRN-300 or DN-300 downloader is not transmitting results:

- 1. Verify that the downloader is plugged in and that the unit has power
 - a. Ensure that the power cable is not faulty and the outlet is working or try another outlet
- 2. Unplug the power cable from the downloader and plug it back in to "restart" the downloader
- 3. Check the light configuration on the back of the downloader when powering on and functioning

a. Initial power up (Boot Process)	
Yellow (Data Activity) Will blink 1 time and stay on	Red (Boot) Will blink 8 times and go off (about 5 seconds)
Green (Link) Will blink 1 time and stay on	Green (Power) Will blink 1 time and stay on
b. During operation:	
Yellow (Data Activity) On	Red (Boot) Off
Green (Link) On	Green (Power) On
\bigcirc	If this light is red and all troubleshooti has been performed, replace downloa

- 4. Ping and Telnet the downloader IP address to verify connectivity
 - a. Click the Windows Start button and open the Run tool; in the Run tool enter CMD to open the command.exe window
 - b. Enter "cd C:\" to go to the root letter drive
 - c. Type in "ping [IP of the downloader]" and press the Enter key
 - i. For example, if the downloader IP address is 192.168.47.77, then enter "ping 192.168.47.77"
 - ii. If the Ping is successful, try Telnet
 - d. Type in "telnet [IP of the downloader] 9999" and press the Enter key
 - i. For example, if the downloader IP address is 192.168.47.77, then enter "telnet 192.168.47.77 9999"
 - ii. If Telnet is successful, verify the settings are correct on "0: Server Configuration" and "2: Channel 2 Configuration"; reprogram if necessary
- 5. If Ping and Telnet fail, advise the customer that the downloader is not accessible on the network
 - a. The downloader may need to be reprogrammed as per *i-STAT 1 System Manual, Section 21: Downloader Programming and Wiring (DN/DRN) Art: 714383*
 - b. The customer may need to investigate a potential networking issue with the IP address for that downloader

APOC has not validated use of virtual IP address with their products. Product connectivity functionality may or may not be affected.

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<u>PUTTY</u>

For customers that are not able to use HyperTerminal, PUTTY is another terminal emulation software that can be used to configure the downloader. For Abbott Point of Care personnel, the PUTTY software is available through GSD. Any terminal emulation software can be used by the customer; the customer's IT is responsible for instructing on the use of the software.

The following steps may be performed before configuring the downloader:

- 1. Configure system com port
 - a. Right click on computer icon on the Windows desktop select properties
 - b. Select Device Manager
 - c. Open PORTS
 - d. Select Com port being used
 - i. Right click, properties
 - 1. Select Port settings Tab
 - a. Document current settings
 - b. Change settings to what is shown as per page 1 of *i-STAT 1 System Manual, Section 21:*
 - Downloader Programming and Wiring (DN/DRN) Art: 714383
 - c. Click on Advanced
 - i. Change the COM port to a number that is not being used (if a message comes up that another program will have issue with the change, pick another number.)
 - ii. Click OK, in the Advanced settings Box
 - iii. Click OK in the Communications Port
 - iv. Windows will close.
- 2. Open PUTTY
 - a. On the left-hand side under Category
 - i. Go to Connection
 - ii. Select Serial
 - 1. Change settings to what is shown per page 1 of *i*-STAT 1 System Manual, Section 21: Downloader Programming and Wiring (DN/DRN) Art: 714383
 - 2. Select or enter the COM port that is being used by the downloader.
 - iii. Follow "Connect to and Program the Downloader" instructions in *i-STAT 1 System Manual, Section 21: Downloader Programming and Wiring (DN/DRN) Art: 714383*

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Wireless Analyzer Troubleshooting

If the customer reports that an i-STAT 1 Wireless Analyzer is not transmitting results wirelessly:

- 1. Verify that the wireless analyzer has been configured for wireless transmission
- 2. Turn the analyzer ON
- 3. Press the MENU key to access the Administration Menu
- 4. Press 8-Wireless to access the wireless menu
 - a. If the option 8-Wireless is not present:
 - i. Press 4-Customization
 - ii. 2-Change
 - iii. Enter Password (or press Enter key)
 - iv. Press 1-Analyzer
 - v. Press right arrow key twice
 - vi. Press 1-Wireless
 - vii. Press 2-Enabled
 - viii. Press MENU to go back to the Administration Menu and select 8-Wireless
- 5. Allow the analyzer to associate with the network
 - a. If the analyzer does not associate, document the error code that occurs
 - b. If the analyzer associates but quickly loses the association and becomes not associated, document this step and outcome
 - c. Select 4-Reset to turn the wireless module off and back on and document if the analyzer is still unable to associate with the network
- 6. If the analyzer successfully associates with the network, select 2-Ping Server
 - a. If Ping Server is not successful, document the error code that occurs
- 7. Select 3-Test Server
 - a. If Test Server is not successful, document the error code that occurs
- 8. If the analyzer associates without issue and the Ping and Test Server options are successful, then go back to the Administration Menu and attempt to transmit a result (select 6-Transmit Data)
 - a. If the record transmits successfully then the issue is resolved
 - b. If the record does not transmit, repeat this troubleshooting process again, documenting any errors
 - i. If the analyzer appears to function intermittently, advise the customer to verify the IP address settings being used (1-View Setup on the Wireless Menu) with IT
 - ii. The analyzer may need to be replaced if the settings are found to function in other i-STAT 1 Wireless Analyzers.

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Configuring Wireless Analyzer with Windows 8 or Above

The i-STAT 1 wireless analyzer (Model 300W) can be configured using the Wireless Configuration Utility (WCU) application installed on a local workstation with Microsoft Windows operating system. The i-STAT 1 Wireless Analyzer requires an ad hoc wireless network connection to perform a configuration update. The Microsoft Windows 7 operating system version supports ad hoc wireless network connections.

If you are using Microsoft Windows 8 or higher operating systems, an ad hoc wireless connection is not supported by the operating system. To configure the i-STAT 1 Wireless Analyzer, an external wireless router is required. Perform the following steps to configure the i-STAT 1 Wireless Analyzer with Microsoft Windows 8 or higher operating system.

- 1. Plug-in power and start the external wireless router.
 - Configure the external wireless router in accordance with the wireless router manufacturer's instructions.
 - a. 2.4 GHz access point mode
 - b. Ad hoc (no security)
 - c. SSID = Abbott-Configuration
 - d. Network LAN

2.

4.

- i. Type = Static IP
- ii. IP address = 192.168.3.1
- iii. Subnet Mask = 255.255.255.0
- iv. Gateway = 0.0.0.0
- e. DHCP = Enabled
 - i. Start IP Address: 192.168.3.100
 - ii. End IP Address: 192.168.3.100
 - iii. Default Gateway: 192.168.3.1
- 3. Install the Abbott Point of Care, Wireless Configuration Utility (WCU), on the Windows workstation which will be used to configure the i-STAT 1 Wireless Analyzers.
 - a. The WCU software may be downloaded from the Abbott Point of Care website.
 - Disconnect the Windows workstation from the corporate network.
- 5. Verify the Windows workstation network settings are set to obtaining an IP address automatically.
- 6. Power-off the Windows workstation.
- 7. Connect the external wireless router to the Windows workstation with a network patch cable (CAT 5e or higher).
- 8. Power-on the Windows workstation.
- 9. Configure the Wireless Analyzer per Section 3 of Technical Bulletin: Configuring Wireless Settings Art: 726066

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Configuring an i-STAT 1 Wireless Analyzer FCC ID: 2AAEX-SDMAC (2.4/5 GHz)

The Network Connectivity utility for i-STAT (AlinIQ NCi) is used to configure the instrument to connect to wireless networks. The NCi utility package must be downloaded from the Abbott Point of Care website. Double click NCi icon to display screen.

Note: Best practice is to install NCi onto a computer that is behind the facility's firewall and has antivirus software installed.

Creating a Network Configuration (NC) File:

Network Configuration Tool:

• Select type of instrument (i-STAT 1 Wireless (with 2.4/5 GHz)).

General Section:

- Select one of these radio buttons:
 - Multiple instruments
 - o Instrument SN (enter analyzer serial number)
- Enter "Configuration Name:"
- "NC File Name:" will auto-populate

Note: Unless facility requires that each instrument have its own unique security credentials, a single NC file may be used for all instruments connecting to the same network.

Wireless Network Connection:

0

- Check box "I want the i-STAT 1 Wireless (with 2.4/5 GHz) to connect to my facility's WIRELESS network"
- Enter the following information:
 - Network Name (SSID):
 - Authentication Type:
 - Network Security Key
 - o IP Address Mode
 - Automatic (DHCP)
 - Use the following IP address
 - DNS Server Address Mode
 - Automatic (DHCP)
 - Use the following IP address
- Check box "I want to set the Wi-Fi Frequency Bands manually."

Data Manager:

- Check box "I want the i-STAT 1 Wireless (with 2.4/5 GHz) to connect to a Data Manager."
- Enter "Data Manager Server Address:" (Must be IP address, cannot use DNS server name (FQDN))

Save the Network Connectivity (incc) file

Note: Best practice is to select Save which will save the file to the Downloads directory. Opening NC (incc) files in a text editor is not recommended.

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Loading a Network Configuration File (.incc) to the i-STAT 1 Wireless, FCC ID 2AAEX-SDMAC

To upload a Network Configuration file (incc) file created by the NCi utility to the I-STAT 1 Wireless, FCC ID 2AAEX-SDMA, follow these steps:

On the instrument:

- 1. Power on the Analyzer with the On/Off key
- 2. Press the MENU key
- 3. Navigate to the Wireless Menu by pressing 8 Wireless
- 4. Wait for the wireless module to initialize, if initialization fails and the Wireless Menu does not display, navigate to the Wireless Menu by pressing 1 (Continue)
- 5. Press 5 Receive Setup. Enter password (if one is set), then press ENT key to display the Waiting for Setup screen

On the computer with wireless network interface:

- 6. Ensure the wireless network is enabled, and its TCP/IPv4 properties set to "Obtain an IP address automatically" (DHCP Enabled)
- 7. Locate the Wireless icon or Network icon in the taskbar near the system clock
- 8. Click on the icon to display the available wireless networks
- 9. In the list of networks displayed, scroll to find the network 'iSTATXXXXXX' where 'XXXXXX' is the last 3 bytes of the wireless module MAC address. For example: iSTAT55E09B
- 10. Select the network, check the box 'Connect automatically', then Click 'Connect'
- 11. Enter password 'istatYYYYYXXXXXX' where 'YYYYYXXXXXX' is the wireless module MAC address (excluding the ':' delimiter between bytes) using numbers and capital letters and 'istat' is in lower case letters. For example: istat84253F55E09B
- 12. Launch the web browser
- 13. In the address bar of the web browser, enter the following address: 'http://192.168.100.1'
- 14. From menu on left, select 'Login'
- 15. Enter login password 'access'
- 16. From menu on left, select 'Load NC File'
- 17. Click Browse and navigate to the location of the Network Configuration file
- 18. Select the Network Configuration file, then click 'Open'
- 19. Click 'Load'.
- 20. Click 'OK' to confirm.
- 21. Click 'OK' to acknowledge load complete.
- 22. Click 'Config Done/Restart'
- 23. Click Yes. Click 'OK' to confirm.

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Slow Transmission Troubleshooting

If the customer reports that i-STAT results are transmitting slowly, but do transmit successfully:

- 1. Verify at what stage in communication the transmission is slow
- 2. Verify that Auto-Transmit is enabled in the i-STAT 1 Analyzer customization settings
- 3. Educate the customer as to the time to result for each cartridge type
- 4. Determine exactly how long transmission was delayed
 - a. Request evidence from the data management system showing the delayed times
- 5. Verify that the customer is placing the i-STAT 1 Analyzer in an i-STAT downloader frequently or communicating wirelessly
- 6. If the issue is specific to wireless transmission
 - a. Access the Wireless Menu on an analyzer, verify that the analyzer associates and the signal is strong; verify that the ping and test server options work
 - b. If there are connectivity issues; troubleshoot and determine if the wireless module is or is not working correctly on one or multiple analyzers
 - i. Transmission may only occur with hardwired downloaders if wireless is failing
 - c. Educate the customer that the wireless analyzer only transmits because of specific stimuli, such as powering off, being placed in a downloader, or manual transmission
 - i. Educate that specific tests may take up to 10 minutes to complete, which can prevent the analyzer from shutting off for an extended period

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Appendix C: i-STAT/DE Systems Page

Main/Status



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View/Set Configuration

Point of Care			
Main / Status	The configuration is not saved until the OK button is clicked. Click the Cancel button to discard changes and return to the Main / Status page.		
View/Set Configuration	Options		
Data Manager Interface (DMI)	Enable use of IR Link IDs		
View Locations	Maximum number of diagnostic files: 100 V		
View Instruments	Construction of the sector of the sect		
View Operators	Backup Directory: C:\DEAUTOBACKUP		
View Patients	Test Result Data Retention Period (months): 4 V		
	Enable DMI (Data Manager Interface) Extended Logging		
	Network		
	Enable Network Communications		
	Maximum Simultaneous Connections: 256		
	Instrument TCP Port Assignments:		
	Instrument Enabled Port		
	i-STAT Series 200 Analyzer		
	i-STAT Series 300 (i-STAT 1) Analyzer		
	Philips Blood Analysis Module		
	Philips Clinical Data Server 6002		
	Send Philips Blood Analysis Module transmission status messages to named hosts		
	Patient List		
	Maximum List Entries: 6000		
	Update Interval (minutes): 1		
	Patient Identifier: Medical record number V		
	Truncate Digits: 0 leading 0 trailing		

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Data Manager Interface (DMI)

Point of Care	
Main / Status	DMI URL: http://localhost/istatdmi/istatdmivvs.asmx
View/Set Configuration	Test Record Statistics
Data Manager Interface (DMI)	Number of All Test Records: 1153 Number of Unsent Test Records: 1153
View Locations	Number of Pending Test Records: 0
View Instruments	
View Operators	DMI Error Log Contents View
View Patients	

View Locations



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View Instruments

Abbott Point of Care					i-STAT/DE Systen	n - View Instruments
	,					
Main / Status	Select Institution:	General Hospital		\checkmark	Refresh Instruments	
View/Set Configuration	 ★ General Hospita ★ PREOP 	al				
Data Manager Interface (DMI)	9 2999	194 - i-STAT - Last Dov	v nload: 8/29/2014 10:11 A	M - Reports: I	Dow nload	
View Locations						
View Instruments						
View Operators						
View Patients						
View Operators Abbott Point of Care						
Main / Status	Select Institution: Fi	iction Hospital		✓ Re	fresh Operators	
View/Set Configuration	 Fiction Hospital POCT - i-STAT 					
Data Manager Interface (DMI)	🖁 A12344	- Certified: 1/1/2015 12	2:00 AM to 12/31/2016 12:0	0 AM		
View Locations						
View Instruments						
View Operators						
View Patients						
View Patients						
Abbott						
Point of Care						
Main / Status	Select Institution:	Fiction Hospital		~	Refresh Patients	
View/Set Configuration	Fiction Hospital & A290981.	A1				
Data Manager Interface (DMI)	A290981	A2 A3				
View Locations	A290981	A4				
View Instruments						
View Operators						
View Patients						

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Appendix D: Shipping

Cartridge Labeling/Storage

Packaging: The room temperature storage time labeled on the cartridge box represents the maximum time that cartridges can be at room temperature (18° C to 30° C).

Room Temperature Storage	Cartridge Pouch Image (Back)	Cartridge Types
14 days	Horn Temperature Storage Laguração di Randampartar - Stockago à lampatritar ambiente - Corservacione a temperatura ambiente - Stockago à Ampanemente da temperatura ambiente - Stockago à Stockago à Ampanemente da temperatura ambiente - Stockago à S	CHEM8+ E3+ 6+ EC4+ G CREA EC8+ ACT Celite ACT Kaolin PT/INR PT ^{plus}
2 months	Account programmer Solicities is known pointer in a factor provider	CG8+ EG6+ EG7+ CG4+ G3+
14 days	No Room Temperature Storage Indicator on blister (portion) packs. 14 days indicator is located on the cartridge box.	cTnl CK-MB BNP β-hCG

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Shipping Consumable Product

Shipper containers are prepared to include cartridge boxes, gel packs, and a temperature strip.

Abbott Point of Care has data that supports a 5-day shipment window. This shipping window is in addition to the 14-day at room temperature specification.

Shipper Container

 Intended to be packed as tightly as possible to avoid shipping damages (internal movements) and keep the area as cool as possible over the shipping period.

Gel Packs

- Included frozen, intended to avoid drastic temperature changes during shipment as the temperature will slowly change during the shipping time.
- It is not uncommon for cartridges to be received from the shipper at room temperature if the shipment conditions exceed the frozen lifetime of the ice bricks included in the shipping container.
- If the temperature strip limits have not been exceeded, the product has not been compromised; then cartridges can be refrigerated and retain the full labeled room temperature storage time.
- APOC has factored the worst case acceptable shipping conditions into account when establishing the room temperature storage time.

Temperature Strip

- Included in the shipper container on the side or top area of the cartridge box area
- Activated (i.e. able to measure the temperature accumulation) by the shipper by removing the tab on the left (perforated area)
- Measures the temperature accumulation over the shipping period



Regions and Sections

There are 4 regions and 2 sections that are activated differently on the temperature strip

- Section 1: Regions 1A-3C: The first three regions monitor the accumulation of heat over time. The card indicators will change as temperature and time is accumulated (for example: temperatures degrees- over a period of time –days)
- Section 2: Region 4 is a distinct region outside of those covered by 1-3 and will only be activated by a sudden change in temperature greater than 34°C (93°F).

Temperature Accumulation

The graph below shows the temperature strip on the y-axis and the number of days on the x-axis. It is the parameters of temperature accumulation over a period of time that will activate the color changes



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This information is confidential to Abbott. The user is responsible for using the appropriate version of this document. (REF-1151/Rev C, DCO- Document Owner: Technical Services Manager)

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Appendix E: Additional Product Information

Торіс	Additional Informa	tion			
Action Ranges	Action Ranges customized by the System Administrator may require adjustments to obtain the action range needed for generating the expected alert on the i-STAT 1 analyzer. See the table below for General Guidance for Rounding Numbers. The i-STAT analyzer JAMS software displays a rounded number based off of floating-point calculations that may result in result not being flagged by the action range limits set within the customization workspace. The System Administrator may adjust the general rounding guidance to meet their facility needs.				
	Table. G (Note dec	eneral Guidance for : <i>Target Lower Limit</i> ar cimal places with which	• Critical/Action Ran ad Target Upper Limit a the analyte result is dis	nge Decimal for Roun are specified with the sar splayed on the i-STAT 1	nding Numbers ne number of Analyzer)
	Number of decimal places in analyte result	< (less than)	> (greater than)	≤ (less than or equal to)	≥ (greater than or equal to)
	0 (i.e., a whole #)	Target Lower Limit -0.5	Target Upper Limit +0.499	Target Lower Limit +0.5	Target Upper Limit -0.501
	1	Target Lower Limit -0.05	Target Upper Limit +0.0499	Target Lower Limit +0.05	Target Upper Limit -0.0501
	2	Target Lower Limit –0.005	Target Upper Limit +0.00499	Target Lower Limit +0.005	Target Upper Limit – 0.00501
	3	Target Lower Limit -0.0005	Target Upper Limit +0.000499	Target Lower Limit +0.0005	Target Upper Limit -0.000501
	Example: Customer would like to enter an action range for Potassium results less than 3.5 mmol/L and greater than 4.9 mmol/L using 1 Decimal Place. The following action range should be entered in the Customization Workspace for Potassium: Low Action Range = 3.5 - 0.05 = 3.45 mmol/L High Action Range = 4.9 + 0.0499 = 4.9499 mmol/L NOTE: For Critical/Action Range limits of "greater than" and "greater than or equal to," there are a small number of cases where a result displayed on the analyzer will appear to be at or below the "Target Upper Limit" value but the out of range arrow may be displayed. This possibility exists due to the range check being applied before rounding of the result for display.				
Reference Range	Reference range will not print if set outside of reportable range (appears dashed out)				
Drug Concentrations	In the individual cartridge Instructions for Use (IFU) and Cartridge and Test Information (CTI) sheets, testing of specific drug concentrations and correlation to the normal dose and frequency were used because of what was listed as pertinent in the Clinical Laboratory Standards Institute (CLSI). Refer to the references of each IFU or CTI sheet for further resource information.				
Interferences	All known interferences and limitations are listed in the Cartridge and Test Information (CTI) sheet and individual cartridge instructions for Use (IFU). It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.				
GFR	The i-STAT 1 System, including all auxiliary products, currently do not support Glomerular Filtration Rates (GFR) calculations. Customers can work with their LIS/HIS for other available options to perform this calculation.				

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Торіс	Additional Information
CPB Mode	Estimating Hematocrit results from CPB mode using the theory section of the manual
Calculation	If assumption is made of a theoretical current hematocrit = 18% (%PCV) and pre-pump patient condition of
	hematocrit = 43% (%PCV) and total protein = 7.0 g/dL, then the arithmetic suggests:
	1. The patients' current Hct to pre-pump Hct ratio is: $18\% / 43\% = 0.4186$.
	2. The patients' current theoretical total protein would be: $0.4186 * 7.0 \text{ g/d} = 2.930 \text{ g/d}$
	3. The patient's corrected benatocrit would likely be: $18\% + 2.930 = 20.93$ or rounded to $21\% (+3\%)$
ACT Count Down	The ACT test has a sensing rate of 3.2 seconds which means that only certain result times are possible for a given
Act count bown	sample. There may however be slight variances during the initiation of the test that would lead to a slight
	difference in the start of the sensing rate making it nossible for one nation test to have a result of 190 and
	another national test a result of 191
B-bCG Analyte	The quantitative result of the $\beta_{\rm e}$ b C assay cannot be disabled globally or by papel. Only the qualitative result
p-ned Analyte	the qualitative result of the p-field assay cannot be disabled globally of by parlet. Only the qualitative result
Tomporatura	Coll be disabled.
Comperature	when using temperature correction for patient temperature, the pH, PCO2, and PO2 are the only analytes that
Correction	are affected because CLSI documentation only provides equations for temperature corrections for these
	analytes. Cartridge must have pO2, pCO2 and pH included in panel to see patient temperature prompt on chart
	page.
Blood Gas Ranges	pO2 and pCO2 ranges have been established using both native patient samples and tonometric whole-blood
	samples (i.e. samples equilibrated with certified gas standards) to provide sample values across the reportable
	range.
Creatinine CO2	The dependence of the I-STAT creatinine with respect to Carbon Dioxide (CO2) is as follows:
Correction	For creatinine results ≤ 2.0 mg/dL, no correction for PCO2 is required.
	For creatinine results > 2.0 mg/dL, the following correction applies:
	Creatinine _{corrected} = creatinine * (1 + 0.0025 * (PCO2 – 40))
	Creatinine correction due to CO2 must be performed manually by customer
Blood Sample Type	FDA granted approval for whole blood sample types to be used with the i-STAT system, not patient or location
	types. If the individual cartridge Instructions for Use (IFU) or Cartridge and Test Information (CTI) Sheet
	intended use is followed, it is an approved/on-label use of the product.
	Abbott Point of Care considers the use of cord blood is within APOC labeling for venous and arterial whole blood
	testing. There are no specific studies that are available specific to cord blood testing.
	A centrifuged sample can be resuspended and run on the i-STAT 1 Analyzer if the testing is performed within the
	recommended test timing criteria found in the cartridge IFU.
	If the ECMO samples are whole blood, testing with Pre-membrane and Post-Membrane ECMO samples would
	not be off-label use. There has not been a study based solely on ECIVIO samples.
Analyzer Life	There is no information available as to expectation of life of the i-STAT 1 Analyzer.
Expectancy	
Battery	Low battery for disposable batteries triggers at 7.4 volts at power on.
Information	Low battery for rechargeable battery pack triggers at 8.2 volts at power on.
	While the cycle is running, if the battery falls below 6.4 volts, even if it started above 7.4 volts, the flashing low
	battery icon will trigger at the end of the testing cycle.
	Dead battery message will display for either battery type at 6.0 volts, either when powered on or if dropped to
	6.0 volts during test cycle.
Thermometer	The thermometer system utilized in the i-STAT 1 Analyzer calibrates the thermometer with accuracy
	specification to +/- 0.01C. It is not a NIST traceable calibrated thermometer system.
Encoded Data	The i-STAT 1 System uses a proprietary embedded operating system and encoded data storage. Other
Storage	encryptions are not compatible with this internal encoding. The i-STAT 1 System is not FIPS-140 compliant.

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Торіс	Additional Information			
MRI, CAT Scan, X-	There are no studies validating the use of the i-STAT 1 System in environments created by MRI, CAT Scan or X-			
Ray	Ray.			
Pneumatic Tube	There are no validated studies to show the ef	fects of shipping i-STAT	products through a pneumatic tube	
	system.			
LAN Filter Cable	LAN filter cable is an FCC requirement to com	ply with FCC emissions	limit. The filter cable limits emissions from	
	the downloader while the wireless analyzer is	seated in it.		
USB Adaptors	APOC has not validated the use of any USB ac	laptors. APOC cannot g	guarantee setup or operation when USB	
	adaptors are in use with APOC products.			
CLEW Meaning	Coefficient, Limits, Extrapolation Windows			
Facility Network	The following category will provide items to c	heck regarding the net	work settings of the network controller that	
Controller Settings	facilitates the network connectivity from the	access points. This info	rmation helps Abbott Point of Care	
	understand the network environment and the	e network connectivity	between the i-STAT Wireless analyzer	
	handheld and i-STAT/DE application. This info	rmation is provided by	the facility IT department.	
	 Mac Address filtering 			
	 Quality of service enabled and prior 	ity		
	 Port sniffing 			
	 Network optimization 			
	 Controller/debugging logs 			
Wireless	There are three instances when an i-STAT 1 W	/ireless Analyzer will co	onnect to DE and download information:	
Download	1. As the analyzer is powering off with unsen	t results		
	2. When "Transmit Data" option is selected (use 'Most Recent' if no	unsent results)	
	3. As analyzer turns on by being placed into t	he downloader (analyz	er must be off when placed into the	
	downloader)			
QCC not stored	For cartridges that include calibrant material, only those codes that occur after the calibrant material is released			
	are stored in the analyzer and transmitted to DMS.			
	Codes that are not stored: Environmental cod	les 2-14 and Analyzer E	rror codes 53, 63, 67, 70, 72 and 86.	
	codes which may or may not be stored: Environmental code 1, Analyzer Error codes 52, 60, 61, 62, 66, 73, 74			
	and 82 and Cartridge Error codes 43, 47 and 48.			
I-STAT 1 System	renormance of the I-STATI System has not been evaluated with all medications or situations. All information			
Performance	available for interferences and infinitations can be found in the FSTATI System Midnudi, the Califord and Test			
	these approved documents is not available.			
i STAT 1 Applyzor	The maximum number of stored results is a minimum of 1000. The total number of stored records is veriable			
Stored Records	The current total number of stored records for	n the analyzer is aroun	d 3942, but this number can be less	
Stored Records	depending on the amount of information that	t is on the record	d 5942, but this number can be less	
	depending on the amount of mormation that	tis on the record.		
	For example, a CHEM8+ cartridge test record	has more information	than a G cartridge test record because a	
	CHEM8+ cartridge outputs more analyte resu	Its than a G cartridge.	Therefore, if an analyzer only ran CHEM8+	
	cartridges, the total number of stored records	s would be less than if t	the analyzer only ran G cartridges.	
Cartridge Result				
Date/Time Stamp	At the end of the test cycle	Chemistry/Blood	G. E3+. EC4+. 6+. EC8+. Crea. CHEM8+.	
	(Just before the motor resets)	Gas/Hematology	G3+, CG4+, EG6+, EG7+, CG8+	
	At the beginning of the test cycle	Coagulation	ACTc, ACTk, PT/INR	
	(At the end of the mixing state when clot	U .		
	detection starts [t=0])			
	At the beginning of the test cycle	Immunoassav	cTnl, CK-MB, BNP, β-hCG	
	(When the countdown bar first displays at	,	, , , , , , , , , , , , , , , , , , , ,	
	the start of the cycle)			
	, ,			

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Topic	Additional Information
Cartridge Release	Abbott Point of Care has developed proprietary finished goods release criteria where all cartridge lots are
Criteria	tested utilizing control and blood samples before release
Cintenia	The control materials are value assigned with production lots which are available at the time. Each production
	lot is finished good tested to ensure product performance with both control and blood samples
Cartridge Pouch	All i-STAT cartridges that are sealed in pouches use the same foil laminate material. The laminate includes
carthage routin	namer foil and plastic and has:
	• a water vanor transmission rate of <0.10 g/m ² /day as per ASTM F1249-06.389C 90
	• oxygen permeability of <0.10 cm $3/m^2/day$ as per ASTM 3985-88.25°C 0%
Cartridge Pouch	The 32-digit numeric barcode contains product identification lot number expire date and product
Barcode	coefficients
Barcouc	
	The barcode also codes for the manufacture date of the cartridge. Therefore, the date/time on the analyzer
	cannot be before the date of manufacture of the cartridge (as would occur when an analyzer is back-dated).
	otherwise a message will display when scanning the cartridge barcode that the lot is "expired".
ISD Files	Procedure for DE
	1. With the handheld out of the downloader, power it on and navigate to the Administration Menu.
	select 6 – Transmit Data
	2. With the Transmit Data screen showing, place the analyzer in the downloader, select 1 – Most
	Recent to send the last 8 files.
	3. Access C:>istat32>ISD file
	4. Highlight the files to be copied then right click, select "Send to" then "Mail Recipient"
	5. Send to techsvc@apoc.abbott.com or oustechsvc@apoc.abbott.com
Cartridge Storage	Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8 °C (35 to 46 °F).
Conditions in Doubt	If storage conditions are in doubt, use liquid controls to verify that the cartridges are performing properly.
Time Bar	The time bar will adjust during the testing cycle and may look to fluctuate forward and back in time as the test
	is running.
Internal Simulator	If the internal simulator test runs during a test (i.e. ACT), the test does add to the time from the insertion of
	the cartridge to the display of a result but DOES NOT increase the reported result itself.
QC Range/Mean	There is variability in QC ranges and means of different lots of the same types of cartridges because of
Variability	matrix effects caused by using highly processed material used in the preparation of the controls which can
	give rise to changes in fluidic and chemical properties, and can affect the measurement of analytes in this
	type of sample. This matrix affects are controlled in whole blood samples and the algorithms used in the
	patient testing pathway which are established in the CLEW software.
Base Excess	BEecf = HCO3 - 24.8 + 16.2 (pH - 7.4)
Information	Calculation is used because extracellular fluid (plasma plus interstitial fluid) compares to arterial plasma.
	BEb = (1 - 0.014*Hb) * [HCO3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)]
	Calculation is used for blood because in addition to HCO3 and pH, hemoglobin must be considered.

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Торіс	Additional Infor	mation					
Rounding Off	Due to factors re not compare.	elated to differenc	es in methodology,	equations used, ar	nd rounding, calcul	lated results may	
	Calculated values displayed on the analyzer and the corresponding values determined using the equations provided in the i-STAT System Manual may differ due to the rounding-off of displayed analyte concentrations. Rounding of the displayed value is necessary to properly represent the analyte concentration to the customer. Therefore, a manual calculation is limited by the resolution of the analyte concentrations displayed on the analyzer. However, the analyzer uses the full precision of the analyte concentrations to determine calculated values.						
	number stored i	n the analyzer me	mory) associated w	ith each value disp	layed on the analy	zer is equal to plus	
	or minus nair or	the displayed rest		:.			
	For example, the	e maximum round	-off error associate	d with the calculate	ed Anion Gap (AG)	[AG (CHEM8+) =	
	(Na + K) – (Cl + (TCO2 – 1)] is dete	rmined as follows:				
	No		1		+05		
	Na		01	i i	± 0.5		
	Cl		1	2	± 0.5		
	TO	O ₂	1		± 0.5		
	AG	(calculated)	N/A	± 1.:	55 (sum of error f	or	
				d	isplayed values)		
Panel Codes	Customers looking to identify the cartridge, are advised to use the cartridge lot number. When the i-STAT 1 analyzer generates a quality check code preventing identification of cartridge a default panel code will be displayed. Refer to <u>C5559</u> for troubleshooting.						
	Info HQ Manage	r and other 3rd pa	arty data managem	ent applications.			
	Table is for infor	mational use only					
	Panel Code	Cartridge	Panel Code	Cartridge	Panel Code	Cartridge	
	01	E3+ FC/+	OB	EG6+	22		
	04	CHEM8+	00	G3+	24		
	05	CG8+		EG7+	20	CK-MB	
	07	G	OF	Crea	2B	BNP	
	08	FC8+	OF	Simulator	20	B-hCG	
	09	6+	20	ACT-C	FO	QCC	
	Cartridge Defau	It Panel Codes:		•			
	Immunoassays:	26					
	Panel Code 00:	Unknown cartrid	ge due to test cycle	terminating prior	to cartridge identi	fication	
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Appendix F: Unexpected Results Tables

Note: When multiple results are provided, indicate the result(s) in question.

Unexpected Results Table

Method	Date	Time Collected	Time Tested	Result (units)	Sample

Tables are a guide and can be edited to reflect the data provided.

Examples:

Method	Date	Time Collected	Time Tested	Result (units)	Sample
i-STAT	18-May-2020	19:10	19:15	cTnl: 0.20 ng/mL	Venous #1
Architect	18-May-2020	19:37	19:58	cTnl: 0.01 ng/mL	Venous #2

Method	Date	Time Collected	Time Tested	Result (units)	Sample
i-STAT	18-May-2020	18:45	18:49	K+: >9.0 mmol/L	Venous #1
EG7+ N19348					
i-STAT	18-May-2020	18:45	18:54	K+: 7.5 mmol/L	Venous #1
CHEM8+ H19333B					
i-STAT	18-May-2020	20:02	20:15	K+: 4.4 mmol/L	Venous #2
CHEM8+ H19333B					

ACT Unexpected Results Table

Date	Time Collected	Time Tested	Result (units)	Heparin Dosage	Heparin Time

Tables are a guide and can be edited to reflect the data provided.

Example:

Date	Time Collected	Time Tested	Result (units)	Heparin Dosage	Heparin Time
18-May-2020	13:10	13:11	146 secs		
18-May-2020				5000 Units	13:25
18-May-2020	13:45	13:46	245 secs		
18-May-2020				3000 Units	13:55
18-May-2020	14:20	14:21	340 secs		
18-May-2020	14:40	14:41	400 secs		
18-May-2020	18:25	18:26	200 secs		

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Appendix G: Barcode Scanner Limitations

There are limitations related to the i-STAT analyzer barcode scanner depending on the model of the scanning device within that analyzer.

Truncation of the Barcode Type Code 39, using the i-STAT 1 Analyzer

The i-STAT 1 Analyzer operator and patient ID maximum length limit is 15 characters. There are some customers that use the truncation feature available in the i-STAT customization to "truncate" IDs that have more than 15 characters. The barcode scanner within the i-STAT 1 Analyzer can impact the functionality of the truncation feature that is expected by the customer.

For i-STAT 1 Analyzers, serial numbers 394482 and above have updated Opticon barcode scanner firmware. All i-STAT Analyzer shipments from Flex post 19-May-2017 have updated Opticon barcode scanner firmware.

Barcode Character Limits	Motorola SE-955	Opticon
Maximum length of barcode character detected by scanner device	30	15
Barcode characters accepted by i-STAT Analyzer software (JAMS)	15	15

Code 39 barcode type behavior comparison between Motorola SE-955 & Opticon Example:

Customer has the following customization settings:

Minimum Length	Maximum Length	Truncate First	Truncate Last
0	15	5	5

Code 39 barcode with 17 characters, 00000871193232000

Motorola SE-955 Analyzer

Step	Description	Output
1	Barcode scanned by barcode reader	00000871193232000
2	Characters sent by the barcode reader to JAMS	00000871193232000
3	JAMS applies truncation: first 5 characters	871193232000
4	JAMS applies truncation: last 5 characters	8711932
5	Characters displayed on Analyzer screen	8711932

Opticon Analyzer

Step	Description	Output
1	Barcode scanned by barcode reader	00000871193232000
2	Opticon barcode reader firmware only accepts the	000008711932320
	first 15 characters of the barcode	
3	Characters sent by the barcode reader to JAMS	000008711932320
4	JAMS applies truncation: first 5 characters	8711932320
5	JAMS applies truncation: last 5 characters	87119
6	Characters displayed on Analyzer screen	87119

Problem: The issue occurs due to the automatic truncation performed by the Opticon barcode reader firmware described in Step 2.

Resolution: The settings in the Analyzer customization can be altered in such a way that the Opticon Analyzer will display that same characters as the Motorola SE-955 Analyzer. Customer will need to create location and preference with truncation for the Opticon barcode scanner in the i-STAT 1 Analyzer. The i-STAT 1 Analyzer with the Opticon scanner will need to be assigned to that location.

Changed customization settings:

Minimum Length	Maximum Length	Truncate First	Truncate Last
0	15	5	3

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Opticon Analyzer

Step	Description	Output
1	Barcode scanned by barcode reader	00000871193232000
2	Opticon barcode reader firmware only accepts the	000008711932320
	first 15 characters of the barcode	
3	Characters sent by the barcode reader to JAMS	000008711932320
4	JAMS applies truncation: first 5 characters	8711932320
5	JAMS applies truncation: last 3 characters	8711932
6	Characters displayed on Analyzer screen	8711932

Code 128 barcode type and IDs with a prefix of "96":

Abbott Point of Care has identified differences in the software and hardware related to the scanning device, that can impact the scanning functionality and ultimately the barcode ID accepted by the i-STAT 1 Analyzer when using code 128 barcode type with an ID prefixed with "96". See tables below.

Problem: The issue occurs due to the "96" prefix ignored by the Opticon barcode reader firmware described in Step 2. **Resolution:** Inform customer that handheld analyzer will require replacement if the customer is unable to avoid using an id with "96" as the pre-fix.

Prior to replacing/repairing analyzer check to ensure the analyzer does not already have an Opticon barcode scanner with updated firmware.

- For i-STAT 1 Analyzers serial number starting with 394482 and above have updated Opticon barcode scanner firmware.
- All i-STAT Analyzer shipments from Flextronics post 19-May-2017 have updated Opticon barcode scanner firmware.

i-STAT 1 Analyzer barcode scanner model Motorola SE-955 versus Opticon with CODE 128 Barcode:

Barcode ID prefix limitation	Motorola SE-955	Opticon
Barcode with Prefix of "96"	Accepts "96"	Ignores "96"

Motorola SE-955 Analyzer:

Step	Description	Output
1	Barcode scanned by barcode reader	96119323200
2	Characters sent by the barcode reader to JAMS	96119323200
3	Characters displayed on Analyzer screen	96119323200

Opticon Analyzer:

Step	Description	Output
1	Barcode scanned by barcode reader	96119323200
2	Opticon barcode reader firmware ignores the first two digits because they are "96"	119323200
3	Characters sent by the barcode reader to JAMS	119323200
4	Characters displayed on Analyzer screen	119323200

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Appendix H: Inquiry Codes

Table below lists inquiry codes used by APOC support personnel who enter customer requests into Rocketware (RW) system.

Inquiry Code	Inquiry Code Description	Coding Scenario
IN0001	Meaning of Quality check	Request meaning of code 23 or suppressed result or why occurred
	codes/message/Alert	Confirmed with customer that code or suppressed result was not experienced
IN0002	Cleaning/maintenance	Products or procedures for cleaning or maintaining i-STAT products
IN0004	Manufacturers Quality System	Manufacturer recommendation for QC/Cal Ver testing
	Instructions	Requirement for running the external simulator
IN0007	Value Assignment Sheet/VAS	Location of acceptable ranges for the quality material
		Request for control ranges for the calculated results
		Request for understanding VAS being used
IN0010	Proficiency Testing	Request for proficiency test material to use with cartridges being tested
		Request with understanding the instructions for performing the proficiency test
IN0011	Performance Verification	Request for performance verification protocol to use with cartridge being tested
		How to validate replacement or new analyzer
		How to verify the reportable range/analytical measurement range (AMR)
IN0012	Regulatory requirements/waiver	Request for waived status of cartridge
	status	IQCP questions
IN0016	CPT codes	Requests for reimbursement codes/CPT codes for cartridge
IN0020	APOC Website Information	Questions related to information on the APOC website
IN0023	Product improvement/ request	Suggestions for product enhancements
		(e.g. CG8+ cartridge packaging color change)
		Is there an i-STAT test for myoglobin?
IN0024	Literature	Location in I-STAT system manual for information
	Interature	Request copy of product action letter after the Quality Directive has expired
100007	Tomporaturo strip/shipmont	Questions about a letter/hotification/literature
1110027	process	General questions about the temperature strip
IN0028	No charge items	Request for red battery carriers with a fuse
IN0030	Training of operators	Request training material to assist in operator training
		Requests for operator training
IN0039	Information not in Literature	**Supplemental code to use with existing inquiry code
		Information provided is not currently available in APOC approved literature
IN0101	Customization	Question regarding customization settings
		Assistance with customization settings in DMS and analyzer
IN0106	Reviewing/interpretation of	Assistance with understanding i-STAT results
	results	What do the internal or external simulator results mean (amp, pot)?
IN0108	Barcode Specifications	What barcode formats/dimensions/specification can be used with the i-STAT?
IN0122	Hardware specifications/	Assistance with clock settings on the analyzer
	operation/ programming	Password assistance to access handheld menu screens
		Assistance/instruction with using product features
		Request specifications of hardware
IN0202	Data System specifications/	APOC system recommendations/specifications
	operation/setup	Setting up/assistance with operators (moving, editing, adding,
		deleting)/locations/reports/inventory/results/apply preferences/passwords/etc.
IN0209	Chart Pages/STATNotes	Questions or assistance specific to STATNotes

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Inquiry Code	Inquiry Code Description	Coding Scenario
IN0228	Interface specs/ operation/	Requests for modification/undate to interface Confirm no issue with interface
	modification/ setup	Assistance with setting up interface communication with/without license key
		interface specifications recommendations
		Questions about different types of interfaces
IN0229	LOINC codes	Request for/question about LOINC codes
IN0400	Consumable use and	Questions about sample collection, handling, etc.
	specifications	Questions about cartridge/control/cal ver handling, storage, expiration, etc.
		Questions about battery life, specifications, etc.
		Requests for troubleshooting tool procedures
		Crea cartridge IDMS traceable?
		CV or SD of the cartridge and/or how does it compare with the lab analyzer?
		Requests for reportable range and/or patient reference range of the test
		Questions about calculated results
IN0403	3 rd party vendor product	Questions about a 3 rd party vendor product
IN0500	Analysis time of cartridges	How long does it take for a cartridge to complete testing?
IN0502	Intended use of cartridge	Can PT/INR cartridge be used to screen stroke patients?
		What cartridge can be used to test for sepsis?
IN0504	Cartridge/Handheld compatibility	Can the customer run X cartridge with the Y type handheld?
		What cartridges can be run on the i-STAT 1 analyzer?
IN0033	QC Scheduler	Any assistance/question with scheduling QC, grace period, dependent cartridges
IN0034	Operator Competency Notification	Any assistance or questions with setting certification expiration reminders
IN0035	Positive Patient ID	Any assistance or questions with setting up positive patient ID, confirmation options
IN0226	eVAS/Auto Pass/Fail	Any assistance or questions with setting liquid QC pass/fail options or assistance with downloading the eVAS file
IN0036	Reportable Range – AQF	Any assistance or questions with how to set reportable ranges
IN0037	APOC Business Systems	OUS/Abaxis/ADD incidents which have questions/ processes where no current
		inquiry code matches
IN0015	MSDS	Questions, assistance, or location of Safety Data Sheet (SDS)
IN0032	Repair Report Requested	Customer requests a repair report PQA must be contacted, use Response: R14
		(Written response requested - PQA notified (See text field)
IN0112	End of Life	Any questions about end of life of a product
IN0302	Software specifics	Questions about 15-day (software expiration) message
		Questions about version or expiration dates
IN0301	Mailing List	Questions about the mailing list customer contact information
		Customer requesting to be included on the mailing list
		Customer asking if they are included on the mailing list
IN0300	Software Package shipments	Customer requests another package or requests status of software package
		shipment
IN0304	Software update process	Assistance with software update of analyzers/DE
1010207		Questions about the process/instructions
110307	Finding/printing SW literature	Any question or assistance with finding the software literature on the website or
10028	Incident closed as duplicate	Un une CD Lice ONLY to cloce incidents because there was another incident energy for the
1110050	mendent closed as duplicate	same issue from the same location
IN0031	Other	Use ONLY when there is no code that matches a current inquiry code
	0	ese este inter interess no code that matches a current inquiry code

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