Document Owner: Technical Services Management

Revision History

REV.	CHANGE ID#	DESCRIPTION
A	DCO-0003828	Initial Release
B	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 F. Added new and updated information to Appendix E. Added Sensor Dependencies table 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, C2585, C2581, C2582, C1070, C2580, C5571, C2595, C2591, C3211, C2568, C1069, C3214, C3221, C1002, C4581, C4332, C4141, C4143, C5567, C1812
C	DCO-0004246	Removed C4129 as no longer applicable.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 intended use information to the troubleshooting section of C1526 (B-hCG 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. Added new resolution to scenario to 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.

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

Table of Contents

1.0 Quality Check Codes for the i-STAT 1 System

Complaint	Description	
Code 1 **Dead Batteries – Replace Batteries** RW Code: C2001 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. 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)? 3. What is the battery voltage? **Note:** It is possible for the battery to read greater than 6.0 volts on the Analyzer Status page and still display code 1.	
	Troubleshooting	
	A. Replace with fresh/new 9-volt lithium batteries or a fully charged 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 the battery carrier are replaced and code 1 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the battery carrier and/or disposable batteries have been replaced and code 1 persists after performing a test	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the i-STAT rechargeable battery is charged or replaced AND all the charging contacts are intact AND code 1 persists after performing a test	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the charging contacts on the analyzer or downloader/recharger are not intact	**THEN** refer to C3213

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

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

Complaint	Description	
Code 4 **Analyzer Interrupted – Use Another Cartridge** RW Code: C2004 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. 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)? 3. What is the battery voltage?	
	Troubleshooting	
	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 carrier resolves code 4	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF replacing the 9-volt lithium batteries and/or the battery carrier does not resolve code 4	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF replacing or recharging the rechargeable battery pack resolves code 4	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the i-STAT rechargeable battery is charged or replaced AND all the charging contacts are intact AND code 4 persists after attempting to test the simulator or cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the charging contacts on the analyzer or downloader/recharger are not intact	**THEN** refer to C3213

Complaint	**Description**	
Code 5 **Analyzer Interrupted – Ready for Use** RW Code: C2005 *Synonyms: N/A*	When attempting to refresh the screen, the i-STAT 1 Analyzer detects "nothing" in memory to refresh.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. 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)? 3. What is the battery voltage?	
	Troubleshooting	
	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 carrier resolves code 5	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF replacing the 9-volt lithium batteries and/or the battery carrier does not resolve code 5	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF replacing or recharging the rechargeable battery pack resolves code 5	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the i-STAT rechargeable battery is charged or replaced AND all the charging contacts are intact AND code 5 persists after attempting to test the simulator or cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the charging contacts on the analyzer or downloader/recharger are not intact	**THEN** refer to C3213

Complaint	Description	
Code 6 **Analyzer Interrupted – Use Another Cartridge** RW Code: C2006 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. 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)? 3. What is the battery voltage?	
	Troubleshooting	
	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 carrier resolves code 6	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF replacing the 9-volt lithium batteries and/or the battery carrier does not resolve code 6	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF replacing or recharging the rechargeable battery pack resolves code 6	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the i-STAT rechargeable battery is charged or replaced AND all the charging contacts are intact AND code 6 persists after attempting to test the simulator or cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the charging contacts on the analyzer or downloader/recharger are not intact	**THEN** refer to C3213

Complaint	**Description**	
Code 8 **Analyzer Interrupted – Use Another Cartridge** RW Code: C2008 *Synonyms: N/A*	The i-STAT 1 Analyzer's internal hardware mechanism did not reset after the last cartridge run.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. 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)? 3. What is the battery voltage?	
	Troubleshooting	
	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 carrier resolves code 8	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF replacing the 9-volt lithium batteries and/or the battery carrier does not resolve code 8	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF replacing or recharging the rechargeable battery pack resolves code 8	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the i-STAT rechargeable battery is charged or replaced AND all the charging contacts are intact AND code 8 persists after attempting to test the simulator or cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the charging contacts on the analyzer or downloader/recharger are not intact	**THEN** refer to C3213

Complaint	Description	
Code 9 **Analyzer Interrupted – Ready for Use** RW Code: C2009 *Synonyms: N/A*	When attempting to refresh the screen, the i-STAT 1 Analyzer's internal hardware mechanism did not fully reset into position.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. 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)? 3. What is the battery voltage?	
	Troubleshooting	
	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 carrier resolves code 9	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF replacing the 9-volt lithium batteries and/or the battery carrier does not resolve code	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF replacing or recharging the rechargeable battery pack resolves code 9	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the i-STAT rechargeable battery is charged or replaced AND all the charging contacts are intact AND code 9 persists after attempting to test the simulator or cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the charging contacts on the analyzer or downloader/recharger are not intact	**THEN** refer to C3213

Complaint	**Description**	
Code 11 **Date Invalid – Check on Status Page** RW Code: C2011 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is date and time on the analyzer(s)? 3. If the date and time is correct, did code occur during coagulation (ACT-C, ACT-K, PT/INR, PT^{plus}) cartridge testing?	
	Troubleshooting	
	A. Verify the cartridge type tested B. If the date on the analyzer is incorrect, have customer correct the date 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 external simulator or cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the date on the analyzer was corrected AND code 11 is resolved after testing an external simulator	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	**Description**	
Code 12 **Expired Software, Update Required – See Manual** RW Code: C2012 *Synonyms: N/A*	The i-STAT 1 Analyzer CLEW/JAMS software has expired. The analyzer date is set after the expiration date of the CLEW/JAMS software.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the CLEW/JAMS version displayed on analyzer status page? 3. What is the analyzer date?	
	Troubleshooting	
	A. If the CLEW/JAMS software has expired, perform the CLEW and JAMS software update 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 resolved	**THEN** the incident resolved • Classification is **Complaint 1**
	IF the date on the i-STAT 1 Analyzer was corrected AND code 12 is resolved	**THEN** the incident 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 electronic simulator	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 13 **Invalid CLEW, Update Required – See Manual** RW Code: C2013 *Synonyms: N/A*	The i-STAT 1 Analyzer CLEW is incompatible with the installed JAMS software	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the CLEW and JAMS version displayed on analyzer status page?	
	Troubleshooting	
	A. Perform the CLEW and JAMS software update if the CLEW or JAMS version is incompatible on the analyzer B. If Code 13 persists after the software update, reseat the disposable batteries or the i-STAT rechargeable battery pack *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 resolved	**THEN** the incident is 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**

Complaint	Description	
Code 14 **Analyzer Error – See Manual** RW Code: C2014 *Synonyms: N/A*	Customization profile in the analyzer is corrupt or invalid	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. Is the impacted i-STAT analyzer used with a data management system? a. What data management system is being used? 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?	
	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 1. Code 14 can occur if the "Action" box for "Invalid Operator" is checked in ID Entry customization and "Use Operator List" is not checked 2. Code 14 can occur is "Use Operator List" is checked and there is no operator list to send to analyzer E. Check the DE system page under the view operators link. If there are no operators listed in DE system have customer 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. G. Check if customer using test system. Often when the customer is testing in the test system operators are not 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 communicating with the data manager resolves the code 14	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF resetting the analyzer to factory settings and placing in the downloader resolves the code 14 after successful communication	**THEN** the issue is resolved • Classification is **Complaint 1**

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

Complaint	**Description**	
Code 15 **Barcode Does Not Match Cartridge Type** RW Code: C2115 *Synonyms: N/A*	The scanned i-STAT cartridge barcode does not match the inserted i-STAT cartridge	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has code 15 occurred? 2. How many code 15 have occurred? 3. Which barcode is being scanned? 4. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Run a new cartridge to verify the cartridge barcode being scanned is from the pouch of the cartridge being tested in 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 window	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 15 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	**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 15 is persistent on a 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 repaired • Classification is **Repair**

Complaint	Description	
Code 17 **No Clot Detected See Manual** RW Code: C1101 *Answer pRE Questions!* *Synonyms: N/A*	No clot was detected during **PT^{plus}/aPTT cartridge** test cycle	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 17 occurred? 2. How many code 17 have occurred? 3. What is analyzer serial number(s)? 4. What was tested on the cartridge – QC material or patient sample? 5. If code 17 occurred while testing QC material a. How is the QC material being handled? b. What is lot number of QC material? 6. If code 17 occurred while testing patient sample a. Is only one patient sample giving the code or multiple patients? b. How is sample collected (i.e. skin puncture, venipuncture)? i. If venous draw, what is the collection device used? What anticoagulant? ii. If fingerstick, how is the sample loaded into the cartridge? c. What is the time from sample collection to testing?	
	Troubleshooting	
	A. Verify that the patient sample is being collected and handled correctly: 1. Venous samples are collected in plain (no anticoagulant), plastic collection device 2. Fingerstick or venous blood samples must be tested immediately 3. Transfer device is plastic and contains no anticoagulant B. If the code 17 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: 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 handling issues	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 17 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 analyzer(s)	**THEN** the suspect cartridge lot 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 17 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot AND specific QC material lot AND other cartridge lots and other QC material lot(s) run without issue on the same i-STAT analyzer(s)	**THEN** the suspect cartridge lot and QC material lot 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 17 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on the other i-STAT analyzer(s)	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 18 **No Clot Detected See Manual** RW Code: C1102 *Answer pRE Questions!* *Synonyms: N/A*	No clot was detected during **PT^{plus}/aPTT cartridge** test cycle	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s)/box number(s) has the code 18 occurred?
	2. How many code 18 have occurred?
	3. What is analyzer serial number(s)?
	4. What was tested on the cartridge – QC material or patient sample?
	5. If code 18 occurred while testing QC material
	  a. How is the QC material being handled?
	  b. What is lot number of QC material?
	6. If code 18 occurred while testing patient sample
	  a. Is only one patient sample giving the code or multiple patients?
	  b. How is sample collected (i.e. skin puncture, venipuncture)?
	  i. If venous draw, what is the collection device used? What anticoagulant?
	  ii. If fingerstick, how is the sample loaded into the cartridge?
	  c. What is the time from sample collection to testing?	

	Troubleshooting	

	A. Verify that the patient sample is being collected and handled correctly:
	  1. Venous samples are collected in plain (no anticoagulant), plastic collection device
	  2. Fingerstick or venous blood samples must be tested immediately
	  3. Transfer device is plastic and contains no anticoagulant
	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:
	  1. Verify QC material handling and testing procedure
	  2. Test a new cartridge with fresh QC material
	D. If persistent code 18 errors, determine and document code rate as appropriate	

	Resolution	
	IF no code 18 occurs after correcting any sample collection or handling issues	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 18 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 analyzer(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 18 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 analyzer(s)	**THEN** the suspect cartridge lot(s) 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 18 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on the other i-STAT analyzer(s)	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 19 **No Clot Detected See Manual** RW Code: C1219 *Synonyms: N/A*	No clot was detected during **PT/INR cartridge** test cycle	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 19 occurred? 2. How many code 19 have occurred? 3. What is analyzer serial number(s)? 4. What was tested on the cartridge – QC material or patient sample? 5. If code 19 occurred while testing QC material: a. How is the QC material being handled? b. What is lot number of QC material? 6. If code 19 occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. Is patient(s) on Coumadin or warfarin? c. How is sample collected (i.e. skin puncture, venipuncture)? i. If venous draw, what is the collection device used? What anticoagulant? ii. If fingerstick, how is the sample loaded into the cartridge? d. What is the time from sample collection to testing? e. Was the patient tested on a different method? i. If patient sample was tested on different method, what is the INR result?	
	Troubleshooting	
	A. Verify that the patient sample is being collected and handled correctly; ensure that finger stick or venous blood samples are tested immediately in a plain plastic collection/transfer device 1. Venous samples are collected in plain (no anticoagulant), plastic collection device 2. Fingerstick or venous blood samples must be tested immediately 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 C. If code occurred while testing QC material 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 rate for the specific cartridge lot number or box number	
	Resolution	
	IF no code 19 occurs after correcting any sample collection or handling issues	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 19 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 analyzer(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 19 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 analyzer(s)	**THEN** the suspect cartridge lot(s) 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 19 is persistent on specific i-STAT analyzer AND those same cartridge lot(s) run without issue on the other i-STAT analyzer(s)	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 20 **Cartridge Error – Use Another Cartridge** RW Code: C1220 *Synonyms: N/A*	No calibrant material detected ***NOTE: Code 20 will <u>not</u> occur with Immunoassay (cTnI, CK-MB, BNP, β-hCG) or Coagulation (ACTc, ACTk, PT/INR) cartridges.***	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s) has the code 20 occurred? 2. How many code 20 have occurred? 3. What is tested on the cartridge – QC material or patient sample? a. If code is occurred while testing QC material, what is the lot number(s)? 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 E. 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 20 is due to improper cartridge storage and handling	**THEN** the incident can be resolved • Classification is **Complaint 1**
	IF running the ceramic conditioning cartridge and new cartridge resolves the code 20 on a specific analyzer	**THEN** the incident can be resolved • Classification is **Complaint 1**
	IF the code 20 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	**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 20 is persistent on specific i-STAT analyzer after using the ceramic conditioning cartridge	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 21 **Cartridge Preburst – Use Another Cartridge** RW Code: C1121 *Synonyms: N/A*	Analyzer detected material on the sensors before it should have	
	Prompts for Meaningful Data Collection	
	1. What was being tested when the code 21 occurred (cartridge or external simulator)? 2. How many code 21 have occurred? 3. If cartridges were being tested a. What cartridge lot number(s)/box number(s)? b. What is tested on the cartridge – QC material or patient sample? i. If code is occurring with QC material, what is the lot number(s)? 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 previously used cartridge? d. How are the cartridges stored? i. Did the cartridges pass initial QC testing? ii. Have the cartridges been frozen at any point? 4. If external simulator was being tested a. What is external simulator serial number? i. Is the blue cap on the external simulator impeding proper insertion of the simulator? 5. What is analyzer serial number(s)?	
	Troubleshooting	
	A. If code occurred while testing cartridges 1. Verify that the user is not pressing on the calibrant pouch of the cartridge 2. Verify that the cartridges have not been frozen 3. 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 insertion (remove cap if necessary) 2. Retest external simulator	
	Resolution	
	IF the code 21 is due to improper storage or handling of the cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 21 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 • Classification is **Complaint 1**
	IF the code 21 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	**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 21 is persistent on multiple i-STAT analyzers after troubleshooting with a single external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the code 21 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**

Complaint	Description	
Code 22 **Cartridge Error – Use Another Cartridge** RW Code: C1222 *Answer pRE Questions!* *Synonyms: N/A*	The mixing of the sample and reagent is compromised ***Note: Code 22 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only***	
	Prompts for Meaningful Data Collection 1. What cartridge lot number(s)/box number(s) has the code 22 occurred? 2. How many code 22 have occurred? 3. What is analyzer serial number(s)? 4. What is tested on the cartridge – QC material or patient sample? 5. If code occurred while testing QC materials a. What is the QC material lot number(s)? b. How are the QC material materials handled? 6. If code occurred while testing patient sample a. Is only one patient sample giving the code or multiple patients? b. What is the sample type tested? c. How 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 C1066) B. If the code is with patient sample 1. Verify the sample type tested 2. Verify the sample is tested immediately after collection 3. Verify that a used cartridge was not tested 4. Verify the cartridge was closed 5. Test a new cartridge with fresh sample C. If the code is with QC 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 handling through troubleshooting AND additional cartridges are tested successfully	**THEN** the incident can be resolved • Classification is **Complaint 1**
	IF the code 22 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND other cartridge lot number are run without issue on the same i-STAT analyzers	**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 22 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	**THEN** the suspect cartridge and QC lot(s) should be investigated • 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 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**

Complaint	Description	
Code 23 **Poor Contact Detected – See Manual** RW Code: C2023 *Synonyms: N/A*	Poor contact between analyzer connector pins and cartridge pads	
	Prompts for Meaningful Data Collection	

	1. Was a cartridge or external simulator being tested at the time of code 23?
	2. How many code 23 have occurred?
	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?
	  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 lot 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	

	Resolution	
	IF running the ceramic conditioning cartridge and new cartridge resolves the code 23	**THEN** the incident is resolved • Classification is **Complaint 1**
	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 • Classification is **Complaint 1**
	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 • Classification is **Repair**
	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**
	IF the code 23 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND other cartridge lot(s) is verified to run without issue on the same analyzers	**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)**

Complaint	Description	
Code 24 **Cartridge Error – Use Another Cartridge** RW Code: C1224 *Synonyms: N/A*	The electrical resistance of the calibrant material (Rcal) used to verify the electrolyte concentration is out of specification	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s) has the code 24 been occurring? 2. Is this a new or old cartridge lot number? a. If new lot, how many code 24 have occurred on each analyzer? b. If old lot, how many code 24 have occurred? 3. How is the cartridge being handled? a. Was center of cartridge pressed? 4. How are the cartridges stored? 5. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Verify cartridge testing procedure – ensure that the customer 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 1. If code is persistent (>5 times per analyzer) document number of codes for the specific cartridge lot number C. 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 cartridge lot number the code 24 is not reproducible	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 24 is determined to be due to improper cartridge handling through troubleshooting and the next cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 24 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**
	IF the code 24 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND other cartridge lot(s) is verified to run without issue on the same analyzers	**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)**

Complaint	Description
Code 25 **Cartridge Error – Use Another Cartridge** RW Code: C1225 *Answer pRE Questions!* *Synonyms: N/A*	The mixing of the sample and reagent is compromised ***Note: Code 25 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only***
	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 QC material a. What is QC material lot number(s)? b. How is the QC material handled before testing? 4. If code occurred while testing patient sample a. Is only one patient sample giving the code or multiple patients? b. How is the patient sample being collected? 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 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 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 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 C1066) B. If the code occurs while patient sample 1. Verify the sample type tested 2. Verify the sample is tested immediately after collection 3. Verify cartridge is filled to fill mark 4. Verify that a used cartridge was not tested 5. Verify the cartridge was closed 6. Test a new cartridge with fresh sample C. If the code occurs while testing QC material 1. Verify the handling of the QC material material(s) 2. Verify cartridge is filled to fill mark 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 handling through troubleshooting and a new cartridge is tested successfully → **THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 25 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s) AND → **THEN** the suspect cartridge lot(s) should be investigated • 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 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 repaired • Classification is **Repair**

Complaint	Description
Code 26 **Cartridge Error – Use Another Cartridge** RW Code: C1226 *Answer pRE Questions!* *Synonyms: N/A*	Internal quality checks for coagulation cartridge failed ***Note: Code 26 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only***
	Prompts for Meaningful Data Collection

	1. What cartridge lot number(s)/box number(s) has the code 26 occurred?
	2. How many code 26 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material
	  a. What is QC material lot number(s)?
	  b. How is the QC material handled before testing?
	5. If code occurred while testing patient sample
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time between sample collection and testing?
	6. 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
	  2. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add C1066)
	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
	  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 after correcting any sample collection or handling issues the code 26 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 26 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	**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 26 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 26 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 repaired • Classification is **Repair**

Complaint	**Description**	
Code 27 **Cartridge Error – Use Another Cartridge** RW Code: C1227 *Synonyms: N/A*	Error detected after calibration	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 27 occurred? 2. How many code 27 have occurred? 3. What analyzer serial number(s)? 4. What is being tested on the cartridge - QC material or patient samples? 5. If code occurred while testing QC material, what is the lot number? 6. How are cartridges stored? 7. 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 cartridge resolves the code 27	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 27 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 repaired • Classification is **Repair**
	IF the code 27 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	**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)**

Complaint	Description	
Code 28 **Cartridge Error – Use Another Cartridge** RW Code: C1228 *Synonyms: N/A*	Poor contact between analyzer and cartridge	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 28 occurred? 2. How many code 28 have occurred? 3. What is analyzer serial number(s)? 4. What is being 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)? 5. How are cartridges filled?	
	Troubleshooting	
	A. Verify cartridge handling and filling – ensure cartridge is filled to fill mark on the cartridge 1. 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 troubleshooting and the next cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF running the ceramic conditioning cartridge and new cartridge resolves the code 28	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 28 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 repaired • Classification is **Repair**
	IF the code 28 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	**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)**

Complaint	Description	
Code 29 **Cartridge Error – Use Another Cartridge** RW Code: C1229 *Synonyms: N/A*	Poor contact between analyzer and cartridge or overfilled cartridge	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 29 been occurring? 2. How many code 29 have occurred? 3. What is analyzer serial number(s)? 4. What is being 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)? 5. How are the cartridges filled?	
	Troubleshooting	
	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, 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 29 is due to improper cartridge filling (overfilling) and the next cartridge is tested successfully after troubleshooting	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF running the ceramic conditioning cartridge and new cartridge resolves the code 29	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 29 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 repaired • Classification is **Repair**
	IF the code 29 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	**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)**

Complaint	Description	
Code 30 **Sample Positioned Beyond Fill Mark – Use Another Cartridge** RW Code: C1130 *Synonyms: N/A*	Overfilled cartridge	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s)/box number(s) has the code 30 been occurring?
	2. How many code 30 have occurred?
	3. What is being 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)?
	4. How are the cartridges being handled?
	  a. Is the sample filled beyond the fill mark?
	  b. If coagulation cartridge (ACTc, ACTk, PT/INR), was a used cartridge tested (additional cause)?
	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 through troubleshooting and the new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 30 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	**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 30 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 repaired • Classification is **Repair**

Complaint	Description	
Code 31 **Unable to Position Sample – Use Another Cartridge** RW Code: C1131 *Synonyms: N/A*	The analyzer did not detect movement of sample across the sensors	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s) has the code 31 been occurring?
	2. How many code 31 have occurred?
	3. What is being 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)?
	4. What is analyzer serial number(s)?
	5. How is the cartridge being handled?
	  a. Was the cartridge closed properly?
	  b. Did the sample go beyond the fill mark on the 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 ceramic conditioning cartridge 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 handling after troubleshooting and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF running the ceramic conditioning cartridge and new cartridge on the specific analyzer resolves the code 31	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 31 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 repaired • Classification is **Repair**
	IF the code 31 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	**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)**

Complaint	Description	
Code 32 **Cartridge Error – Use Another Cartridge** RW Code: C1232 *Synonyms: N/A*	Error detected after calibration	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What cartridge lot number(s)/box number(s) has the code 32 been occurring? 3. How many code 32 have occurred? 4. What is being 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)? 5. How are cartridges stored? 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 cartridge resolves the code 32	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 32 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 repaired • Classification is **Repair**
	IF the code 32 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	**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)**

Complaint	Description	
Code 33 **Cartridge Error – Use Another Cartridge** RW Code: C1233 *Synonyms: N/A*	Cartridge Error (possible mechanism damage)	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 33 been occurring? 2. How many code 33 have occurred? 3. What is being 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)? 4. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Run 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	
	Resolution	
	IF after running additional cartridges the code 33 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 33 is persistent on only 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 repaired • Classification is **Repair**
	IF the code 33 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	**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)**

Complaint	Description	
Code 34 **Unable to Position Sample – Use Another Cartridge** RW Code: C1134 *Synonyms: N/A*	The analyzer did not detect movement of sample across the sensors.	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s) has the code 34 been occurring?
	2. How many code 34 have occurred?
	3. What is being 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)?
	4. What is analyzer serial number(s)?
	5. How is the cartridge being handled?
	  a. Was the cartridge closed properly?
	  b. Did the sample go beyond the fill mark on the 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 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 ceramic conditioning cartridge 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 handling after troubleshooting and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF running the ceramic conditioning cartridge and a new cartridge on the specific analyzer resolves the code 34	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 34 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 repaired • Classification is **Repair**
	IF the code 34 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	**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)**

Complaint	Description	
Code 35 **Sample Positioned Short of Fill Mark – Use Another Cartridge** RW Code: C1135 *Synonyms: N/A*	Underfilled cartridge	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s)/box number(s) has the code 35 been occurring?
	2. How many code 35 have occurred?
	3. What is being 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)?
	4. How are the cartridges being handled?
	  a. Is the sample reaching the fill mark on the cartridge?
	  b. Was an empty cartridge with no sample tested?
	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 35 is determined to be due to underfilled cartridge or improper cartridge handling through troubleshooting and the new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 35 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	**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 35 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 repaired • Classification is **Repair**

Complaint	Description	
Code 36 **Sample Positioned Short of Fill Mark – Use Another Cartridge** RW Code: C1136 *Synonyms: N/A*	Underfilled cartridge	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s)/box number(s) has the code 36 been occurring?
	2. How many code 36 have occurred?
	3. What is being 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)?
	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 troubleshooting and the new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	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	**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 36 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 repaired • Classification is **Repair**

Complaint	Description	
Code 37 **Sample Positioned Beyond Fill Mark – Use Another Cartridge** RW Code: C1137 *Synonyms: N/A*	Overfilled cartridge	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 37 been occurring? 2. How many code 37 have occurred? 3. What is being 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)? 4. How are the cartridges being handled? a. Is the sample filled beyond 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 37 is due to overfilled cartridge through troubleshooting and the new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 37 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	**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 37 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 repaired • Classification is **Repair**

Complaint	Description	
Code 38 **Insufficient Sample – Use Another Cartridge** RW Code: C1138 *Synonyms: N/A*	Not enough sample in sample well or bubbles in sample	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 38 been occurring? 2. How many code 38 have occurred? 3. What is analyzer serial number(s)? 4. What is being 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)? 5. How is the sample collected and handled? 6. How are the cartridges being handled? a. Is the sample reaching the fill mark on the cartridge?	
	Troubleshooting	
	A. Verify proper sample collection and handling B. Verify that the cartridge is being 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 D. 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 38 is due to underfilled cartridge or improper sample handling through troubleshooting AND additional cartridges have been tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF running the ceramic conditioning cartridge on the specific analyzer resolves the code 38	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 38 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 repaired • Classification is **Repair**
	IF the code 38 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	**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)**

Complaint	**Description**	
Code 39 **Insufficient Sample – Use Another Cartridge** RW Code: C1139 *Synonyms: N/A*	Insufficient sample in the sample well of the cartridge ***Note: Code 39 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only***	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 39 have occurred? 3. What cartridge lot number(s)/box number(s) has the code 39 been occurring? 4. What is being 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)? 5. How are the cartridges being handled? a. Is the sample reaching the fill mark on the cartridge? b. Is the cartridge being closed properly?	
	Troubleshooting	
	A. Verify that the cartridge is being filled to the fill mark and cartridge is closed 1. 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 through troubleshooting and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 39 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	**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 39 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 repaired • Classification is **Repair**

Complaint	Description	
Code 40 **Cartridge Error – Use Another Cartridge** RW Code: C1240 *Synonyms: N/A*	Poor contact between analyzer and cartridge	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 40 have occurred? 3. What cartridge lot number(s)/box number(s) has the code 40 been occurring? 4. What is being 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)?	
	Troubleshooting	
	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	
	Resolution	
	IF the code 40 is resolved after running the ceramic conditioning cartridge and a new cartridge on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 40 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 repaired • Classification is **Repair**
	IF the code 40 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	**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)**

Complaint	Description	
Code 41 **Cartridge Error – Use Another Cartridge** RW Code: C1241 *Synonyms: N/A*	No calibrant material detected, calibrant material arrived too late, or poor contact between analyzer and cartridge.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 41 have occurred? 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 patient samples? a. If code occurred while testing QC material, what is the QC material lot number(s)? 5. How are cartridges handled?	
	Troubleshooting	
	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 conditioning cartridge	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 41 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 repaired • Classification is **Repair**
	IF the code 41 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	**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)**

Complaint	Description	
Code 42 **Cartridge Error – Use Another Cartridge** RW Code: C1142 *Synonyms: N/A*	Analyzer detected material on the sensors before it should have	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. How many code 42 have occurred?
	3. What cartridge lot number(s)/box number(s) has the code 42 been occurring?
	4. What is being 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)?
	5. How are the cartridges handled?
	  a. Did user press on the calibrant pack in the center of the cartridge?
	  b. Did the user insert and test a previously used cartridge?
	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 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 number or box number	
	Resolution	
	IF the code 42 is due to improper storage or handling of the cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 42 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	**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 42 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 repaired • Classification is **Repair**

Complaint	Description	
Code 43 **Cartridge Error – Use Another Cartridge** RW Code: C1143 *Synonyms: N/A*	Sensor reading out of specification	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. How many code 43 have occurred?
	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 patient samples?
	5. If code occurred while testing QC material, what is the QC material lot number(s)?
	6. How is the cartridge being handled?
	  a. Did user press on the calibrant pack in the center of the cartridge?
	  b. Did the user insert and test a previously used cartridge?
	7. How are the cartridges stored?
	  a. Have the cartridges been frozen at any point?	

	Troubleshooting	
	A. Verify the user is not pressing on the calibrant pouch of the cartridge B. Verify the cartridges have not been frozen or dropped 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 conditioning cartridge on analyzer experiencing the code then run a new cartridge on the analyzer	
	Resolution	
	IF the code 43 is due to improper storage or handling of the cartridges and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running the ceramic conditioning cartridge and new cartridge the code 43 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	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	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the code 43 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	**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)**

Complaint	Description	
Code 44 **Unable to Position Sample – Use Another Cartridge** RW Code: C1244 *Answer pRE Questions!* *Synonyms: N/A*	The analyzer did not detect movement of sample across the sensors. ***Note: Code 44 occurs with Coagulation (ACTc, ACTk, PT/INR) cartridges only***	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s)/box number(s) has the code 44 been occurring?
	2. How many code 44 have occurred?
	3. What is analyzer serial number(s)?
	4. What is being 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)?
	5. How is the cartridge being handled?
	  a. Was the cartridge closed properly?
	6. How is the patient sample being collected and handled?
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is time duration from sample collection to testing on the cartridge?
	7. If multiple codes occurred on 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?	

	Troubleshooting	

	A. Verify the cartridge is properly closed
	B. Verify the patient sample type tested, sample collection and 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 C1066)
	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 number or box number
	F. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method.	

	Resolution	
	IF the code 44 is due to improper cartridge or sample handling and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 44 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	**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 44 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 44 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 repaired • Classification is **Repair**

Complaint	Description	
Code 45 **Cartridge Error – Use Another Cartridge** RW Code: C1245 *Synonyms: N/A*	Calibrant material was seen at an incorrect time in the testing sequence or the cartridges being run are not yet at room temperature ***Note: Code 45 is specific to 6+, CHEM8+, CG4+, CG8+, Crea, E3+, EC4+, EC8+, EG6+, EG7+, G, G3+ cartridges***	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 45 have occurred? 3. What cartridge lot number(s)/box number(s) has the code 45 been occurring? 4. How long are cartridges allowed to equilibrate to room temperature prior to testing?	
	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 new cartridge tests successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 45 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	**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 45 occurs again, resulting in a code 55	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 46 **Cartridge Error - Use Another Cartridge** RW Code: C1146 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge Error ***Note: Code 46 occurs with coagulation (ACTc, ACTk, PT/INR) cartridges only***	
	Prompts for Meaningful Data Collection	

	1. What cartridge lot number(s)/box number(s) has the code 46 been occurring?
	2. How many code 46 have occurred?
	3. What is analyzer serial number(s)?
	4. What is being 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)?
	5. How is the cartridge being handled?
	  a. Was the cartridge closed properly?
	6. How is the patient sample being collected and handled?
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time duration from sample collection 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 different 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 and 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 C1066)
	D. Run a new cartridge for 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. Verify times of codes, whether result was produced on i-STAT cartridge or alternate testing method	

	Resolution	
	IF the code 46 is due to improper cartridge or sample handling and new cartridge tests successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 46 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	**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 46 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 46 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 repaired • Classification is **Repair**

Complaint	Description	
Code 47 **Cartridge Not Inserted Properly – Reinsert Cartridge** RW Code: C1147 *Synonyms: N/A*	Cartridge or external electronic simulator not inserted properly	
	Prompts for Meaningful Data Collection	
	1. Is a cartridge or external simulator being tested at the time of code 47? 2. What is analyzer serial number(s)? 3. What cartridge type/lot number has the code 47 been occurring? 4. What is external simulator serial number? a. Is the blue cap on the external simulator impeding proper insertion of the simulator?	
	Troubleshooting	
	A. Run a cartridge or external simulator by inserting straight into the analyzer until it clicks into place 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 cartridge and a new cartridge is tested successfully after troubleshooting	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 47 is resolved after re-testing the external simulator	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 47 is persistent on multiple i-STAT analyzers after troubleshooting with a single external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the code 47 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 48 **Analyzer Error – See Manual** RW Code: C2048 *Synonyms: N/A*	The analyzer connector pins contacted the cartridge or external simulator sensors too soon, may be due to fiber contamination	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 48 have occurred? 3. Is the code 48 occurring during cartridge or simulator testing? a. Is the cartridge or simulator being inserted straight into the analyzer? 4. What cartridge type/lot number(s) has the code 48 been 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 or external simulator AND retest was successful	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF running the contact pin cleaning kit and external simulator resolves the code 48	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 48 is persistent on specific i-STAT analyzer after troubleshooting.	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 49 **Poor Contact Detected – See Manual** RW Code: C2049 *Synonyms: N/A*	Poor contact between the analyzer contact pins and cartridge	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 49 been occurring? 2. What is analyzer serial number(s)? 3. How many code 49 have occurred? 4. What is being 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)?	
	Troubleshooting	
	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 cartridge resolves the code 49	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 49 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 repaired • Classification is **Repair**
	IF the code 49 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	**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)**

Complaint	Description
Code 50 **Analyzer Error – Use Electronic Simulator** RW Code: C2050 *Synonyms: N/A*	Poor connection between the cartridge and i-STAT analyzer
	Prompts for Meaningful Data Collection
	1. What cartridge type/lot number(s)/box number(s) has the code 50 been occurring? 2. How many code 50 have occurred? 3. What is analyzer serial number(s)? a. What is battery voltage? 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)? 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

1. If code is persistent on a specific cartridge lot number, determine and document code rate for the specific cartridge lot number or box number
2. Verify sample type tested, sample collection and handling procedure (sample bubbles may cause code), document testing elevation if applicable
3. 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

Note: Codes 50, 126 and 128 are sometimes related to electrical 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 after testing external simulator, a non-immunoassay cartridge is tested successfully on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the code 50 is persistent on specific i-STAT analyzer when testing non-immunoassay cartridge lot(s) AND those same cartridges are verified to run without issue on the other analyzers	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
IF running the ceramic conditioning cartridge resolves the code 50 when testing immunoassay cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the code 50 is due to improper cartridge or sample handling through troubleshooting and additional cartridges were tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the code 50 is persistent on multiple i-STAT analyzers only on specific cartridge lot(s) after troubleshooting AND other cartridge lot(s) run without issue on the same i-STAT analyzers	**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 50 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 lot(s) 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 running the ceramic conditioning cartridge on a specific analyzer does not resolves the code 50 when testing immunoassay cartridges	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
IF code 50 is occurring with codes 126 and 128 when testing immunoassay cartridges on a specific analyzer and troubleshooting does not resolve	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 51 **Analyzer Error – Use Electronic Simulator** RW Code: C2051 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	
	1. What cartridge type and lot number(s) has the code 51 been occurring? 2. How many code 51 have occurred? 3. 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)? 4. What is analyzer serial number(s)? 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 voltage; 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 simulator and new cartridge successfully on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 51 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 repaired • Classification is **Repair**
	IF the code 51 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	**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)**

Complaint	Description	
Code 52 **Analyzer Error – Use Electronic Simulator** RW Code: C2052 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	

	1. What cartridge type and lot number(s) has the code 52 been occurring?
	2. How many code 52 have occurred?
	3. 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)?
	4. What is analyzer serial number(s)?
	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 carrier (i.e. red/green)?
	  d. If i-STAT rechargeable, what is the Born-on-Date (BOD)?
	  e. Is the cartridge or simulator being inserted straight 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 cartridges, review sample/QC material handling and cartridge filling
	  1. Test a new cartridge from the same cartridge lot number and box
	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 52 is resolved by testing the external simulator and cartridge successfully on specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 52 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 repaired • Classification is **Repair**
	IF the code 52 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	**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)**

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

Complaint	Description	
Code 54 **Analyzer Error – Use Electronic Simulator** RW Code: C2054 *Synonyms: N/A*	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 low 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 successfully on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 54 is persistent on specific i-STAT analyzer after running the electronic simulator	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 55 **Analyzer Error – See Manual** RW Code: C2055 *Synonyms: N/A*	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***	
	Prompts for Meaningful Data Collection	
	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? 3. When did code 55 appear on the analyzer? 4. What was being testing on the analyzer when code 55 occurred? 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 code 45 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**

Complaint	Description	
Code 56 **Analyzer Error – See Manual** RW Code: C2056 *Synonyms: N/A*	i-STAT analyzer detects noise on the thermal circuit	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. Where in the facility is analyzer being used for testing? a. Is the analyzer being used in a different location than it is typically used in?	
	Troubleshooting	
	A. Move the analyzer to a different location in the facility, away from potential sources of electronic interference 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 is resolved after troubleshooting	**THEN** the incident is resolved • 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**

Complaint	Description	
Code 57 **Analyzer Error – See Manual** RW Code: C2057 *Synonyms: N/A*	Failure to make proper pin connection inside the analyzer, may be caused by fiber contamination	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 57 have occurred? 3. What cartridge type/lot number(s)/ has the code 57 been occurring on?	
	Troubleshooting	
	A. Run the contact pin cleaning kit on any i-STAT analyzer generating code 57 B. Run the external electronic simulator to see if the issue persists	
	Resolution	
	IF running the contact pin cleaning kit and external simulator resolves the code 57	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 57 is persistent on specific i-STAT analyzer after troubleshooting.	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 58 **Analyzer Error – Use Electronic Simulator** RW Code: C2058 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage on the analyzer?	
	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	
	Resolution	
	IF after running the electronic simulator the code 58 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 58 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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

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

Complaint	**Description**	
Code 61 **Analyzer Error – Use Electronic Simulator** RW Code: C2061 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage on the analyzer?	
	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	
	Resolution	
	IF after running the electronic simulator the code 61 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 61 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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

Complaint	Description	
Code 63 **Analyzer Error – See Manual** RW Code: C2063 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage on the analyzer?	
	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	
	Resolution	
	IF after running the electronic simulator the code 63 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 63 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 64 **Analyzer Error – Use Electronic Simulator** RW Code: C2064 *Synonyms: N/A*	Analyzer electronics error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	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	
	Resolution	
	IF after running the electronic simulator the code 64 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 64 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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

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

Complaint	**Description**	
Code 67 **Analyzer Error – See Manual** RW Code: C2067 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 67 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 67 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code 68 **Analyzer Error – See Manual** RW Code: C2068 *Synonyms: N/A*	Damaged contact pins or dirt on shorting bar	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is battery voltage? 3. How many code 68 have occurred? 4. What cartridge type/lot number(s) has the code 68 been occurring on?	
	Troubleshooting	
	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 simulator resolves the code 68	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 68 is persistent on the specific i-STAT analyzer after troubleshooting.	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 69 **Cartridge Type Not Recognized – Use Another Cartridge** RW Code: C2069 *Synonyms: N/A*	The analyzer was unable to verify the cartridge type when reading the cartridge sensors.	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. How many code 69 have occurred?
	3. Is a cartridge or external simulator being tested at the time of code 69?
	4. If cartridge was being tested
	  a. What is the lot number/box number?
	  b. What is the cartridge expiration date?
	  c. Was the barcode on the pouch of the cartridge tested scanned in response to the prompt "Scan Cartridge 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 analyzer?
	6. If external simulator was being tested
	  a. What is external simulator serial number?
	  b. Is the blue cap on external simulator impeding proper insertion of simulator?	

	Troubleshooting	

	A. Verify that the cartridge tested is not expired
	B. Verify that the user is scanning the barcode on the cartridge pouch that is going to be tested
	C. Verify that the analyzer has the current CLEW/JAMS version
	D. Run a new cartridge to see if the issue persists
	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 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, older CLEW/JAMS software version or scanning incorrect barcode and after troubleshooting a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running the ceramic conditioning cartridge the code 69 is resolved on the specific analyzer(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 69 occurs when running the external simulator only and is resolved by removing/adjusting the blue cap	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 69 is persistent on only 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 repaired • Classification is **Repair**
	IF the code 69 is persistent on multiple i-STAT analyzers after troubleshooting with a single external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the code 69 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	**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)**

Complaint	Description	
Code 70 **Analyzer Error – See Manual** RW Code: C2070 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage on the analyzer?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 70 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 70 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 72 **Analyzer Error – See Manual** RW Code: C2072 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 72 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 72 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 73 **Analyzer Error – See Manual** RW Code: C2073 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 73 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 73 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 74 **Analyzer Error – See Manual** RW Code: C2074 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 74 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 74 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 79 **Cartridge Error – Use Another Cartridge** RW Code: C1279 *Synonyms: N/A*	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	
	1. What is analyzer serial number(s)? 2. How many code 79 have occurred? 3. What cartridge type/lot number(s) has the code 79 been occurring on?	
	Troubleshooting	
	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 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 79 is persistent on specific i-STAT analyzer after troubleshooting on multiple cartridge lots AND those 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**
	IF the code 79 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	**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)**

Complaint	Description	
Code 80 **Cartridge Error – Use Another Cartridge** RW Code: C2080 *Synonyms: N/A*	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	
	1. What is analyzer serial number(s)? 2. How many code 80 have occurred? 3. What cartridge type/lot number has the code 80 been occurring on?	
	Troubleshooting	
	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 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 troubleshooting on multiple cartridge lots AND those 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**
	IF the code 80 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	**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)**

Complaint	Description	
Code 81 **Cartridge Error – Use Another Cartridge** RW Code: C1281 *Synonyms: N/A*	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	
	1. What is analyzer serial number(s)? 2. How many code 81 have occurred? 3. What cartridge type/lot number has the code 81 been occurring on?	
	Troubleshooting	
	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 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 troubleshooting on multiple cartridge lots AND those 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**
	IF the code 81 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	**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)**

Complaint	Description	
Code 82 **Analyzer Error – See Manual** RW Code: C2082 *Synonyms: N/A*	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 7 mmHg.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage on the analyzer? 3. What is the pressure reading?	
	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 code 82 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 82 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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

Complaint	Description	
Code 84 **Analyzer Error – See Manual** RW Code: C3210 *Synonyms: N/A*	Underlying hardware failure in the i-STAT 1 Wireless Analyzer	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Replace or repair the analyzer if wireless feature is required by customer B. Wireless feature can be disabled on analyzer if customer would like to continue using the analyzer via wired transmission	
	Resolution	
	IF the code 84 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF wireless feature is disabled for continued use of analyzer as non-wireless	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	Description	
Code 85 **Analyzer Error – See Manual** RW Code: C2085 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 85 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 85 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 86 **Analyzer Error – See Manual** RW Code: C2086 *Synonyms: N/A*	Thermistor out of specification; suspect inadequate airflow	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. Is the analyzer stored on a downloader/recharger when the code 86 occurs?
	3. Is the analyzer or downloader/recharger with the analyzer close to a heat source, such as heater vents or electronic equipment?
	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. 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 downloader/recharger) to an area with adequate ventilation resolved the code 86	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 86 is resolved after switching to a different battery (rechargeable/disposable) AND testing the external simulator AND cartridge successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 86 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code 87 **Cartridge Error – Use Another Cartridge** RW Code: C1287 *Synonyms: N/A*	Electrode reading out of specification	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 87 have occurred? 3. What cartridge lot number(s)/box number(s) has the code 87 occurred?	
	Troubleshooting	
	A. 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 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 cartridge the code 87 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 87 is persistent on only 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 repaired • Classification is **Repair**
	IF the code 87 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	**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)**

Complaint	**Description**	
Code 89 **Analyzer Error – See Manual** RW Code: C2089 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage on the analyzer?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 89 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 89 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 90 **Analyzer Error – See Manual** RW Code: C2090 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage? 3. What cartridge lot number(s)/box number(s) has the code 90 occurred? 4. How is cartridge tested? a. What testing pathway was selected (i.e. cartridge test, simulator)?	
	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 code 90 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the user confirms that the code 90 was due to selecting the simulator pathway when running a cartridge	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 90 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 91 **Analyzer Error – See Manual** RW Code: C2091 *Synonyms: N/A*	Analyzer error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 91 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 91 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 92 **Analyzer Error – See Manual** RW Code: C2092 *Synonyms: N/A*	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.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage? 3. What is pressure reading?	
	Troubleshooting	
	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 code 92 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 92 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 93 **Analyzer Error – See Manual** RW Code: C2093 *Synonyms: N/A*	Power supply error	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. Was a CLEW/JAMS software update recently performed?	
	Troubleshooting	
	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 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 simulator the code 93 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 93 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 94 **Analyzer Error – See Manual** RW Code: C2094 *Synonyms: N/A*	Memory allocation error; software self-test failure	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 94 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 94 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 95 **Test Cancelled by Operator** RW Code: C2095 *Synonyms: N/A*	User did not enter required information on the analyzer before the analyzer powered down.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code 95 errors have occurred? 3. What customization preference is currently loaded on the impacted analyzer(s)? a. Are there any fields in the relevant preferences set as "mandatory"? b. Does customer still want these fields to be set as mandatory? 4. Does customer use a data management system/program (DMS)?	
	Troubleshooting	
	A. Verify the customization preferences being used on the impacted analyzer(s) B. Verify in the customization workspace or in the analyzer customization if any fields such as sample type, patient temperature, FIO2 etc. on the chart page or STATNotes (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 settings on the analyzers. C. If customer does not use data management system (DMS), reset analyzer to factory default settings, then test a cartridge to verify code resolution. 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 2. Scan Cartridge Barcode F. Run a cartridge to determine if the code 95 persists ***Important Note:*** *Code 95 can also occur if the user does not see the mandatory prompts such as patient ID on the analyzer before a cartridge test; reset analyzer to factory default settings, then test a cartridge to verify code resolution*.	
	Resolution	
	IF it is determined that the code 95 was due to user not entering mandatory information before power down and after troubleshooting a new cartridge was tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF it is determined that the code 95 was due to incorrect customization setting and after troubleshooting a new cartridge was tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 95 is persistent on only specific i-STAT analyzer that are confirmed to have the correct preference AND all other analyzers are functioning as expected with the same preference	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code 96 **Analyzer Error – See Manual** RW Code: C2096 *Synonyms: N/A*	Electronic failure	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 96 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 96 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code 97 **Analyzer Error – See Manual** RW Code: C2097 *Synonyms: N/A*	Electronic failure	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	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	
	Resolution	
	IF after running the electronic simulator and cartridge the code 97 is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 97 is persistent on specific i-STAT analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 120 **Cartridge Error – Use Another Cartridge** RW Code: C2120 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 120 been occurring? 2. How many code 120 have occurred? 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)? 5. What is analyzer serial number(s)? 6. What is the elevation of the testing site? (i.e. testing occurred in CO, UT, AB)?	
	Troubleshooting	
	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 lot number or box number C. Document testing elevation when applicable	
	Resolution	
	IF after running additional cartridges the code 120 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 120 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	**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 120 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 120 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 121 **Cartridge Error – Use Another Cartridge** RW Code: C2121 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 121 been occurring? 2. How many code 121 have occurred? 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)? 5. What is analyzer serial number(s)?	
	Troubleshooting	
	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 lot number or box number	
	Resolution	
	IF after running additional cartridges the code 121 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 121 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	**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 121 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 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 121 is persistent on only 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 122 **Cartridge Error – Use Another Cartridge** RW Code: C2122 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 122 been occurring? 2. How many code 122 have occurred? 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)? 5. What is analyzer serial number(s)?	
	Troubleshooting	
	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 lot number or box number	
	Resolution	
	IF after running additional cartridges the code 122 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 122 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	**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 122 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 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 122 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 123 **Cartridge Error – Use Another Cartridge** RW Code: C2123 *Answer pRE Questions!* *Synonyms: N/A*	Reagent compromised with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	

	1. What cartridge type, lot number(s)/box number(s) has the code 123 been occurring?
	2. How many code 123 have occurred?
	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)?
	5. What is the storage temperature for the cartridges?
	6. How are cartridges handled?
	  a. Are cartridges closed completely before testing?
	  b. Is there any damage to cartridge pouch?
	7. What is analyzer serial number(s)?
	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 too high 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	
	Resolution	
	IF after running additional cartridges the code 123 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 123 is confirmed to be due to improper cartridge handling AND additional cartridge(s) tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 123 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	**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 123 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 123 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 124 **Cartridge Error – Use Another Cartridge** RW Code: C2124 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 124 been occurring? 2. How many code 124 have occurred? 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)? 5. What is analyzer serial number(s)?	
	Troubleshooting	
	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 lot number or box number	
	Resolution	
	IF after running additional cartridges the code 124 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 124 is persistent on multiple i-STAT analyzer(s) after troubleshooting but only on specific cartridge lot(s) AND other cartridge lot(s) run without issue on the same i-STAT analyzers	**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 124 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 124 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 125 **Cartridge Error – Use Another Cartridge** RW Code: C2125 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 125 been occurring? 2. How many code 125 have occurred? 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)? 5. What is analyzer serial number(s)?	
	Troubleshooting	
	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 lot number or box number	
	Resolution	
	IF after running additional cartridges the code 125 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 125 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	**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 125 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 125 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 126 **Cartridge Error – Use Another Cartridge** RW Code: C2126 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error or poor connection between analyzer and immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	

	1. What cartridge type, lot number(s)/box number(s) has the code 126 been occurring?
	2. How many code 126 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material
	  a. What is lot number(s)?
	  b. How is QC material stored?
	  c. How is QC material testing performed?
	5. If code occurred while testing 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 is time duration from sample collection 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, handling, and testing of the QC material
	  1. Test a new cartridge with fresh QC material
	B. Verify the patient sample type tested, sample collection and handling procedure
	  1. Test a fresh sample on a new cartridge from the same cartridge lot number and box
	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
	E. 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
	
	Note: Codes 50, 126 and 128 are sometimes related to electrical 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 126 is confirmed to be due to improper sample handling and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 126 is resolved after running the ceramic conditioning cartridge on the specific analyzer(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 126 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	**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 126 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 126 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 126 is occurring with codes 50 and 128 on a specific analyzer and troubleshooting does not resolve	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 127 **Cartridge Error – Use Another Cartridge** RW Code: C2127 *Answer pRE Questions!* *Synonyms: N/A*	Overfilled cartridge or cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	

	1. What cartridge type, lot number(s)/box number(s) has the code 127 been occurring?
	2. How many code 127 have occurred?
	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)?
	5. How is the cartridge being filled?
	  a. Is sample going beyond the fill mark?
	6. How is the cartridge being handled?
	  a. Is pressure being applied to calibrant pack?
	  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 previously tested cartridge was not inserted C. Test a new cartridge from the same cartridge 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 after running additional cartridges the code 127 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 127 is due to overfilling or mishandling the cartridge AND after troubleshooting additional cartridge(s) tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 127 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	**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 127 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 127 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 128 **Cartridge Error – Use Another Cartridge** RW Code: C2128 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 128 been occurring? 2. How many code 128 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? 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 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 materials are 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 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 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 **Note:** Codes 50, 126 and 128 are sometimes related to electrical 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 control storage or handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 128 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 128 is due to improper sample type, collection or sample handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 128 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 128 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 128 is persistent on multiple i-STAT analyzers after troubleshooting but only on specific cartridge lot(s)	**THEN** the suspect cartridge lot(s) should be investigated • 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 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 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 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**

Complaint	Description	
Code 129 **Cartridge Error – Use Another Cartridge** RW Code: C2129 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 129 been occurring? 2. How many code 129 have occurred? 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)? 5. If code occurred while testing 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? 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? 7. What is analyzer serial number(s)? 8. 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. Verify that calibrant pack was not pre-burst and a previously tested cartridge was not inserted 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 number or box number F. Document testing elevation if applicable	
	Resolution	
	IF the code 129 is due to improper sample type/collection/handling or improper cartridge handling and after troubleshooting code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 129 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	**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 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 – Use Another Cartridge** RW Code: C2130 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 130 been occurring? 2. How many code 130 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? d. How is the QC material being handled? 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 (*Technical Bulletin: Analyzer Coded Messages Art: 714260*) D. Test 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 number or box number	
	Resolution	
	IF the code 130 is due to improper control or sample handling or cartridge filling through troubleshooting and a new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 130 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF code 130 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 130 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	**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 130 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 130 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 131 **Cartridge Error – Use Another Cartridge** RW Code: C2131 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges
	Prompts for Meaningful Data Collection

	1. What cartridge type, lot number(s)/box number(s) has the code 131 been occurring?
	2. How many code 131 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material:
	  a. What is lot number(s)?
	  b. How is the QC material stored?
	  c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?
	5. If code occurred while testing 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 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 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 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

	IF the code 131 is determined to be due to improper control storage or handling after troubleshooting and the code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 131 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 131 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 131 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 131 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 131 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	**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 131 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 131 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 132 **Cartridge Error – Use Another Cartridge** RW Code: C2132 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 132 been occurring? 2. How many code 132 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 5. If testing occurred while testing 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 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 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	
	IF the code 132 is due to improper control storage or handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 132 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 132 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 132 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 132 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 132 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	**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 132 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	**THEN** the suspect cartridge and QC material lot(s) should be investigated • 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 132 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 133 **Cartridge Error – Use Another Cartridge** RW Code: C2133 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 133 been occurring? 2. How many code 133 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material, what is the lot number(s)? 5. What is analyzer serial number(s)? 6. What is the elevation of the testing site? (i.e. in CO, UT, AB)?	
	Troubleshooting	
	A. Test a new cartridge from the same cartridge lot number and box 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. Document testing elevation if applicable	
	Resolution	
	IF after running additional cartridges the code 133 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 133 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	**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 133 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 133 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 134 **Cartridge Error – Use Another Cartridge** RW Code: C2134 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 134 been occurring? 2. How many code 134 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. How is the sample collected (whole blood or plasma)? 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, 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 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 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 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 storage or handling after troubleshooting and code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 134 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 134 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 134 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 134 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 134 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	**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 134 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 134 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 135 **Cartridge Error – Use Another Cartridge** RW Code: C2135 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	

	1. What cartridge type, lot number(s)/box number(s) has the code 135 been occurring?
	2. How many code 135 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material:
	  a. What is lot number(s)?
	  b. How is the QC material stored?
	  c. How is the QC material filled into the cartridge? Dropper tip or other transfer device?
	5. If code occurred while testing 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 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 (*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 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 control storage or handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 135 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF the code 135 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 135 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 135 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 135 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	**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 135 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 135 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 136 **Cartridge Error – Use Another Cartridge** RW Code: C2136 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges
	Prompts for Meaningful Data Collection
	1. What cartridge type/lot number(s)/box number(s) has the code 136 been occurring? 2. How many code 136 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 5. If code occurred while testing 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 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 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 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	
	Resolution	
	IF the code 136 is determined to be due to improper control storage or handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 136 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 136 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 136 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 136 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 136 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	**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 136 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 136 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 137 **Cartridge Error – Use Another Cartridge** RW Code: C2137 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 137 been occurring? 2. How many code 137 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 5. If code occurred while testing 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 is used to load the sample into the cartridge? 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 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 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 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	
	Resolution	
	IF the code 137 is determined to be due to improper control storage or handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 137 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 137 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 137 is not reproducible on specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 137 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 137 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	**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 137 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	**THEN** the suspect cartridge and QC material lot(s) should be investigated • 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 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 – Use Another Cartridge** RW Code: C2138 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error (may be due to invalid sample type) with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 138 been occurring? 2. How many code 138 have occurred? 3. What is tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material stored? c. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 5. If code occurred while testing 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 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 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 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 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 storage or handling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 138 is due to improper cartridge handling or filling after troubleshooting and the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 138 is due to improper sample type, collection or sample handling after troubleshooting the code is not reproducible on additional cartridges.	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 138 is not reproducible on specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF code 138 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 138 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	**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 138 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 138 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 140 **Lot Expired** RW Code: C2140 *Answer pRE Questions!* *Synonyms: N/A*	Lot number in cartridge barcode is expired with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 140 been occurring? a. What is the expiration date on the cartridge? b. What is the current date/time in the analyzer? 2. How many code 140 have occurred? 3. Is there a different non-expired cartridge lot or a second i-STAT analyzer available for troubleshooting? 4. What analyzer serial number(s)?	
	Troubleshooting	
	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	
	Resolution	
	IF the code 140 is due to improper date/time in the analyzer and after troubleshooting a new cartridge was tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 140 is due to use of expired cartridges and after troubleshooting a new cartridge was tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the cartridge lot(s) are verified to not be expired per their labeling AND the date/time in the analyzer(s) is confirmed to be correct AND the code 140 is resolved after running a different cartridge lot on the same analyzer(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 cartridge lot(s) are verified to not be expired per their labeling AND the date/time in the analyzer is confirmed to be correct AND the code 140 is not reproducible using the same cartridge lot(s) on a different analyzer	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code 141 **Test Cancelled by Operator** RW Code: C2141 *Answer pRE Questions!* *Synonyms: N/A*	Operator failed to enter required information with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What analyzer serial number(s)? 2. How many code 141 have occurred? 3. What cartridge type, lot number(s)/box number(s) has the code 141 been occurring?	
	Troubleshooting	
	A. Verify customization settings in analyzer for required/mandatory information related to sample type, patient temperature, etc. on the chart page B. Restore to factory settings and download the analyzer to pick up the specific customization profile C. Run 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	
	IF it is determined that the code 141 was caused by the user not entering mandatory information before power down and after troubleshooting a new cartridge was tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 141 is persistent on specific i-STAT analyzer that are confirmed to have the current CLEW/JAMS software on multiple cartridge lots 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 the code 141 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	**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)**

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Complaint	Description
Code 142 **Cartridge Error – Use Another Cartridge** RW Code: C2142 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges
	Prompts for Meaningful Data Collection

	1. What cartridge type, lot number(s)/box number(s) has the code 142 been occurring?
	2. How many code 142 have occurred?
	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)?
	5. If code occurred while testing 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 type of collection device?
	  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 142 is due to a specific lot of evacuated collection tubes being used AND after troubleshooting code is not reproducible on additional cartridges of the same lot number	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges of the same lot number the code 142 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 142 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	**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 142 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 142 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 143 **Cartridge Error – Use Another Cartridge** RW Code: C2143 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	

	1. What cartridge type, lot number(s)/box number(s) has the code 143 been occurring?
	2. How many code 143 have occurred?
	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)?
	5. If code occurred while testing 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 type of collection device?
	  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 collection tubes being used AND after troubleshooting code is not reproducible on additional cartridges of the same lot number	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF after running additional cartridges of the same lot number the code 143 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 143 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	**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 143 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 143 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 144 **Cartridge Error – Use Another Cartridge** RW Code: C2144 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 144 been occurring? 2. How many code 144 have occurred? 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)? 5. What is analyzer serial number(s)? 6. What is the elevation of the testing site? (i.e. in CO, UT, AB)?	
	Troubleshooting	
	A. Test a new cartridge with fresh sample on the same cartridge lot number and box 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. Document testing site elevation when applicable	
	Resolution	
	IF after running additional cartridges the code 144 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 144 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	**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 144 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 144 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 145 **Cartridge Error – Use Another Cartridge** RW Code: C2145 *Answer pRE Questions!* *Synonyms: N/A*	Sample not detected with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 145 been occurring? 2. How many code 145 have occurred? 3. If code occurred while testing QC material: a. What is lot number(s)? b. How is the QC material filled into the cartridge? Dropper tip or other transfer device? 4. How was the cartridge handled? a. Was the cartridge closed completely? b. Was the cartridge filled to the fill mark? 5. What is analyzer serial number(s)? 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 1. Test a new cartridge with fresh QC material using a transfer device instead of dropper tip (dropper tip can be removed) B. Verify that the cartridge is filled properly (*Technical Bulletin: 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 through troubleshooting code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 145 is due to the cartridge not being properly closed and through troubleshooting code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 145 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF code 145 is occurring with only QC material and is resolved after removing the dropper tip from QC vial and using a transfer device to fill cartridge	**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 145 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	**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 145 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 145 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 146 **Cartridge Error – Use Another Cartridge** RW Code: C2146 *Answer pRE Questions!* *Synonyms: N/A*	Overfilled immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridge	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 146 been occurring? 2. How many code 146 have occurred? 3. If code occurred while testing QC material, what is the lot number(s)? 4. If code occurred while testing patient sample a. What is the sample type tested (whole blood or plasma)? b. How is the sample collected? 5. How was cartridge filled? a. Did sample go past fill mark on cartridge? 6. What is analyzer serial number(s)?	
	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 reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 146 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	**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 146 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 147 **Analyzer Error – See Manual** RW Code: C2147 *Synonyms: N/A*	Analyzer not capable of running immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? a. Check if the analyzer has the 'i' symbol that allows immunoassay cartridge testing 2. How many code 147 have occurred? 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?	
	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 confirmed to have the current CLEW/JAMS software on multiple cartridge lots 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 148 **Cartridge Error – Use Another Cartridge** RW Code: C2148 *Answer pRE Questions!* *Synonyms: N/A*	Sample not detected when testing immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	

	1. What cartridge type, lot number(s)/box number(s) has the code 148 been occurring?
	2. How many code 148 have occurred?
	3. If code occurred while testing QC material:
	  a. What is lot number(s)?
	4. How was the cartridge handled?
	  a. Was the cartridge closed completely?
	  b. Was the cartridge filled to the fill mark?
	5. What is analyzer serial number(s)?
	6. What is the elevation of the testing site? (i.e. in CO, UT, AB)?	

	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 inserting 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 through troubleshooting code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 148 is due to the cartridge not being properly closed and through troubleshooting code is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code 148 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 148 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	**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 148 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 149 **Cartridge Error – Use Another Cartridge** RW Code: C2149 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 149 occurred? 2. How many code 149 have occurred? 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)? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. What sample type is being tested (whole blood or plasma)? c. How is sample collected? d. What collection device is being used? 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 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 B. If one code 149, then draw a fresh sample and test 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 149 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 149 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 149 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)**

Complaint	Description	
Code 150 **Cartridge Error – Use Another Cartridge** RW Code: C2150 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge type, lot number(s)/box number(s) has the code 150 been occurring? 2. How many code 150 have occurred? 3. What is being tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material, what is lot number(s)? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. What sample type is being tested (whole blood or plasma)? c. How is the sample collected? d. What collection device is being used? 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, AB)?	
	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 D. If code is persistent, request the patient's White Blood Cell (WBC) count, if available 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 after running a new cartridge the code 150 is not reproducible on a specific analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 150 is resolved after retesting BNP cartridge with plasma sample	**THEN** the incident is resolved • 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 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)**

Complaint	Description	
Code 151 **Cartridge Error – Use Another Cartridge** RW Code: C2151 *Answer pRE Questions!* *Synonyms: N/A*	Cartridge Error with immunoassay (cTnI, BNP, CK-MB and β-hCG) cartridges	
	Prompts for Meaningful Data Collection	
	1. What cartridge lot number(s)/box number(s) has the code 151 been occurring? 2. How many code 151 have occurred? 3. What is being tested on the cartridge – QC material or patient sample? 4. If code occurred while testing QC material, what is lot number(s)? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. What sample type is being tested (whole blood or plasma)? c. How is sample collected? 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 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 • Classification is **Complaint 1**
	IF the code 151 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 151 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)**

Complaint	Description	
Code 165 **Cartridge Error – Use Another Cartridge** RW Code: C1103 *Answer pRE Questions!* *Synonyms: N/A*	Material detected on sensors before expected due to testing a used cartridge or not allowing cartridges to equilibrate to room temperature prior to testing.	
	Questions	

	1. What cartridge type and lot number(s)/box number(s) has the code 165 been occurring?
	2. How many code 165 have occurred?
	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)?
	5. If code occurred while testing patient sample:
	  a. How is sample collected?
	  b. How many minutes after collection are the samples tested?
	6. How is the cartridge being handled?
	  a. Was a used cartridge inserted into the analyzer?
	  b. How long were cartridges allowed to equilibrate 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	
	IF after running additional cartridges the code is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code was due to testing a used cartridge or cold cartridge and the next cartridge(s) was tested successfully after proper cartridge handling the code 165 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 165 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	**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 165 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 repaired • Classification is **Repair**

Complaint	Description	
Code 166 **Cartridge Error – Use Another Cartridge** RW Code: C1104 *Answer pRE Questions!* *Synonyms: N/A*	Sample arrived at sensor too late, possible due to underfilled cartridge or air bubble in sample.	
	Questions	
	1. What cartridge type and lot number(s)/box number(s) has the code 166 been occurring? 2. How many code 166 have occurred? 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)? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. How is sample collected? c. How many minutes after collection are the samples tested? 6. How are the cartridges being filled? a. Is the sample reaching the fill mark on the cartridge? b. What is used to fill the cartridge? 7. What is analyzer serial number(s)?	
	Troubleshooting	
	A. Verify proper sample handling and sample loading to cartridge 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 troubleshooting and the new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 166 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	**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 166 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 repaired • Classification is **Repair**

Complaint	Description	
Code 167 **Cartridge Error – Use Another Cartridge** RW Code: C1105 *Answer pRE Questions!* *Synonyms: N/A*	Sample arrived at sensor too early, possible due to overfilled cartridge.	
	Prompts for Meaningful Data Collection	
	1. What cartridge type and lot number(s)/box number(s) has the code 167 been occurring? 2. How many code 167 have occurred? 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)? 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. How is sample collected? c. How many minutes after collection are the samples tested? 6. How are the cartridges being handled and filled? a. Is the sample filled beyond the fill mark on the 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 troubleshooting and the new cartridge is tested successfully	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running additional cartridges the code is not reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 167 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	**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 167 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 repaired • Classification is **Repair**

Complaint	**Description**	
Code 170 **Cartridge Error – Use Another Cartridge** RW Code: C1106 *Answer pRE Questions!* *Synonyms: N/A*	Resistance values detected during test cycle was too high	
	Prompts for Meaningful Data Collection	

	1. What cartridge type and lot number(s)/box numbers(s) has the code 170 been occurring?
	2. How many code 170 have occurred?
	3. What is tested on the cartridge – QC material or patient sample(s)?
	4. If code occurred while testing QC material:
	  a. What is product name and lot number?
	  b. How is QC material handled? Describe testing procedure.
	5. If code occurred while testing patient sample:
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time between sample collection and testing?
	6. How is the cartridge being handled?
	  a. Was a used cartridge inserted into the analyzer?
	  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 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 reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after correcting any sample collection or handling issues the code 170 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 170 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	**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 170 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 repaired • Classification is **Repair**

Complaint	Description	
Code 171 **Cartridge Error – Use Another Cartridge** RW Code: C1107 *Answer pRE Questions!* *Synonyms: N/A*	Bubble detected on or near the sensors	
	Prompts for Meaningful Data Collection	
	1. What cartridge type and lot number(s)/box numbers(s) has the code 171 been occurring? 2. How many code 171 have occurred? 3. What is tested on the cartridge – QC material or patient sample(s)? 4. If code occurred while testing QC material: a. What is product name and lot number? b. How is QC material handled? Describe testing procedure. 5. If code occurred while testing patient sample: a. Is only one patient sample giving the code or multiple patients? b. What is the sample type tested? c. How is the sample collected? d. What is the time between sample collection and testing? 6. How is the cartridge being handled? a. Was a used cartridge inserted into the analyzer? 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 reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after correcting any sample collection or handling issues the code 171 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 171 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	**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 171 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 repaired • Classification is **Repair**

Complaint	Description	
Code 172 **Cartridge Error – Use Another Cartridge** RW Code: C1108 *Answer pRE Questions!* *Synonyms: N/A*	Bubble detected on or near the sensors	
	Prompts for Meaningful Data Collection	

	1. What cartridge type and lot number(s)/box numbers(s) has the code 172 been occurring?
	2. How many code 172 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material:
	  a. What is product name and lot number?
	  b. How is QC material handled? Describe testing procedure.
	5. If code occurred while testing patient sample:
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time between sample collection and testing?
	6. How is the cartridge being handled?
	  a. Was a used cartridge inserted into the analyzer?
	  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 reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after correcting any sample collection or handling issues the code 172 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 172 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	**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 172 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 repaired • Classification is **Repair**

Complaint	Description	
Code 173 **Cartridge Error – Use Another Cartridge** RW Code: C1109 *Answer pRE Questions!* *Synonyms: N/A*	Bubble detected on or near the sensors	
	Prompts for Meaningful Data Collection	

	1. What cartridge type and lot number(s)/box number(s) has the code 173 been occurring?
	2. How many code 173 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material:
	  a. What is product name and lot number?
	  b. How is QC material handled? Describe testing procedure.
	5. If code occurred while testing patient sample:
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time between sample collection and testing?
	6. How is the cartridge being handled?
	  a. Was a used cartridge inserted into the analyzer?
	  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 reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after correcting any sample collection or handling issues the code 173 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 173 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	**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 173 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 repaired • Classification is **Repair**

Complaint	Description	
Code 174 **Cartridge Error – Use Another Cartridge** RW Code: C1110 *Answer pRE Questions!* *Synonyms: N/A*	Bubble detected on or near the sensors	
	Prompts for Meaningful Data Collection	

	1. What cartridge type and lot number(s)/box number(s) has the code 174 been occurring?
	2. How many code 174 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material:
	  a. What is product name and lot number?
	  b. How is QC material handled? Describe testing procedure.
	5. If code occurred while testing patient sample:
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time between sample collection and testing?
	6. How is the cartridge being handled?
	  a. Was a used cartridge inserted into the analyzer?
	  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 reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after correcting any sample collection or handling issues the code 174 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 174 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	**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 174 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 repaired • Classification is **Repair**

Complaint	Description	
Code 175 **Cartridge Error – Use Another Cartridge** RW Code: C1111 *Answer pRE Questions!* *Synonyms: N/A*	Bubble detected on or near the sensors	
	Prompts for Meaningful Data Collection	

	1. What cartridge type and lot number(s)/box number(s) has the code 175 been occurring?
	2. How many code 175 have occurred?
	3. What is tested on the cartridge – QC material or patient sample?
	4. If code occurred while testing QC material:
	  a. What is product name and lot number?
	  b. How is QC material handled? Describe testing procedure.
	5. If code occurred while testing patient sample:
	  a. Is only one patient sample giving the code or multiple patients?
	  b. What is the sample type tested?
	  c. How is the sample collected?
	  d. What is the time between sample collection and testing?
	6. How is the cartridge being handled?
	  a. Was a used cartridge inserted into the analyzer?
	  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 reproducible on the analyzer	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after correcting any sample collection or handling issues the code 175 is resolved	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the code 175 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	**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 175 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 repaired • Classification is **Repair**

2.0 Electronic Simulator Codes for the i-STAT 1 System

2.1 Internal Electronic Simulator Codes

Complaint	Description	
Code G **Internal Simulator** RW Code: C201G *Synonyms: N/A*	Simulator Failure: Amperometric channel out of limits ***Internal simulator failure G may be analyzer or cartridge related***	
	Prompts for Meaningful Data Collection	
	1. What is the cartridge type/lot number(s) showing the internal simulator code G? 2. Is code occurring on one analyzer or multiple analyzers? 3. How many code G have occurred? a. If multiple code G, are they all from the same box of cartridges? b. How many total cartridges were used for the specific cartridge lot number? c. What is the internal simulator schedule customization setting on the analyzer (lock out enabled or disabled)?	
	Troubleshooting	
	A. 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 B. For multiple internal simulator code G 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	
	Resolution	
	IF the external simulator test displays PASS on one i-STAT Analyzer AND the error is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the internal simulator failure code G rate is less than allowable rate for a specific cartridge lot number	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the internal simulator FAIL G is occurring on a specific i-STAT analyzer AND other i-STAT analyzer(s) test the same cartridge lot successfully	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator failure code G rate is greater than allowable rate (see note above) for a specific cartridge lot number on multiple analyzers that pass the external simulator test	**THEN** the suspect cartridge lot should be investigated • Classification is **Complaint 2** **Ask customer if cartridges are available to be returned for investigation and document request(s)**

Complaint	Description	
Code L **Internal Simulator Code L** RW Code: C201L *Synonyms: N/A*	Simulator Failure: Potentiometric channel out of limits ***Internal simulator failure L may be analyzer or cartridge related***	
	Prompts for Meaningful Data Collection	
	1. What is the cartridge type/lot number(s) showing the internal simulator code L? 2. Is code occurring on one analyzer or multiple analyzers? 3. How many code L have occurred? a. If multiple code L, are they all from the same box of cartridges? b. How many total cartridges were used for the specific cartridge lot number? c. What is the internal simulator schedule customization 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) 1. If the external simulator passes, analyzer(s) can 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	
	Resolution	
	IF the external simulator test displays PASS on one i-STAT analyzer AND the error is not reproducible on additional cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the internal simulator failure code L rate is less than allowable rate for a specific cartridge lot number	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the internal simulator FAIL L is occurring on a specific analyzer AND other analyzer(s) test the same cartridge lot successfully	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator failure code L rate is greater than allowable rate (see note above) for a specific cartridge lot number on multiple analyzers that pass the external simulator test	**THEN** the suspect cartridge lot should be investigated • Classification is **Complaint 2** **Ask customer if cartridges are available to be returned for investigation and document request(s)**

Complaint	**Description**	
Code B **Internal Simulator Code B** RW Code: C201B *Synonyms: N/A*	Simulator Failure: Potentiometric channel out of limits.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. How many code B have occurred? 3. What is the cartridge type/lot number(s) showing the internal simulator code B?	
	Troubleshooting	
	A. Perform the external electronic simulator test on the analyzer B. Repeat cartridge testing if the external simulator test passes	
	Resolution	
	IF the external simulator test displays PASS on one or multiple i-STAT analyzer(s) and code B was not reproduced with repeat cartridge testing	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF one i-STAT analyzer displays FAIL during the external simulator test AND other i-STAT analyzer(s) testing the same external simulator PASS	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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

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

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

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Complaint	**Description**	
Code G **External Simulator Code G** RW Code: C200G *Synonyms: N/A*	Simulator Failure: Amperometric channel out of limits. Can occur if external simulator not inserted straight.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 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?	
	Troubleshooting	
	A. Clean the external simulator contacts and the inside of the blue cap with alcohol B. Repeat the external simulator test C. If code G continues after cleaning, rerun the same external 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 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 → Customization → Change → *Password* → QC Tests → Simulator → Int Simulator)	
	Resolution	
	IF the external simulator contacts/inside of the blue cap were cleaned with alcohol AND the repeat external simulator test displayed PASS on one or multiple i-STAT Analyzers	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF multiple i-STAT analyzers continue to experience code G after repeating the external simulator test using the same external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF one i-STAT analyzer continues to experience code G after repeating the external simulator test AND other i-STAT analyzers testing the same external simulator PASS	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator displays PASS on the analyzer AND only one external simulator is available	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the external and internal simulator displays FAIL on the analyzer AND only one external simulator is available	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code L **External Simulator Code L** RW Code: C200L *Synonyms: N/A*	Simulator Failure: Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the serial number of the external electronic simulator(s) that experienced code L? 3. Has external simulator test been repeated on analyzer?	
	Troubleshooting	
	A. Equilibrate the i-STAT analyzer and external simulator to the environment for 30 minutes (i.e. in the same room or bench top) B. Repeat the external simulator test C. If code L continues after equilibration, rerun the same external simulator on a different i-STAT analyzer, or run a different external simulator the same i-STAT analyzer D. 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 → Customization → Change → *Password* → QC Tests → Simulator → Int Simulator)	
	Resolution	
	IF the i-STAT analyzer(s) AND the external simulator(s) have equilibrated to the environment for 30 minutes AND the repeat external simulator test displayed PASS	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF multiple i-STAT analyzers continue to experience code L after repeating the external simulator test using the same external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF one i-STAT analyzer continues to experience code L after repeating the external simulator test AND other i-STAT analyzers testing the same external simulator PASS	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator displays PASS on the analyzer AND only one external simulator is available	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the external and internal simulator displays FAIL on the analyzer AND only one external simulator is available	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code B **External Simulator Code B** RW Code: C200B *Synonyms: N/A*	Simulator Failure: Potentiometric channel out of limits.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the serial number of the external electronic simulator (s) that experienced code B? 3. Has external simulator test been repeated on analyzer?	
	Troubleshooting	
	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 → Customization → Change → *Password* → QC Tests → Simulator → Int Simulator)	
	Resolution	
	IF the repeat external simulator test displays PASS on one or multiple i-STAT analyzer(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF multiple i-STAT analyzers continue to experience code B after repeating the external simulator test using the same external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF one i-STAT analyzer continues to experience code B after repeating the external simulator test AND other i-STAT analyzers testing the same external simulator PASS	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator displays PASS on the analyzer AND only one external simulator is available	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the external and internal simulator displays FAIL on the analyzer AND only one external simulator is available	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Code R **External Simulator Code R** RW Code: C200R+ *Synonyms: N/A*	Simulator Failure: Resistance reading on conductometric channel out of limits.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 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?	
	Troubleshooting	
	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 → Customization → Change → *Password* → QC Tests → Simulator → Int Simulator)	
	Resolution	
	IF the repeat external simulator test displays PASS on one or multiple i-STAT analyzer(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF multiple i-STAT analyzers continue to experience code R after repeating the external simulator test using the same external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF one i-STAT analyzer continues to experience code R after repeating the external simulator test AND other i-STAT analyzers testing the same external simulator PASS	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal electronic simulator displays PASS on the analyzer AND only one external simulator is available	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the external and internal simulator displays FAIL on the analyzer AND only one external simulator is available	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code r **External Simulator Code r** RW Code: C200R- *Synonyms: N/A*	Simulator Failure: Resistance reading on conductometric channel out of limits.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 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?	
	Troubleshooting	
	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 → Customization → Change → *Password* → QC Tests → Simulator → Int Simulator)	
	Resolution	
	IF the repeat external simulator test displays PASS on one or multiple i-STAT analyzer(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF multiple i-STAT analyzers continue to experience code r after repeating the external simulator test using the same external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	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	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator displays PASS on the analyzer AND only one external simulator is available	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the external and internal simulator displays FAIL on the analyzer AND only one external simulator is available	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Code t **External Simulator Code t** RW Code: C200T- *Synonyms: N/A*	Simulator Failure: Thermal probe failure	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the serial number of the external electronic simulator(s) that experienced code t? 3. Has external simulator test been repeated on analyzer?	
	Troubleshooting	
	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 → Customization → Change → *Password* → QC Tests → Simulator → Int Simulator)	
	Resolution	
	IF the repeat external simulator test displays PASS on one or multiple i-STAT analyzer(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF multiple i-STAT analyzers continue to experience code t after repeating the external simulator test using the same external simulator	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF one i-STAT analyzer continues to experience code t after repeating the external simulator test AND other i-STAT analyzers testing the same external simulator PASS	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the internal simulator displays PASS on the analyzer AND only one external simulator is available	**THEN** the external simulator should be replaced • Classification is **Repair**
	IF the external and internal simulator displays FAIL on the analyzer AND only one external simulator is available	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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	**Product powers down unexpectedly** • 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	→ Jump to Section

3.1.1. i-STAT Power/Activation Issues

Complaint	Description	
Display Screen Not Functioning Properly RW Code: C2525 *Synonyms: Screen display scrambled, lines, bars, pixels, blurry, fuzzy, blank*	Analyzer powers on and the display screen is either faded, completely blank or shows lines, dark spots, or blank portions. Analyzer has dim back-lighting.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the appearance of the screen? 3. What is the current battery voltage on the analyzer status screen? 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. Document screen appearance (if display screen is cracked, refer to C2595) 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 or charging the batteries and checking battery door and contacts	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF troubleshooting does not resolve the issue and the analyzer display continues to not function	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF the analyzer display screen is cracked	**THEN** refer to C2595

Complaint	Description	
Key(s) difficult to press / not responding RW Code: C2530 *Synonyms: Keys nonresponsive, dead, press several times or multiple times, squishy, sticky, no click or feedback*	Analyzer keys are not responsive or are difficult to push	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the current battery voltage on the analyzer status screen? 3. 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	
	Resolution	
	IF the analyzer keypad functions correctly after changing or charging the batteries and checking battery door and contacts	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF troubleshooting does not resolve the issue and the analyzer keypad continues to be unresponsive	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description
No activation / power / screen refresh RW Code: C2510 *Synonyms:* *Hardware not turning on, not responding, dead*	The i-STAT analyzer is not turning on at all and gives no audio or visual response when trying to power on. Analyzer will activate when powered on; the screen activates/flashes then goes blank. The i-STAT logo appears and then the screen goes blank. Alternatively, the analyzer screen may be stuck and will not respond to key presses, typically showing "Insert Cartridge", "Remove Cartridge", or "Cartridge Locked". i-STAT Printer, Martel Printer and i-STAT Downloaders (all models) will not power on.
	Prompts for Meaningful Data Collection
	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 serial number(s)? b. Has battery been charged? c. Is i-STAT printer connected to A/C power? 3. If downloader has no power: a. What is downloader serial number? b. 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/JAMS 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)

	E. If i-STAT printer, provide replacement cables for troubleshooting F. If Martel printer, replace printer (cables are not available) **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 cables for troubleshooting D. If DS-300, DRS-300, DN-300 or DRN-300 model, replace downloaders (cables are not available)	
	Resolution	
	IF the analyzer powers on successfully or the analyzer screen refreshes successfully after changing or charging the batteries and checking battery orientation, door, contacts and carrier	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the analyzer powers on successfully after reinstalling the CLEW/JAMS software	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF replacement cables resolve power issue with i-STAT printer and DRC-300 downloader	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF troubleshooting does not resolve the issue and the analyzer will not power on or the display continues to be stuck on same screen	**THEN** the i-STAT analyzer must be replaced or repaired • Classification is **Repair**
	IF troubleshooting does not resolve the issue and the downloader will not power on	**THEN** the downloader must be replaced • Classification is **Repair**
	IF the printer Power lights do not indicate acceptable operating conditions AND the above troubleshooting does not allow printing	**THEN** the printer must be replaced • Classification is **Repair** **Note: Martel printers will be replaced with i-STAT Printer kit**

Complaint	**Description**	
Product powers down unexpectedly RW Code: C2506 *Synonyms: Analyzer turning off, shutting down, prematurely*	Analyzer does turn on successfully, however is turning off in the middle of a test or while running a test or when navigating through the analyzer menus.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the current battery voltage on the analyzer status screen? 3. 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. Replace with new 9-volt lithium batteries or a fully charged i-STAT rechargeable battery pack. 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 battery 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 changing or charging the batteries and checking battery door, contacts and carrier	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF troubleshooting does not resolve the issue and the analyzer continue to power off unexpectedly	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
Cartridge/Sim doesn't lock RW Code: C2521 *Synonyms: Not clicking*	i-STAT cartridge, external simulator or troubleshooting tool can be inserted but does not lock into place on the i-STAT analyzer.	
	Prompts for Meaningful Data Collection	
	1. Is the issue impacting one i-STAT analyzer or multiple analyzers? a. What is analyzer serial number(s)? 2. Is the cartridge/simulator/tool inserting fully and not locking into place in the analyzer? 3. Does the issue occur after running specific external simulator(s)? a. What is the external simulator serial number(s)? b. Is there visible damage to the latch engagement surface on the back of the simulator?	
	Troubleshooting	
	1. If the cartridge/simulator **can be fully inserted but is not locking into place**, perform the Latch Return Tool 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 of the simulator	
	Resolution	
	IF the cartridge/simulator inserts and locks into place successfully after running the Latch Return Tool AND simulator is not damaged	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the cartridge/simulator inserts but does not lock into place after running the Latch Return Tool AND simulator is not damaged	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**
	IF the cartridge/simulator inserts but does not lock into place after running the Latch Return Tool AND simulator is damaged OR latch is flipped following second simulator test	**THEN** the external simulator should be replaced • Classification is **Repair**

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Complaint	**Description**	
Cartridge/Sim cannot be inserted RW Code: C2520 *Synonyms: Cartridge blocked, something in the way*	i-STAT cartridge, external simulator or troubleshooting tool cannot be inserted into the i-STAT analyzer.	
	Prompts for Meaningful Data Collection	
	1. What is being tested (cartridge, external simulator, troubleshooting tool) in the analyzer? 2. Is the issue impacting one i-STAT analyzer or multiple analyzers? a. What is analyzer serial number(s)?	
	Troubleshooting	
	A. If the cartridge/external simulator/troubleshooting tool **cannot be fully inserted,** repair or replace analyzer	
	Resolution	
	IF the cartridge/external simulator/troubleshooting tool cannot be inserted in a specific analyzer	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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Complaint	Description	
Cartridge/Simulator Stuck RW Code: C2540 *Synonyms: Cartridge jammed, locked, frozen*	The i-STAT analyzer has a cartridge or electronic simulator locked in the cartridge port and it cannot be released through normal operation.	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. Is a cartridge or simulator stuck in analyzer?
	  a. If simulator, what is serial number?
	3. What is the current battery voltage on the analyzer status screen?
	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 charging the batteries AND the analyzer is functioning properly	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the cartridge/simulator is not released after troubleshooting on specific analyzer	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair** **Note:** If an external simulator is stuck in the analyzer, then it will also need to be replaced DO NOT FORCEFULLY REMOVE the stuck simulator or cartridge

Complaint	Description	
Unexpected Barometric Pressure Reading RW Code: C2535 *Synonyms: Pressure off, wrong, doesn't match*	The i-STAT analyzer is showing a barometric pressure reading that is different than a comparative analyzer or an external barometer or is otherwise different than expected.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 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? a. Is the external barometer in same location as analyzer or at a remote location?	
	Troubleshooting	
	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 accurate after troubleshooting	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the analyzer barometric pressure is determined to be inaccurate on specific analyzer after troubleshooting	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Date/Time displayed is unexpected RW Code: C2512 *Answer pRE Questions!* *Synonyms: Date or time is wrong, incorrect*	The i-STAT analyzer is showing or reporting a date and time that is incorrect or unexpected.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the date/time displayed on the analyzer and what should it be showing? a. Is the issue occurring due to daylight savings time? b. Is this a new or replacement analyzer, being used for the first time? 3. Is a data management system being used? a. What is the data management system? b. Has the analyzer communicated with data management system recently? c. Where is the main data management server located?	
	Troubleshooting	
	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 Clock to CDS" setting and communicating with the data management system	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the date/time is corrected after verifying the time on the data management server and communicating with the data management system	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the date/time is NOT corrected after troubleshooting and a third party DMS is in use: issue referred to DMS vendor support; issue is confirmed to be resolved	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the date/time is corrected manually on the analyzer and is maintained	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF specific analyzer is unable to maintain the correct date/time after troubleshooting and all other analyzers have correct date/time	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Analyte displayed is inconsistent with cartridge labeling RW Code: C5559 *Answer pRE Questions!* *Synonyms: Results missing, wrong, different, incorrect*	The i-STAT analyzer is not identifying the correct cartridge being inserted; Analyzer is reporting analytes that are different than the labeling on the cartridge being run. For example, analyzer incorrectly identifies ACT cartridge when PT/INR cart is inserted; the analyzer reports ACT results 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.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the lot number / box number of the cartridges being used? 3. What analytes were reported on the analyzer? What analytes were expected?	
	Troubleshooting	
	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 the issue and subsequent cartridge runs produce the expected results	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF specific i-STAT analyzer continues to misidentify cartridges after troubleshooting and same cartridge lot number(s) run successfully on another i-STAT analyzer	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**
	IF misidentification is persistent with specific cartridge lot(s) on multiple i-STAT analyzers after troubleshooting	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2** **Request cartridges be returned for investigation and document request(s)**

3.2 Barcode Scanning 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	→ 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 o 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 o Analyzer may add/delete/change characters or symbols from the ID/product barcode o 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	→ Jump to Section

3.2.1. Barcode Scanning Issues

Complaint	Description	
Scanner beam not functioning as expected RW Code: C2562 *Synonyms: Scanner dead, fuzzy, blurry, partial, off, not scanning*	No light is emitted from the barcode scanner, light functions intermittently, or the light is otherwise compromised, be it blurry, skewed, partial, a single dot, or flickering. This code should not be used if the laser scanner light on the analyzer is emitted and looks as expected and is not scanning the barcode or IDs.	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. At what prompt on the i-STAT analyzer display is the user pressing the scan button?
	  a. Is the user holding down the scan button or just pressing it?
	3. What is the appearance of the scanner beam?
	4. Is there dirt or debris on the scanner window?
	5. What is the current battery voltage on the Analyzer Status screen?
	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 changing or charging the batteries	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the analyzer barcode scanner functions correctly after cleaning the barcode scanner	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the analyzer barcode scanner functions after correcting the analyzer handling, either pressing at the wrong analyzer prompt or not holding the button down long enough	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF troubleshooting does not resolve the issue and the analyzer barcode scanner continues to emit no light, function intermittently, or be otherwise compromised	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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.

Complaint	Description	
Analyzer message "ID Not in Valid ID List" RW Code: C2563 *Synonyms: Not scanning, ID not in list, Invalid ID*	Analyzer barcode scanner beam turns on and reads the operator or patient ID barcode (or manual entry) but the analyzer displays message "ID Not in Valid ID List".	
	Prompts for Meaningful Data Collection	
	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? 2. What ID is being scanned – operator ID or patient ID? a. How many IDs are showing this issue? b. Are the ID(s) in question new or old? c. Were any changes made to the specific ID(s) in question? i. If yes, when and what are the changes? d. Are the ID(s) successfully scanned by other analyzers? e. Was the analyzer docked/communicating with DMS after the changes to the ID(s)? f. Do the analyzer(s) have the current operator/patient list number under customization? 3. Is customization done on a data management system or directly on the analyzer? 4. Does the analyzer have the correct customization profile for that location? a. Are the ID(s) on the list in DE system for that location/facility? b. Is customization enabled globally and for the location in customization workspace?	
	Troubleshooting	
	A. Verify the number of analyzer(s) and ID(s) that are affected B. Verify if the ID(s) in question are scanned successfully by another analyzer(s) C. Verify if any changes were made to the ID(s) recently to cause this issue D. Verify that the customization settings on the analyzer are appropriate given the barcode being scanned and the information on the operator/patient list (check truncation settings) E. Verify the analyzer is uploading the correct customization 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 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 customization 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 appropriate 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 O. Inquire if fluorescent or LED lighting is being used; try turning lights off when scanning **Note:** For any system using DE, when an operator certification expires, it translates to the DE as "Operator Not on List" and therefore will display "Operator Not on List" instead of "Certification Expired". The handheld will perform the actions customized for operator not on list. Verify operator certification dates in DMS.	
	Resolution	
	IF the analyzer accepts the operator/patient ID the above troubleshooting	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the analyzer accepts the operator/patient ID after resolution by DMS vendor support	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the analyzer accepts the operator ID after cleaning barcode scanner or after following proper scanning procedure	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description	
Barcode scanned - Unexpected info displayed RW Code: C3200 *Answer pRE Questions!* *Synonyms: Not scanning*	Analyzer barcode scanner light turns on and reads the barcode, but the analyzer display shows unexpected characters, either adding, deleting, or changing characters/symbols.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. Which barcode(s)/ID is being scanned? 3. Are all barcodes/IDs impacted or only specific barcodes/IDs? 4. If product barcode, what is the lot number / box number of the product being scanned? 5. If operator or patient ID a. What are the characteristics of the operator or patient ID barcode being scanned (length, type, etc.)? b. What characters are showing when scanned? c. Were any changes made to the ID(s) in question? d. What is the barcode format of the ID in question? 6. How far away is the analyzer from the barcode being scanned and at what angle? 7. 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. Inquire if fluorescent or LED lighting is being used; try turning lights off when scanning	
	Resolution	
	IF the analyzer scans the barcode correctly after above troubleshooting steps	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF specific analyzer continues to show unexpected characters 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 must be replaced or repaired • Classification is **Repair**

Complaint	Description	
Product barcode will not scan / Invalid Number RW Code: C3223 *Synonyms: Not scanning*	Analyzer barcode scanner beam emits but the cartridge or the APOC QC material barcodes are not read or the analyzer reads the barcodes and gives the error message "Invalid Number". Blue CG4+ Cartridges part number 03P85-51 scanned with message "Invalid Cart." Message displayed.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the lot number / box number of the product being scanned? 3. What barcode on APOC product is being scanned? 4. Is the issue occurring with one barcode or multiple barcodes? 5. How far away is the i-STAT analyzer from the barcode being scanned and at what angle? 6. What type of lighting is used in the operating environment? 7. 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)? **"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, PCO2 and PO2) outside of the reportable range on Blue CG4 cartridge?	
	Troubleshooting	
	A. Inquire if fluorescent or LED lighting is being used; try turning 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 appropriate distance from the barcode being scanned (3-9 inches/8-23 cm) and at a proper angle (about 10 degrees) D. Verify scanner beam is covering entire length of barcode E. Change or charge the batteries to reach the required operational 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 individual cartridge pouch I. Verify that the cal ver material lot is scanned from the barcode on the box of the kit not ampule/vial **"Invalid Cart." Message** Occurs when Blue CG4+ Cartridges part number 03P85-51 is being 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 ranges. C. Assist customer with adjusting ranges (if applicable) D. Assist customer with disabling analyte(s) on Blue CG4+ cartridge panel (if applicable) E. Download updated customization preference to analyzer and retest cartridge	
	Resolution	
	IF the analyzer scans the product correctly after above troubleshooting	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF specific analyzer continues to either not scan cartridge/control barcodes or give the error "Invalid	**THEN** the i-STAT analyzer must be replaced or repaired • Classification is **Repair**

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

Complaint	Description
Unable to Enter / Scan ID RW Code: C2585 *Answer pRE Questions!* *Synonyms: Not scanning*	Analyzer barcode scanner emits light but does not recognize/read the operator or patient ID barcode. Alternatively, scanner reads barcode (or manual entry) but shows "Invalid Length".
	Prompts for Meaningful Data Collection
	1. What is analyzer serial number(s)? 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 a. What is the length of the ID barcode scanned? 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? 4. If the ID is not recognized by the analyzer and no message is displayed 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 1. 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 1. Try different barcode sub-settings under code 39 and I2of5 C. If using a data management system 1. 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. If fluorescent or LED lighting is being used; try turning lights off or shielding the scanner from the light when scanning F. Clean barcode scanner window G. Verify the user is holding the barcode scanner an appropriate distance from the barcode being scanned (3-9 inches/8-23 cm) and at a proper angle (about 10 degrees) H. Verify scanner beam is covering entire length of barcode I. Change or charge the batteries to reach the required operational voltage J. Verify battery carrier is red, battery contacts are in good condition and battery door is holding battery secure

	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**

3.3 Battery Related Issues

Complaint	**Description**
Battery – Low/frequently replaced RW Code: C2581 *Synonyms: Battery low, dead, weak, icon flashing*	The i-STAT hardware or analyzer indicates low battery voltage or requires frequent charging/replacement of batteries to maintain functionality
	Prompts for Meaningful Data Collection
	1. What i-STAT hardware is being impacted? a. What is the serial number(s)? 2. If an i-STAT analyzer is impacted: a. What type of batteries are being used? b. If 9-volt lithium, what is the color of the battery carrier (i.e. red/green)? c. If i-STAT rechargeable, 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 back of the i-STAT analyzer? iii. Is the issue associated with specific downloader/recharger serial number? d. Are the battery contacts in good condition? 3. What cartridge types are tested on the i-STAT analyzer?
	Troubleshooting
	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 batteries → **THEN** the issue is resolved • Classification is **Complaint 1**

	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 replaced • Classification 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**

Complaint	**Description**	
Battery – Unable to recharge/ replace RW Code: C2582 *Synonyms: Battery dead, weak, low, stuck, jammed, broken*	The i-STAT hardware - the user is unable to recharge the battery or unable to replace the battery	
	Prompts for Meaningful Data Collection	
	1. What i-STAT hardware is impacted? a. What are the serial numbers of the impacted device(s)? 2. If an i-STAT analyzer is impacted: are i-STAT rechargeable batteries being used? a. What is the born-on date of the battery? b. Are the charging pins present on the i-STAT downloader/recharger and the charging pads present on the i-STAT analyzer? c. Is the issue associated with a specific downloader/recharger serial number? 3. Is the battery oriented correct and the contacts in good condition?	
	Troubleshooting	
	A. Ensure that the analyzer is seated properly in the downloader/recharger and that red or green light illuminates on downloader/recharger B. Verify that all four gold charging pins are present on the downloader/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 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 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 in downloader). If analyzer is missing feet, send replacement feet to customer and add C2595 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 printer using rechargeable battery, battery requires replacement.	
	Resolution	
	IF the issue is resolved by the above troubleshooting	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF it is identified that the battery cannot be charged because the i-STAT analyzer and/or downloader/recharger have missing or damaged charging pins/contacts	**THEN** refer to C3213
	IF specific i-STAT analyzer cannot recharge the battery AND the same battery is confirmed to work without issue in other i-STAT analyzers	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

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

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

3.4 Smoking/Burning/Injury Related Issues

Complaint	Description	
Equipment (Smoking/Burning /Fire/Explosion) RW Code: C1070 *Answer pRE Questions!* *Synonyms: melted, damaged, combusting, fire, sparks, smoke, charred*	i-STAT hardware suffered a failure resulting in exploding/combusting, being on fire, or emitting smoke	
	Prompts for Meaningful Data Collection 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. What power cables were being used with the i-STAT hardware at the time of the event? 3. When (date/time) did the event occur and what was being done with the hardware during the event? 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)? 5. Was the user injured because of the smoking/burning/fire/explosion event?	
	Troubleshooting A. Verify if the user was injured during the event; if injury occurred see code C1065 B. Verify if the user was using the correct APOC supplied power cables and/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) 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 not 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 incorrect battery/cables were used	**THEN** the i-STAT hardware should not be replaced at no 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 correct battery/cables were used	**THEN** the i-STAT hardware should be replaced and 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**

Complaint	Description	
Product "Hot" to touch RW Code: C2580 *Answer pRE Questions!* *Synonyms: hot, burning, uncomfortable, painful, dangerous*	The i-STAT hardware is hot enough to burn or harm the user	
	Prompts for Meaningful Data Collection	
	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? 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)? c. Is the issue attributable to a specific rechargeable battery? 5. Was the user injured because of the hot product?	
	Troubleshooting	
	A. Verify if the user was injured during the event; if injury occurred see code C1065 B. Verify if the user was using the correct power cables and/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) C. Notify Technical Services 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 incorrect battery/cables were used	**THEN** the i-STAT hardware should not be replaced at no 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 correct battery/cables were used	**THEN** the i-STAT hardware should be replaced and 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**

Complaint	Description	
Product warm but not "Hot to Touch" RW Code: C5571 *Answer pRE Questions!* *Synonyms: hot, burning, uncomfortable*	The i-STAT hardware is warmer than expected by the customer, but not hot enough to cause burns or harm the user	
	Prompts for Meaningful Data Collection	
	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? 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? 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)? c. Is the issue attributable to a specific rechargeable battery? 5. Was the user injured because of the warm product?	
	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 and/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 not 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 incorrect battery/cables were used	**THEN** the i-STAT hardware should not be replaced at no 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 correct battery/cables were used	**THEN** the i-STAT hardware should be replaced and 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**

Complaint	Description	
User Injured RW Code: C1065 *Answer pRE Questions!* *Synonyms: cut, bleeding, blood, bruised, hurt, shocked, smacked, zapped*	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.).	
	Prompts for Meaningful Data Collection	
	1. Was the injury caused by i-STAT hardware or consumable product? a. What is the lot number or serial number of the product that caused the injury? 2. If the user was shocked: were Abbott power cables or batteries/battery carrier used for the i-STAT hardware involved? a. How was the hardware handled? b. Did the user touch electrical contacts? 3. If the user was cut or bruised: how was the product being handled? a. If cut on a control ampule: was the appropriate protective equipment worn and precautions taken to 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 product or use of incorrect power cables/batteries/battery carrier AND the user confirms understanding of correct use of the product AND the product is currently functioning without issue	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the user was cut on i-STAT product due to a manufacturing defect or damage incurred from shipment (NOT caused by mishandling or physical damage incurred at customer site)	**THEN** the i-STAT product should be investigated • Classification is **Complaint 2**
	IF the user was shocked by i-STAT hardware and it is verified that they were using the correct power cables/batteries/battery carrier at the time of the incident AND the issue is not attributable to incorrect handling of the hardware	**THEN** the i-STAT hardware should 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**

3.5 Cosmetic Damage Issues

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

3.6 Miscellaneous Analyzer Issues

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

Complaint	Description
Testing Disabled/No Result Displayed RW Code: C2591 *Synonyms: Cannot be found, can't be found, "pre-warm" error for ACT test; Zero for ACT*	The i-STAT 1 Analyzer(s) does not display the test result(s) or testing is disabled (i-STAT 1 Analyzer displays "Upload Required" or "Simulator Required" when powered on) or ACT result is displayed as zero "0"

Prompts for Meaningful Data Collection

1. What is analyzer serial number(s)?
2. What is displayed (error/message) on the i-STAT 1 Analyzer?
3. What is cartridge type/lot number (if applicable)?
    a. Which analyte result is impacted (if applicable)?
    b. Was test cancelled/stopped during ACT cartridge test cycle? (ACT result will be "0")
4. Is Data Management used with the i-STAT 1 Analyzer(s)?
    a. If yes, what data manager is being used?
    b. Can the user access customization workspace in DMS?
5. Is Operator Test Select being used during testing on the i-STAT 1 Analyzer(s)?
6. Is analyte(s) in question disabled globally or by panel in DMS?
7. 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.

1. 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 1 Analyzer

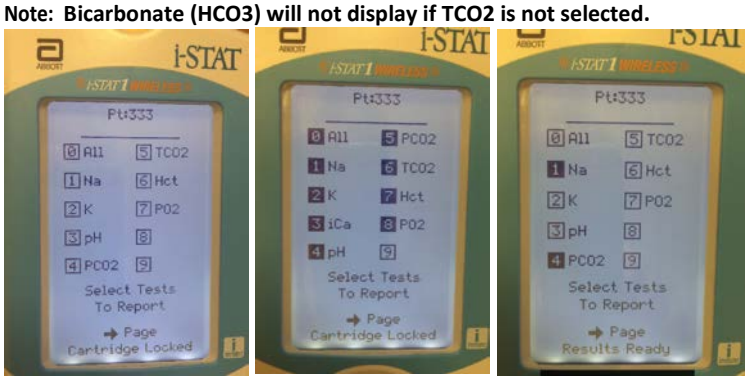
D. Verify if the customization preference on the analyzer matches the preference for its location in DMS customization workspace

E. Determine if analyte(s) on the cartridges are disabled; either globally or by panel under DMS customization workspace

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.



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 "0".

H. Re-test the cartridge to verify that the issue is resolved after the above troubleshooting

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

Complaint	**Description**	
Device Message "Memory Full" RW Code: C2572 *Synonyms: N/A*	The i-STAT 1 Analyzer(s) memory is 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)? a. If yes, what data manager is being used?	
	Troubleshooting	
	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 delete results (as necessary) to "free" up memory (per customer's discretion) Note: The analyzer does not warn if there are 1000 unsent results. It warns if it detects that storing more results will require deleting unsent results. Results are stored in sequential order, so eventually to store new results the analyzer needs to overwrite the oldest results. This warning indicates that doing so will delete records that were not previously transmitted.	
	Resolution	
	IF downloading results OR deleting results resolves the "Memory Full" message	**THEN** the issue is resolved • Classification is **Complaint 1**

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

Complaint	Description	
Cleaning Tool Stuck RW Code: C3211 *Synonyms: Jammed, locked*	The i-STAT 1 Analyzer has a Contact Pin Cleaning Tool, Ceramic Conditioning Cartridge or Latch Return Tool stuck in the cartridge port and cannot be removed	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. Which tool is stuck in analyzer? 3. What quality check code or issue occurred leading to use of tool?	
	Troubleshooting	
	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 additional cartridges to ensure that the analyzer is functioning properly **If Ceramic Conditioning Cartridge or Latch Return Tool is stuck:** A. Change or charge the batteries to reach the required operational voltage 1. Verify battery carrier with a red fused bottom is being used with 9-volt Lithium batteries 2. Verify appropriate rechargeable battery is being used and is not exhausted B. Ensure that the pins in the battery compartment are in good condition C. 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 D. If Ceramic Conditioning Cartridge or Latch Return Tool is released, run cartridge or simulator to ensure the analyzer is functioning properly	
	Resolution	
	IF the tool is removed after troubleshooting AND the analyzer is functioning properly	**THEN** the issue is resolved • 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 Functionality not as Expected per Customer RW Code: C2568 *Synonyms: does not work, has an issue/error*	The i-STAT 1 Analyzer is not performing as expected and no specific error codes are being generated or user does not know the specific details of the issue with the analyzer ***Note: C2568 should only be used when there is no other specific complaint code available*** Examples: • Analyzer displays "Remove Cartridge" when simulator is inserted • Analyzer displays "Temperature Out of Range, Check Status Page" • User expecting the analyzer to perform a function it is not capable of performing • i-STAT analyzer does not beep when testing is completed • When running test on analyzer, the results are not displaying on the initial page. User must arrow over to see results. • User not able to get into the utility menu on analyzer • Wireless analyzer is losing configuration settings

Prompts for Meaningful Data Collection

1. What is the analyzer serial number?
2. What and when is the issue occurring?
3. Are any codes or messages being displayed by the analyzer(s)?

Troubleshooting

A. Request specific details regarding complaint (request screenshots or pictures of the issue)
B. Verify if the analyzer shows the message/error currently
C. For "Temperature Out of Range, Check Status Page" message:
    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
E. 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 - Reset
        f. Must wait for Status to indicate State: **Associated.**
        g. Press 1 - View Setup (All wireless settings including IP address will display)

Resolution

IF the complaint is resolved with discussion of customization settings on the analyzer/DMS, testing procedures and performance specifications AND product is determined to be functioning as expected	**THEN** issue is resolved • Classification is **Complaint 1**
IF the wireless configuration settings are viewed by following troubleshooting above	**THEN** issue is resolved • Classification is **Complaint 1**

4.0 Accessories

Components	Description	
Cables *Synonyms: N/A*	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? a. What are the serial number(s) of the hardware? 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 printer utilize the same type of power adapter (currently orderable), while the DS-300, DRS-300, DN-300, DRN-300, and Martel Printer use different power adapters (not currently orderable) B. A complete DRC-300 downloader or i-STAT PR-300 printer power cable consists of two components, the power adapter and the power cable; the power cable is specific to the country of use C. Replacement cables can be sent at no charge if required to troubleshoot or resolve a current issue reported by customer	
	Scenarios	
	IF the customer reported damaged cables for a DRC-300 downloader or i-STAT (PR-300) printer	**THEN** the cables can be sent at no charge • Classification is **Complaint 1 with** C2595
	IF the customer has lost/misplaced cables or has damaged cables for a DRC-300 downloader or i-STAT (PR-300) printer and the cables are needed to resolve a currently documented issue (i.e. software update, transmission issues, power issues)	**THEN** the cables can be sent at no charge • Classification is **Complaint 1**
	IF the customer has lost/misplaced cables for a DRC-300 downloader or i-STAT (PR-300) printer and the customer has not reported a currently documented issue that needs to be resolved	**THEN** the customer should purchase the cables through Customer Service
	IF the customer has lost/misplaced cables or has damaged cables for a DS-300, DRS-300, DN-300, DRN-300 downloader or a Martel printer and they require replacement cables (power cable or DB9 serial cable)	**THEN** the i-STAT hardware should be replaced • Classification is **Repair** **Replacement cables for the older model downloaders (DS-300, DRS-300, DN-300, DRN-300) only available through the RGA process.** **Martel printers will be replaced with i-STAT Printer kit.**

Components	Description	
Feet *Synonyms: N/A*	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	
	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 downloader/recharger	**THEN** the feet can be sent at no charge • Classification is **Complaint 1 with** C2595
	IF the customer is not currently missing feet from the i-STAT analyzer or downloader/recharger, but would like to order additional feet as spares	**THEN** the feet CANNOT be sent per OEC regulations

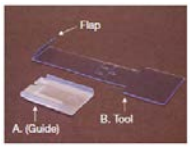
Components	Description	
Battery Door(s) *Synonyms: N/A*	The i-STAT 1 Analyzer has a removable door to hold the batteries in place.	
	Prompts for Meaningful Data Collection	
	1. What i-STAT hardware is impacted? a. What are the serial number(s) of the hardware? (Note: battery doors for printers are not available) 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 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** C2595
	IF the battery door is not damaged or misplaced and the customer is requesting spare doors	**THEN** the door CANNOT be sent per OEC regulations
	IF the battery door is damaged and the customer confirms that the i-STAT analyzer also has damage, specifically around the battery compartment	**THEN** the i-STAT hardware should be replaced • Classification is **Repair**

Components	Description	
Battery Carrier(s) *Synonyms: N/A*	The i-STAT 1 Analyzer utilizes a removable plastic battery carrier to house two disposable 9-Volt Lithium batteries. The disposable batteries can be replaced with a rechargeable battery pack if desired.	
	Prompts for Meaningful Data Collection	
	1. What i-STAT Analyzer serial number? 2. Is the battery carrier damaged or misplaced? 3. Is the hardware experiencing an issue (not powering on, powering off prematurely, etc.)?	
	Additional Information	
	A. If the battery carrier is damaged, verify if the i-STAT analyzer 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 regardless of the customer complaint New Battery Carrier  WITH FUSE Old Battery Carrier  NO FUSE	
	Scenarios	
	IF the battery carrier is misplaced	**THEN** the carrier can be sent at no charge • Classification is **Inquiry**
	IF the battery carrier is damaged	**THEN** the carrier can be sent at no charge • Classification is **Complaint 1 with** C2595
	IF the battery carrier is not damaged or missing and the customer is requesting spare carriers AND the customer has the battery carrier with red base	**THEN** the carriers CANNOT be sent per OEC regulations
	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

5.0 Tools for Troubleshooting

Tool	Description
Ceramic Conditioning Cartridge (CCC)  *Synonyms: N/A*	In case of contact related errors such as suppressed (***) results for hematocrit and Quality Check Codes 20, 23, 27, 28, 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 Ceramic Conditioning Cartridge. **Instructions** 1. Run an external Electronic Simulator a. 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 2. Run the CCC two times a. Initiate the CCC cycle as you would initiate an external Electronic Simulator b. 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 3. Update the CCC Usage Log a. Update the CCC Usage Log to keep track of the number of restoration cycles performed with the current ceramic strip in the CCC b. If necessary, replace or rotate the ceramic strip so CCC is ready for future use (Note: Use 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/QC 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 CCC but they are not currently experiencing a quality check code that warrants the use of the CCC	**THEN** the CCC can be sent at no charge • Classification is **Inquiry**
IF the customer reports that a quality check code is occurring that warrants the use of the CCC	**THEN** the CCC can be sent at no charge for troubleshooting • Classification is **Complaint 1** (C1071)

Tool	Description
Contact Pin Cleaning Kit  *Synonyms: N/A*	The Contact Pin Cleaning Kit may be used when Quality Check Code 48, 57, or 68 is generated on the i-STAT 1 Analyzer 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).

Instructions

1. Power OFF the analyzer and remove the batteries
2. Hold the Tool Guide [A] with thumb on the arrow and insert it into the cartridge port
    a. Push the Tool Guide in until it snaps into place, similar to a cartridge
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
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) has cleared
    a. If code has not cleared, repeat with a **NEW** Contact Pin Cleaning Tool/Guide

Additional Information

A. Refer to *Technical Bulletin: Contact Pin Cleaning Kit Procedure Art: 730566*, for more information

Scenarios

IF the customer is requesting a Contact Pin Cleaning Kit but they are not currently experiencing a quality check code that warrants the use of the Contact Pin Cleaning Kit per the support guide	**THEN** the Contact Pin Cleaning Kit can be sent at no charge • Classification is **Inquiry**
IF the customer reports that a quality check code is occurring that warrants the use of the Contact Pin Cleaning Kit per the support guide	**THEN** the Contact Pin Cleaning Kit can be sent at no charge for troubleshooting • Classification is **Complaint 1** (C1071)

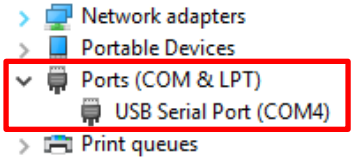
Tool	Description	
Latch Return Tool *Synonyms: N/A*	If the i-STAT 1 Analyzer is not locking cartridges and/or simulators into place, then the Latch Return Tool may resolve the issue.	
	Instructions 1. Insert the Latch Return Tool into the cartridge port of the handheld with the arrow facing up and in the direction of the port 2. Push the tool into the cartridge port until it stops and a click is heard, then remove by pulling it from the handheld  3. Attempt to run a cartridge; ensure that it locks into place **4. Attempt to run an electronic simulator twice to rule out simulator as cause of the issue**	
	Additional Information 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 information.	
	Scenarios	
	IF the customer is requesting a latch return tool but they are not currently experiencing a locking issue that warrants the use of the latch return tool per the support guide	**THEN** the latch return tool can be sent at no charge • Classification is **Inquiry**
	IF the customer reports that they are experiencing a locking issue that warrants the use of the latch return tool per the support guide	**THEN** the latch return tool can be sent at no charge for troubleshooting • Classification is **Complaint 1** (C1071)

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**	→ Jump to Section
C1069	**No comport available in JammLite** • TCP/IP is only option	→ 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	→ Jump to Section
C1069	**"IR Link cannot be configured to perform CLEW update" message**	→ 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

6.1.1 Unable to Perform Software Update Scenarios

Complaint	Description	
JammLite: "Downloader Could Not Be Configured to Perform the Update" Message RW Code: C1069 *Synonyms: N/A*	"Downloader could not be configured to perform the update" message appears in JammLite Utility.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage? 3. Which comport was selected? 4. What is the downloader serial number? a. Are appropriate downloader cables connected to power and computer? b. Have USB drivers been installed on the computer (if applicable)? 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 Bulletin: Instructions 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 (*Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690*), verify under device manager and ports if the USB drivers for the downloader are installed  1. May have to restart the computer after the driver has been downloaded to see ports D. Verify downloader is connected properly using i-STAT supplied 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 open which could be using comport F. Try plugging the USB cable or the DB9:DB9 cable to a different port if multiple ports are available on the computer/laptop	
	Resolution	
	IF software update is successful after connecting downloader cables correctly	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after installing DRC-300 drivers	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after selecting correct comport or closing any open program	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF customer referred to facility IT department due to lack of admin rights; and the update successful with help from IT or after obtaining admin rights	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	Description	
JammLite: No Comports Available (TCP/IP only option) RW Code: C1069 *Synonyms: TCP/IP only port available*	No comports available in JammLite Utility (TCP/IP only port available)	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. What is the battery voltage?
	3. Which comport is available?
	4. What is the downloader serial number?
	  a. Are appropriate downloader cables connected to power and computer?
	  b. Have USB drivers been installed on the computer (if applicable)?
	  c. Does customer have administrative rights?
	5. Are there any programs running on computer that may be using the comport?	

	Troubleshooting	

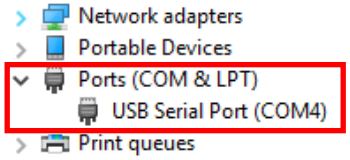
	A. Review software update procedure (*Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using www.pointofcare.abbott Art: 731335*)
	B. If DRC-300, assist with installing USB drivers (administrative rights required)
	  1. Using another computer with admin rights is an option if available
	C. After download of the USB drivers for DRC-300 downloader (*Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690*) verify under device manager and ports if the USB drivers for the downloader are installed
	 
	
	  1. 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 supplied 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 open which could be using comport
	F. Try plugging the USB cable or the DB9:DB9 cable to a different port if multiple ports are available on the computer/laptop	

	Resolution	
	IF software update is successful after connecting downloader cables correctly	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after installing DRC-300 drivers	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after selecting correct comport or closing any other open program	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF customer referred to facility IT department due to lack of admin rights; and the update successful with help from IT or after obtaining admin rights	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	**Description**	
JammLite: "Port Specified for Update Could Not Be Opened" Message RW Code: C1069 *Synonyms: N/A*	"Port specified for the update could not be opened" message appears in JammLite Utility	
	Prompts for Meaningful Data Collection	

	1. What is analyzer serial number(s)?
	2. What is the battery voltage?
	3. Which comport was selected?
	4. What is the downloader serial number?
	  a. Are appropriate downloader cables connected to power and computer?
	  b. Have USB drivers been installed (if applicable)?
	  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 Bulletin: Instructions 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 (*Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690*) verify under device manager and ports if the USB drivers for the downloader are installed
	 
	
	  1. 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 supplied 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 open which could be using comport
	F. Try plugging the USB cable or the DB9:DB9 cable to a different port if multiple ports are available on the computer/laptop	

	Resolution	
	IF software update is successful after connecting downloader cables correctly	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after installing DRC-300 drivers	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after selecting correct comport or closing any open program(s)	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF customer referred to facility IT department due to lack of admin rights; and the update successful with help from IT or after obtaining admin rights	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	**Description**	
JammLite: No or Incorrect CLEW and/or Application (JAMS) RW Code: C1069 *Synonyms: no CLEW and/or JAMS (application)*	No/Incorrect CLEW and Application (JAMS) available in JammLite Utility	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage? 3. What displayed for CLEW and Application? 4. What is the downloader serial number?	
	Troubleshooting	
	A. Review software update procedure 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. Select correct software from drop down menu in JammLite Utility C. Download current software **Note:** Suggest customer create a folder on the computer to save software file. Old software files may require deletion from computer D. Verify if customer have administrative rights to download the software to the computer/laptop, refer to facility IT department to obtain administrative rights	
	Resolution	
	IF software update is successful after selecting correct software from drop down menu	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after downloading the current software	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF customer referred to facility IT department due to lack of administrative rights; and the update successful with help from IT or after obtaining administrative rights	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	**Description**	
JammLite: "IR Link Cannot Be Configured to Perform CLEW Update" Message RW Code: C1069 *Synonyms: N/A*	"IR Link cannot be configured to perform CLEW update" message appears when attempting to perform software update with JammLite Utility.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage? 3. Which instrument was selected in JammLite Utility? 4. What is the serial number of the downloader?	
	Troubleshooting	
	A. Review software update procedure 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 instrument	**THEN** the incident is resolved • Classification is **Complaint 1**

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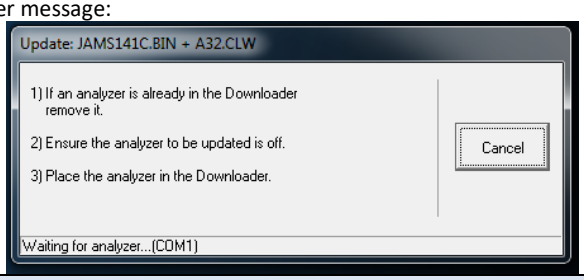
Complaint	**Description**	
JammLite: Nothing Happens When Analyzer is Placed in Downloader RW Code: C1069 *Synonyms: N/A*	Unable to perform the i-STAT CLEW and JAMS software update via JammLite Utility. Nothing happens when analyzer is placed in downloader.	
	Prompts for Meaningful Data Collection	
	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? 4. Was analyzer powered off when placed in downloader?	
	Troubleshooting	
	A. Review software update procedure 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. Remind user of computer message:  	
	Resolution	
	IF software update is successful after following software update instructions	**THEN** the incident is resolved • Classification is **Complaint 1**

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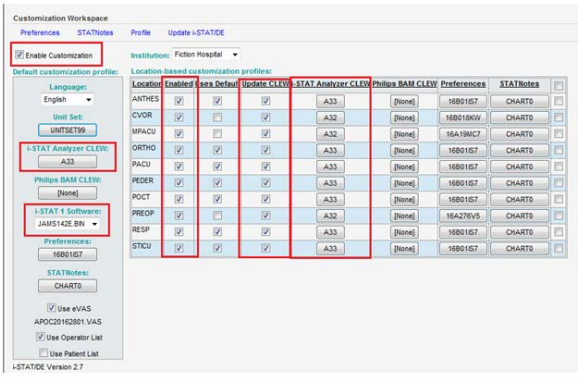
Complaint	**Description**	
Customization Workspace: Unable to Update CLEW and JAMS RW Code: C1069 *Synonyms: no CLEW or JAMS*	Unable to update CLEW and JAMS in customization workspace CLEW and JAMS not available	
	Prompts for Meaningful Data Collection	
	1. What data management program is being used? 2. What is DE version?	
	Troubleshooting	
	A. Review software update procedure (*Technical Bulletin: Network Options for Updating the i-STAT 1 Handheld using www.pointofcare.abbott Art: 731336*) B. Reminder: CLEW and JAMS do not automatically populate customization workspace. They must be selected. C. Verify DE version 1. If version is ≥ 2.0, repeat software upload via "Update i-STAT/DE" > "Upload Update File" i. User may have to save software in a folder on desktop (instead of directly on desktop) or save software file on shared drive 2. If the software still not available in customization workspace refer user to Data manager support (for third party Data manager) 3. If version is < 2.0, refer to facility IT department to install in DE server	
	Resolution	
	IF customization workspace is successfully updated after following correct steps for the procedure	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF customization workspace is not successfully updated after repeating upload procedure in DE customization and user is referred to 3rd party data manager vendor and update was successfully completed by the vendor support	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	Description
Customization Workspace: Will Not Update, Goes Back to Administration Menu RW Code: C1069 *Synonyms: N/A*	Unable to perform the i-STAT CLEW and JAMS software update via Customization Workspace. Nothing happens when analyzer is placed in downloader, analyzer display reverts to Administration Menu.
	Prompts for Meaningful Data Collection 1. What is analyzer serial number(s)? 2. What is the battery voltage? 3. What data management program is being used? 4. What is DE version? 5. Was the correct software file uploaded to Customization workspace?
	Troubleshooting A. Review software update procedure *(Technical Bulletin: Network Options for Updating the i-STAT 1 Handheld using www.pointofcare.abbott Art: 731336)* B. Verify the following in customization workspace: 1. "Enable Customization" is checked 2. i-STAT Analyzer CLEW is current 3. i-STAT 1 Software is current 4. "Enabled" or "Enable Updates" is checked for location 5. "Update CLEW" is checked for location 6. i-STAT Analyzer CLEW is current for location  C. Repeat software update with analyzer seated in downloader D. Run simulator on analyzer and download test, then repeat update. E. Verify software installed in analyzer (update process will 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 customization workspace → **THEN** the incident is resolved • Classification is **Complaint 1**
	IF software update is successful after repeating update procedure **or** analyzer has current software already installed → **THEN** the incident is resolved • Classification is **Complaint 1**

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

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Complaint	Description	
Handheld-to-Handheld: Unable to Perform Software Update RW Code: C1069 *Synonyms: software update not working*	Unable to perform the i-STAT CLEW and JAMS software update via handheld-to-handheld procedure	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. What is the battery voltage?	
	Troubleshooting	
	A. Review software update procedure 1. *Technical Bulletin: Instructions for Updating i-STAT 1 Handheld Software using www.pointofcare.abbott Art: 731335* 2. *Quick Reference Instructions for Handheld-to-Handheld Transfer Art: 732160* B. Verify: 1. Analyzers IR windows are lined up correctly 2. Receiving analyzer is not powered on C. Clean IR windows on the analyzers	
	Resolution	
	IF software update is successful after following software update instructions	**THEN** the incident is resolved • 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 RW Code: C1004 *Synonyms: N/A*	Customer did not receive the software update package	
	Prompts for Meaningful Data Collection	
	1. Request customer's contact information	
	Troubleshooting	
	A. Check mailing list 1. Verify contact information on software mailing. 2. If not correct or missing, notify administrator to 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 did not received package	**THEN** advise customer that the software is available on the APOC website • Classification is **Complaint 1**
	IF customer is not on mailing list or information is incorrect on mailing	**THEN** advise customer that the software is available on the APOC website • Classification is **Complaint 1**
	IF customer is on mailing list to receive no- web package and did not receive package after 10 business days from software release	**THEN** request no-web (CD) software package be sent to customer • Classification is **Complaint 1**

Complaint	**Description**	
Product Received Damaged RW Code: C5560 *Synonyms: Software CD received broken, Software update not working from CD*	Customer received software package with broken CD	
	Prompts for Meaningful Data Collection	
	1. Request customer's contact information	
	Troubleshooting	
	A. Check mailing list 1. Verify contact information on software mailing. 2. If not correct or missing, notify administrator to 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. If customer is not willing to perform update via APOC website, send no-web (CD) software package to customer.	
	Resolution	
	IF software update CD is broken	**THEN** request replacement no-web (CD) software package and investigate shipping • Classification is **Complaint 2**

7.0 Quality Material Results Issues

Complaint	**Description**
Quality Material Precision RW Code: C1620 *Synonyms: failed, low, high, bias, failed precision*	The precision study results using APOC Control products are not acceptable, do not match the expected %CV and/or SD
	Prompts for Meaningful Data Collection
	1. What cartridge lot number(s) is used? 2. What is control lot number and level(s)? 3. Which analyte is not meeting precision expectations? 4. Which control is not matching the expected %CV/SD? 5. What is the control result (with units of measure), %CV and SD of the precision study? 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 I. 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.

Chi-Square Multipliers for use when 2 levels of control are tested

Sample size (*n*)	Multiplier
4	1.77
8	1.51
10	1.45
11	1.43
12	1.41
13	1.39
14	1.38
16	1.35
20	1.31
24	1.29
28	1.26
32	1.25
36	1.23
40	1.22
44	1.21
48	1.20
52	1.19
56	1.19
60	1.18
64	1.17
68	1.17
72	1.16
76	1.16
80	1.16

b. If the customer's SD is at or below the upper limit, the precision is acceptable.

Note: APOC does not provide acceptance criteria. The facility should determine the imprecision which can be tolerated by the medical/lab director.

3. If results are still higher than the Chi-Square value, precision study should be repeated with 20 replicates.

K. If the results are not acceptable after repeating the precision study, provide a replacement control from a different lot number

Resolution	
IF the %CV/SD of the control results are within the Precision Data in Performance Characteristics section of CTI sheets or IFUs or QC section 14	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the %CV/SD of the control results are within the Precision Data in Performance Characteristics section of CTI sheets or IFUs or QC section 14 after using the chi-square value	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the %CV/SD of the control results are within the Precision Data in Performance Characteristics section of CTI sheets or IFUs or QC section 14 after precision study is repeated with 20 replicates	**THEN** complaint is resolved • Classification is **Complaint 1**
IF the precision study is still unacceptable and a new control lot number is provided	**THEN** the QC material lot in question should be investigated • Classification is **Complaint 2** **Ask customer if QC material are available to be returned for investigation and document request(s)**

Complaint	Description
Sodium (Na) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1321 Na - High QC/Cal Ver C1322 Na - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the Na result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. What is analyzer serial number(s)?

Troubleshooting

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. 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 following 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 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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Potassium (K) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1323 – K - High QC/Cal Ver C1324 – K - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the K result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. What is analyzer serial number(s)?

Troubleshooting

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 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
    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 following 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 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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule/vial of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Chloride (Cl) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1325 – Cl - High QC/Cal Ver C1326 – Cl - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the Cl result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. 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 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/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. If testing cartridges without sensors for pH, PCO2, 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 from the same lot number using a new 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 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.

Resolution

IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule/vial of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Ionized Calcium (iCa) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1327 iCa - High QC/Cal Ver C1328 iCa - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges. **Prompts for Meaningful Data Collection** 1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is QC material lot number and level? 3. What is the iCa result (with units of measure)? 4. Which VAS is being reviewed? What is the VAS acceptable range? 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? 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? a. If not used for the first time – were the control/cal ver results in range on previous testing? 9. What is CLEW version on the analyzer? 10. How are cartridges stored and handled? 11. What is analyzer serial number(s)? **Troubleshooting** 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 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 heparin 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. 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 **Note: When using cartridges that contain sensors for ionized calcium, 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 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.

	Resolution	
	IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
pH **i-STAT or TriControl Control or Calibration Verification Results are Out of Range** *Synonyms: failed, low, high, bias* RW Codes C1329 pH - High QC/Cal Ver C1330 pH - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges. **Prompts for Meaningful Data Collection** 1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is QC material lot number and level? 3. What is the pH result? 4. Which VAS is being reviewed? What is the VAS acceptable range? 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? 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? a. If not used for the first time – were the control/cal ver results in range on previous testing? 9. What is CLEW version on the analyzer? 10. How are cartridges stored and handled? 11. 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 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. 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 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)

	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 cartridges and with one level of control only, then the problem is probably being caused by the control. 3. 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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule/vial of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
pCO2 i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1331 PCO2 - High QC/Cal Ver C1332 PCO2 - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges. **Prompts for Meaningful Data Collection** 1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is QC material lot number and level? 3. What is the pCO2 result (with units of measure)? 4. Which VAS is being reviewed? What is the VAS acceptable range? 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? 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? a. If not used for the first time – were the control/cal ver results in range on previous testing? 9. What is CLEW version on the analyzer? 10. How are cartridges stored and handled? 11. 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 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. 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 cartridges that contain sensors for pCO2, 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 pCO2.** *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

	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) 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 cartridges and with one level of control only, then the problem is probably being caused by the control. 3. 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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 1 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)**

Complaint	Description
pO2 **i-STAT or TriControl Control or Calibration Verification Results are Out of Range** *Synonyms: failed, low, high, bias* RW Codes C1333 – PO2 - High QC/Cal Ver C1334 – PO2 - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges. **Prompts for Meaningful Data Collection** 1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is QC material lot number and level? 3. What is the pO2 result (with units of measure)? 4. Which VAS is being reviewed? What is the VAS acceptable range? 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? 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? a. If not used for the first time – were the control/cal ver results in range on previous testing? 9. What is CLEW version on the analyzer? 10. How are cartridges stored and handled? 11. 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 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. Verify 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 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 pO2 H. If pO2 is out of range, verify customer site elevation. Correct pO2 results (if applicable) I. 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 pO2, 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 pO2.** *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 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)
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 cartridges and with one level of control only, then the problem is probably being caused by the control.
3. 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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
IF pO2 out of range controls are acceptable after correcting for altitude	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Glucose (Glu) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1335 – Glucose - High QC/Cal Ver C1336 – Glucose - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the glucose result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. 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 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/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. 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 new ampule of control/cal ver from the same lot number making sure to follow proper handling and transfer instructions

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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.

Resolution

IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
BUN/Urea i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1337 BUN - High QC/Cal Ver C1338 BUN - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the BUN or Urea result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. 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 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/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. If testing cartridges without sensors for pH, PCO2, 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 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)

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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.

Resolution

IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Hematocrit (Hct) TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1339 Hematocrit - High QC/Cal Ver C1340 Hematocrit - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type, lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the Hct result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
5. What is the EDTA customization setting on the analyzer? Is the correct VAS range (K2/K3 EDTA) used?
6. How is the control/cal ver stored and handled?
7. Was the correct pathway used on the analyzer for testing of control/cal ver material?
8. Are the other analytes from the cartridge testing within range?
9. 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?
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 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/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. If testing cartridges without sensors for pH, 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 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)

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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.

Resolution

IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Lactate (Lac) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1342 – Lactate - High QC/Cal Ver C1343 – Lactate - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type, lot number(s)/box number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the Lactate result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. 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 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/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. 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

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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.

Resolution

IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 1 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)**

Complaint	Description
Creatinine (Crea) i-STAT or TriControl Control or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes C1344 – Creatinine - High QC/Cal Ver C1345 – Creatinine - Low QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the Creatinine result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
7. If testing CHEM8+ cartridge, 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?
    a. If not used for the first time – were the control/cal ver results in range on previous testing?
9. What is CLEW version on the analyzer?
10. How are cartridges stored and handled?
11. What is analyzer serial number(s)?

Troubleshooting

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. If testing cartridges without sensors for pH, PCO2, PO2 and ionized calcium (i.e. Crea) 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 making sure to follow proper handling and transfer instructions

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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.

Resolution

IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**

	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 1 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)**

Complaint	Description
TCO2 **i-STAT or TriControl Control or Calibration Verification Results or CHEM8+ Level 1b Results are Out of Range** *Synonyms: failed, low, high, bias* RW Codes C1420 TCO2 High - QC/Cal Ver C1421 TCO2 Low - QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges. **Prompts for Meaningful Data Collection** 1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is QC material lot number and level? 3. What is the TCO2 result (with units of measure)? 4. Which VAS is being reviewed? What is the VAS acceptable range? 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? 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? a. If not used for the first time – were the control/cal ver results in range on previous testing? 9. What is CLEW version on the analyzer? 10. How are cartridges stored and handled? 11. What is analyzer serial number(s)? **Troubleshooting** 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 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 TCO2, 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: 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 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)

	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 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) 3. 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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF after running a new cartridge with a new ampule of control/cal ver (from the same lot numbers) 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**
	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges type/lot number for a specific lot number of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material should be investigated • Classification is **Complaint 2** **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 1 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 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)**

Complaint	Description
Troponin (cTnI) Controls or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes for C1348 Troponin High - QC/Cal Ver C1349 Troponin Low - QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the troponin result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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)?

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)
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 equilibration prior to testing
    2. 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 procedure was followed
    1. Verify vials were gently mixed, avoiding foaming
    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 Verification Art: 714377

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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
IF after running a new cartridge with a new vial of control/cal ver (from the same lot numbers) the result is in range	**THEN** the incident is resolved • Classification is **Complaint 1**
IF after running a new cartridge with a new vial of control/cal ver the result is in range	**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**

	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 material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 QC material lot(s) AND other cartridge lots and other QC material lot(s) run without issue on the same i-STAT 1 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)**

Complaint	Description
CK-MB Controls or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes for C1422 CK-MB High - QC/Cal Ver C1423 CK-MB Low - QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the CK-MB result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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)?

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)
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 equilibration prior to testing
    2. 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 procedure was followed
    1. Verify vials were gently mixed, avoiding foaming
    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 Verification Art: 714377

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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
IF after running a new cartridge with a new vial of control/cal ver (from the same lot numbers) the result is in range	**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**

	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 material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 QC material lot(s) AND other cartridge lots and other QC material lot(s) run without issue on the same i-STAT 1 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)**

Complaint	Description
BNP Controls or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes for C1424 BNP High - QC/Cal Ver C1425 BNP Low - QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the BNP result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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)?

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)
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 equilibration prior to testing
    2. 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 procedure was followed
    1. Verify vials were gently mixed, avoiding foaming
    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 Verification Art: 714377

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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
IF after running a new cartridge with a new vial of control/cal ver (from the same lot numbers) the result is in range	**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**

	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 material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 QC material lot(s) AND other cartridge lots and other QC material lot(s) run without issue on the same i-STAT 1 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)**

Complaint	Description
β-hCG Controls or Calibration Verification Results are Out of Range *Synonyms: failed, low, high, bias* RW Codes for C1427 B-hCG High - QC/Cal Ver C1428 B-hCG Low - QC/Cal Ver	Control or Calibration Verification results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control or Calibration Verification results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the β-hCG result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
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?
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)?

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)
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 equilibration prior to testing
    2. 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 procedure was followed
    1. Verify vials were gently mixed, avoiding foaming
    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
Technical Bulletin: i-STAT Total β-hCG Controls and Calibration Verification Material Art: 730475
Cartridge and Test Information Sheet: Total Beta-Human Chorionic Gonadotropin (β-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 correct ranges on VAS	**THEN** the incident is resolved • Classification is **Complaint 1**
IF control/cal ver results are in range per VAS acceptable ranges	**THEN** the incident is resolved • Classification is **Complaint 1**
IF after running a new cartridge with a new vial of control/cal ver (from the same lot numbers) the result is in range	**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**
	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 material lot numbers are producing acceptable results with the same analyzers and cartridges lot numbers.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 QC material lot(s) AND other cartridge lots and other QC material lot(s) run without issue on the same i-STAT 1 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)**

Complaint	Description
Prothrombin Time (PT/INR) Control Results are Out of Range *Synonyms: failed, high, low, bias* RW Codes C1346 Prothrombin Time High - QC/Cal Ver C1347 Prothrombin Time Low - QC/Cal Ver	Control results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the PT/INR result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
5. How is the control stored and handled?
6. Was the correct pathway used on the analyzer for testing of control material?
7. Is the control lot number being used for the first time on this cartridge lot number?
    a. If not used for the first time – were the control 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)?

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
    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 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 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 troubleshooting when trying to determine QC specific issue
3. Provide a different cartridge lot number for troubleshooting 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 correct ranges on VAS	**THEN** the incident is resolved • 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**

	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges for a specific lot of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 issue on the same i-STAT 1 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)**

Complaint	Description
ACT Celite Control Results are Out of Range *Synonyms: failed, high, low, bias* RW Codes C1376 ACT Celite Low - QC/Cal Ver C1377 ACT Celite High - QC/Cal Ver	Control results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the ACT result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
5. How is the control stored and handled?
6. Is the control lot number being used for the first time on this cartridge lot number?
    a. If not used for the first time – were the control results in range on previous testing?
7. What is CLEW version on the analyzer?
8. How are cartridges stored and handled?
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
    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 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 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 troubleshooting when trying to determine QC specific issue
3. Provide a different cartridge lot number for troubleshooting 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 correct ranges on VAS	**THEN** the incident is resolved • 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**
IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges for a specific lot of QC material	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2**

	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 issue on the same i-STAT 1 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)**

Complaint	Description
ACT Kaolin Control Results are Out of Range *Synonyms: failed, high, low, bias* RW Codes C1378 – ACT Kaolin Low - QC/Cal Ver C1379 – ACT Kaolin High - QC/Cal Ver	Control results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.

Prompts for Meaningful Data Collection

1. What cartridge type and lot number(s) is the out of range result occurring?
2. What is QC material lot number and level?
3. What is the ACT result (with units of measure)?
4. Which VAS is being reviewed? What is the VAS acceptable range?
5. How is the control stored and handled?
6. Is the control lot number being used for the first time on this cartridge lot number?
    a. If not used for the first time – were the control results in range on previous testing?
7. What is CLEW version on the analyzer?
8. How are cartridges stored and handled?
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
    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 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 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 troubleshooting when trying to determine QC specific issue
3. Provide a different cartridge lot number for troubleshooting 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 correct ranges on VAS	**THEN** the incident is resolved • 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**

	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges for a specific lot of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 issue on the same i-STAT 1 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)**

Complaint	Description	
PT^{plus} Control Results are Out of Range *Synonyms: failed, high, low, bias* RW Codes C1429 – PT plus High – QC/Cal Ver C1430 – PT plus Low – QC/Cal Ver	Control results are outside of the acceptable ranges on the value assignment sheets (VAS). Customer reports a positive or negative trend/bias in Control results but still within acceptable VAS ranges.	
	Prompts for Meaningful Data Collection 1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is QC material lot number and level? 3. What is the PT/INR result (with units of measure)? 4. Which VAS is being reviewed? What is the VAS acceptable range? 5. How is the control stored and handled? 6. Is the control lot number being used for the first time on this cartridge lot number? a. If not used for the first time – were the control results in range on previous testing? 7. What is CLEW version on the analyzer? 8. How are cartridges stored and handled? 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 1. Verify equilibrated to room temperature for at least 45 minutes, no longer than 4 hours 2. Verify proper 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 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. *Technical Bulletin: i-STAT PT^{plus}/aPTT Controls Art: 757539* **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 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 material is showing acceptable results on other cartridge type/lot number(s)	
	Resolution	
	IF results are acceptable when using the correct VAS or correct ranges on VAS	**THEN** the incident is resolved • 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**

	IF the out of range result is persistent on multiple i-STAT 1 Analyzers and cartridges for a specific lot of QC material after troubleshooting AND other QC material lot numbers are producing acceptable results with the same analyzers and cartridges.	**THEN** the QC material lot(s) should be investigated • Classification is **Complaint 2** **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 issue on the same i-STAT 1 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)**

Complaint	**Description**	
3rd Party Vendor Quality Material Out of Range RW Code: C1426 *Synonyms: Eurotrol or Bio-Rad QC is not in*	Third Party Quality Control Material is out of range or failed when tested on i-STAT cartridges. Customer is not using APOC quality control material (e.g. Bio-Rad, Eurotrol)	
	Prompts for Meaningful Data Collection	
	1. What cartridge type and lot number(s) is the out of range result occurring? 2. What is 3rd party QC material lot number and level? 3. Which analyte(s) is out of range? 4. What are the results (with units of measure)? 5. How are cartridges stored and handled? 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 3rd Party vendor. • Classification is **Complaint 1**
	IF APOC QC materials are unacceptable	**THEN** troubleshoot the APOC QC materials per appropriate complaint code

8.0 Cartridge Results Unexpected/Unacceptable

Complaint	Description
Sodium (Na) Unexpected Patient Results *Answer pRE questions!* RW Code: C1501 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's sodium (Na) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a resuls printout or picture of the i-STAT results): 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 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 (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)

E. Verify anticoagulant used for sample collection
   1. Sodium heparin will increase sodium (Na) results

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 the patient sample is being collected correctly
   1. Evacuated Tubes:
      a. Plain (no anticoagulant, red top tube) or lithium heparin (green top tube)
         i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
      b. Fill tubes to labeled capacity. 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**
      b. Fill heparin syringes to labeled capacity. 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. 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

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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 (something other than whole blood) 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 • Classification is **Complaint 1**
IF the sample is not tested within the required time after collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Potassium (K) Unexpected Patient Results *Answer pRE questions!* RW Code: C1502 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's potassium (K) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 (Appendix F) 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 C1066)

E. Verify anticoagulant used for sample collection
   1. **EDTA (purple top tube) will cause elevated potassium (K) results**
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, educate customer on proper collection if needed
   1. Evacuated Tubes:
      a. Plain (no anticoagulant) or lithium heparin (green top tube)
         i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
      b. Fill tubes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios
      c. Ensure 16-20 gauge needle used for collection (higher than 20 g may cause hemolysis)
   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 capacity. Incorrect filling leads to higher heparin-to-blood ratios
      c. Ensure 16-20 gage needle used for collection (higher than 20 g may cause hemolysis)
   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 (will cause elevated K results)
   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
   2. Sample was not hemolyzed (will cause elevated K results)
   3. Sample was not put on ice (will cause elevated K results)
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
IF the sample is collected with an incorrect anticoagulant (i.e. EDTA)	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the sample is not tested within the required time after collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Chloride (Cl) Unexpected Patient Results *Answer pRE questions!* RW Code: C1503 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's chloride (Cl) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 Chloride 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)

E. Verify anticoagulant used for sample collection

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)
      i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
   b. Fill tubes to labeled capacity. 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**
   b. Fill heparin syringes to labeled capacity. 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. 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

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Ionized Calcium (iCa) Unexpected Patient Results *Answer pRE questions!* RW Code: C1504 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's ionized calcium (iCa) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): Was the patient sample retested on a new i-STAT cartridge? 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 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)

E. Verify anticoagulant used for sample collection
   1. **EDTA will cause decreased iCa results**

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 the patient sample is being collected correctly
   1. Evacuated Tubes:
      a. Plain (no anticoagulant) or lithium heparin
         i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
      b. Fill tubes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios and will cause decreased iCa results
   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 capacity. Incorrect filling leads to higher heparin-to-blood ratios and will cause decreased iCa results
   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. 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

I. Transfer devices with heparin will decrease iCa

J. Verify the patient sample is being handled correctly for each analyte.
   1. Air exposure will decrease iCa

K. Verify medications/treatments patient is receiving are not known to interfere per cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Glucose (Glu, G) Unexpected Patient Results *Answer pRE questions!* RW Code: C1505 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's glucose results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 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)

E. Verify anticoagulant used for sample collection
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)
            i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
        b. Fill tubes to labeled capacity. 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**
        b. Fill heparin syringes to labeled capacity. 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. 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
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
BUN/Urea Unexpected Patient Results *Answer pRE questions!* RW Code: C1506 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's BUN or urea results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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

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 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)
      i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
   b. Fill tubes to labeled capacity. 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**
   b. Fill heparin syringes to labeled capacity. 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. 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

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
pH Unexpected Patient Results *Answer pRE questions!* RW Code: C1507 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's pH results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 (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)

E. Verify anticoagulant used for sample collection
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 Tubes:
        a. Plain (no anticoagulant) or lithium heparin (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. Incorrect 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 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
    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, 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 increase in pH
    2. Mixed well to avoid clotting
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
PCO2 Unexpected Patient Results *Answer pRE questions!* RW Code: C1508 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's pCO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 pCO2 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)

E. Verify anticoagulant used for sample collection
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 Tubes:
        a. Plain (no anticoagulant) or lithium heparin (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. Underfilled tubes decrease pCO2. Incorrect 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 of a sample collected without an anticoagulant is not supported US**
        b. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-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, 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 pCO2
    2. Avoid bubbling with pipet when filling cartridge
    3. Mixed well to avoid clotting
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
PO2 Unexpected Patient Results *Answer pRE questions!* RW Code: C1509 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's pO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 pO2 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 cartridge is handled correctly 1. pO2 results will be decreased when testing in cold cartridge. E. 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)

F. Verify anticoagulant used for sample collection

G. Verify the patient sample is being tested within 10 minutes of collection if testing anticoagulated samples or immediately if testing samples collected without anticoagulant

H. Verify that the patient sample is being collected correctly

1. Evacuated Tubes:
   a. Plain (no anticoagulant) or lithium heparin (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. Incorrect 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 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
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, heel) may cause hemolysis
4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid contamination

I. Verify the patient sample is being handled correctly

1. Avoid air exposure. pO2 values in sample will equilibrate to room air pO2 due to air exposure.
2. Sample should not be iced. pO2 values will be falsely elevated if iced samples are tested.
3. Mixed well to avoid clotting

J. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Hematocrit (Hct) Unexpected Patient Results *Answer pRE questions!* RW Code: C1511 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's hematocrit (Hct) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): Was the patient sample retested on a new i-STAT cartridge? Hemoglobin (Hb) result: i-STAT critical cut-off values for Hct and Hb: 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): EDTA (K2/K3) calibration customization setting on analyzer: CPB applied for testing in i-STAT Analyzer (yes or no): 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

A. Verify reason for considering the i-STAT Hematocrit 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)
E. Verify anticoagulant used for sample collection
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)
            i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
        b. Fill tubes to labeled capacity. 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**
        b. Fill heparin syringes to labeled capacity. 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. 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 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 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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Hemoglobin (Hb) Unexpected Patient Results *Answer pRE questions!* RW Code: C1512 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's hemoglobin (Hb) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): Was the patient sample retested on a new i-STAT cartridge? Hematocrit (Hct) result: i-STAT critical cut-off values for Hct and Hb: 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): EDTA (K2/K3) calibration customization setting on analyzer: CPB applied for testing in i-STAT Analyzer (yes or no): 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**

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 (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)
E. Verify anticoagulant used for sample collection
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)
            i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
        b. Fill tubes to labeled capacity. 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**
        b. Fill heparin syringes to labeled capacity. 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. 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 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 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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
TCO2 Unexpected Patient Results *Answer pRE questions!* RW Code: C1513 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's TCO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 TCO2 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) E. Verify anticoagulant used for sample collection

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 Tubes:
   a. Plain (no anticoagulant) or lithium heparin (green top tube)
      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**
   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**
   b. Fill heparin syringes to labeled capacity. 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**
      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 filling cartridge
3. Mixed well to avoid clotting

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Anion Gap (AG, AnGap) Unexpected Patient Results *Answer pRE questions!* RW Code: C1514 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's Anion Gap (AG) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results. **Anion Gap is available with CHEM8+ and EC8+ cartridges.** Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): Was the patient sample retested 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 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 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

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 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 Tubes:
      a. Plain (no anticoagulant) or lithium heparin (green top tube)
         i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
      b. Fill tubes to labeled capacity. 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**
      b. Fill heparin syringes to labeled capacity. 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. 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

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Base Excess (BE) Unexpected Patient Results *Answer pRE questions!* RW Code: C1515 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's Base Excess (BE) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): Was the patient sample retested on a new i-STAT cartridge? Name of the comparative lab instrument (if applicable): What calculation was used on 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: 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 BEb) 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. Verify 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 (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)

E. Verify anticoagulant used for sample collection

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 Tubes:
   a. Plain (no anticoagulant) or lithium heparin (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. Incorrect 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 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
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, 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. Mixed well to avoid clotting

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
sO2 Unexpected Patient Results *Answer pRE questions!* RW Code: C1516 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's sO2 results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 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 C1066)

E. Verify anticoagulant used for sample collection
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 Tubes:
        a. Plain (no anticoagulant) or lithium heparin (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. Incorrect 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 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
    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, 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. Mixed well to avoid clotting
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
HCO3 (Bicarbonate) Unexpected Patient Results *Answer pRE questions!* RW Code: C1517 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's bicarbonate (HCO3) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 Bicarbonate (HCO3) 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)

E. Verify anticoagulant used for sample collection
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 Tubes:
        a. Plain (no anticoagulant) or lithium heparin (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. Underfilled tubes decrease HCO3. Incorrect 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 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
    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, 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 HCO3
    2. Avoid bubbling with pipet when filling cartridge
    3. Mixed well to avoid clotting
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Creatinine (Crea) Unexpected Patient Results *Answer pRE questions!* RW Code: C1518 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's creatinine (crea) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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. Verify reason for considering the i-STAT Creatinine 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)

E. Verify anticoagulant used for sample collection

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)
      i. **CHEM8+ cartridge: Use of a sample collected without an anticoagulant is not supported in US**
   b. Fill tubes to labeled capacity. 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**
   b. Fill heparin syringes to labeled capacity. 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. 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

I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU (**hydroxyurea will elevate results**)

Medication note: Hydroxyurea is generic name and may be known by trade names (i.e. Droxia, Hydrea, etc.)

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF the patient is taking Hydroxyurea with Crea unexpected patient results	**THEN** the incident is resolved • Classification is **Complaint 1**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
ACT Celite (ACT C) Unexpected Patient Results *Answer pRE questions!* RW Code: C1519 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's ACT Celite results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table Was the patient sample retested on a new i-STAT cartridge? 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 lot number: Heparin 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: 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:

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
    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
I. Verify the patient sample is being handled correctly
    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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF patient is not receiving heparin for ACT unexpected patient results	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2** C1066 will be added as supplemental code
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
ACT Kaolin (ACT K) Unexpected Patient Results *Answer pRE questions!* RW Code: C1521 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's ACT Kaolin results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table Was the patient sample retested on a new i-STAT cartridge? 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 lot number: Heparin 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: 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:

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 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
    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
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

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF patient is not receiving heparin for ACT unexpected patient results	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2** C1066 will be added as supplemental code
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Lactate (Lac) Unexpected Patient Results *Answer pRE questions!* RW Code: C1520 *Synonyms: i-STAT rsults - high, low, discrepant, not reliable, different, cannot trust*	Patient's lactate results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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 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 Lactate 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, advise 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 **immediately** after collection (**delayed testing will cause elevated lactate results**)
G. Verify that the patient sample is being collected correctly
    1. Evacuated Tubes:
        a. Plain (no anticoagulant) or lithium heparin (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. Incorrect 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 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
    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, 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. Mixed well to avoid clotting
I. Verify medications/treatments patient is receiving are not known to interfere per Cartridge IFU

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Troponin (cTnI) Unexpected Patient Results *Answer pRE questions!* RW Code: C1522 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's cardiac troponin I (cTnI) results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table Was the patient sample retested on a new i-STAT cartridge? 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

C. Verify comparative instrument troponin (cTnT, high sensitivity cTnI or high sensitivity cTnT) being tested (if applicable)

Note: The results of different troponin assays are not generally comparable: cTnI 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.

D. Collect information for the results table (Appendix F)

E. Verify sample type used
   1. Whole blood or plasma
   2. If something other than whole blood or plasma is used for testing, advise customer of correct sample type and review intended use per CTI sheet (add C1066)

F. Verify anticoagulant used for sample collection
   a. Samples must be collected in sodium or lithium heparin
   b. Testing samples collected with other anticoagulants will cause decreased results

G. Verify the patient sample is being tested within 30 minutes of collection if testing anticoagulated samples or immediately if testing samples collected without anticoagulant

H. 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:
      a. Plain (no anticoagulant) or lithium heparin or balanced heparin
      b. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios
   3. Capillary Tube: not recommended
   4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid contamination

I. Verify the patient sample is being handled correctly
   1. Mixed well to avoid clotting

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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Prothrombin Time/INR (PT/INR) Unexpected Patient Results *Answer pRE questions!* RW Code: C1523 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's PT/INR results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): Was the patient sample retested on a new i-STAT cartridge? 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: Sample tested from a fingerstick: The first drop of blood tested: 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 PT/INR results to be unexpected/different B. Verify if the i-STAT test was repeated

C. Collect information for the results table (Appendix F)
   a. If INR result is <0.9, asked if patient is or has been taking Coumadin/Warfarin
      i. This result may occur if patient has discontinued oral anticoagulant therapy prior to procedure
      ii. This result may occur if patient is not or has never been on oral anticoagulant therapy (off label use, add C1066)
D. Verify intended use of the cartridge
   1. i-STAT PT/INR monitors oral anticoagulant (Coumadin, warfarin) testing
   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 the patient sample is being tested immediately after collection
G. 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
   4. Skin Puncture:
      a. Test first drop of blood (do not wipe off)
      b. Chlorhexidine gluconate (skin cleanser) 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
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

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
IF the sample is collected with an incorrect anticoagulant	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the patient is not on Coumadin/warfarin and the PT/INR result is unexpected	**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	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
CK-MB Unexpected Patient Results *Answer pRE questions!* RW Code: C1524 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's CK-MB results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table 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 (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: 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 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 C1066) E. Verify anticoagulant used for sample collection

a. Samples must be collected in sodium or lithium heparin
b. Testing samples collected with other anticoagulants will cause decreased results

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:
      a. Plain (no anticoagulant) or lithium heparin or balanced heparin
      b. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios
   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

I. 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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
BNP Unexpected Patient Results *Answer pRE questions!* RW Code: C1525 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's BNP results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table 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): 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 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 C1066) E. Verify anticoagulant used for sample collection (must be collected with **EDTA**)

F. Verify the patient sample is being tested within 30 minutes of collection if testing anticoagulated samples
G. Verify that the patient sample is being collected correctly
    1. Evacuated Tubes:
        a. EDTA (purple/lavender top tube)
        b. Fill tubes to labeled capacity. Incorrect filling leads to higher anticoagulant-to-blood ratios
    2. Syringe:
        a. EDTA
        b. Fill syringes to labeled capacity. Incorrect filling leads to higher anticoagulant-to-blood ratios
    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 (clotted samples will cause increased results)
    2. Avoid hemolysis (gross hemolysis will cause decreased results)
I. 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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Total β-hCG Unexpected Patient Results *Answer pRE questions!* RW Code: C1526 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's β-hCG results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint **Prompts for Meaningful Data Collection** Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table Was the patient sample retested on a new i-STAT cartridge? 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 C1066)

C. Verify if the i-STAT test was repeated
D. Collect information for the results table (Appendix F)
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 sheet (add C1066)
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 minutes of collection if testing anticoagulated samples
H. Verify that the patient sample is being collected correctly
    1. Evacuated Tubes:
        a. Sodium or lithium heparin (green top tube)
        b. Fill tubes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios
    2. Syringe:
        a. Sodium or lithium heparin
        b. Fill heparin syringes to labeled capacity. Incorrect filling leads to higher heparin-to-blood ratios
        c. Syringes must be plastic
    3. Capillary Tube: not acceptable
    4. Indwelling line: back flush line 5-6 times the volume of catheter, connectors and needle to avoid contamination
I. Verify the patient sample is being handled correctly
    1. Mixed well to avoid clotting (clotted samples will cause increased results)
    2. Avoid hemolysis (gross hemolysis will cause decreased results)
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
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 collection per APOC literature	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
PT^{plus} Unexpected Patient Results *Answer pRE questions!* RW Code: C1527 *Synonyms: i-STAT results - high, low, discrepant, not reliable, different, cannot trust*	Patient's PT/INR results from the i-STAT system are not what the customer was expecting. i-STAT results do not match the patient's clinical picture or are different when compared to lab instrument results, other i-STAT results or i-STAT retest results Note: The prompts should be used to collect information during the initial call/contact as applicable to complaint
	Prompts for Meaningful Data Collection
	Cartridge type and lot number used: Why is the i-STAT result considered to be discrepant/unexpected: Unexpected Results Table All results from i-STAT cartridge (can request a results printout or picture of the i-STAT results): 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: Patient sample type used: How is sample collected? Collection device (syringe, evacuated tube, capillary): 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 Sodium 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
   a. Monitor patients receiving anticoagulant therapy with coumarin derivatives.
   b. 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 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
   4. Skin Puncture:
      a. Test first drop of blood (do not wipe off)
      b. Chlorhexidine gluconate (skin cleanser) 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
   1. 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 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
IF the sample is collected with an incorrect anticoagulant	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the patient is not on anticoagulant therapy and the PT/INR result is unexpected	**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	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**
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	**THEN** the cartridge lot(s) should be investigated • Classification is **Complaint 2**
IF unexpected patient results are reported and incorrect sample type and anticoagulant use is ruled out	**THEN** the suspect cartridge lot(s) should be investigated • Classification is **Complaint 2**

Complaint	Description
Star Outs	When a sensor does not pass internal quality checks, the *** symbols are displayed instead of results.

Prompts for Meaningful Data Collection

1. What cartridge type, lot number(s) and box number(s) (if applicable) is the star-out occurring?
2. Which analyte(s) starred out?
3. How many star-outs have occurred? How many total cartridges have been tested?

Note: Request approximate cartridge numbers tested so far when exact numbers are not known

4. If multiple star-outs occurred with ACT cartridges:
    a. What are the times the star-out occurred?
    b. Did ACT cartridge produce a result?
        i. If yes, what was result?
        ii. If no, was sample testing on a different instrument? What instrument and what was result?
    c. Was patient being administered heparin?
5. How many analyzers are showing star-outs?
6. What is being tested on the cartridge? Patient sample, QC material or proficiency material?
7. Was patient sample/QC material/proficiency material retested after star-out result?
    a. Did the retest give successful results?
    b. Was repeat testing on same sample?
8. If star out occurred while testing patient sample:
    a. How was patient sample collected?
    b. Which anticoagulant?
9. Star-outs occurring with one or multiple patients?
10. If star-out occurred while testing QC material, what is QC material lot number?
11. If star-out occurred while testing proficiency survey, what is the name and number of the survey?
12. How are cartridges stored and handled?
13. Have star-outs occurred with one operator or multiple operators?

RW Codes for star outs (red indicates pRE):

C1299	β-hCG
C1301	Na (K, Cl, Hct)
C1302	K (anion gap)
C1303	Cl (anion gap)
C1304	BUN (eGFR)
C1305	iCa
C1306	pH
C1307	pH + PCO2 (TCO2, anion gap, BE, sO2)
C1308	PO2 (sO2)
C1309	Glucose
C1310	Hematocrit (Cl, BUN, PO2, glucose, sO2)
C1311	Creatinine (eGFR)
C1312	Lactate
C1313	ACT Celite
C1314	Prothrombin Time
C1315	Troponin
C1316	ACT Kaolin
C1317	TCO2
C1318	CK-MB
C1319	BNP
C1296	PT plus

Troubleshooting

A. If one star out occurred on a patient or QC fluid, test a fresh sample/QC fluid on a new i-STAT cartridge
B. If star-outs persist on patient sample
    1. Determine the star-out rate (number of cartridges which starred-out versus the total number of cartridges tested)
    2. Verify patient sample type tested and anticoagulant used to collect patient sample
    3. Verify if star out results are occurring on single patient or multiple patients
    4. Verify if star-outs are occurring on a specific cartridge lot number
    5. Verify if star-outs are from one box or different boxes of the cartridge lot number
    6. Verify number of star-outs from one box (*Is it more than 3 from one individual box?)*
    7. If star-outs occurred with ACT cartridge, confirm patient was administered heparin.
        i. i-STAT ACT test monitors heparin, not angiomax or other anticoagulants
        ii. If using ACT cartridge for any other reason, advise customer of intended use per CTI/IFU (add C1066)
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)
D. Verify cartridge storage, handling and expiration date
    1. Verify storage (high temperature may cause **BUN/Urea** star-outs)
    2. Verify handling (prolonged exposure of cartridge to air may cause **pH/pCO2** star-outs)
    3. Verify expiration date (expired cartridges may cause star-outs)
E. Verify if star-out results are isolated to a specific analyzer serial number

If ONLY Hematocrit analyte star-outs (no other analytes) are occurring on a specific analyzer: Perform ceramic conditioning cartridge

Proficiency Material star-out

Verify validated proficiency material is being tested (*i-STAT 1 System Manual, Section 16: Proficiency or External QC Testing Art: 714378*)

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 sample or new ampule/vial of QC material or proficiency sample the star-out is not reproducible	**THEN** complaint is resolved • Classification is **Complaint 1**
IF the star out rate is less than 3% and there were no more than 3 star-out cartridges per box	**THEN** complaint is resolved • Classification is **Complaint 1**
IF star-out is persistent on specific cartridge lot number at a rate of greater than 3% or more than 3 cartridges starred out in an individual box	**THEN** the suspect cartridge lot should be investigated • Classification is **Complaint 2** **Request cartridges be returned for investigation and document request(s)**
IF the star-out 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** **Request cartridges and QC material be returned for investigation and document request(s)**
IF running the ceramic conditioning cartridge resolves the hematocrit star-out	**THEN** complaint is resolved • Classification is **Complaint 1**
IF the star-out results persist on a specific analyzer and other analyzers do not show star outs on the same cartridge lot number	**THEN** the i-STAT analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description
Results Suppressed (< >) or Outside of Reportable Ranges RW Code: C3214 *Synonyms: carrots or brackets instead of results*	The i-STAT analyzer displays < or > when the result is below or above the reportable range of the test. Results that are dependent on a result that is flagged with a (< or >) will display a (< >) symbol. **Prompts for Meaningful Data Collection** 1. What are the flags displayed - < or > or <>? 2. What analytes are showing the flags? 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)? 5. What are all the test results on cartridge? Request screen shots or pictures of the results from analyzer and/or DMS 6. What is the name and lot number of the QC material, if cal ver or control is tested? 7. 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 sensor dependencies 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 or low result for analyte) 2. If the results do not match the patient condition (UR) i. Verify user has retested freshly drawn sample ii. Confirm results (are the results the same or different upon retest?) iii. ***Note: This is an unexpected result (UR) issue. Use unexpected results complaint code, follow the steps/process for UR***. D. If the issue is occurring with control material or proficiency survey material: 1. Check if customized reportable ranges are used in the DMS (*Technical Bulletin: Reportable Range 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. If <> is displayed for results when testing in the cal ver path, ask user to retest following proper procedure i. If issue persists after retesting provide a different lot number of the cal ver material G. If **all** control results are displayed with suppressed symbols (<>) instead of results: *1.* Verify customization settings for "Control Results Display Format" (*Technical Bulletin: Liquid Quality Control Schedule and Lockout Art: 730077)*

	2. Advise to change to numeric if results are required	
	Resolution	
	IF the patient results match the clinical condition of the patient AND user understands reason for the flags/symbols displayed with result (<, > or < >)	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the patient results do not match the clinical condition and/or lab results or retest results on next i-STAT cartridge	**THEN** the issue is to be investigated as Unexpected patient results complaint • Classification is **Complaint 2**
	IF control or proficiency results are obtained with no flags/symbols (<, > or < >) after retesting and/or restoring to factory settings on the analyzer (to apply default reportable ranges)	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF correct testing pathway (cal ver pathway) is used for retesting calibration verification material AND correct results with no flags/symbols (<, > or < >) are obtained	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF correct testing pathway (cal ver pathway) was used for retesting calibration verification material AND the suppressed symbols (< >) symbols are still displayed with a specific cal ver lot number	**THEN** the issue should be investigated • Classification is **Complaint 2**
	IF all control results are suppressed and in customization "Control Results Display Format" is set to suppress	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description
Unacceptable Method Comparison *Answer pRE questions!* RW Codes: C1850 Na C1851 K C1852 Cl C1853 iCa C1854 Glucose C1855 BUN/Urea C1856 pH C1857 PCO2 C1858 PO2 C1859 Hematocrit C1860 Hemoglobin C1861 TCO2 C1862 Anion Gap C1863 BE C1864 sO2 C1865 HCO3 C1866 Creatinine C1867 ACT Celite C1868 Lactate C1869 ACT Kaolin C1870 Troponin C1871 PT/INR C1872 CK-MB C1873 BNP C1874 β-hCG C1661 PT*plus* *Synonyms: i-STAT results – correlation study, high, low, different, does not match*	Method Comparison study is done for an assessment of the bias/difference between two methods or to compare i-STAT results to another instrument used as a reference method. The results between the i-STAT and comparative instrument must be within a predetermined accuracy limit. 20-50 different patient samples may be included in the study; however, customers may perform method comparison studies with a small sample size (2-5 samples). Correlation study or comparison study results are high, low, discrepant, do not match comparative instrument, are not within the allowable difference between methodologies. **Results are not used to diagnose patients**. **Prompts for Meaningful Data Collection** 1. What is cartridge type/lot number? 2. Which analyte results for method comparison are unacceptable? 3. What are the results for the comparison study (with units of measure)? 4. What is the patient sample type tested on the i-STAT 1 system? 5. Was the same sample draw tested on i-STAT system and lab instrument? 6. What is the anticoagulant used for i-STAT samples? 7. What is the collection and test date/time for i-STAT and the lab instrument? 8. How is the cartridge handled? 9. How is the sample collected and handled? 10. What is the facility's acceptable accuracy limit for analyte? 11. If **cTnI** method comparison results are unacceptable: a. What is the troponin type (i.e. cTnI, high sensitivity, cTnT) being tested on comparative instrument? 12. If **Hct or Hb** method comparison results are unacceptable: a. What is the EDTA (K2/K3) customization on the i-STAT analyzer? b. What is the microhematocrit (MH) method calibration (K2/K3 EDTA) on the lab instrument? (All instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference method) c. Was CPB mode used for the testing on the i-STAT system? d. Was the sample tested immediately or was there a delay in testing? 13. If **ACT** method comparison results are unacceptable: a. What is the ACT (prewarm or nonwarm) customization on the i-STAT analyzer? b. What is the comparative instrument ((prewarm or nonwarm)? 14. If **Base Excess** method comparison results are unacceptable: a. What is the Base Excess (BEecf or BEb) customization on the i-STAT analyzer? b. What Base Excess is the comparative instrument using? 15. If **Anion Gap** method comparison results are unacceptable: a. What calculation is used on comparative method? 16. Was the sample mixed before testing? How many times was it mixed? **Troubleshooting** A. Confirm with customer that i-STAT results were NOT used in diagnosing patients B. Verify one specific cartridge lot number is used for the study C. Verify sample type used on the i-STAT 1 system 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 accuracy limits 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:

1. Verify comparative instrument troponin (cTnT, high sensitivity cTnI or high sensitivity cTnT) being tested (if applicable)
2. The results of different troponin assays are not generally comparable: cTnI 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

K. If **ACT** method comparison results are unacceptable:
1. Verify sample was collected without anticoagulant
2. Verify sample was tested immediately after draw
3. Verify calibration mode used for testing on i-STAT analyzer (prewarm or nonwarm) and comparative method are the same

L. If **Base Excess** method comparison results are unacceptable:
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 unacceptable:
1. Verify calculation used on comparative method is the same as the i-STAT cartridge

N. If **Hct or Hb** method comparison results are unacceptable:
1. Verify the EDTA (K2/K3) setting on the i-STAT 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 after draw or if there was any delay
4. Verify if sample was mixed properly before testing

Note: Analyzer is suspected only when multiple unacceptable method comparison results are generated on a specific i-STAT analyzer serial number compared to different analyzer(s) that generate acceptable results for the same 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 • Classification is **Complaint 1**
IF the results for the 2 methods when compared are within the accuracy limits	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the results for the 2 methods when compared are within the accuracy limits but are outside the facility's acceptable limits	**THEN** the incident is resolved • Classification is **Complaint 1**
IF unacceptable method comparison results are reported and none of the above is true	**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 sample is tested outside the test timing for i-STAT system	**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 method comparison results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine lot number via internal systems	**THEN** the 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)**

Complaint	Description
Unacceptable Comparison - Regulatory *Answer pRE questions!* RW Codes: C1604 Na C1605 K C1606 Cl C1607 iCa C1608 Glucose C1609 BUN/Urea C1612 pH C1613 PCO2 C1614 PO2 C1615 Hematocrit C1616 Hemoglobin C1617 TCO2 C1618 Anion Gap C1619 BE C1631 sO2 C1632 HCO3 C1633 Creatinine C1634 Lactate C1635 ACT Kaolin C1636 PT/INR C1637 BNP C1638 β-hCG C1641 ACT Celite C1642 Troponin C1643 CK-MB *Synonyms: i-STAT results – correlation study, high, low, different, does not match*	i-STAT to i-STAT results do not compare. The results are not used to help diagnose a patient. Includes split sample testing and lot-to-lot comparison testing. **Testing must be performed on patient samples and not control material.** **Prompts for Meaningful Data Collection** 1. What is cartridge type/lot number? 2. Which analyte results are unacceptable? 3. What are the results for the comparison study (with units of measure)? 4. What is the patient sample type tested on the i-STAT system? 5. What is the collection and test date/time? 6. How is the cartridge handled? 7. How is the sample collected and handled? What is the anticoagulant used for i-STAT samples? 8. What is the facility's acceptable accuracy limit for analyte? 9. Was the sample tested immediately or was there a delay in testing? 10. Was the sample mixed before testing? How many times was it mixed? 11. What is analyzer serial number? **Troubleshooting** A. Confirm testing performed on patient samples and not control material B. Verify one specific cartridge lot number is used for the study C. Verify anticoagulant used for sample collection D. Verify cartridge handling E. Verify that the patient sample is being collected, handled and tested correctly for each analyte/cartridge type F. Verify the table for accuracy limits for each analyte G. Document comparison results in question in the incident summary (do not state "see attachment") H. If more than one analyzer was used for study, verify settings are the same for both analyzers 1. **ACT**: prewarm or nonwarm 2. **Base Excess**: BEecf or BEb 3. **Hct/Hb**: K3EDTA or K2EDTA, CPB-mode: yes or no **Note:** Analyzer is suspected only when multiple unacceptable comparison results are generated on a specific i-STAT analyzer serial number compared to different analyzer(s) that generate acceptable results for the 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 • Classification is **Complaint 1**
IF the compared results are within the accuracy limits	**THEN** the incident is resolved • Classification is **Complaint 1**
IF the compared results are within the accuracy limits but are outside the facility's acceptable limits	**THEN** the incident is resolved • Classification is **Complaint 1**
IF unacceptable comparison results are reported and none of the above is true	**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 sample is tested outside the test timing for i-STAT system	**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 comparison results or cartridge type/ lot number is still unknown after due diligence, PQA/TS will determine lot number via internal systems	**THEN** the 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)**

Complaint	Description
Unacceptable Proficiency Survey Results *Synonyms: failed, bias – positive or negative*	Proficiency survey results are not considered acceptable. Results are acceptable but show a positive or negative bias compared to mean values. Results are acceptable but are not within specific established SD or SDI limits on the survey report. Survey examples:

CAP	Critical Care/Aqueous Blood Survey (AQI AQ3, AQI AQ4)
	Quality Cross Check (AQIQ)
API	i-STAT Chemistry (including Blood Gas)
	Verification Program
WSLH	Blood Gas/Electrolytes/Metabolites (PT01050)
	QE (Quality Evaluation) Product

RW Codes

C1701	Na
C1702	K
C1703	Cl
C1704	iCa
C1705	pH
C1706	PCO2
C1707	PO2
C1708	Glucose
C1709	Urea/BUN
C1710	Hematocrit
C1711	Creatinine
C1712	ACT Celite
C1713	PT/INR
C1714	ACT Kaolin
C1715	Hemoglobin
C1716	TCO2
C1717	Troponin
C1718	CK-MB
C1719	BNP
C1720	Lactate
C1721	β-hCG
C1722	PT plus

Prompts for Meaningful Data Collection

1. Which analyte(s) is unacceptable?
2. What is cartridge type, lot number(s)?
3. Who is the proficiency (external quality control) provider?
4. What is proficiency survey name and sample identifier?
5. Why are results considered unacceptable (e.g. out of range, higher than expected SDI, bias, etc.)?
6. What are the unacceptable results (with units of measure) for each sample in the survey and the acceptable peer range for each sample?
7. Request a copy of the survey results report and the handling instructions.
8. What is the CLEW version on analyzer?
9. When were controls last tested? Were results acceptable?
10. How are cartridges stored and handled?
11. What analyzer serial number(s) are impacted?
12. What testing pathway was used?
13. Was analyzer on level surface during testing of Hct/Hb, ACT, PT/INR and immunoassay (cTnI, BNP, CK-MB, β-hCG) cartridges?
14. How are survey samples handled? Request copy of handling instructions.

Troubleshooting

A. Verify the analyte that has unacceptable proficiency results
B. Verify validated proficiency material is being tested for the cartridge type tested (refer to i-STAT 1 System Manual, Section 16: Proficiency or External QC Testing (Art: 714378))
C. Verify why the results are considered unacceptable (e.g. out of range, higher than expected SDI, bias, etc.)
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 handled per survey instructions
K. Exposure of the survey samples to air could affect pH, ***P***CO2, ***P***O2, TCO2 and ionized calcium results – Do not use transfer pipette to transfer sample to cartridge
L. Verify testing was performed on analyzer in proficiency pathway
    1. Proficiency Test pathway uses K3EDTA standardization and disables CPB mode for Hematocrit.
    2. 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

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

Complaint	Description	
Off Label Use of Product RW Code: C1066 *Answer pRE Questions!* *Synonyms: N/A*	APOC i-STAT Cartridge is used for testing outside of the intended use statement in the individual cartridge Instructions For Use (IFU) or Cartridge and Test Information (CTI) sheet. Examples: • Serum, urine, body materials or culture media samples tested. • ACT cartridges used for monitoring Angiomax • PT/INR cartridges used as screening test prior to surgery or in stroke patients • Total β-hCG is intended to be used as an aid in the early detection of pregnancy	
	Prompts for Meaningful Data Collection	
	1. What is the lot number of the cartridge(s)? 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 type is being used for human diagnostic testing D. Determine and document if there is any impact to patient care E. Inform the customer that the use is Off-Label and document in the incident the reference used by TSS to provide the customer with the intended use information	
	Resolution	
	IF the APOC cartridge is used outside of the intended use and proper intended use was discussed with customer	**THEN** complaint code C1066 should be added to product • Classification is determined based on customer complaint (**Complaint level 1 or 2**)

9.0 Advanced Quality Feature (AQF) Issues

Complaint	Description
Advanced Quality Feature not functioning as expected RW Code: C3222 *Synonyms: eVAS, PPID, QC Schedule, Reportable range customization, operator competency, not working*	The i-STAT 1 Analyzer can be customized to utilize various advanced quality features with the release of JAMS132, and DE version 2.3. Advanced Quality Features include: • Quality Control Pass/Fail Determination (eVAS) • Quality Control Scheduling and Lockout • Positive Patient Identification (PPID) • Operator Competency Notification • Reportable Range Customization
	Prompts for Meaningful Data Collection 1. What is occurring that is different than expected? 2. Were any changes made to the customization settings recently? 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 QC 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 QC 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 2. 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 QC P/F determination is manual. 4. Pass is displayed for a failed QC results or vice versa – If the control was tested as non-APOC control and the QC P/F determination was performed manually by the user. 5. If an end-user does not select PASS or FAIL upon completion of test, then the result determination will 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 AQF literature below

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 expected.
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 customization 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 work, review the technical bulletins
    1. *Reportable Range Customization (Art: 730009)*
    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 functioning to specification after reviewing the instructions	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the advanced quality feature is functioning to specification after choosing the correct settings	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the advanced quality feature is functioning to specification and user error was determined to be cause	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the advanced quality feature is functioning to specification on the analyzer and the results in third party DMS have flagged messages; refer to Vendor support	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description	
Analyzer message "Certification expired" RW Code: C2566 *Synonyms: Not certified, ID not working*	The i-STAT 1 Analyzer displays message "certification expired" when scanning or entering an operator ID.	
	Prompts for Meaningful Data Collection	
	1. How many analyzers are displaying message when scanning/entering operator ID? a. What are the analyzer serial numbers? 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? a. When did the analyzer last successfully communicate with the data manager? 3. Is the operator in question included in the operator list in the data management system? 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 ensure that the 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 applicable) 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 again J. Ensure that customization is enabled in the customization workspace to allow the latest operator list to update in the i-STAT 1 Analyzer when placed in a downloader **NOTE: If the issue occurs on multiple i-STAT analyzers or multiple operator IDs suspect an issue with the DE/DMS; if the issue occurs on only one i-STAT 1 Analyzer suspect that the analyzer has not updated its operator list information**	
	Resolution	
	IF the message does not persist after placing the i-STAT 1 Analyzer in the downloader or restoring to factory setting then docking the analyzer to pick up the current operator list from DMS	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist 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 message does not persist after troubleshooting the DE/DMS system to update with the latest operator information and placing the analyzer in the downloader	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description	
Analyzer message "Does not match selected level" RW Code: C3217 *Synonyms: eVAS not working, not scanning, eVAS error*	The i-STAT 1 Analyzer displays message "does not match selected level" when attempting to run controls to meet QC schedule.	
	Prompts for Meaningful Data Collection	
	1. Did the message appear when scanning the cartridges or the controls? a. What are the lot number(s) of the product(s) not scanning? b. Does the product being scanned match the product specified in the customization profile QC schedule? c. What eVAS file is downloaded in the analyzer? 2. What is the analyzer serial number(s)? 3. Request printouts of the results from analyzer or pictures of the message or menus on the analyzer (if appropriate). The results printout contains additional information that is not shown on the analyzer screen for that result.	
	Troubleshooting	
	A. Verify the product type, lot number and level that was scanned 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 the product again F. If appropriate reset the analyzer to factory settings and place in a downloader, ensure that communication is successful; verify that the customization profile updates in the analyzer status screen and scan the products again	
	Resolution	
	IF the error does not persist after scanning the correct product specified in the customization OR the customization was changed to match the product being scanned	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the error does not persist after enabling customization in the customization workspace and placing the analyzer in the downloader	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description
eVAS not loading into Device/DMS RW Code: C3221 *Synonyms: No eVAS, not working*	The eVAS file is not uploading or updating successfully in the i-STAT 1 Analyzer or the DE Customization Workspace.
	Prompts for Meaningful Data Collection

	1. Is the eVAS file not uploading to analyzer(s) or the DE Customization Workspace?
	2. What data management system is being used?
	  a. What DE version is being used (if applicable)?
	  b. Is the current eVAS file visible in the Customization Workspace?
	  c. What is the analyzer serial number(s)?
	  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.
	
	D. 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

	2. The error "banker error" may appear in the VASLOG.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 *Technical Bulletin: Liquid Quality Control Pass/Fail Customization Art: 730078*	**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

Complaint	Description	
Incorrect information displayed for PPID RW Code: C2565 *Synonyms: Year of birth incorrect, does not match, patient name incorrect, patient gender incorrect, patient ID does not match*	When using the Positive Patient ID (PPID) feature the operator will see the patient ID number, patient name, patient gender, and (optional) patient date of birth. If any of this information is incorrect in the i-STAT 1 Analyzer per the customer's expectation, given the data in their ADT feed, then further troubleshooting should be performed. The operator may also see incorrect patient information in DE System or the data management software, such as Info HQ.	
	Prompts for Meaningful Data Collection	
	1. What patient information is incorrect or does not match? 2. Is the incorrect PPID information showing on i-STAT 1 Analyzer(s), or in DE System/data management system/LIS/HIS/EMR/etc.? 3. Is a patient list in use on the analyzer and DMS? 4. What is the data management system used? What is version of DMS (if appropriate)? 5. If analyzers are impacted, what is the analyzer serial number(s)? 6. When did the analyzer last successfully communicate with the data manager? 7. Does the information show correctly in a different system (e.g. DE system, data management software, ADT feed, etc.)? 8. If DE/data management is impacted, where is the information incorrect? 9. 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 what patent information is incorrect or mismatched 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 provided F. For incorrect patient date of birth, verify that the patient'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 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. Third-party data management vendor support will restart services for third-party DMS/LIS	
	Resolution	
	IF the patient information is corrected on the i-STAT 1 Analyzer after placing in downloader	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the patient information is corrected in DE or the data management system after allowing the systems to refresh or restart	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description	
Analyzer message "Invalid eVAS" RW Code: C3215 *Synonyms: No eVAS, not working*	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? 2. Is a DMS in use for this i-STAT 1 Analyzer(s)? 3. When did the analyzer last successfully communicate with the data manager? 4. Is the eVAS (automatic pass/fail determination) feature currently in use on the analyzer? 5. Has the current eVAS file been successfully uploaded to DE Customization Workspace? 6. Request pictures of the message or menus on the analyzer (as appropriate) and or screenshots of the data manager results/errors.	
	Troubleshooting	
	A. Verify if a DMS is in use; if not in use restore analyzer to factory settings B. Verify that the i-STAT 1 Analyzer has recently communicated with the data management system to ensure that the current eVAS has been uploaded C. Review the eVAS feature with the customer; if the pass/fail determination was set to "automatic via eVAS" in error and customer does not have a eVAS file on the analyzer or DMS customization workspace, this message will occur. Have customer change setting to either "none" or "manual" D. Review the control Pass/Fail determination settings in analyzer or customization workspace to check if it is set to "none" or "manual" and eVAS file is in use in DMS customization workspace E. Verify current eVAS file has been uploaded successfully to the DE System page F. Review printout, picture and/or screenshots provided G. 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 H. Reset the analyzer to factory settings and place in a downloader, ensure that communication is successful; verify that the customization profile updates in the analyzer status screen **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 option until CLEW software is current.**	
	Resolution	
	IF the message does not persist after changing the pass/fail determination to "none" or "manual"	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist after placing the i-STAT 1 Analyzer in the downloader or 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 message does not persist after uploading the current eVAS file and placing the analyzer in the downloader	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist after updating to current CLEW or after disabling eVAS use	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	**Description**	
Analyzer message "Lot Expired" RW Code: C3219 *Synonyms: eVAS not working, not scanning, eVAS error*	The i-STAT 1 Analyzer is showing a message "Lot Expired" when scanning cartridge pouch barcode. 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.	
	Prompts for Meaningful Data Collection	
	1. What is the lot number of the cartridge or control in question? 2. Did the message show when scanning the cartridges or the controls? a. What is the expiration date of the product? b. What is the lot number displayed by holding down on the scan key when scanning the product barcode? 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 date/time in the analyzer	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the cartridge or control product is verified to be expired	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description	
Analyzer message "Lot not in eVAS" RW Code: C3216 *Synonyms: invalid lot, no eVAS, not working*	The i-STAT 1 Analyzer is displaying message "Lot not in eVAS" when attempting to scan controls or cartridge.	
	Prompts for Meaningful Data Collection	
	1. When is the message occurring – during scanning of control or cartridge? 2. What is the lot number(s) of the cartridges and controls scanned? 3. What is the analyzer serial number(s)? 4. Does the analyzer have the current eVAS file number? 5. Has the current eVAS file been successfully uploaded to Customization Workspace? 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. 1. Verify that user is scanning the barcode on the control vial/ampule 2. Verify user is scanning the correct cartridge type when prompted to scan the cartridge barcode based on 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 rule out user error **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 eVAS file on the analyzer/DMS	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist after scanning the correct product for the prompt displayed on the analyzer	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist after scanning the correct cartridge for the control lot number scanned	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message persists AND correct eVAS is downloaded AND issue is not resolved after the above troubleshooting	**THEN** issue requires investigation • Classification is **Complaint 2**

Complaint	Description	
Analyzer message "Year of birth invalid number" RW Code: C2564 *Synonyms: Year of birth incorrect, does not match*	When using the Positive Patient ID (PPID) feature the operator has the option (through customization) to verify the patient information by entering the patient's year of birth. If the year of birth does not match the information on the patient list currently in the i-STAT 1 analyzer, then the message "Year of birth invalid number" will appear. *Positive Patient Identification (PPID) Customization (Art: 730211)*	
	Prompts for Meaningful Data Collection	
	1. When is the message appearing on the analyzer? 2. What is the analyzer serial number(s)? 3. What is the Data Management System in use? 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 the patient list in DE system and DMS? 8. What is the patient Date of Birth (DOB) in the patient list in DE system and ADT feed in DMS? 9. When did the analyzer last successfully communicate with 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. The 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 page E. If the year of birth or DOB is incorrect in the ADT feed in DMS, please have the user correct it F. If using the PPID customization setting to "enter" year of birth, it may be necessary to change the setting to "confirm" or "replicate" the DOB; this will show the DOB that the i-STAT 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 accepted after entering correct year of birth	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist and the year of birth is accepted after placing the i-STAT 1 Analyzer in a downloader	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the message does not persist and the year of birth is accepted after the customer corrects the patient information in the ADT feed	**THEN** the issue is resolved • Classification is **Complaint 1**

10.0 Printer Issues

Complaint	Description
Printer printing slow/stopped RW Code: C5472 *Synonyms: Unable to Print, Will not Print, Won't Print, Cannot Print, Can't Print, is not Printing, Isn't Printing, Does Not Print, Doesn't Print*	Printer powers on but is printing slowly or has stopped printing If printer does not power on, refer to C2510 **Prompts for Meaningful Data Collection** 1. What is printer serial number(s)? 2. What is the color of the Status and Power light on the printer? 3. Is printing occurring directly from analyzer or via downloader? 4. Is the printer plugged into AC power? 5. If the issue occurs with i-STAT Printer, will i-STAT Printer successfully print while connected to AC power? 6. If the issue occurs with Martel Printer, does the Martel printer have a removable battery door? 7. Is the paper loaded correctly in the printer? 8. Is the correct i-STAT supplied paper used in the printer? 9. If the printer does not print when the analyzer is in the downloader, check the printer to downloader cable connections 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) E. If the i-STAT Printer status light is red, allow the printer to cool down and then print F. Verify printer has the correct i-STAT supplied paper and is correctly installed (paper feeds from under the roll) G. 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 for i-STAT Printer, battery requires replacement. H. Clean IR window on the analyzer and printer I. If printer is not printing from analyzer in the downloader 1. Verify if analyzer prints directly 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. Try 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 allows printing — **THEN** the incident is resolved • Classification is **Complaint 1**

	IF the printer does not have a removable battery compartment AND recharging the battery does not allow printing	**THEN** the printer should be replaced • Classification is **Repair** **Note: Martel printers will be replaced with i-STAT Printer kit**
	IF cleaning the IR window or shielding IR window from fluorescent light allows printing	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF printer will print after loading the correct paper roll or loading the paper roll correctly	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF analyzer will print directly from printer but not when connected to downloader and replacing the printer interface cable resolves the printing issue	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the printer Status or Power lights do not indicate acceptable operating conditions AND the above troubleshooting does not allow printing	**THEN** the printer should be replaced • Classification is **Repair** **Note: Martel printers will be replaced with i-STAT Printer kit**

Complaint	**Description**	
Paper Error (Jam, Load, Eject) RW Code: C5474 *Synonyms: Jammed, Stuck, Blocked, Obstructed*	Paper is not feeding or is stuck or jammed in printer.	
	Prompts for Meaningful Data Collection	
	1. What is printer serial number(s)?	
	Troubleshooting	
	A. Turn the printer off, clear the jam, and re-insert the printer paper B. Press the paper feed button C. Perform a Self-Test (*i-STAT 1 System Manual, Section 7: Portable Printer (Martel and i-STAT 1 Printer) Art: 714369*)	
	Resolution	
	IF clearing the jam AND performing a successful Self-Test resolves the printing issue	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF clearing the jam AND the Self-Test fails OR the paper does not feed	**THEN** the printer should be replaced • Classification is **Repair** **Note: Martel printers will be replaced with i-STAT Printer kit**

Complaint	**Description**	
Thermal Printhead Melted RW Code: C5242 *Answer pRE Questions!* *Synonyms: Deformed, warped*	Thermal print head 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? 3. What batteries were being used with the printer?	
	Troubleshooting	
	A. Verify with the customer the melted component(s); specifically, the print head	
	Resolution	
	IF the print head is melted	**THEN** the printer and accessories should be replaced and investigated • Classification is **Complaint 2** **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**

Complaint	Description	
Printout - Info not as Expected RW Code: C5241 *Answer pRE Questions!* *Synonyms: Crooked, pixelated, smeared, smudged, incorrect results, missing information/results, faded, illegible*	The print out is faint, blurry, or misaligned or partial results are printed. The information printed does not match the information displayed on the i-STAT 1 Analyzer.	
	Prompts for Meaningful Data Collection	
	1. Why is printout not as expected? 2. What is printer serial number (s) with the issue? 3. What is analyzer serial number(s) with the issue? 4. Is the information to be printed, displayed on the i-STAT 1 Analyzer? 5. Does the information on the print out match the results in the i-STAT 1 Analyzer? 6. Are pictures or screen shots of the printouts in question and the complete results available?	
	Troubleshooting	
	A. Charge or change battery on the printer in question B. Perform the printer Self-Test (*i-STAT 1 System Manual, Section 7: Portable Printer (Martel and i-STAT 1 Printer) Art: 714369*) C. Reprint specific results **Note:** Thermal difference (thermal probe check results) is not a printable result If printed results appear inconsistent with a patient's clinical 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. o 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 and/or reprint is successfully (not faint, blurred or misaligned, incomplete/partial)	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF after battery recharge/replacement the Self-Test does not print OR reprint is faint, blurred or misaligned or incomplete/partial	**THEN** the printer should be replaced • Classification is **Repair** **Note: Martel printers will be replaced with i-STAT Printer kit**
	IF the results on the print out do not match the analyzer data	**THEN** the printer should be replaced • 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 but do not match patient's clinical assessment	**THEN** repeat sample testing on new cartridge and refer to **Unexpected Results troubleshooting**

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

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

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.

Complaint	Description
GS000 Wireless Module is not configured RW Code: C3229 *Synonyms: N/A*	The wireless module on the i-STAT 1 Wireless Analyzer is not configured and should be programmed.
	Prompts for Meaningful Data Collection 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 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. 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. 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 code **GS000:** A. Program the wireless analyzer as per appropriate instructions: 1. GainSpan: Technical Bulletin: Configuring Wireless Settings Art: 726066 i. Ensure that the "Reset Wireless Module to Factory Defaults" option is not 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 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 wireless settings on the i-STAT 1 Analyzer or disabling wireless feature → **THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS000 persists after reprogramming → **THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description
GS001 DHCP process time out RW Code: C3233 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer cannot obtain an IP address from the DHCP server; there is no IP address present in analyzer

Prompts for Meaningful Data Collection

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
    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. 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 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 code

GS001:

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 to successfully associate with the network after troubleshooting	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the code GS001 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 GS001 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
GS002/GS010 Connection to AP has failed RW Code: C3231 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer is not able to associate with the access point; the access point rejected the association request.
	Prompts for Meaningful Data Collection
	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 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. 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 - 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 code **GS002/GS010:** A. If only one wireless analyzer is generating code and all others are working, then reconfigure the 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. 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?

i. If certificates have been updated, all the analyzers will need to be reconfigured (the Gainspan analyzer configuration date of must be within the start date and expiration date of the certificates)

ii. Reset the wireless module to factory settings then reprogram the analyzer with the correct network settings

b. Has the customer updated the certificates on the Wireless LAN Controller to SHA-256?

i. If the i-STAT 1 Wireless analyzer has the old Gainspan wireless module (two blue corners on the back) and site is using SHA-256 type certificates, then the analyzer should be replaced to a with an analyzer with the new Gainspan module (two orange/gold corners) Note: will not support SHA-3

2. If PSK authentication

a. Advise customer to have IT check the wireless network

E. If above troubleshooting does not resolve

1. Confirm firewalls are off

Note: It may take several attempts to configure the analyzers

Resolution	
IF the code GS002 and/or GS010 does not persist and the analyzer successfully associates with the wireless network after programming with the correct SSID or security information OR resetting the wireless module to factory defaults and then reprogramming	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the code GS002 and/or GS010 does not persist and the analyzer successfully associates with the wireless network after moving to an area with strong wireless signal	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the code GS002 and/or GS010 is not resolved on an i-STAT 1 analyzer using the old Gainspan module (two blue corners) and the customer is using SHA-256 certificates	**THEN** the analyzer should be replaced or repaired • Classification is **Repair** Analyzer will be replaced with a wireless module that is SHA-256 capable

Complaint	Description
GS003 Error creating TCP connection to port RW Code: C3232 *Synonyms: N/A*	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-STAT DE server.
	Prompts for Meaningful Data Collection 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 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. 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 GS003? 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 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 code **GS003:** 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
	Resolution **IF** the code GS003 does not persist and the analyzer successfully transmits results after programming with the correct i-STAT DE server IP address and port number **THEN** the issue is resolved • Classification is **Complaint 1**

	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 Unable to receive setup ad hoc RW Code: C3234 *Synonyms: N/A*	i-STAT 1 Wireless Analyzer (GainSpan) cannot connect to the ad hoc network during the wireless configuration process; analyzer is unable to successfully receive setup. 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)? 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) **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 *Technical Bulletin: Configuring Wireless Settings Art: 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? 4. Is the correct JAVA version (1.6+) being used with the Wireless Setup Utility? 5. 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? 'istatYYYYYYXXXXXX' where 'YYYYYYXXXXXX' 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

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 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.)
    2. 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 'istatYYYYYYXXXXXX' where 'YYYYYYXXXXXX' 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.

	Resolution	
	IF the code GS020 and/or GS021 does not persist and the analyzer successfully receives setup after following the configuration instructions	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS020 and/or GS021 does not persist and the analyzer successfully receives setup after disabling any firewalls or antivirus software	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS020 and/or GS021 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 GS020 and/or GS021 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 GS020 and/or GS021 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 GS020 and/or GS021 does not persist and the 5 GHz analyzer successfully receives network configuration file after repeating procedure	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS020 and/or GS021 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	
GS022, GS023 – config storage failed to erase/write to flash RW Code: C3226 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer failed to erase/write the configuration to flash; configuration not successful.	
	Prompts for Meaningful Data Collection	
	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 b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256 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 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 code **GS022/GS023:** 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 *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 GS022 and/or GS023 does not persist and the analyzer is successfully configured after reprogramming	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS022 and/or GS023 does not persist and the analyzer is successfully configured after loading correct Client or CA certificates	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS022 and/or GS023 persists on the specific analyzer after reprogramming and all other analyzers have been programmed successfully	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
GS024, GS025 – Wireless config file corrupt/empty RW Code: C3227 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer configuration file is corrupt or empty; configuration not successful.	
	Prompts for Meaningful Data Collection	
	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 b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256 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 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 code **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 analyzer is successfully configured after reprogramming	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS024 and/or GS025 does not persist and the analyzer is successfully configured after loading correct Client or CA certificates	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code GS024 and/or GS025 persists after reprogramming on a specific analyzer and other analyzers have been programmed successfully	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description
GS030 Device software failed to enable module RW Code: C3230 Synonyms: N/A	The i-STAT 1 Wireless Analyzer customization failed to enable wireless module; analyzer did not reboot the wireless module after updating firmware
	Prompts for Meaningful Data Collection 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 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. 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 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 code **GS030:** 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 troubleshooting
	Resolution **IF** the code GS030 does not persist and the analyzer successfully connects to the network after resetting the wireless module → **THEN** the issue is resolved • Classification is **Complaint 1** **IF** the code GS030 persists after resetting → **THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
iE53(x) Unable to receive setup ad hoc RW Code: C3208 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer cannot connect to the ad hoc network during the wireless configuration process; analyzer is unable to successfully receive setup. Code iE53C or iE53D	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. When is the code occurring on the analyzer(s)? *3.* Have all the wireless setup steps been properly completed per *Technical Bulletin: Configuring Wireless Settings Art: 726066*? a. Is WLAN 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 up? 4. Are there any firewalls or security settings blocking the connection of the i-STAT to the ad-hoc network? 5. Is the correct JAVA version (1.6+) being used with the Wireless Setup Utility? 6. 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 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 code **iE53(x):** A. Verify that the computer is set up correctly as per *Technical Bulletin: Configuring Wireless Settings Art: 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 or antivirus software that may be blocking the connection to the ad-hoc network, WCU, or JAVA; the customer may need to use a computer that is not on their local domain to avoid their network security policies D. If the JAVA version is suspect, uninstall all current JAVA versions and reinstall the Wireless Setup Utility, installing the JAVA bundled with the installer E. Verify that customer's Windows login credentials have read AND write access to location "C:\Abbott\i-STAT1 Wireless Setup Utility"	
	Resolution	
	IF the code iE53C and/or iE53D does not persist and the analyzer successfully receives setup after following the configuration instructions	**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 any firewalls or antivirus software	**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 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 repaired • Classification is **Repair**

Complaint	Description	
S/E200 Wireless Module is not configured RW Code: C3224 *Synonyms: N/A*	The wireless module on the i-TAT 1 Wireless Analyzer is not configured and should be programmed.	
	Prompts for Meaningful Data Collection	
	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? 4. 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. 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 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 programming the wireless settings on the analyzer	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
S/E213 – No WLAN connection avail. RW Code: C3228 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer doe not detect an available WLAN connection.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number(s)? 2. When is the code occurring on the analyzer(s)? 3. Have the analyzer(s) successfully transmitting results 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 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 code **S/E213:** A. Verify with the customer (IT department) that a WLAN connection is available B. Reset the wireless module to factory settings (program the wireless analyzer as per *Technical Bulletin: Configuring Wireless Settings Art: 726066* and ensure that "Reset Wireless Module to Factory Defaults" is checked in the Wireless Setup Utility) then reprogram the analyzer with the correct network settings C. 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 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 other analyzer(s) are working as expected	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description
Other wireless code displayed RW Code: C3212 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer displays an error code associated with the wireless functionality that is not currently defined in a specific complaint code. Wireless analyzer displays "Time Out" after pressing 4-Reset and no other codes occur
	Prompts for Meaningful Data Collection 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 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, PEAPv0/EAP – MSCHAPv2)?
	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 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 code **Other Codes/Issues** A. Verify error code/message displayed on the analyzer(s) B. Verify the steps 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)

	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 troubleshooting and the analyzer successfully associates with the network and transmits results	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF "Time Out" message after pressing 4-Reset and no other codes occur	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**
	IF the error code/message persist on specific analyzer(s) after all the troubleshooting above	**THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	**Description**	
WiFi connection slow RW Code: C4701 *Synonyms: Wireless not strong, successful, reliable*	The customer reports that the wireless network connection is 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)? 3. How was the wireless network determined to be slow? 4. How are wireless transmission being initiated? a. Manually by selecting transmit on the analyzer? b. Automatically by relying on the auto-transmit feature before the analyzer times out?	
	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.e. -60dBm, -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 IT department to troubleshoot	
	Resolution	
	IF the i-STAT 1 Wireless Analyzer is found to associate readily with the wireless network and has a medium to strong signal	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the wireless network is determined to be weak or difficult to connect to reliably and is resolved after help from facility's IT department.	**THEN** the issue is resolved • Classification is **Complaint 1**

Complaint	Description
30000 Device software failed to enable module RW Code: C3225 *Synonyms: N/A*	The i-STAT 1 Wireless Analyzer customization failed to enable wireless module; analyzer did not reboot the wireless module after updating firmware
	Prompts for Meaningful Data Collection 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 b. Two orange/gold triangles on the corners of the Mfg. Label on the back = GainSpan V02 (w SHA256 support) 3. Have the analyzer(s) successfully been functioning wirelessly 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 analyzer 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 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 code **30000:** 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 successfully connects to the network after resetting the wireless module → **THEN** the issue is resolved • Classification is **Complaint 1**
	IF the code 30000 persists after resetting → **THEN** the analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description
Unable to configure downloader/ wireless analyzer/ Alinity RW Code: C1023 Synonyms: Downloader, Bas, cradle, i-STAT, dock, not working, cannot be configured, cannot program	The customer reports that the i-STAT downloader or downloader/recharger, i-STAT 1 Wireless Analyzer, or the i-STAT Alinity Instrument cannot be configured successfully. If the customer reports a specific error code or message during configuring, see the appropriate complaint code. **Prompts for Meaningful Data Collection** 1. What is the serial number of the product that cannot be configured? 2. What steps have been performed to attempt to configure the hardware? 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? 5. Has the user configured another downloader/wireless analyzer successfully using the same laptop/PC recently? 6. Is this new hardware or has it been in use without issue at an earlier date? **Troubleshooting** Verify the following information is available and has been provided by facility IT department: A. IP address B. Gateway IP address C. Subnet mask D. DE server IP address If programming an **i-STAT 1 Downloader**: 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 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 **i-STAT 1 Wireless Analyzer**: 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 operating systems 2. Refer to appropriate troubleshooting for codes GS020/GS021 and iE53x. 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 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

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 handheld/configuration utility being setup at a time?
H. Was the correct SSID, Authentication type, Encryption type, Security Key, entered?
I. 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 performed 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 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 'iSTATXXXXXX' 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 address on the analyzer to confirm the correct MAC address.
    1. The network password for the wireless analyzer is 'istatYYYYYYXXXXXX' where 'YYYYYYXXXXXX' is the wireless module MAC address. (e.g. istat84253F55E09B)
D. 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.
E. After a successful configuration (setup successful displays 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 successfully configured after programming per the instructions	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the i-STAT 1 Wireless Analyzer is successfully configured after obtaining administrative rights to the computer	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the i-STAT downloader cannot be successfully configured AND other downloaders are able to be successfully configured using the same computer setup in the same time interval	**THEN** the downloader should be replaced • Classification is **Repair**
IF the i-STAT wireless analyzer cannot be successfully configured AND other wireless analyzers are able to be successfully configured using the same computer setup in the same time interval	**THEN** the wireless analyzer should be replaced or repaired • Classification is **Repair**

12.0 Transmission Issues

Complaint	Description
Unsuccessful/Slow transmission i-STAT 1>DE>Third Party Data Management System (DMS) RW Code: C4133 *Synonyms: Results no crossing*	Data is not transmitting from the i-STAT 1 analyzer to the Third-Party Data Management System (DMS) using the DE system or the transmission is slow. Transmission may be occurring through a hardwired i-STAT downloader or wirelessly through the i-STAT 1 Wireless Analyzer. 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. • 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
	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? 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? **<u>For slow transmission issues:</u>** 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/pictures from data manager when appropriate. 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 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) 2. 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

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 or facility IT 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
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
I. 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 3-test 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:
    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
   2. 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
      b. Channel 2 configuration displays the settings for communication to i-STAT DE server (the remote IP address should match the IP address of DE server).
      c. If the settings are incorrect or have appeared to have reverted to default settings, reconfigure the downloader per i-STAT 1 System Manual, Section 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:// followed by the IP address, then press enter.
   1. If the APOC DRC-300 login page displays, choose from the menu options available to verify the current settings or re-configure per Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690.

For slow transmission with i-STAT 1 Wireless Analyzer or i-STAT 1 Analyzer with tests done in or outside of the downloader:

A. 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.e. -60dBm, -50dBm, etc.).
   2. The wireless analyzer does not support roaming, so the wireless analyzer must not be moved from one location 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 Time Out setting (default is 2 minute), minimum allowable inactivity timeout limit is 45 seconds
   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 the user input is made on the page or the forward arrow is used on the keypad to advance screen to the next screen to allow transmission.
   3. Check if there are any CHART page or STATNotes items set to "Required". If items are set to required, inform user that mandatory requirements for chart page items are expected to cause 15-minute transmission delay to allow operator time to enter the required information. This 15 minutes time is not customizable.
   4. Check if customer has comment codes set to "Required". If Comment codes are required, inform user that there is potential 15-minute transmission delay to allow operator to enter comment code.
   5. Check if "Limit number of record in transmit all" is enabled. This option allows the customer to limit the number of test results that are retransmitted when an end user selects "Transmit All". The i-STAT Analyzer will store 1000 test results. If this feature is not enabled and user selects the "transmit all" option, all results within the i-STAT Analyzer are re-transmitted.
   6. Check if "Operator Test Selection" option is enabled. If this is enabled, a 15-minute transmission delay may be expected.
   7. For immunoassay cartridge tests the time stamp for the result will be at the beginning of the test cycle; e.g. the Troponin test is a 10-minute test with a time stamp at the beginning of the test so may be perceived as a 10-minute delay even when it is transmitted to DMS soon after the test is complete.
   8. If multiple simultaneous tests are done on the analyzer without allowing the analyzer to power off then the test results will only transmit after the final cartridge test

Resolution

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

Complaint	Description
Unsuccessful/Slow transmission, i-STAT 1>DE>Info HQ RW Code: C4132 *Synonyms: Results not crossing*	Data is not transmitting from analyzer to DE to Info HQ Manager data management system successfully. This code is also used for slow transmission issues from analyzer to Info HQ **Prompts for Meaningful Data Collection** 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? 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? 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? **<u>For slow transmission issues:</u>** 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) 2. 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

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
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
I. 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 3-test 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:
    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
    2. 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

b. Channel 2 configuration displays the settings for communication to i-STAT DE server (the remote IP address should match the IP address of DE server).
c. If the settings are incorrect or have appeared to have reverted to default settings, reconfigure the downloader per i-STAT 1 System Manual, Section 21: Downloader Programming and Wiring (DN/DRN) Art: 714383.

l. **Web Browse** the IP address of the DRC-300 by opening web browser window; in address line enter HTTP:// followed by the IP address, then press enter.
1. If the APOC DRC-300 login page displays, choose from the menu options available to verify the current settings or re-configure per Technical Bulletin: i-STAT 1 Downloader/Recharger (model number DRC-300) Art: 728690.

For slow transmission with i-STAT 1 Wireless Analyzer or i-STAT 1 Analyzer with tests done in or outside of the downloader:

A. 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.e. -60dBm, -50dBm, etc.).
2. The wireless analyzer does not support roaming, so the wireless analyzer must not be moved from one location 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 Time Out setting (default is 2 minute), minimum allowable inactivity timeout limit is 45 seconds
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 the user input is made on the page or the forward arrow is used on the keypad to advance screen to the next screen to allow transmission.
3. Check if there are any CHART page or STATNotes items set to "Required". If items are set to required, inform user that mandatory requirements for chart page items are expected to cause 15-minute transmission delay to allow operator time to enter the required information. This 15 minutes time is not customizable.
4. Check if customer has comment codes set to "Required". If Comment codes are required, inform user that there is potential 15-minute transmission delay to allow operator to enter comment code.
5. Check if "Limit number of record in transmit all" is enabled. This option allows the customer to limit the number of test results that are retransmitted when an end user selects "Transmit All". The i-STAT Analyzer will store 1000 test results. If this feature is not enabled and user selects the "transmit all" option, all results within the i-STAT Analyzer are re-transmitted.
6. Check if "Operator Test Selection" option is enabled. If this is enabled, a 15-minute transmission delay may be expected.
7. For immunoassay cartridge tests the time stamp for the result will be at the beginning of the test cycle; e.g. the Troponin test is a 10-minute test with a time stamp at the beginning of the test so may be perceived as a 10-minute delay even when it is transmitted to DMS soon after the test is complete.
8. If multiple simultaneous tests are done on the analyzer without allowing the analyzer to power off then the test results will only transmit after the final cartridge test

Resolution	
IF a specific downloader(s) or analyzer(s) is suspect and issue is resolved through troubleshooting	**THEN** the issue is resolved • Classification is **Complaint 1**
IF a specific downloader(s) is suspect and issue is NOT resolved through troubleshooting	**THEN** replace the downloader in question • Classification is **Repair**
IF a specific analyzer(s) is suspect and issue is NOT resolved through troubleshooting	**THEN** replace or repair the analyzer in question • Classification is **Repair**

	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**

Complaint	Description	
Unsuccessful/Slow Transmission Info HQ to Third Party Interface RW Code: C4141 **Unsuccessful/Slow transmission Info HQ to APOC Interface** RW Code: C4143 *Synonyms: Results not crossing*	Data is not transmitting or is slow from Info HQ to the LIS/HIS successfully. The results have successfully transmitted to Info HQ.	
	Prompts for Meaningful Data Collection	

	1. What version of Info HQ is being used?
	2. Is the transmission unsuccessful or slow?
	3. What interface vendor is being used (e.g. APOC, Meditech, 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?
	  a. Have all records stopped transmitting past a specific date/time or are only particular records impacted?
	6. Date/time when communication stopped (how long has it been down)?
	  a. Is the transmission issue intermittent or is it completely/consistently down?
	  b. Was there any network outage recently?
	7. Have there been any updates or modifications to the Info HQ server?
	8. Are there any interface messages in Info HQ?
	9. Is the Info HQ configured with correct LIS settings? Were any changes made to settings?
	10. What is the interface "Sent" status in Info HQ for the impacted records?
	11. Have the records been resent from Info HQ?
	
	For slow transmission
	1. Is there any delayed transmission from analyzer to info HQ? (if yes, see C4132)
	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?	

	Troubleshooting	

	A. Attempt to resend the records in Info HQ by highlighting the record and clicking the "Send to LIS" button (check the resend box if necessary)
	B. If using APOC interface (Mirth), and resending the results does not resolve, escalate to DMS escalation team
	C. Ensure that the interface has been successfully configured for Info HQ by the APOC implementation team if this is a newly implemented site
	D. Restart of Info HQ server might be the option
	  1. Info HQ team (APOC Princeton) will perform restart for Info HQ
	  2. JResult Net Vendor (Data Innovations) will perform the restart of their servers	

	Resolution	
	IF the record(s) transmit successfully after resending the records	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the record(s) transmit successfully after correcting the interface settings	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the record(s) do not transmit after resending AND the interface settings have been confirmed to be correct.	**THEN** the issue should be referred to the interface vendor for troubleshooting • Classification is **Complaint 1**
	IF the customer reports that the transmission is slow from InfoHQ to interface/LIS/HIS	**THEN** the issue should be referred to the interface/LIS/HIS vendor for troubleshooting • Classification is **Complaint 1**

13.0 Data Management System (DMS) Issues

Complaint	Description
Data – Unable to find/lost RW Code: C2590 *Answer pRE Questions!* *Synonyms: N/A*	Results or data is unable to be found or is missing. This may apply to both the analyzer, data management systems, and Hospital systems.
	Prompts for Meaningful Data Collection

	1. Where is the data lost/unable to be found (DMS, analyzer, LIS/HIS)?
	2. What are the serial numbers of i-STAT 1 Analyzers?
	  a. What pathway was used for cartridge testing?
	  b. Are there any unsent results on Analyzer Status page?
	3. What data management system is being used?
	4. What is the version of Info HQ software?
	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 data on the analyzer or Info HQ → **THEN** the issue is resolved • 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 the analyzer → **THEN** the issue is investigated • Classification is **Complaint 2**

Complaint	Description	
Results changed or affected during transmission RW Code: C4325 *Answer pRE Questions!* *Synonyms: Data, results, records, wrong incorrect*	The records in the data management system (DMS) or Interface or LIS/HIS have incorrect or different information that does not match the information in the i-STAT 1 Analyzer or DMS.	
	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 correct? 2. What version of DE is being used? 3. What data management system or version of Info HQ is being used (if applicable)? 4. 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 that the results in the i-STAT 1 Analyzer are correct B. Verify what information appears to be incorrect or different 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. 4. Customer states specific information displayed in DMS 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 BEecf and Hb* while sending patient test results to LIS system 7. i-STAT results are flagged as critical on the analyzer and when going into LIS they are no longer being flagged as critical	
	Resolution	
	IF results in the DMS are verified to match the i-STAT 1 Analyzer	**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 Analyzer, work with DMS vendor on issue resolution	**THEN** refer customer to DMS vendor for issue resolution • Classification is **Complaint 1**
	IF results in the Interface/LIS/HIS do not match the DMS and i-STAT 1 Analyzer	**THEN** refer customer to Interface/LIS/HIS vendor for issue resolution • Classification is **Complaint 1**

Complaint	**Description**	
Re-appearance of aged data RW Code: C4561 *Synonyms: Old records results transmitting*	Records have populated in the data management system, interface, or LIS from the i-STAT 1 analyzer that are not current (old records from an earlier date).	
	Prompts for Meaningful Data Collection	
	1. Where are the old records showing (e.g. DMS, interface, LIS)? a. How many old records have populated? b. What is the date/time stamp on the records for date performed and date transmitted? 2. Did the old records transmit at one time (one event), multiple times (multiple events), or is this an intermittent issue? 3. What version of DE is being used (if applicable)? 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. Verify 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 DMS or if they only show in the interface/LIS F. Review printout, pictures and/or screenshots provided	
	Resolution	
	IF the customer confirms that records were manually retransmitted from the i-STAT 1 Analyzer, causing them to populate in the DMS/interface/LIS	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the customer confirms that records were manually retransmitted from Info HQ, causing them to populate in the interface/LIS	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the customer states that the old records do not show in the DMS but they do show in LIS/interface	**THEN** refer the incident to the interface or LIS vendor for further investigation • Classification is **Complaint 1**

Complaint	Description	
DMS Report info is incorrect RW Code: C4585 *Synonyms: Data, results, records, wrong incorrect in report*	The records in the data management system (DMS) have incorrect information that does not match the information in the 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? a. Is the information in the i-STAT 1 Analyzer correct? b. Is the information in DE correct (if applicable)? c. Is the information in the DMS data viewer correct (outside of the report)? 2. What version of DE is being used (if applicable)? 3. What data management system or version of Info HQ is being used (if applicable)? 4. What is the expected information on the report? 5. How is the information captured/displayed on the analyzer? 6. When appropriate, what are the customization settings in customization workspace? 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 not shown on the analyzer screen for that result.	
	Troubleshooting	
	A. Verify that the results or information in the i-STAT 1 Analyzer are correct B. Verify what information appears to be incorrect in the DMS; 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/displayed on the analyzer E. If this is related to any of the customization settings, verify 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 2. Internal simulator report in Info HQ shows blank operator ID field 3. PWeb report does not have reference ranges for some analytes 4. The reference ranges displayed in DMS report is incorrect 5. The QML report indicates "test not available", the results on the analyzer are all acceptable	
	Resolution	
	IF results in the DMS report are verified to match the i-STAT 1 Analyzer and the DMS	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF data available on the report is not what is expected by the customer but meets DMS specifications or matches information input into other DMS fields	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the information on the analyzer is correct and the third party DMS report is not matching the analyzer info	**THEN** refer customer to third party DMS vendor • Classification is **Complaint 1**
	IF the information on the analyzer is correct and the Info HQ report is not matching the analyzer info	**THEN** the issue is NOT resolved • Classification is **Complaint 2**

Complaint	Description
Alarm/Error message on DMS PC/Webpage RW Code: C4332 *Synonyms: Flag, warning, alert, window, pop up*	The customer reports that an alarm or error message is occurring on the data management system or webpage.
	Prompts for Meaningful Data Collection
	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? 3. Is the error preventing normal operation of the software or webpage? 4. When did the error start to occur? 5. Have there been any updates to the DE and/or DMS server? 6. When does the error message show (e.g. during start up, when accessing a specific window)? 7. 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.
	F. Review printout, pictures and/or screenshots (if provided)
	
	If occurring with Info HQ:
	A. Error occurs when user attempts to login to Info HQ
	  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)
	  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
	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-Party DMS:
	A. 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.
	B. If the alarms are related LIS settings not matching DMS settings refer customer to LIS 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.

	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 removes the error message	**THEN** the issue is resolved • 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 DMS products after advanced troubleshooting	**THEN** the issue is NOT resolved • Classification is **Complaint 2**

Complaint	Description
Customization – system won't update/incorrectly displayed RW Code: C4411 *Synonyms: Incorrect customization, not functioning correctly, as expected, settings wrong*	The customer reports that the i-STAT 1 Analyzer is not receiving the correct customization settings from the data management system or the customization settings are not displaying correctly or updating in the customization workspace.
	Prompts for Meaningful Data Collection

	1. What is the specific issue occurring?
	2. Is the issue occurring on the analyzer or DE/DMS?
	3. Are the customization settings updating and displaying correctly in the Customization Workspace?
	  a. What preference number is expected to display?
	  b. What customization settings are incorrect?
	4. Is the i-STAT 1 Analyzer receiving the incorrect customization settings?
	  a. What is analyzer serial number(s)?
	  b. What customization preference number is on the i-STAT 1 Analyzer Status screen?
	  c. What is the expected preference number?
	  d. Was the i-STAT analyzer recently placed in a downloader?
	  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 STATNotes 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 not shown on the analyzer screen for that result.

	Troubleshooting

	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 wirelessly verify that the analyzer IP is assigned to the correct location
	D. Verify "enable customization" is checked globally
	E. Verify "enabled" is checked for all locations in the Customization Workspace
	F. Reset the analyzer to factory settings then place in a downloader to communicate (or enable wireless and communicate wirelessly) and check the preference shown in the Analyzer Status screen to verify if analyzer is picking up 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 (physical) picks up the settings of the location the analyzer is downloaded
	If sample-type customization is not functioning:

A. No DMS:
   1. 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 2nd Page > STATNotes (disabled or XXXXXXXX for profile)

B. DMS (no STATNotes)
   1. 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

Examples:

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

Resolution	
IF the customization updates successfully after troubleshooting steps above	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the customization settings are not displaying correctly or as expected in the analyzer or DMS even after all troubleshooting	**THEN** the issue is NOT resolved • Classification is **Complaint 2**

Complaint	Description
Unable to access/ login to webpage RW Code: C4581 *Synonyms: Can't login, get onto website*	The customer is unable to login to or access the APOC website, DE/Data Management webpages or Info HQ Manager
	Prompts for Meaningful Data Collection
	1. What webpage cannot be accessed? a. Does the webpage not open at all? b. Is login information being rejected? c. Is there an error message showing when attempting to open the webpage? (refer to C4332) 2. What version of DE is being used (if applicable)? 3. What data management system or version of Info HQ is being used (if applicable)? 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://**[servername or IP address]**/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 HQ, verify the link being used: http://[servername]/Data Manager C. If unable to log into Info HQ: 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

	IF the user can access the DE System and/or Customization 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 vendor • Classification 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**

Complaint	**Description**	
Unable to install DMS version/setup SW RW Code: C4200 *Synonyms: Cannot install*	The customer is unable to install DMS version/setup SW (applies to APOC DMS)	
	Prompts for Meaningful Data Collection	
	1. What is the name and version of DMS being installed? a. At what step is the user stuck? b. Is there an error message occurring during installation? (add/refer to C4332) 2. What is the operating system on the computer used for DMS installation? 3. What instructions is the user following for the installation steps?	
	Troubleshooting	
	A. Verify name and version of DMS being installed B. Verify the operating system on the laptop or computer used for installation 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 instructions	**THEN** the issue is resolved • 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 installation instructions	**THEN** the issue is not resolved • Classification is **Complaint 2**

Complaint	Description	
DMS Functionality not as Expected per Customer RW Code: C2569 *Synonyms: N/A*	The Data Management System (DMS) is not performing as expected and no specific error codes are being generated. ***Note: C2569 should only be used when there is no other specific complaint code available.***	
	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? 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? 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 expected	**THEN** issue is resolved • Classification is **Complaint 1**
	IF the DMS is not an Abbott Point of Care product and the analyzer is functioning as expected	**THEN** advise the customer to contact DMS vendor support for issue resolution

14.0 Downloader Issues

Complaint	Description
Unable to configure downloader/ wireless analyzer/ Alinity RW Code: C1023 Synonyms: Downloader, Base, cradle, i-STAT, dock, not working, cannot be configured, cannot program	The customer reports that the i-STAT downloader or downloader/recharger, i-STAT 1 wireless analyzer, or the i-STAT Alinity cannot be configured successfully. If the customer reports a specific error code or message during configuring, see the appropriate complaint code. **Prompts for Meaningful Data Collection** 1. Is the issue regarding configuration of an i-STAT downloader or wireless analyzer? a. Is one product impacted or multiple products? 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? 3. What steps have been performed to attempt to configure the hardware? **Troubleshooting** Verify the following information is available and has been provided by customer IT: A. IP address B. Gateway IP address C. Subnet mask D. DE server IP address If programming an **i-STAT Downloader**: 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 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 IT department there have been no changes to network If programming an **i-STAT 1 Wireless Analyzer**: 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 operating system 2. Refer to appropriate troubleshooting for codes GS020/GS021 and iE53x. 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 previously configured, verify with IT department there have been no 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

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 handheld/configuration utility being setup at a time?
H. Was the correct SSID, Authentication type, Encryption type, Security Key, entered?
I. 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 performed 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 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 'iSTATXXXXXX' 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 address on the analyzer to confirm the correct MAC address.
    1. The network password for the wireless analyzer is 'istatYYYYYYXXXXXX' where 'YYYYYYXXXXXX' is the wireless module MAC address. (e.g. istat84253F55E09B)
D. 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.
E. After a successful configuration (setup successful displays 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 successfully configured after programming per the instructions	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the i-STAT 1 Wireless Analyzer is successfully configured after obtaining administrative rights to the computer	**THEN** the issue is resolved • Classification is **Complaint 1**
IF the i-STAT downloader cannot be successfully configured AND other downloaders are able to be successfully configured using the same computer setup in the same time interval	**THEN** the downloader should be replaced • Classification is **Repair**
IF the i-STAT wireless analyzer cannot be successfully configured AND other wireless analyzers are able to be successfully configured using the same computer setup in the same time interval	**THEN** the wireless analyzer should be replaced or repaired • Classification is **Repair**

Complaint	Description	
Downloader/Base Station not functioning as expected RW Code: C1027 *Synonyms: Downloader, Base, cradle, i-STAT, dock, not working, blinking lights*	The customer reports that the i-STAT downloader or downloader/recharger is not functioning as expected. **Examples:** • Proximity light does not light up when analyzer placed in downloader however communication occurs • Battery charging lights do not light up however battery charges If the customer is reporting that the unit is not charging batteries, not printing or not transmitting, see other appropriate troubleshooting and complaint codes.	
	Prompts for Meaningful Data Collection	
	1. Is the unexpected behavior occurring on one i-STAT downloader or multiple downloaders? a. What is the serial number of the downloader(s)? b. If DRC-300 Downloader/Rechargers are involved, what is the firmware version of DRC-300 Downloader/Rechargers that are experiencing the issue? i. The firmware version can be viewed on the DRC-300 configuration page. 2. What is the exact nature of the unexpected behavior? 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 life of the product or if it started after the product was already in use	
	Resolution	
	IF the behavior of the downloader is confirmed to be to specification	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the behavior of the downloader is found to not be to specification AND the downloader was functioning as expected at an earlier date	**THEN** the downloader should be replaced • Classification is **Repair**
	IF the behavior of the downloader is found not to be specification AND the downloader has been functioning out of specification since it was received	**THEN** the downloader should be investigated • Classification is **Complaint 2** C5555 may need to be added

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

15.0 Cartridge Issues

Complaint	Description	
Closure Failure (Snap/Clip) RW Code: C1804 *Answer pRE Questions!* *Synonyms: Wll not close, won't close, does not snap, doesn't snap, will not stay closed, difficult/hard to close, pops open*	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).	
	Prompts for Meaningful Data Collection	
	1. What is the type and lot number of the impacted cartridge(s)? 2. What is the box number of the impacted cartridge(s)? 3. How many cartridges will not close?	
	Troubleshooting	
	A. Verify cartridge storage, filling, and handling conditions B. Verify that the cartridge was closed properly before inserting into i-STAT analyzer C. If it is a new user, have the user test another cartridge from the same box or lot number of cartridges	
	Resolution	
	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**

Complaint	Description	
Cartridge won't Fill as Expected RW Code: C1805 *Answer pRE Questions!* *Synonyms: Will not fill, does not fill, sample pooling and not being drawn into cartridge, sample is pulled quickly in cartridge past fill line*	The i-STAT Cartridge(s) does not fill with patient sample or QC material materials.	
	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)? 3. What transfer device is used for filling cartridge? 4. How many cartridges will not fill? 5. Is the user new to i-STAT cartridge use? 6. Are other users able to fill the same cartridges properly?	
	Troubleshooting	
	A. Verify transfer device used for filling cartridges B. Verify cartridge filling and handling conditions C. Review cartridge filling procedure with user **Note:** *Burst calibrant packs causing calibrant material to enter the material path will prevent sample from reaching the fill mark. Cartridges resting on padded surface while filling may cause blockage of air vent on underside of cartridge preventing sample from flowing to fill mark.* 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 material AND cartridge filling and handling conditions are acceptable	**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 filled or handled incorrectly AND the retest of additional cartridges is successful	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	Description	
Cartridge Pouch Damaged RW Code: C1810 *Answer pRE Questions!* *Synonyms: Ripped, torn, slashed, punctured*	The i-STAT Cartridge(s) pouch is punctured or damaged upon removal from the cartridge 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)? 3. How many cartridges have damaged pouches?	
	Troubleshooting	
	A. Verify cartridge storage and handling conditions B. Verify shipping conditions C. Advise user not to use the cartridge if pouch is damaged D. Request photo of cartridge damage	
	Resolution	
	IF the cartridge pouches are damaged AND cartridge storage and handling conditions are acceptable	**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 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**

Complaint	Description	
Incorrect Cartridge Count in Box RW Code: C1811 *Synonyms: Not enough, wrong, missing, too many*	The i-STAT Cartridge box includes incorrect quantity of cartridges.	
	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)? 3. Is this a newly opened box of cartridges?	
	Troubleshooting	
	A. Verify 25 cartridges are present in the box for all cartridge types except for PT/INR; only 24 cartridges are shipped per PT/INR box	
	Resolution	
	IF the cartridge box has incorrect cartridge quantity AND the quantity of expected cartridges have been verified	**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 box has the expected quantity of cartridges	**THEN** the incident is resolved • Classification is **Complaint 1**

Complaint	Description	
Missing Cartridge in Pouch/Portion Pack RW Code: C1824 *Synonyms: Empty pouch*	The i-STAT Cartridge pouch or clear portion pack is missing a cartridge.	
	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)? 3. How many cartridge pouches/portion packs have missing cartridges?	
	Troubleshooting	
	A. Verify that the cartridge is missing from the cartridge pouch/pack 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)**

Complaint	Description	
Visible Leak RW Code: C1803 *Answer pRE Questions!* *Synonyms: Leaking, Dripping*	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)? 2. What is the box number of the impacted cartridge(s)? 3. How many cartridges with visible leak? 4. Did any quality check codes occur? a. What quality check code(s) occurred (if applicable)?	
	Troubleshooting	
	A. Verify cartridge storage conditions and handling B. Request photo of the visible leak for the cartridge	
	Resolution	
	IF the cartridge(s) have a visible leak AND cartridge storage and handling conditions are acceptable	**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)**

Complaint	Description	
Foreign Material Found in Product RW Code: C1812 *Answer pRE Questions!* *Synonyms: Debris, hair, dust, particles, marks*	The i-STAT Cartridge(s) has foreign material (hair, extra sensor chip, red dot) in or on the cartridge. 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	
	1. What is the lot number of the impacted cartridge(s)? 2. What is the box number of the impacted cartridge(s)? 3. What is the QC material lot number? 4. What is the serial number of APOC product?	
	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	**THEN** the product should be investigated • Classification is **Complaint 2**

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16.0 Miscellaneous

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

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Complaint	Description	
Dispensing Tip Use Issues RW Code: C5567 *Synonyms: Difficult to pull, cap is stuck, tight, hard*	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)? 2. What is the specific issue with dispensing tip(s)?	
	Troubleshooting	
	A. Verify the impacted dispensing tip(s) are manufactured by Abbott B. Identify the specific issue being experienced with the dispensing tip	
	Resolution	
	IF the dispensing tip(s) are verified to have an issue AND the dispensing tips are manufactured by Abbott	**THEN** the dispensing tip(s) should be replaced and investigated • 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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Complaint	Description	
Product Labeling Incomplete/ Incorrect/ Missing RW Code: C1050 *Answer pRE Questions!* *Synonyms: N/A*	Customer facing literature is missing information, incomplete or incorrect. Product labeling is incomplete, missing or incorrect.	
	Prompts for Meaningful Data Collection	
	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)? a. What is the lot number(s) or serial number(s) of products?	
	Troubleshooting	
	A. Document the specific details of what is incorrect, incomplete or missing B. Request a photo to understand the issue if appropriate	
	Resolution	
	IF the customer facing literature is missing information OR is incomplete OR is incorrect	**THEN** the specific documents should be reviewed and investigated • Classification is **Complaint 2**
	IF product labeling is missing information OR is incomplete OR is incorrect	**THEN** the specific product should be investigated • Classification is **Complaint 2**

Complaint	Description	
No/Limited Information Provided by Customer RW Code: C2567 *Synonyms: N/A*	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. **Examples for use in Rocketware Complaint System:** • Customer reports discrepant/unexpected results without providing specific analyte, cartridge or results (i.e. "discrepant blood gas results") o Use C2567 and select "Yes" for pRE screening question so MERC is aware o **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 o Use complaint code for the unexpected analyte(s) and C2567 o Once results are provided, remove C2567. Removing the code will trigger notification to MERC.	
	Prompts for Meaningful Data Collection	
	1. What is the serial number or lot number of the product(s) in question? 2. 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**

Complaint	Description	
General Maintenance/Loaner Return RW Code: C5600 *Synonyms: Loaner*	International customer returned a loaner analyzer and it is sent for maintenance at repair center. International customer requests maintenance on analyzer. No issues reported with analyzer.	
	Prompts for Meaningful Data Collection	
	1. What is analyzer serial number?	
	Troubleshooting	
	A. Verify no issues reported with analyzer	
	Processing	
	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 RW Code: C1061 *Synonyms: QD, Field Action, customer Letter*	Code is used when directed through a PQA approved Quality Directive.	
	Prompts for Meaningful Data Collection	
	1. As per Quality Directive	
	Troubleshooting	
	A. As per Quality Directive	
	Resolution	
	IF the incident being documented aligns with an approved active quality directive (not expired)	**THEN** use code as directed by the quality directive

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Complaint	Description	
Unable to return product - Directive RW Code: C1064 *Synonyms: QD, Field Action, customer Letter*	Code is used in conjunction with a Quality Directive issued by PQA	
	Prompts for Meaningful Data Collection	
	1. As per Quality Directive	
	Troubleshooting	
	A. As per Quality Directive	
	Resolution	
	IF the incident being documented aligns with an approved active quality directive (not expired)	**THEN** add code to product as directed by the quality 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 RW Code: C5555 **Supplemental Code** *Answer pRE Questions!* *Synonyms: First use 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)? 2. Was the product used for patient testing? 3. When was the product received? 4. How many uses of the product have occurred? 5. What type of battery is being used (if applicable)? a. What color is the battery holder (if applicable)? b. What is the rechargeable battery BOD (if applicable)? **Note:** C5555 is supplemental code used in addition to the complaint code used for the reported customer complaint.	
	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 the first week of use AND with less than or equal to 10 uses	**THEN** the product(s) should be replaced and investigated • Classification is **Complaint 2**
	IF the i-STAT product(s) did not fail during initial use OR within the first week of use OR has greater than 10 uses	**THEN** troubleshoot the impacted product(s)

Complaint	Description	
Resolution not in Current Literature RW Code: C2573 **Supplemental Code** *Synonyms: N/A*	The issue was resolved with assistance or aid from sources that are not in current support literature. There is no product deficiency. **Note:** C2573 supplemental code used in addition to the complaint code used for the reported customer complaint	
	Prompts for Meaningful Data Collection	
	1. Not Applicable	
	Troubleshooting	
	A. Verify the information used to troubleshoot the issue is not in current literature	
	Resolution	
	IF the information used to troubleshoot and resolve the issue is not in current literature and there is no product deficiency	**THEN** the issue is resolved • Classification is **Complaint 1**

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

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

Complaint	Description	
Unknown DMS Vendor RW Code: C5563 **Supplemental Code** *Synonyms: N/A*	Supplemental Code is added when troubleshooting informatics complaint and the data management system being used is from an unknown third-party vendor.	

Third-Party DMS	Vendor
AegisPOC	Abbott Rapid Diagnostics
RALS	Abbott Rapid Diagnostics
PrecisionWeb	Abbott Diabetes Care
AQURE	Radiometer
Bio-Connect	Bio-Asia
Harvest/Trellis	Orchard
CobasIT 1000	Roche
POCcelerator	Siemens
UniPOC	Siemens
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	
	Processing	
	IF the data management system vendor is unknown	**THEN** add the code to product
	IF the data management system vendor is known	**THEN** do not add code to product

18.0 Shipping Issues

Complaint	Description	
Compromised Product RW Code: C1002 *Synonyms: box is warm, temperature strip colored, ice packs are melted*	Compromised product. Box is warm, ice/gel packs are melted, temperature strip is colored.	
	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-party Distributor? a. If APOC, what is the order number or the purchase order number (PO#)? b. If third-party Distributor, who is the distributor? What is the PO#? 3. What is the appearance of the temperature strip? Which windows have color? (Note: May request image of the temperature strip if unable to verify during customer contact) 4. When was the product ordered and when was it delivered to the customer? 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 product to a sister facility?	
	Troubleshooting	
	A. Verify the product type, lot number and quantity from the shipment B. Verify the temperature strip was activated C. Verify if there is color in any windows on the temperature strip – specifically if there is color in windows 3 or 4 or both. D. If the temperature strip indicates product is compromised (color in windows 3 and/or 4), use the PO# to verify if the product was shipped direct from APOC to customer? E. 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 compromised based on the temperature strip status	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the product was received compromised based on the temperature strip status and customer shipped it on their own to a sister facility	**THEN** the issue is resolved • Classification is **Complaint 1**
	IF the product was received a few days late by the customer as it was left on the dock/receiving area and the product is compromised based on the temperature strip status	**THEN** the product should NOT be replaced as we cannot confirm the temperature status of the 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 compromised based on the temperature strip status	**THEN** the product should be replaced and the shipment error investigated • Classification is **Complaint 2**
	IF the product is compromised based on the temperature strip status (color in windows 3 and/or 4) AND was ordered from a third-party Distributor and shipped direct to customer	**THEN** the product should be replaced and the shipment error investigated • Classification is **Complaint 2**
	IF the product is compromised based on the temperature strip status (color in windows 3 and/or 4) AND was ordered from a third-party Distributor and NOT shipped direct to customer from APOC	**THEN** refer customer to distributor for replacement and investigate shipping complaint • Classification is **Complaint 2**

Complaint	Description	
Shipment Error RW Code: C1004 *Synonyms: delayed, missing, incorrect shipment*	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	
	1. Was the product(s) directly ordered from APOC or a third-party Distributor? a. If APOC, what is the order number or the purchase order number (PO#)? b. If distributor, who is the distributor? What is the PO#? 2. Was the order shipped to the wrong address? 3. Was correct shipping information provided by customer when placing the order? (Check with APOC customer service on this to confirm) 4. What is the product type and lot number or serial number or part number? 5. If incomplete order, what products/part numbers are 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 and quantity from the shipment D. Verify if the product was shipped to customer directly from APOC E. In case of incorrect order, verify customer ordered correct product F. Verify products or part numbers missing from the order	
	Resolution	
	IF the product was ordered from APOC AND the shipping address is correct in ISS or confirmed by APOC Customer Service	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the product was ordered from APOC AND correct product was shipped based on customer's order	**THEN** the incident is resolved • Classification is **Complaint 1**
	IF the product was ordered from APOC AND was shipped to incorrect address	**THEN** the product should be replaced and the shipment error should be investigated • Classification is **Complaint 2**
	IF the product was ordered from APOC AND customer received incorrect product or incomplete order and is compromised due to this or the facility never received the shipment	**THEN** the correct product or missing component of the order should be replaced and the shipment error should be investigated • Classification is **Complaint 2**
	IF the APOC shipment delivery to customer was delayed and product is compromised	**THEN** the product should be replaced and the shipment error should be investigated • Classification is **Complaint 2**
	IF the product was ordered from a third-party Distributor and was not shipped direct from APOC	**THEN** refer customer to distributor for replacement and investigate shipping complaint • Classification is **Complaint 2**

Complaint	Description	
Missing Ice Pack RW Code: C1000 *Synonyms: No 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 third-party Distributor? a. If APOC, what is the order number or the purchase order number(PO#)? b. If distributor, who is the distributor? What is the PO#? 2. Who received and unpacked the box? 3. What is the product type and lot number from the shipment?	
	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 APOC AND the ice pack (gel pack) is missing	**THEN** the product should be replaced and the order should be investigated • Classification is **Complaint 2**
	IF the product was ordered from a third-party Distributor AND shipped directly from APOC and the ice pack (gel pack) is missing	**THEN** the product should be replaced and the order should be investigated • Classification is **Complaint 2**
	IF the product was ordered from a third-party Distributor (not shipped direct from APOC) AND the ice pack (gel pack) is missing	**THEN** refer customer to distributor for replacement and investigate shipping complaint • Classification is **Complaint 2**

Complaint	Description	
Missing Temperature Strip RW Code: C1005 *Synonyms: No Strip, No 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? a. If APOC, what is the order number or the purchase order number (PO#)? b. Who is the distributor? What is the PO#? 2. What is the product type and lot number from shipment? 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 Temperature Strip is missing	**THEN** the product should be replaced and the order should be investigated • Classification is **Complaint 2**
	IF the product was ordered from a third-party Distributor and shipped direct from APOC to customer	**THEN** the product should be replaced and the order should be investigated • Classification is **Complaint 2**
	IF the product was ordered from a third-party Distributor and not shipped direct from APOC	**THEN** refer customer to distributor for replacement and investigate shipping complaint • Classification is **Complaint 2**

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

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
pH	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.
cTnI, 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. Analyte Range of Slope Values**

	cTnI 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 Gap	A difference in the calculated anion gap may be due to the difference in equations: i-STAT EC8+: (Na + K) - (Cl + 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 *P*CO2	*P*CO2 and pH	HCO3, BE, TCO2, anion gap, sO2
Hct		Hb
Hct (fluidics problem - movement or quality of calibrant or sample)	Cl, urea, glucose, *P*O2, lactate, creatinine	Anion Gap, sO2, Hb
*P*O2		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.

Appendix B: Additional Transmission Troubleshooting

Downloader Troubleshooting: DRC-300

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
4. 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

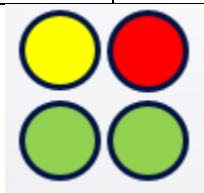
APOC has not validated use of virtual IP address with their products. Product connectivity functionality may or may not be affected.

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 Note: Will blink when activity is occurring	Red (Boot) Off
Green (Link) On	Green (Power) On

If this light is red and all troubleshooting has been performed, replace downloader

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.

PUTTY

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*

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.

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.
2. 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
        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.
4. 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*

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
  - 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:

- 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
  - 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.

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 'istatYYYYYYXXXXXX' where 'YYYYYYXXXXXX' 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.

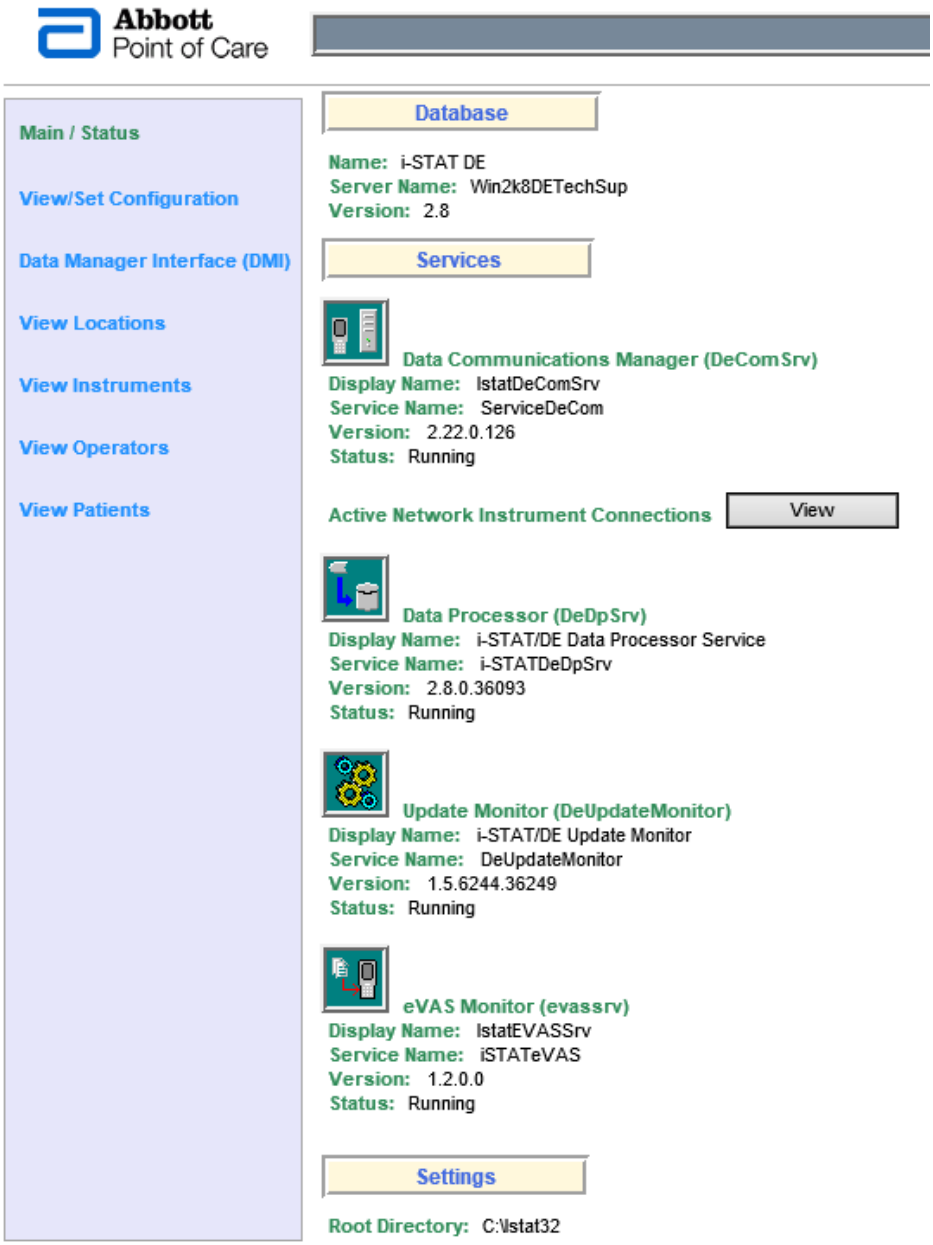
Slow Transmission Troubleshooting

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

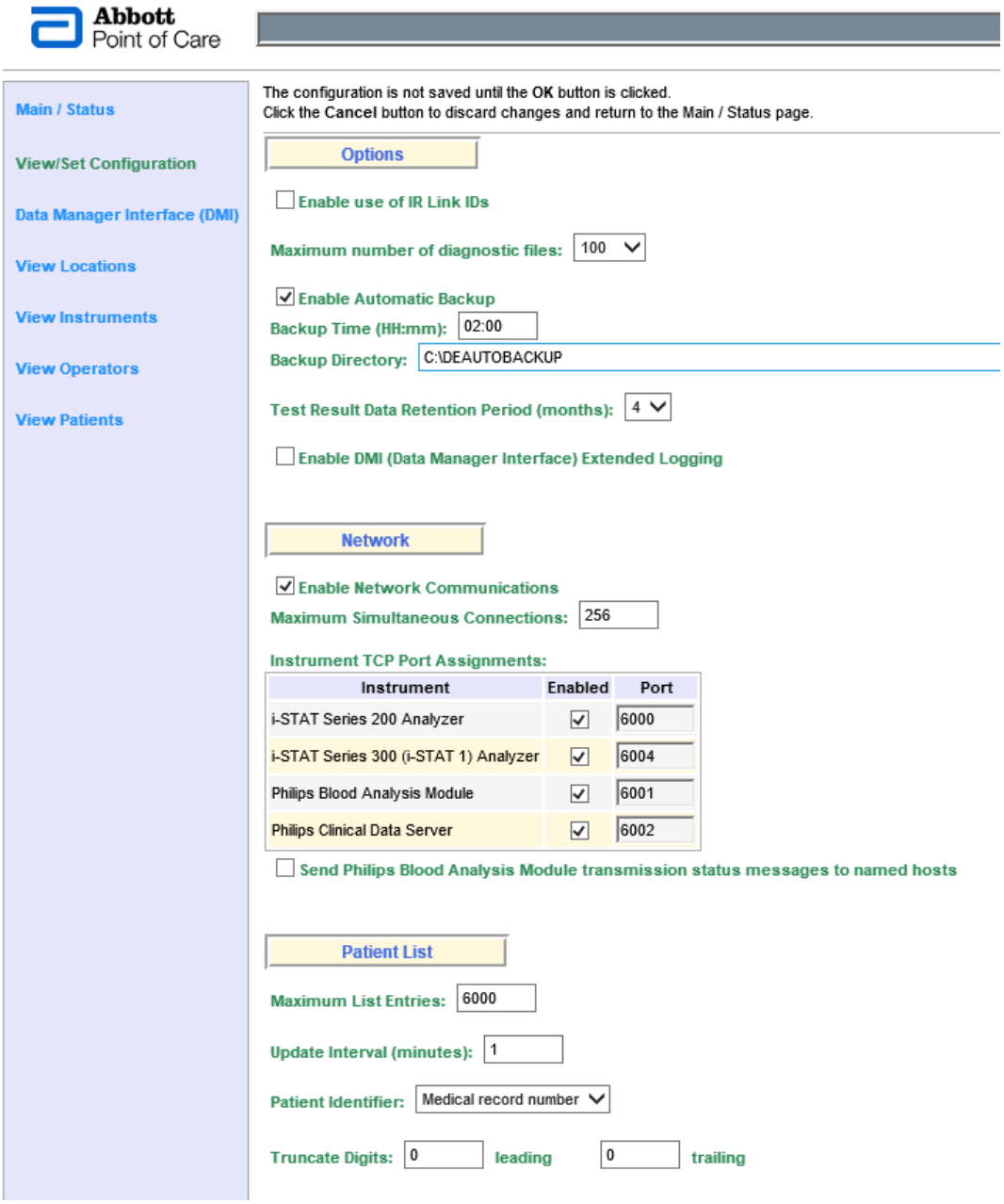
1. Verify at what stage in communication the transmission is slow
2. Verify that Auto-Transmit is enabled in the i-STAT 1 Analyzer customization settings
3. Educate the customer as to the time to result for each cartridge type
4. Determine exactly how long transmission was delayed
    a. Request evidence 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

Appendix C: i-STAT/DE Systems Page

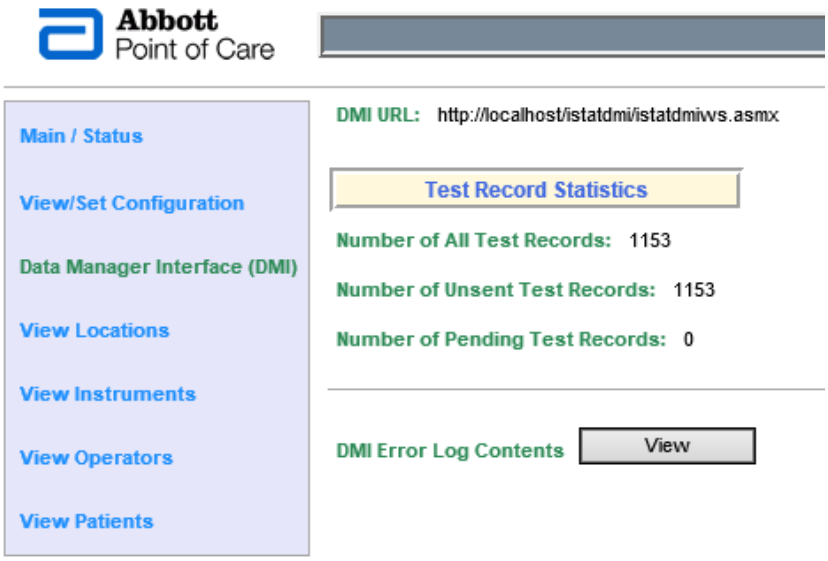
Main/Status



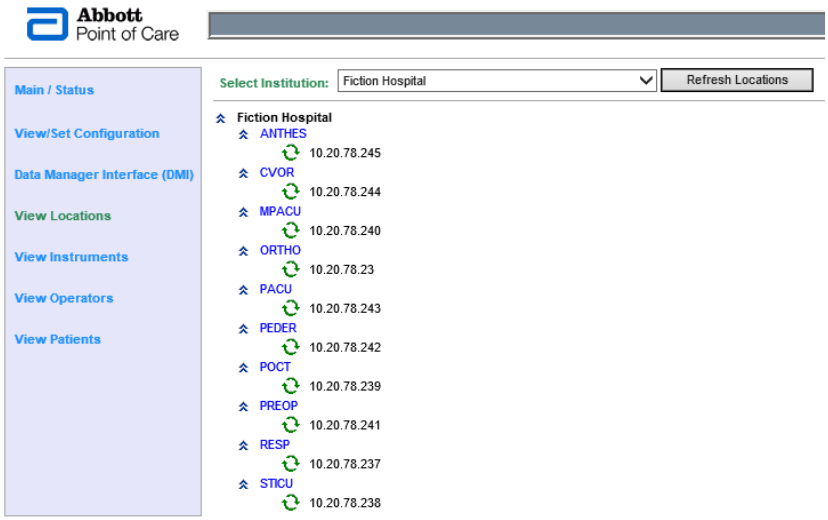
View/Set Configuration



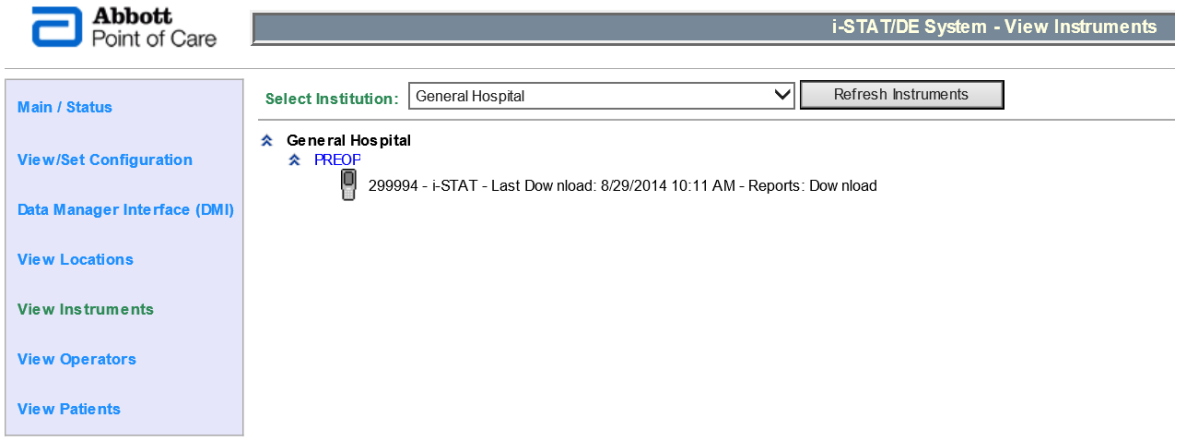
Data Manager Interface (DMI)



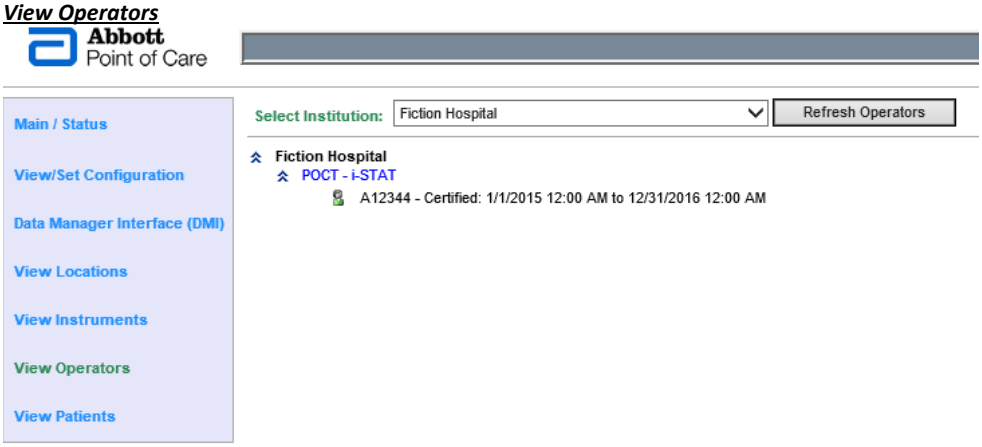
View Locations



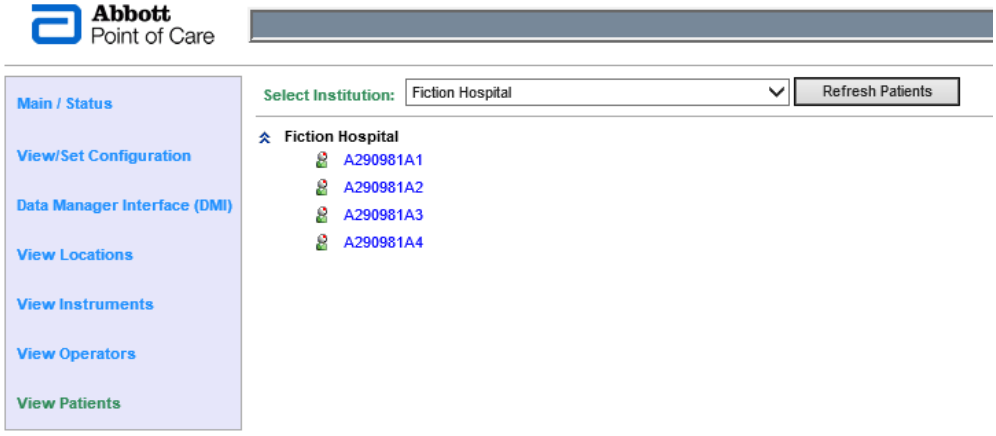
View Instruments



View Operators



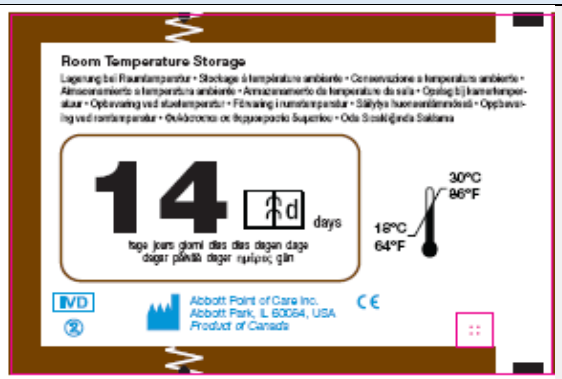
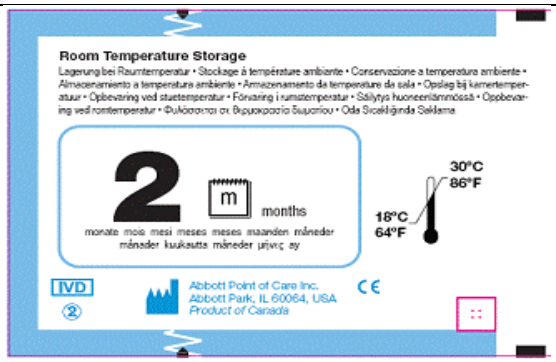
View Patients



Appendix D: Shipping

<u>Cartridge Labeling/Storage</u>

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

Room Temperature Storage	Cartridge Pouch Image (Back)	Cartridge Types
14 days		CHEM8+ E3+ 6+ EC4+ G CREA EC8+ ACT Celite ACT Kaolin PT/INR PT^{plus}
2 months		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.	cTnI CK-MB BNP β-hCG

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

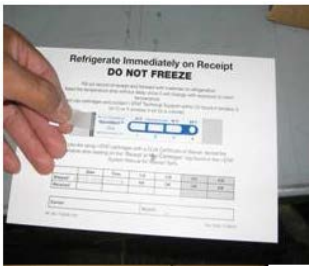
- Intended to be packed as tightly as possible to avoid shipping damages (internal movements) and keep the area as cool as possible over the shipping period.

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



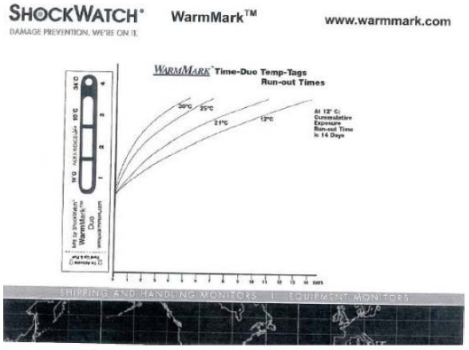
Regions and Sections

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 34ºC (93ºF).

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



Appendix E: Additional Product Information

<table>
<tr><th>Topic</th><th>Additional Information</th></tr>
<tr><td>Action Ranges</td><td>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. General Guidance for Critical/Action Range Decimal for Rounding Numbers
(Note: Target Lower Limit and Target Upper Limit are specified with the same number of decimal places with which the analyte result is displayed on the i-STAT 1 Analyzer)
<table>
<tr><th>Number of decimal places in analyte result</th><th><
(less than)</th><th>>
(greater than)</th><th>≤
(less than or equal to)</th><th>≥
(greater than or equal to)</th></tr>
<tr><td>0
(i.e., a whole #)</td><td>Target Lower Limit
−0.5</td><td>Target Upper Limit
+0.499</td><td>Target Lower Limit
+0.5</td><td>Target Upper Limit
−0.501</td></tr>
<tr><td>1</td><td>Target Lower Limit
−0.05</td><td>Target Upper Limit
+0.0499</td><td>Target Lower Limit
+0.05</td><td>Target Upper Limit
−0.0501</td></tr>
<tr><td>2</td><td>Target Lower Limit
−0.005</td><td>Target Upper Limit
+0.00499</td><td>Target Lower Limit
+0.005</td><td>Target Upper Limit
−0.00501</td></tr>
<tr><td>3</td><td>Target Lower Limit
−0.0005</td><td>Target Upper Limit
+0.000499</td><td>Target Lower Limit
+0.0005</td><td>Target Upper Limit
−0.000501</td></tr>
</table>

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.</td></tr>
<tr><td>Reference Range</td><td>Reference range will not print if set outside of reportable range (appears dashed out)</td></tr>
<tr><td>Drug Concentrations</td><td>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.</td></tr>
<tr><td>Interferences</td><td>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.</td></tr>
<tr><td>GFR</td><td>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.</td></tr>
</table>

Topic	Additional Information
CPB Mode Calculation	Estimating Hematocrit results from CPB mode using the theory section of the manual 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 g/dL = 2.930 g/dL. 3. The patient's corrected hematocrit 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 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 possible for one patient test to have a result of 190 and another patient test a result of 191.
β-hCG Analyte Enable	The quantitative result of the β-hCG assay cannot be disabled globally or by panel. Only the qualitative result can be disabled.
Temperature Correction	When using temperature correction for patient temperature, the pH, PCO2, and PO2 are the only analytes that 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 Correction	The dependence of the i-STAT creatinine with respect to Carbon Dioxide (CO2) is as follows: 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 ECMO samples.
Analyzer Life Expectancy	There is no information available as to expectation of life of the i-STAT 1 Analyzer.
Battery Information	Low battery for disposable batteries triggers at 7.4 volts at power on. 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 Storage	The i-STAT 1 System uses a proprietary embedded operating system and encoded data storage. Other encryptions are not compatible with this internal encoding. The i-STAT 1 System is not FIPS-140 compliant.

Topic	Additional Information
MRI, CAT Scan, X-Ray	There are no studies validating the use of the i-STAT 1 System in environments created by MRI, CAT Scan or X-Ray.
Pneumatic Tube	There are no validated studies to show the effects of shipping i-STAT products through a pneumatic tube system.
LAN Filter Cable	LAN filter cable is an FCC requirement to comply 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 adaptors. APOC cannot guarantee setup or operation when USB adaptors are in use with APOC products.
CLEW Meaning	Coefficient, Limits, Extrapolation Windows
Facility Network Controller Settings	The following category will provide items to check regarding the network settings of the network controller that facilitates the network connectivity from the access points. This information helps Abbott Point of Care understand the network environment and the network connectivity between the i-STAT Wireless analyzer handheld and i-STAT/DE application. This information is provided by the facility IT department. - Mac Address filtering - Quality of service enabled and priority - Port sniffing - Network optimization - Controller/debugging logs
Wireless Download	There are three instances when an i-STAT 1 Wireless Analyzer will connect to DE and download information: 1. As the analyzer is powering off with unsent results 2. When “Transmit Data” option is selected (use 'Most Recent' if no unsent results) 3. As analyzer turns on by being placed into the downloader (analyzer 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 codes 2-14 and Analyzer Error 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 Performance	Performance of the i-STAT 1 System has not been evaluated with all medications or situations. All information available for interferences and limitations can be found in the i-STAT 1 System Manual, the Cartridge and Test Information (CTI) sheets and/or individual cartridge Instructions For Use (IFU). Other information outside of these approved documents is not available.
i-STAT 1 Analyzer Stored Records	The maximum number of stored results is a minimum of 1000. The total number of stored records is variable. The current total number of stored records for the analyzer is around 3942, but this number can be less depending on the amount of information that is 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 results than a G cartridge. Therefore, if an analyzer only ran CHEM8+ cartridges, the total number of stored records would be less than if the analyzer only ran G cartridges.
Cartridge Result Date/Time Stamp	**At the end of the test cycle** (Just before the motor resets) — Chemistry/Blood Gas/Hematology — G, E3+, EC4+, 6+, EC8+, Crea, CHEM8+, G3+, CG4+, EG6+, EG7+, CG8+ **At the beginning of the test cycle** (At the end of the mixing state when clot detection starts [t=0]) — Coagulation — ACTc, ACTk, PT/INR **At the beginning of the test cycle** (When the countdown bar first displays at the start of the cycle) — Immunoassay — cTnI, CK-MB, BNP, β-hCG

Topic	Additional Information
Cartridge Release Criteria	Abbott Point of Care has developed proprietary finished goods release criteria where all cartridge lots are tested utilizing control and blood samples before release. 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 paper, foil, and plastic and has: • a water vapor transmission rate of <0.10 g/m2/day as per ASTM F1249-06 38ºC,90 • oxygen permeability of <0.10 cm3/m²/day as per ASTM 3985-88 25ºC,0%
Cartridge Pouch Barcode	The 32-digit numeric barcode contains product identification, lot number, expiry date and product coefficients. 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 Conditions in Doubt	Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8 °C (35 to 46 °F). 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 Variability	There is variability in QC ranges and means of different lots of the same types of cartridges because of 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 Information	BEecf = HCO3 - 24.8 + 16.2 (pH - 7.4) 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.

Topic	Additional Information
Rounding Off	Due to factors related to differences in methodology, equations used, and rounding, calculated results may not compare. 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. The round-off error (difference between the rounded number displayed on the analyzer screen and the actual number stored in the analyzer memory) associated with each value displayed on the analyzer is equal to plus or minus half of the displayed resolution of that value. For example, the maximum round-off error associated with the calculated Anion Gap (AG) [AG (CHEM8+) = (Na + K) – (Cl + (TCO2 – 1)] is determined as follows: Na: 1: ± 0.5 K: 0.1: ± 0.05 Cl: 1: ± 0.5 TCO_2: 1: ± 0.5 AG (calculated): N/A: ± 1.55 (sum of error for displayed 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 C5559 for troubleshooting. Panel code is intended to be used within the proprietary software of CDS and i-STAT/DE with integration into Info HQ Manager and other 3rd party data management applications. Table is for informational use only

Panel Code	Cartridge	Panel Code	Cartridge	Panel Code	Cartridge
01	E3+	0A	CG4+	22	PT/INR
02	EC4+	0B	EG6+	24	ACT-K
04	CHEM8+	0C	G3+	26	cTnI
05	CG8+	0D	EG7+	2A	CK-MB
07	G	0E	Crea	2B	BNP
08	EC8+	0F	Simulator	2C	B-hCG
09	6+	20	ACT-C	F0	QCC

Cartridge Default Panel Codes:
Immunoassays: 26
Coagulation: 24

Panel Code 00: Unknown cartridge due to test cycle terminating prior to cartridge identification

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	cTnI: 0.20 ng/mL	Venous #1
Architect	18-May-2020	19:37	19:58	cTnI: 0.01 ng/mL	Venous #2

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

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		

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 Ana*lyzer**

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 first 15 characters of the barcode**	000008711932320
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

Opticon Analyzer

Step	Description	Output
1	Barcode scanned by barcode reader	00000871193232000
2	**Opticon barcode reader firmware only accepts the first 15 characters of the barcode**	000008711932320
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

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 codes/message/Alert	Request meaning of code 23 or suppressed result or why occurred **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 Instructions	Manufacturer recommendation for QC/Cal Ver testing
		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 status	Request for waived status of cartridge
		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	Customer letter/ notifications/ literature	Location in i-STAT system manual for information
		Request copy of product action letter after the Quality Directive has expired
		Questions about a letter/notification/literature
IN0027	Temperature strip/shipment process	Request i-STAT products packaged or shipped
		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 results	Assistance with understanding i-STAT 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/ operation/ programming	Assistance with clock settings on the analyzer
		Password assistance to access handheld menu screens
		Assistance/instruction with using product features
		Request specifications of hardware
IN0202	Data System specifications/ operation/setup	APOC system recommendations/specifications
		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

Inquiry Code	Inquiry Code Description	Coding Scenario
IN0228	Interface specs/ operation/ modification/ setup	Requests for modification/update to interface. Confirm no issue with interface.
		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 specifications	Questions about sample collection, handling, etc.
		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	3rd party vendor product	Questions about a 3rd 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
		Questions about the process/instructions
IN0307	Finding/printing SW literature	Any question or assistance with finding the software literature on the website or on the CD
IN0038	Incident closed as duplicate	Use ONLY to close incidents because there was another incident opened for the same issue from the same location
IN0031	Other	Use ONLY when there is no code that matches a current inquiry code