i-STAT 1

Important!

i-STAT 1 System Manual Update

As of April 2024, the current i-STAT 1 System Manual has been updated. Please **ADD** and **DELETE** the sheets as listed below. Once the updates have been completed these instructions may be discarded. If you have any questions about these instructions, please contact your i-STAT Support Services provider.

A▶ ADD SHEET ◀D DESTROY SHEET

	Item	Art#
A▶	i-STAT 1 System Manual Cover Sheet	714336-01R
◀D	i-STAT 1 System Manual Cover Sheet	714336-01Q (or lower)
A▶	i-STAT 1 System Manual Table of Contents	714362-01AH
◀D	i-STAT 1 System Manual Table of Contents	714362-01AG (or lower)
	System Components Tab	
A▶	i-STAT 1 System Manual Section 3: i-STAT 1 Analyzer	714364-01Y
◀D	i-STAT 1 System Manual Section 3: i-STAT 1 Analyzer	714364-01X (or lower)
A▶	i-STAT 1 System Manual Section 6: i-STAT 1 Downloader	714368-01O
◀D	i-STAT 1 System Manual Section 6: i-STAT 1 Downloader	714368-01N (or lower)
	Procedures Tab	
A▶	i-STAT 1 System Manual Section 11: Troubleshooting the Analyzer	714381-01N
◀D	i-STAT 1 System Manual Section 11: Troubleshooting the Analyzer	714381-01M (or lower)
A▶	Technical Bulletin: Analyzer Coded Messages	714260-01W
◀D	Technical Bulletin: Analyzer Coded Messages	714260-01V (or lower)
A▶	i-STAT 1 System Manual Section 12: Quality Control	714376-01V
◀D	i-STAT 1 System Manual Section 12: Quality Control	714376-01U (or lower)
A▶	i-STAT 1 System Manual Section 13: Calibration Verification	714377-01U
◀D	i-STAT 1 System Manual Section 13: Calibration Verification	714377-01T (or lower)

A ► ADD SHEET ◄ D DESTROY SHEET

	Item	Art#
A►	i-STAT 1 System Manual Section 15: Customization	714371-01L
◄D	i-STAT 1 System Manual Section 15: Customization	714371-01K (or lower)

END

Abbott

i-STAT 1
System Manual

Rev. Date: 18-MAR-2024 Art: 714336-01R

Patents: www.abbott.us/patents

Symbol Technologies Corporation is the owner of US Patent No. 5,532,469.

Trademarks

Windows is a trademark of Microsoft Corporation.

RELEASE NOTES

The Table of Contents was updated to reflect current page numbering of each section.

Section 3 (i-STAT 1 Analyzer) and Section 15 (Customization) were both updated to include a new image which displays the updated contents of the Analyzer Status Page. A new Release parameter was added to the Status Page describing the current released version of application software installed in the analyzer.

- A new EMC Regulations section was added directly after the Specifications table in Section 3 to indicate that the i-STAT 1 Wireless System is compliant with IEC 61326-1 and IEC 61326-2-6 requirements

Section 6 (i-STAT 1 Downloader/Recharger) was updated to include instructions for configuring the DRC-300 using Windows 11. Additionally, a row was added to the DRC-300 LED Indicator table to clarify the behavior of the LED lights when a spare battery is placed in the recharging compartment.

Section 11 (Troubleshooting the Analyzer) was updated to include Quality Check Code 69.

The Analyzer Coded Messages Technical Bulletin was updated to include Quality Check Code 69.

Section 12 (Quality Control) and Section 13 (Calibration Verification) were both updated to move the procedure for testing the quality control or calibration verification materials toward the beginning of each section.

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IVD

CE

For information related to Article 33 of the EU REACH regulation (EC No.1907/2006), please refer to pmis.abbott.com. If you have issues logging into the website, contact Abbott at: abbott.REACH@abbott.com.

Art: 714336-01R Rev. Date: 18-MAR-2024

Contents

SYSTEM COMPONENTS

CARTRIDGE AND TEST INFORMATION

PROCEDURES

CARE AND SOFTWARE UPDATES

TECHNICAL BULLETINS

i-STAT 1 ANALYZER 3

INTRODUCTION

The i-STAT 1 Analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of specific analytes in whole blood.

For information on the analytes that can be measured using i-STAT Cartridges, refer to the Cartridge and Test Information (CTI) sheets or Instructions for Use (IFU), located at www.globalpointofcare.abbott.

BEFORE YOU USE THE ANALYZER

Install Batteries

See the Care of the Analyzer section in this manual for the procedure to install the disposable batteries. If a rechargeable battery is to be used, the disposable batteries can be used while the rechargeable battery pack is charged in the Downloader/Recharger. Charge rechargeable batteries fully before use. See the i-STAT 1 Downloader section for this procedure. When using a rechargeable battery, store the disposable battery carrier for possible future use.

Check Date and Time

Press the On/Off key and check that the date and time at the top of the display are correct. To change the date and time, see Administration Menu in this section.

Check Software

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have standard CLEW and application software. If a different CLEW and/or application software is in use in your facility, it must be installed in new, repaired or replaced analyzers before they are put into use. Check the Analyzer Status page for the installed CLEW and application software. For steps to verify the software, see *Procedures for Customization using the Analyzer Keypad* in Section 15 of this manual. See under "Standardization and Calibration" in section 4 of this manual for an explanation of CLEW.

Customization

Analyzers can be customized for many site-specific testing requirements. See Section 15 in this manual for a list of customizable parameters and their default values. To change the customization profile via the analyzer keypad see "Customization" under "Administration" in this section of the manual. To change the customization profile via i-STAT/DE, see the "i-STAT/DE User Guide" located at www.globalpointofcare.abbott.

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have the factory default settings in the customization profile, as indicated by the DEFAULT0 on the Analyzer Status page. If analyzers in your facility do not use the default customization profile, the appropriate customization profile should be installed before a new, repaired or replaced analyzer is put into use.

Perform Quality Check

Use the Electronic Simulator to verify the cartridge-reading performance of new or repaired analyzers.

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DESCRIPTION

Specifications

DIMENSIONS	Width 7.68 cm (3.035 in.) Length 23.48 cm (9.245 in.) Depth 7.24 cm (2.85 in.)
WEIGHT	With rechargeable battery 650 grams (22.9 oz.) With disposable battery 635 grams (22.4 oz.)
POWER	Two 9-volt lithium batteries, or rechargeable battery.
CALIBRATION	Factory: electronic, mechanical, thermal, pressure
MEMORY/CLOCK BACKUP POWER	Lithium Battery
DISPLAY	Dot matrix supertwist liquid crystal
COMMUNICATION LINK	Infrared light-emitting diode (LED)
OPERATING TEMPERATURE	16-30°C (61-86°F) for i-STAT cartridge testing
TRANSPORT TEMPERATURE	-10-46°C (14-115°F)
RELATIVE HUMIDITY	10-90% non-condensing
BAROMETRIC PRESSURE	300-850 mmHg
LASER SCANNER	Complies with U.S. 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No. 50, dated June 24, 2007. EN 60825-1:2014 IEC 60825-1:2014

EMC

The i-STAT 1 Wireless (Model 300W) System is compliant with:
IEC 61326-1: Electrical Equipment for measurement, control and laboratory use - EMC requirements - Part1: General requirements.
IEC 61326-2-6: Electrical Equipment for measurement, control and laboratory use -EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment.

Software

All analyzer functions are controlled by application software that can be updated as additional tests and features are developed. Coefficients used to maintain the accuracy of cartridge results over time are programmed into the analyzer via CLEW software updates every six months. See under “Standardization and Calibration” in Section 4 of this manual for an explanation of CLEW.

Power

There are two power options for the analyzer: disposable and rechargeable. The analyzer is shipped with a battery carrier for use with two disposable Ultralife 9-Volt lithium batteries (APOC List Number: 06F21-26). Ultralife 9-Volt lithium batteries are manufactured by Ultralife Battery and Energy Products and sold by Abbott Point of Care for use with the i-STAT 1 Analyzer. Only i-STAT rechargeable batteries (APOC List Number: 06F23-55) may be used.

Note: The Ultralife 9-volt lithium battery (APOC List Number: 06F21-26) has a safety feature that provides protection preventing the i-STAT 1 Analyzer from overheating due to component failure within the analyzer circuitry.

Battery Compartment

The battery compartment is located at the display end of the analyzer next to the laser barcode scanner window. The procedure for changing disposable and rechargeable batteries can be found in the Routine Care of the Analyzer and Downloader section of this manual.

Disposable Batteries

The analyzer requires two 9-volt lithium batteries. The lifetime for a set of batteries is mainly dependent on the mix of cartridges in use. Cartridges that require thermal control consume more energy because of heating. Coagulation and immunoassay cartridges consume more energy because of the longer test cycle. A minimum of 400 thermally controlled cartridge uses, about 100 coagulation cartridges, or 50 immunoassay cartridges can be expected before replacement is necessary. Backlighting, if used continuously, may reduce battery life up to 50%. Extensive laser scanning will affect battery life slightly.

The lithium batteries should be removed from the analyzer when long periods, such as six months, of no use are anticipated.

Rechargeable Battery

The analyzer can be powered by a nickel-metal-hydride rechargeable battery. The battery capacity for one full charge is 30% (minimum) of the capacity of one set of disposable lithium batteries (see above). If the analyzer is not in use, batteries will lose approximately 10-30% of their charge over 30 days if not recharged.

Store rechargeable batteries in a cool dry place when not in use.

The battery recharges when the analyzer is placed in a Downloader/Recharger. The battery pack can be removed from the analyzer and placed in the separate recharging compartment on the Downloader/Recharger. Full recharge from a discharged state takes approximately 40 hours. The analyzer will display “Low Battery” when battery recharge is needed.

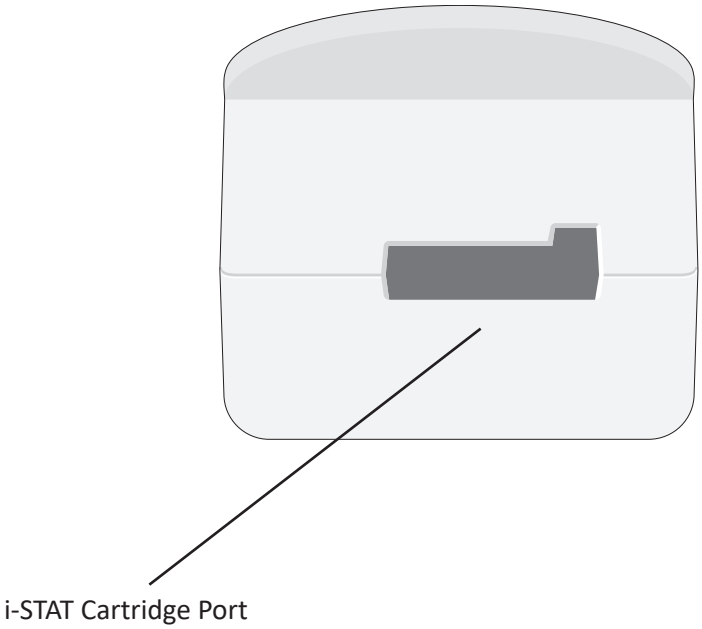
Caution: Do not short circuit, incinerate or mutilate the recharegable batteries.

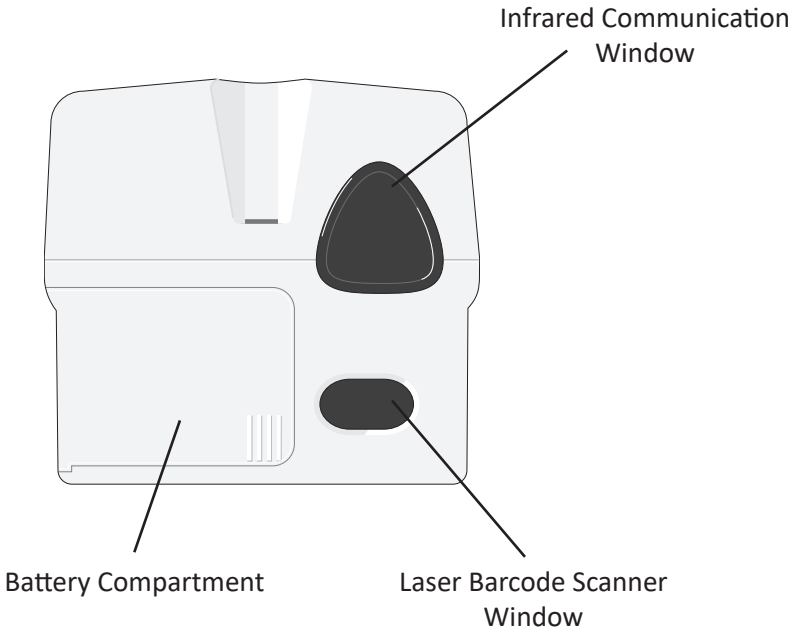
Low Battery Warning

The analyzer will display “Low Battery” when the On/Off key is pressed. Additionally, a flashing battery icon will display on the results screens, as well as the Test Menu and Administration Menu screens when battery replacement is needed. Data is not lost when batteries are fully discharged.

Additional Power A lithium battery inside the analyzer maintains the clock/calendar and customization profile. This battery should last seven years.

Cartridge Port Cartridges and the Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer.





Infrared Communication Window

The Infrared Communication Window provides the analyzer with two-way communication to i-STAT/DE via a Downloader, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.

Thermal Control

The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and fluids that come into contact with the sensors to 37°C. This subsystem is activated automatically when a cartridge containing tests which require thermal control at 37°C is inserted into the analyzer.

Barometric Pressure Sensor

The analyzer contains a solid-state barometric pressure sensor, which determines the ambient atmospheric pressure used for the $\boldsymbol{P}O_2$ sensor calibration.

Cartridge Test Cycle

An operator starts a cartridge test cycle either by selecting i-STAT Cartridge from the Test Menu or Quality Tests from the Administration Menu.

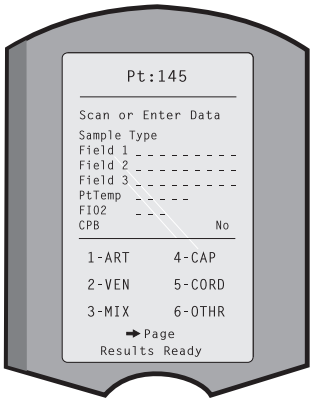
The analyzer:

- makes electrical contact with the cartridge
- identifies the cartridge type
- releases calibration fluid to the sensors (when applicable)
- mixes sample and reagent (when applicable)
- measures barometric pressure
- heats the sensors to 37°C (when required by the test)
- measures electrical signals generated by the sensors and calibration fluid (when applicable)
- displaces the calibrant solution with sample (when applicable)
- measures electrical signals generated by the sensors and sample
- accepts the operator and patient IDs scanned or entered by the operator
- accepts chart page information
- calculates and displays results
- stores results

Data Entry

Data that can be scanned into the analyzer or entered via the keypad include:

- Operator ID
- Patient ID, Proficiency ID, or Simulator ID
- Cartridge Lot Number
- Control Lot Number
- Cal Ver Kit Lot Number
- Comment codes for patient and control results
- Chart Page
  - Sample Type
  - Patient Temperature - The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees centigrade. When a patient temperature is entered, blood gas results will be displayed at both 37°C and the patient's temperature.
  - FIO2
  - Free Fields: three fields, up to 9 characters each



See the Customization section in this manual for barcode formats recognized by the analyzer.

Storage of Results

The analyzer automatically stores up to 1,000 test records. A test record consists of:

- a set of results
- the date and time the test was performed
- the cartridge type
- all information entered by barcode scanner or keypad including:
  - Operator and Patient IDs
  - Lot numbers for controls and cartridges
  - Chart page data
  - Serial number of the Electronic Simulator
- the serial number of the analyzer
- the number of times the analyzer has been used
- the software and CLEW versions installed in the analyzer
- the name of the analyzer's customization profile

Quality Check Codes, which may appear during the test cycle indicating a problem with the sample, calibration, sensors, mechanical or electrical functions of the analyzer, are also stored.

The Analyzer Status option under the Administration Menu lists the number of stored records as "Total" and "Unsent" records. Test records are stored as "Unsent" until the analyzer uploads data to i-STAT/DE at which time the records are marked as sent. The analyzer can be customized to display a Memory Full prompt or to disable testing until data is transmitted to i-STAT/DE. Otherwise, the oldest data is overwritten when the memory becomes full. Stored test records can be reviewed through the Data Review option on the Administration Menu screen described later in this section.

LCD Display and Backlight

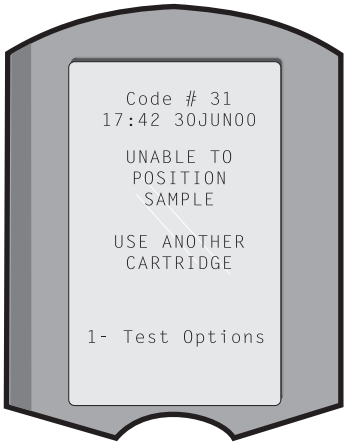
Test results, operator prompts and other messages are displayed on the analyzer's LCD Screen. The backlight for the display is turned on and off by pressing the 0 key for one second. The backlight will automatically turn off after ninety seconds and when the analyzer powers down or is turned off. The backlight cannot be turned on while data entry screens are displayed.

Audible Indicator

The analyzer will beep to indicate:

- whenever a key is pressed.
- a successful barcode entry.
- results are ready.
- a Quality Check Message is displayed.

The analyzer can be customized to disable beeping when a key is pressed or results or messages are displayed.



Time Out

The analyzer automatically turns off after a certain period of inactivity.

- **Results displayed:** Results are displayed for 2 minutes before the analyzer turns off provided that a mandatory Comment Code prompt is not displayed. This Inactivity Time Out default time can be increased using Customization.

  If a mandatory Comment Code prompt is displayed, the analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater. In the case of a missed required Comment Code, results will be stored and "_ _ _" will be entered as the Comment Code.

- **Prompting for mandatory data when results are ready for display:** The analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater, if there is no response to a mandatory data prompt. A mandatory data prompt is a prompt for information that must be entered before pending results are displayed.

  In the case of a missed mandatory data prompt, results will not be stored and the test record will state "Test Cancelled by Operator."

- **Waiting for insertion of cartridge:** After the prompt "Insert Cartridge" is displayed, the analyzer will wait 15 minutes for the operator to insert a cartridge unless the analyzer is in the Proficiency path, in which case the analyzer will wait 5 minutes. If a cartridge is not inserted, the analyzer will turn off. This timeout cannot be customized.

- **Other:** The analyzer will turn off after 2 minutes of inactivity (no keys pressed) in all other circumstances.

Keypad

There are 19 keys located directly below the display. When using the keypad to enter information, the number of dashes in the data entry line will indicate how many characters can be entered on the line. The dash where the next entry will be placed will flash.

Key	Function
SCAN	Activates the barcode scanner. Information that can be entered into the analyzer via the scanner includes: operator ID, patient ID, control and cartridge lot number, patient chart data and comment codes.
← →	Used to move the cursor on the Set Clock screen and to move up and down the alphabet when the ABC key is pressed. The → (right arrow) key is used as a page key to move from one screen to the next. When Patient ID Recall is enabled, the → key will recall the last patient ID when the analyzer is prompting for Patient ID. The ← (left arrow) key is used to backspace and clear keypad entries, and to move backward through the screens within a menu.
ABC	Used to enter alpha characters on data entry screens. When the ABC key is pressed the letter A is entered. The arrow keys are used to move up and down the alphabet. To enter a second letter, press the ABC key once to move to the next position and again to enter an A. To enter a number after a letter, press a numbered key. To erase a letter, press the ABC key to move to the next position, then use the ← key to backspace and clear the letter.
0 – 9	Used to enter digits on data entry screens and to select menu options and stored records.
•	Enters a decimal point or a comma separator according to the analyzer's Customization Profile.
	Used to turn the screen backlight on and off.
Enter 	Used to respond to a prompt to complete an action, such as entering an operator or patient ID via the keypad.
MENU	Used to return to the previous menu and switch between the Test and Administration Menus.
Print 	Used to print either directly to the portable printer or to the portable printer attached to a Downloader.
On/Off 	Turns the analyzer on or off. When the analyzer is on, the On/Off key must be pressed for a second to turn the analyzer off. This key is inactive when a test is in progress and when the analyzer is prompting for mandatory data.

i-STAT 1 Menu Tree There are two main menus: The Test Menu and the Administration Menu.

Test Menu

1- Last Result

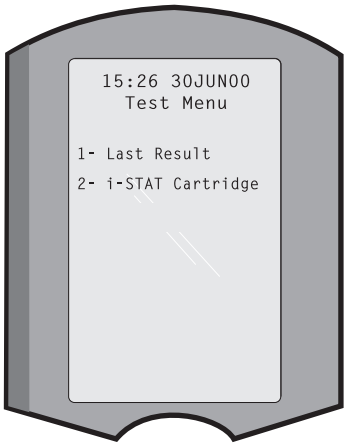
2- i-STAT Cartridge

Administration Menu

1. Analyzer Status	Temp Pressure Battery Uses Serial CLEW Release Version Custom Stored Records Total Unsent	
2- Data Review	1-Patient 2-Control 3-Proficiency 4-Cal Ver 5- Simulator 6- All 7- List	
3-Quality Tests	1-Control 2- Proficiency 3- Cal Ver 4- Simulator	
4- Customization	1-View	1- Analyzer 2- ID Entry 3- Patient Tests 4- QC Tests 5- Results
	2-Change	1- Analyzer 2- ID Entry 3- Patient Tests 4- QC Tests 5- Results 6- Password 7- Restore Factory Settings
5- Set Clock		
6- Transmit Data	1- Most Recent 2- This Month 3- Last Month 4- All 5- Unsent	
7-Utility	1- Send Software 2- Clear Memory 3- Receive Software	

TEST MENU

The Test Menu is displayed when the analyzer is turned on using the On/Off key.

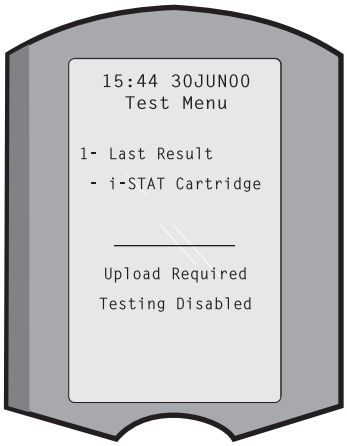


The options are:

- 1 - Last Result
- 2 - i-STAT Cartridge

Option 2 is used for testing patient samples.

Note: If the handheld is customized to disable testing under certain conditions, the disabled option will be listed without its number so that it cannot be selected.

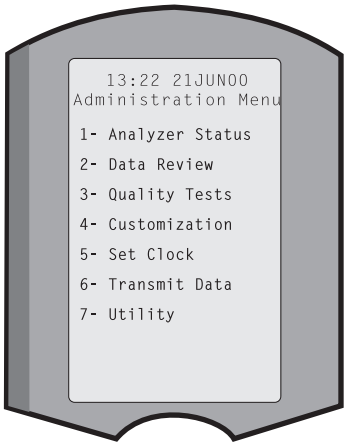


ADMINISTRATION MENU

Overview

The Administration Menu is accessed by pressing the Menu key from the Test Menu screen. The options are:

1 - Analyzer Status
2 - Data Review
3 - Quality Tests
4 - Customization
5 - Set Clock
6 - Transmit Data
7 - Utility



Analyzer Status

The Analyzer Status screen contains information about the condition or "status" of the analyzer. Fresh readings are made whenever this option is selected.

Temp Room temperature.

Pressure Barometric pressure.

Battery Battery voltage.

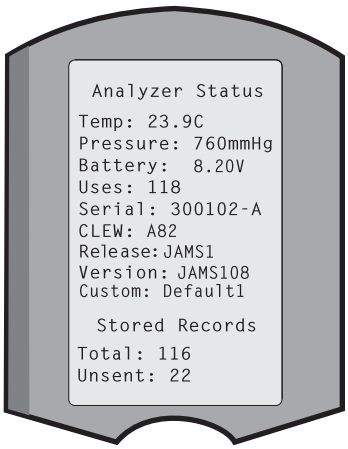
Uses Total number of cartridge and simulator test cycles, whether or not results reported.

Serial Serial number of the analyzer.

CLEW Version of standardization data installed in the analyzer.

Release The current release version of application software installed in the analyzer.

Version The full version of application software installed in the analyzer.



Custom Customization profile name.

Stored Records Total: The number of test records in the analyzer's memory. The maximum storage capacity is 1,000 test records, which include records with results and Quality Check Codes for patients and controls both liquid and electronic.

Unsent: The number of test records that have not been transmitted to i-STAT/DE.

Data Review

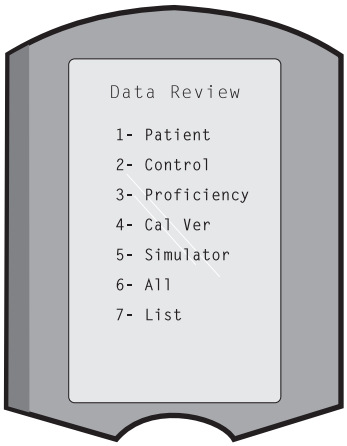
The Data Review function allows the operator to review stored results by the categories listed below. The number of test records stored is indicated at the bottom center of the screen as x/y where x is the record on the screen and y is the total number of stored records in the selected category. The 1 and 2 keys are used to scroll through the stored records as indicated on the bottom right and left of the screen. The most recent test record is always in the first position. The right arrow key is used to page through the screens of the displayed record.

1 - Patient The records for a patient are recalled by scanning or entering via the keypad the Patient ID. If no Patient ID is entered, all patient tests are recalled.

2 - Control

3 - Proficiency

4 - Cal Ver

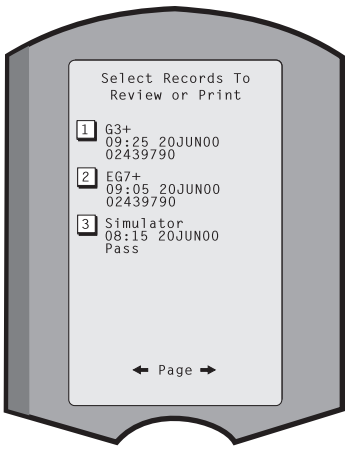


5 - Simulator All external and internal Electronic Simulator records.

6 - All All test records in the analyzer's memory.

7 - List

Records are listed with Cartridge type, date and time of test, patient ID, control lot, proficiency ID, or Cal Ver lot and test level as applicable. Any number of test records can be selected for viewing or printing using the number keys. Pressing the number key corresponding to a record selects a record; pressing the number key a second time deselects the record.



To view one or more records, select the records and press the Enter key. To print records, select the records and press the Print key.

Quality Tests

Non patient tests can be initiated from the Quality Tests menu. Options are:

1 - Control

2 - Proficiency (external quality control)

3 - Cal Ver (Calibration Verification for cartridges)

4 - Simulator (cartridge-reading function only)

When testing is initiated from one of these options, the handheld prompts the operator to scan or enter the Operator ID; the Control Lot Number, Proficiency ID, Cal Ver Kit Lot Number, or Simulator ID as applicable; and the Cartridge Lot Number.

When the Quality Tests option is used, results can be reviewed according to the corresponding options under the Data Review option.

Customization

Analyzers can be customized for site-specific testing characteristics and requirements. A complete list of customizable parameters and their default values can be found in the Customization section. An analyzer can be customized via the keypad or via i-STAT/DE. Items that cannot be customized via the analyzer's keypad are operator lists, test strip lists, reference and action ranges, sample types and order of items on the Chart page.

i-STAT/DE's Customization function can be used to create one customization profile for all analyzers or different profiles for different locations. When the Customization function is enabled, the profiles are transmitted to the analyzers when they are placed in a Downloader.

Caution: If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB: Automatically Adjust" or "CPB: Do Not Adjust" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional affect of pump fluid during cardiopulmonary bypass surgery. If an analyzer customized for the CVOR as "CPB: Automatically Adjust" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If an analyzer customized as "CPB: Do Not Adjust" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

It is recommended that only one method, i-STAT/DE or the keypad, be used to customize all analyzers within a site. If both methods are in use, and the Customization function is not disabled in i-STAT/DE, any changes made to the profile of an analyzer via the keypad will be overwritten the next time the analyzer is placed in the downloader.

The customization profile of an analyzer is identified in the Customization option under the Administration Menu on the analyzer. DEFAULT0 indicates that the analyzer has factory settings. When an analyzer has been customized via i-STAT/DE, the name assigned to the profile by i-STAT/DE is listed. If the default or i-STAT/DE profile is changed on the analyzer, the profile is listed as 00000000.

Viewing the Customization Profile

Select **4- Customization** from the Administration Menu, select **1- View** then select from the Customization Menu:

1 - Analyzer

2 - ID Entry

3 - Patient Tests

4 - QC Tests

5 - Results

Select a category to review. Use the ← and → keys to scroll through the preferences for each category and use the ← key to return to the Customization menu.

The Customization review option on the analyzer does not display the certified operator list. This item can be viewed in i-STAT/DE.

Note:

- Outside the USA, the following changes should be considered: language, unit set, date format and decimal separator.

1 - Analyzer

First page
Date Format
Sound
Auto-transmit
Memory Full
Batch Mode Timeout

Second page
Inactivity Timeout
Upload Schedule
Clock Password
Sync Clock
Patient Record Limit Access

Third page
Wireless (only available with the i-STAT wireless analyzer)

2 - ID Entry

1 – Operator ID

First page
Minimum Length
Maximum Length
Repeat ID
Manual Entry
Code I2of5

Second page
Code 128
EAN-8, EAN-13
Codabar
Code 93
Code 39

Third page
Code 39 Check Digit
Truncate First
Truncate Last
Operator List
Not Certified Action
Not In List Action
Fourth page
Warn User
Print ID

2 – Patient ID

First page
Minimum Length
Maximum Length
Repeat ID
ID Recall
Manual Entry

Second page
Code I2of5
Code 128
EAN-8, EAN-13
Codabar
Code 93
Third page
Code 39
Code 39 Check Digit
Truncate First
Truncate Last
Patient List
Not in List Action
Fourth page
Lockout Override
Confirmation Method
Print ID

3 - Patient Tests

First page
Cartridge Auto-chart
Cartridge Information
Cartridge Barcode
Cartridge Lot Number
Comment Code In Range

Second page
Comment Code Out of Range
Cart Sample Type
Result Output
Downloader Lockout
STATNotes

4 - QC Tests
1 – Simulator
Ext Simulator
Int Simulator
Int Simulator Schedule Option
2 – Cartridge QC
First page
Pass/Fail Method
Comment Code In Range
Comment Code Out of Range
Result Format
APOC fluid Lot Scan Only
Second page
eVAS Name
5 - Results
1 – ACT/Ref Ranges
2 – Display Ranges
3 – Units
4 – Options
First page
Decimal Separator
Test Selection
Hematocrit
Base Excess
ACT-C
Second page
ACT-K
Print Ref. Ranges

Changing the Profile

To customize via the handheld keypad, select **4- Customization** from the Administration Menu, then select **2- Change**. If the handheld has already been customized with a password, enter the password. If not, press the Enter key. (It is recommended that the Change function be password protected). Then make selections from the Customization menu. To change a setting, select the item by pressing the number key corresponding to the item, then select the setting. Use the → key to view all items. After all items have been set, turn the handheld off to save and activate the settings.

Note:

- Outside the USA, the following changes should be considered: language, unit set, date format and decimal separator.

1 - Analyzer

First page
Language
Date Format
Sound
Auto-transmit
Memory Full

Second page
Batch Mode Timeout
Inactivity Timeout
Upload Schedule
Clock Password
Sync Clock

Third page
Wireless (available with the i-STAT 1 wireless)

2 - ID Entry

1 – Operator ID

First page
Minimum Length
Maximum Length
Repeat ID
Manual Entry
Code I2of5

Second page
Code 128
EAN-8, EAN-13
Codabar
Code 93
Code 39

Third page
Code 39, Check Digit
Truncate First
Truncate Last
Print ID

2 – Patient ID

First page
Minimum Length
Maximum Length
Repeat ID
ID Recall
Manual Entry

Second page
Code I2of5
Code 128
EAN-8, EAN-13
Codabar
Code 93

Third page
Code 39
Code 39 Check Digit
Truncate First
Truncate Last

3 - Patient Tests

First page
Cartridge Auto-chart
Cartridge Information (functionality preset by analyzer firmware)
Cartridge Barcode (functionality preset by analyzer firmware)
Cartridge Lot Number (functionality preset by analyzer firmware)
Comment Code, In Range

Second page
Comment Code, Out of Range
Cart Sample Type
Result Output
Downloader Lockout

4 - QC Tests

1 – Simulator

Ext Simulator
Int Simulator
Int Simulator Schedule Option

2 – Cartridge QC
- Pass/Fail Method
- Comment Code In Range
- Comment Code Out of Range
- Result Format
- APOC Fluid Lot Scan Only

5 - Results

1 – Units and Ranges

2 – Options

- First page
- Decimal Separator
- Test Selection
- Hematocrit
- Base Excess
- ACT-C
- Second page
- ACT-K
- Print Ref. Ranges

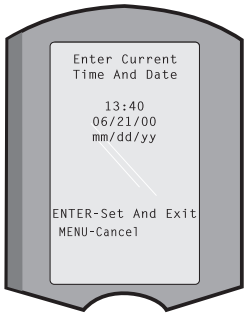
6 - Password

7 - Restore Factory Settings

Note: For additional procedures related to customization using the analyzer keypad, refer to *Procedures for Customization using the Analyzer Keypad* in Section 15 of this manual.

Set Clock

If the analyzer is customized with a password, the Set Clock function will be password protected. If a password has not been assigned, pressing the Enter key will display the time and date screen. Use the arrow keys to move the cursor to the digit to be changed. Use a number key to change the digit. Press Enter to accept the changes or Menu to cancel the changes. An invalid entry, such as 13 for a month, will not be accepted.



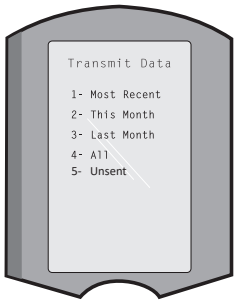
The format of the date on this screen can be customized using the i-STAT/DE customization function, as mm/dd/yy or dd/mm/yy. The analyzer recognizes years in which February has 29 days.

The analyzer can be customized using i-STAT/DE to synchronize or update the real time clock to the i-STAT/DE's clock at the time of each download. This option eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Saving Time. Otherwise, the clock must be manually changed for Daylight Savings Time changes.

Transmit Data

Unsent test records are automatically transmitted to i-STAT/DE when an analyzer is placed in a Downloader/Downloader/Recharger. In some cases it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:

1 – Most Recent
2 – This Month
3 – Last Month
4 – All
5 – Unsent



Most Recent is the result from the last cartridge tested.

The analyzer can be customized using i-STAT/DE to apply a date range limit to the Transmit All functions.

Auto-transmit is temporarily disabled when the Transmit Data option is selected to allow the user to control transmission of data.

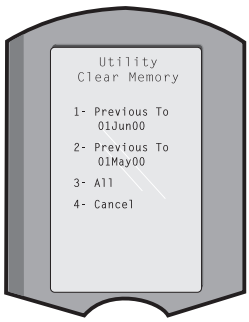
Utility

The Utility menu can be password protected using the Customization function on the analyzer or in i-STAT/DE.

1 – Send Software: Allows the analyzer to transmit software to another analyzer. See the Software Update section of this manual.

2 – Clear Memory: Erases results from the analyzer's memory. Options are:

- 1 – Previous to 01MMMYY (where MMMYY is current month and year, such as 01JUN00)
- 2 – Previous to 01mmmyy (where mmmyy is previous month and year, such as 01May00)
- 3 – All
- 4 – Cancel



3 – Receive Software: Allows users to remotely request a JAMS and CLEW update for the analyzer from i-STAT/DE. See section 17 (Updating Software) for full details.

LASER BARCODE SCANNER

Laser Barcode Scanner

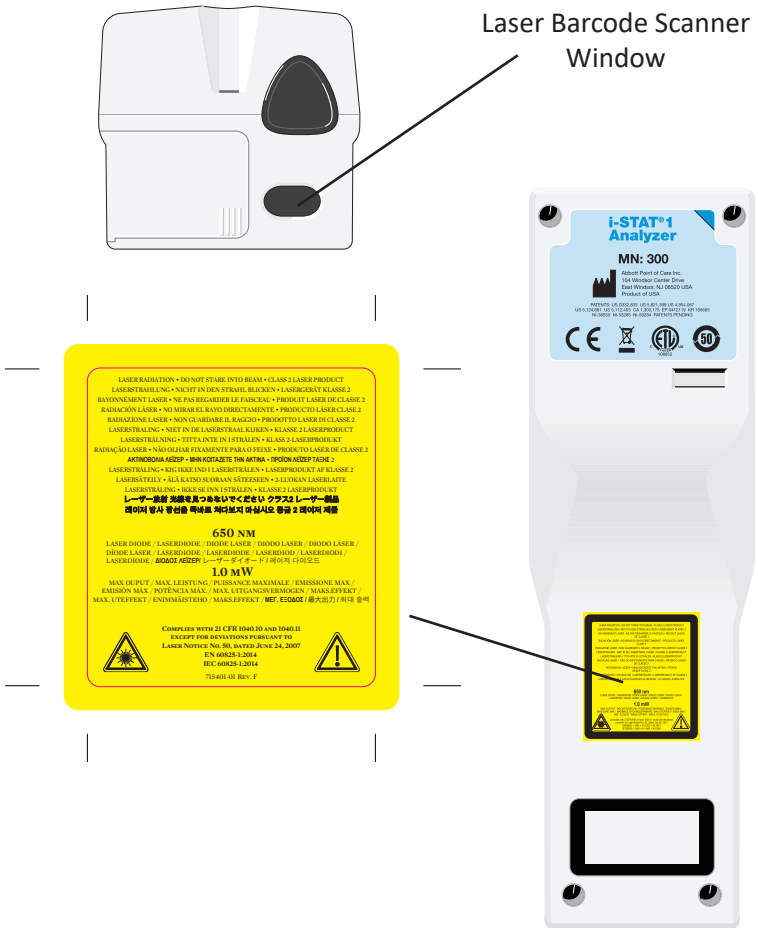
The barcode scanner is used to scan barcode information into the analyzer. Parameters that can be entered into the analyzer via the scanner include: operator and patient IDs, control and cartridge lot numbers, comment codes and patient chart data. The laser beam emerges from the recessed window on the front of the analyzer adjacent to the battery compartment. The laser beam automatically turns off after 3-4 seconds or after the barcode is successfully scanned.

Laser Specifications

The barcode scan engine is manufactured by Motorola Inc. or Opticon Inc. The scan engine contains a laser diode that emits laser radiation at a frequency of 650 nm. The scan engine outputs power (i.e., the power output of the engine if removed from this product) up to 1.9 mW in scanning mode. The scanner in this product only operates when the Scan key is pressed. The scan engine is intended to be used in a Class 2 device.

Warning Labels

Warning labels are shown below. The warning labels are located on the back or under-side of the analyzer, as shown. The location of the laser window from where the analyzer emits the laser beam is also shown below.



Caution

Do not open the analyzer. The analyzer may only be opened by factory authorized service personnel. **Class 2 laser radiation when open; DO NOT stare into the laser aperture or the laser beam, or point the laser beam at other persons.**

Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

Class 2 laser scanners use a low power, visible light diode. As with any bright light source, such as the sun, the user should avoid staring directly into the laser beam. Momentary exposure to a Class 2 laser is not known to be harmful.

Barcode Label Quality

To ensure that printed barcode labels are reliably read by i-STAT handhelds, the best available printing methods and settings should be used. However, as specified in the *Health Industry Bar Code (HIBC) Provider Applications Standard* (ANSI/HIBC 1.3-2010), the quality of printed labels should meet the minimum grade level of 1.5.

Ambient Lighting from LED Light Sources

The analyzer's barcode scanning functionality may experience interference when scanning barcodes under ambient light from an LED light source. This interference results in the analyzer being unable to scan a barcode at all (no beep acknowledgement). When scanning barcodes under ambient light from an LED light source, it is recommended that the barcode be shielded from the ambient light when attempting to scan the barcode.

Procedure

Before scanning, check to see what information is required by the displayed prompt. Hold the analyzer 3-9 inches (8 – 23 cm) from the barcode to be scanned. An angle of about 10 degrees from perpendicular is best. Hold the analyzer and place the object to be scanned on a flat surface or, place the analyzer on a flat surface and hold the object in front of the analyzer. Avoid accidentally scanning other nearby items. Avoid pointing the beam into anyone's eyes.

STEP	ACTION
1	Press and hold down the Scan key to start the barcode scanner. The analyzer emits a visible red beam.
2	Position the analyzer and barcode so the beam forms a red line that spans the entire barcode. Increasing distance between the barcode and analyzer lengthens the red line. The analyzer does not need to touch the barcode.
3	When the analyzer accepts the barcode, it will beep in acknowledgement and automatically turn off the beam. The beam will also turn off after 3-4 seconds.
4	View the data that was scanned by the analyzer and verify that it is correct.
5	Release the Scan key.
Note:	If the Scan key is released as soon as the beep is heard, the next prompt will be displayed and the information scanned will not be able to be viewed.

PROMPTS AND MESSAGES

Prompts

Either before or during the testing cycle, the analyzer will display prompts that require an operator action or keypad entry, such as “Enter Operator ID.” Prompts are described in the manual when used. Some prompts require input before results are displayed. Prompts for the following information are mandatory:

- Operator ID
- Patient ID
- Lot Numbers for Quality Tests
- Cartridge Lot Number

Startup Messages

When the On/Off key is pressed the analyzer may display one or more startup messages. A startup warning message indicates an action that should be taken in the near future to maintain the analyzer in working condition. If the analyzer is customized to disable testing under certain conditions, a startup lockout message indicates the action that must be taken before testing is re-enabled.

Quality Check Messages

If the analyzer detects a problem during power on, a Quality Check message will be displayed indicating the action that must be taken before testing can begin.

A Quality Check message will also be displayed and testing halted if the analyzer detects a problem during the test cycle.

Startup messages and Quality Check messages are described in the Troubleshooting section of this manual. “Upload Required, Testing Disabled” is an example of a startup lockout message, “Battery Low ” is an example of a startup warning message, and “Unable to Position Sample” is an example of a quality check failure during the testing cycle.

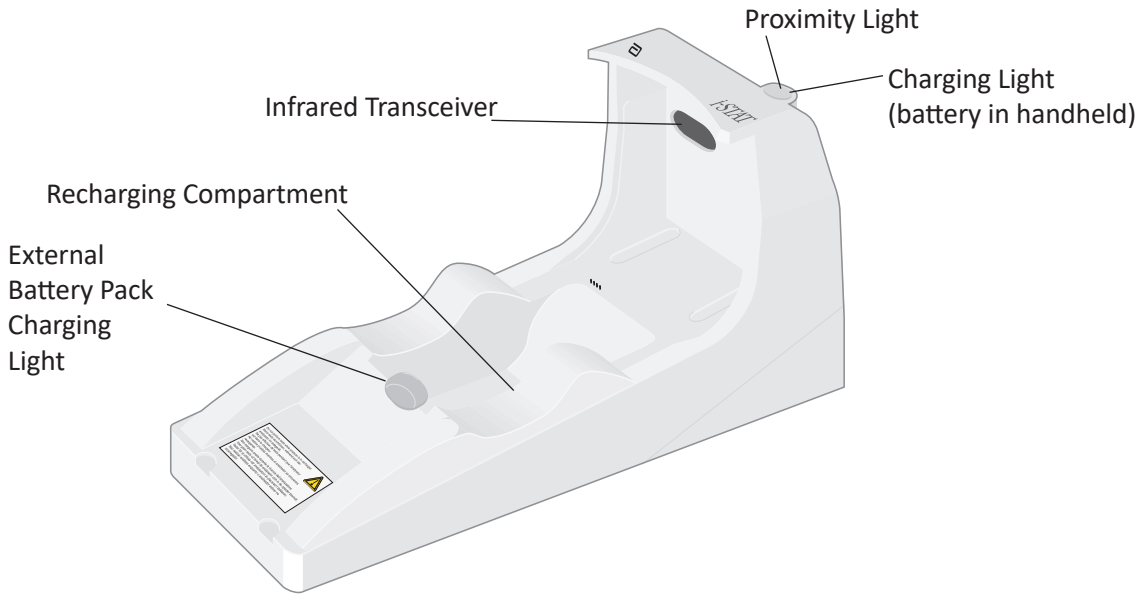
Note: The “Cartridge Locked” or “Simulator Locked” prompt is always displayed when a cartridge or Electronic Simulator is inserted into the analyzer. Any attempt to remove a cartridge or Electronic Simulator before this prompt is removed from the screen may cause damage to the analyzer.

i-STAT 1 DOWNLOADER/RECHARGER 6

OVERVIEW

This document contains the instructions for using the i-STAT 1 Downloader/Recharger (Model Number DRC-300), which is used to:

- transmit i-STAT 1 handheld test records via infrared signals using USB or network cabling to i-STAT/DE software.
- transmit data from i-STAT/DE to the i-STAT 1 handheld, via infrared signals.
- recharge the rechargeable battery installed in the i-STAT 1 handheld or a rechargeable battery installed in the recharging compartment of the DRC-300.



If you have questions regarding the information in this document, please contact your Support Services representative.

TABLE OF CONTENTS

IDENTIFICATION OF THE i-STAT 1 DOWNLOADER/RECHARGER

Previously, there were two separate versions of the i-STAT 1 Downloader/Recharger, one with serial connection capabilities to the Data Manager (DRS-300) and one with network connection capabilities to the Data Manager (DRN-300). To distinguish the DRC-300 from the previous DRS-300 and DRN-300 downloader/recharger versions, look at the Model Number (MN) label on the underside of the downloader/recharger. The i-STAT downloader/recharger will have an MN DRC-300 (Figure 1).

Figure 1

SPECIFICATIONS OF THE DRC-300

Specifications	
Size	4.12 in (10.4 cm) Wide 9.60 in (24.4 cm) Long 5.00 in (12.7 cm) High
Weight	1.2 lb. (0.55 kg)
Power	AC-DC power adapter Input 12Vdc
Operating Temperature	15 to 40 °C 59 to 104 °F
Storage Temperature	-20 to 50 °C -4 to 122 °F
Pollution Degree (Allowable ambient pollution level)	2
Installation Category (Allowable overvoltage specification)	2
Communication to Data Manager	USB, or Network
Communication Link to and from Handheld	Infrared Transceiver
<u>Indicator LEDs</u> Power Proximity Charge	 N/A Blue Red/Green
Configuration	By host computer

Note: This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements.

POWER SUPPLY SPECIFICATIONS

Specifications	
Input	100 – 240V 50 – 60Hz 1.1A
Output	12Vdc 3A max

DRC-300 INDICATOR LEDs

Handheld Battery LED (near top of the DRC-300)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging

Spare Battery (near middle of DRC-300)	
Off	No Rechargeable Battery
Green	Trickle Charging
Blink Green Then Off	Charging

POWER REQUIREMENTS

The DRC-300 requires one power outlet. The DRC-300 must be used with the AC power supply adapter supplied with the DRC-300. Using the Y-Splitter cable, the DRC-300 power supply can be used to supply power to the i-STAT Printer (Model Number PR-300), which reduces the number of power outlets required in the downloading and printing area.

CAUTIONS

- The DRC-300 is not intended for use in the patient environment (i.e., within 1.5 meters of the physical location of the patient).
- Users should not connect the DRC-300 to a medical electrical system.
- Do not place metal objects on or near the exposed gold charging contacts.
- Be sure to install all cables and power supplies so they do not post a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as a disconnect device for the DRC-300; therefore the socket outlet must be easily accessible and installed (or located) near the DRC-300.
- Use only the AC power supply provided with the DRC-300 to power the DRC-300.
- Only APOC provided printers may be connected to the DRC-300 printer port.
- A network cable and USB cable may NOT be connected to the DRC-300 at the same time.
- If using rechargeable batteries to power the handheld, use only rechargeable batteries and recharging equipment supplied by your APOC distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients.
- A falling handheld may cause injury. Always place the handheld and peripherals on a stable surface or in a location where it will not cause injury if dropped.
- Security Consideration: Disable TFTP (Trivial File Transfer Protocol) to prevent malicious downloads to the DRC and enhance security.

RUNNING CARTRIDGES IN A HANDHELD DOCKED IN THE DRC-300

All i-STAT cartridges may be run in handhelds that are docked in the DRC-300.

DRC-300 EFFECT ON AMBIENT OPERATING TEMPERATURE RANGE

The operating temperature for an i-STAT 1 handheld is 16 °C to 30 °C. The DRC-300 and Rechargeable Battery may raise the temperature of the i-STAT 1 handheld 2 °C to 3 °C relative to the ambient temperature if:

- The handheld is frequently lifted and replaced into the DRC-300
- Multiple cartridges are run in the handheld while it is in the DRC-300.

TRANSMITTING DATA FROM THE DRC-300 TO i-STAT/DE

1. Place handheld in the DRC-300 cradle. If properly aligned, the blue proximity light will turn on and a “Waiting to Send” message will be displayed on the handheld until communication is established with the i-STAT/DE software.
2. Once the handheld establishes communication with the i-STAT/DE software, a “Communication in Progress” message will then appear on the handheld display and the arrows will circle until the transmission is complete.

Note: Do not move handheld until the “Communication in Progress” message disappears.

TRANSMITTED INFORMATION

The following information is transmitted from the i-STAT 1 handheld with each test record:

- Date and time the test was performed.
- Operator and Patient ID or Quality Test fluid lot number.
- All information entered by the operator, e.g., lot numbers, sample types, and comment codes.
- Result(s).
- Serial number of the handheld.
- Uses count on the handheld.
- Application software full version in the handheld.
- CLEW standardization software in the handheld.

CHARGING BATTERIES BEFORE USE

Place a new rechargeable battery in the recharging compartment on the DRC-300 for forty hours. The battery will then be 100% charged and ready for use. A handheld with disposable batteries may be placed on the DRC-300 to download data until the rechargeable battery is ready.

RECHARGEABLE BATTERY LIFE

A fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge of the battery by either:

- Keeping the rechargeable battery in a handheld that is periodically placed on the DRC-300, or
- Storing the rechargeable battery separately in the external charging bay of the DRC-300.

CHARGING A RECHARGEABLE BATTERY WHILE INSTALLED IN THE HANDHELD

Placing a handheld containing the rechargeable battery in the DRC-300 will automatically initiate charging of the rechargeable battery. The indicator light on top of the DRC-300 will be:

- green (trickle charge),
- red (fast charge), or
- blinking red (fast charge pending).

Note: No damage will be caused if a handheld with disposable batteries installed is placed in the DRC-300.

CHARGING A RECHARGEABLE BATTERY IN THE EXTERNAL RECHARGE COMPARTMENT

Placing a rechargeable battery into the external recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

1. The battery pack has two labels: one for orientation in the handheld and one for orientation in the DRC-300. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2. To remove the battery after it is charged, back the pack out of the compartment.

CONFIGURING THE i-STAT 1 DRC FOR NETWORK OPERATION

This section includes procedures to configure the i-STAT 1 DRC-300 to transmit data between the i-STAT 1 handheld and the Data Manager PC running the i-STAT/DE software.

Successful programming of the i-STAT 1 DRC-300 for network operation, requires the completion of all the following steps in sequence.

Note 1: Example screenshots were captured with Windows® XP and are for example purposes only. The appearance of your screens may differ.

Note 2: To perform the following steps, it may be necessary to log into the Windows PC with **Administrator rights**.

Note 3: If the MAC address of the DRC-300 is required, it will be displayed on the Current Settings screen, shown below at Step 10 or the mac address information may be displayed as part of the serial number label.

Note 4: The Windows Operation System workflow instructions in this section are for guidance only. Instructions may differ based on specific operation system subtypes.

Increasing Number of Simultaneous Connections

It may be necessary to increase the number of simultaneous connections allowed by your data manager to 256, in order to maintain data transmissions to the i-STAT/DE software after installing a DRC-300 on your facility's network. This action does not apply when using a DRC-300 for USB serial communication. The following instructions will increase the number of simultaneous connections allowed by i-STAT/DE.

i-STAT/DE Customers

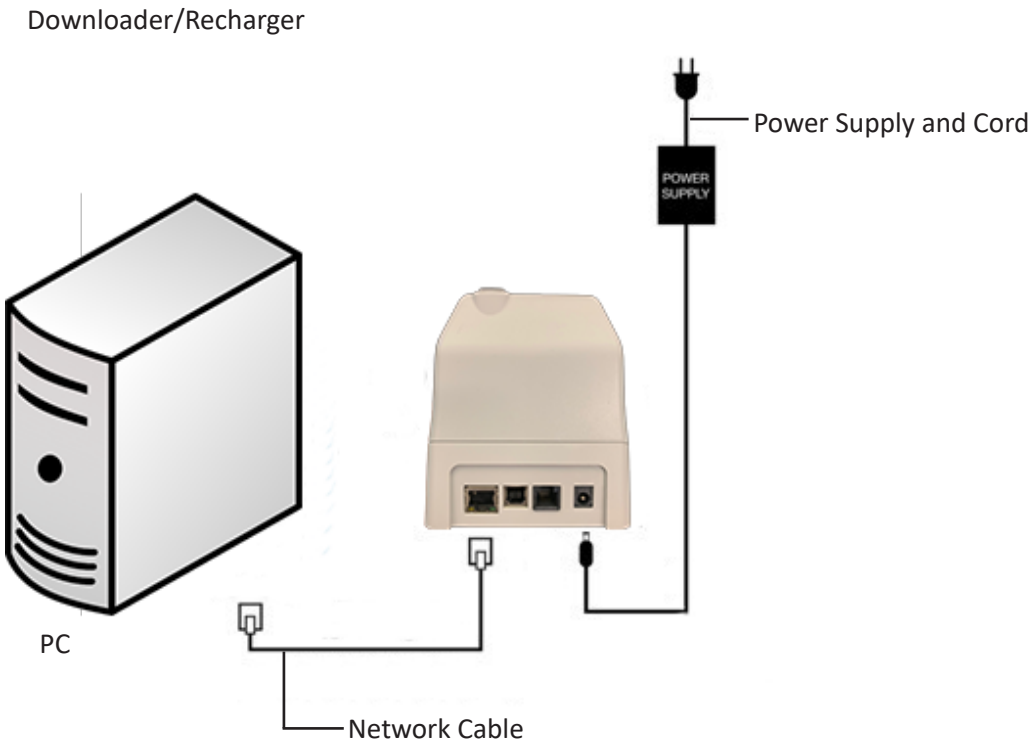
i-STAT/DE is used with Info HQ, RALS or a third-party Data Manager.
For more information on the i-STAT/DE software, refer to the *i-STAT/DE User Guide* located at www.globalpointofcare.abbott. Before beginning, consult with your IT department as Steps 1 thru 6 may require their support.

1. Identify the DE Server name. Use this information in step 2.
2. Using Microsoft Edge or Google Chrome, type http://< ServerName> / istatdesystem, where **<ServerName>** is the DE Server name identified in step 1, into the address line and then press **ENTER**
3. At the i-STAT/DE System–Main/Status page, select **View/Set Configuration.**
4. At the "**Maximum simultaneous connections**" selection box, increase the number of connections to **<256>**.
5. Click **OK**.
6. Reboot the i-STAT DE Server. i-STAT DE will then start with 256 connections.
7. You may now continue uploading as normal.

Procedure for Configuring the DRC-300

1. Preparation: For each DRC-300 to be configured, determine the
   - IP Address (on the same network as the Data Manager PC).
   - Gateway Address.
   - Subnet Mask.
   - IP Address of Data Manager.
2. **Do NOT connect the DRC-300 to a PC.** Depending on the Domain policies, network connectivity may be needed to access network TCP/IP settings.

Note 2.1: Use a standard network cable. A crossover cable is not required.



3. **Change the PC Network Configuration to detect the DRC-300.** On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Change Adapter Options**.

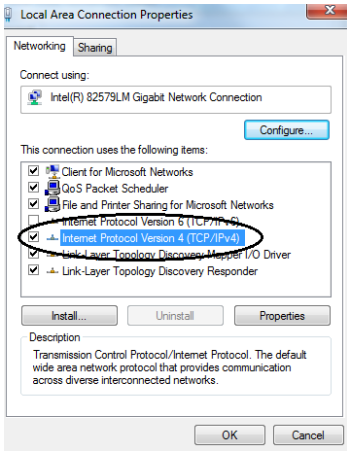
   Windows 10: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Change Adapter Options**.

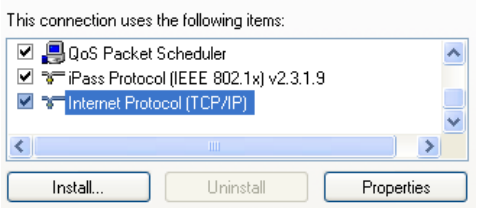
   Windows 11: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Advanced Network Settings** → **More Network Adapter Options.**

4. Right click on **"Ethernet"** and select **Properties**.

5. In ethernet properties, verify that only ONE Internet Protocol (TCP/IP) version is checked. If multiple versions are checked, uncheck all until there is only ONE checked. Select that TCP/IP, then click **Properties.**

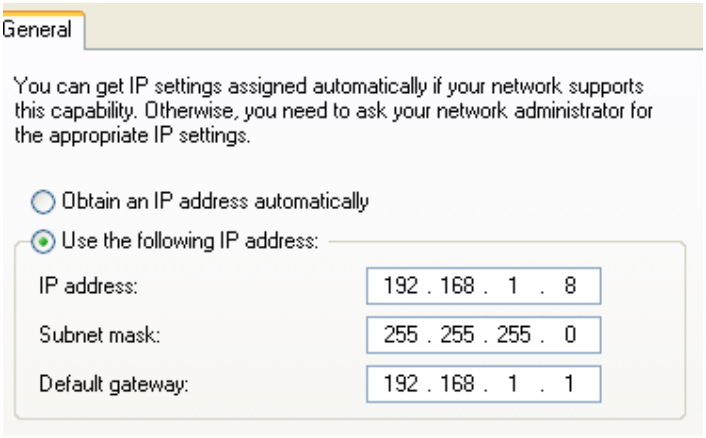
6. Record all Internet Protocol (TCP/IP) Properties for later use.





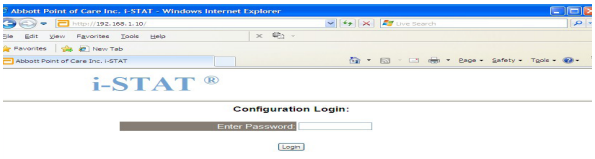
7. Select the **"Use the following IP Address"** radio button and input the following information:

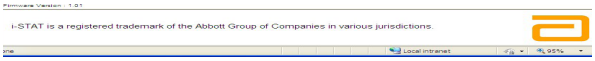
   - IP Address: 192.168.1.8
   - Subnet Mask: 255.255.255.0
   - Default Gateway: 192.168.1.1



8. Unplug network cable from the wall and plug it into the back of the DRC-300 and apply power to the DRC-300.

9. Using Microsoft Edge or Google Chrome or another browser, navigate to http://192.168.1.10. The Abbott Point of Care Inc. i-STAT login screen should appear.





Note 9.1: Internet connectivity is not required. Do not plug the computer into the facility's network.

Note 9.2: If the webpage does not appear, check the following:

1. Check to make sure the network cable is connected
2. Check to make sure that power has been applied to the DRC-300.
3. Check the proxy settings to make certain they are disabled.
4. Type "Internet Options" in the Windows search bar → **Connections** tab → LAN Settings**.**
5. Under **Proxy server**, deselect the **Use a proxy server for your LAN** check box, if selected.
6. Reset the DRC-300.

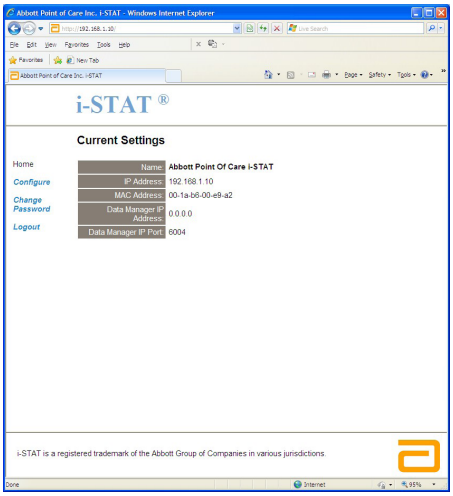
Note: 9.3: If the webpage does not appear, the password to the DRC-300 has been forgotten, or the DRC-300 IP address settings are unknown, it is possible to *temporarily** reset all DRC-300 settings back to factory default.

1. Connect the network cable between the PC and the DRC-300, if not already connected. Press and hold the factory reset button (shown below) on the underside of the DRC-300 while applying power, until the green light below the network connector on the back of the DRC-300 illuminates.

2. Once the DRC-300 has been reset, go to Step 9 of this section.

*The DRC-300 will stay at the factory default settings until power to the DRC-300 is disconnected, or until configuration is complete.

10. At the Configuration Login screen, enter your password and click **Login.** If a separate password has not been assigned, the default password is **"i-STAT"** and is case sensitive. Following a successful login, the home page will appear.



Note 10.1: Abbott Point of Care recommends changing the default password.

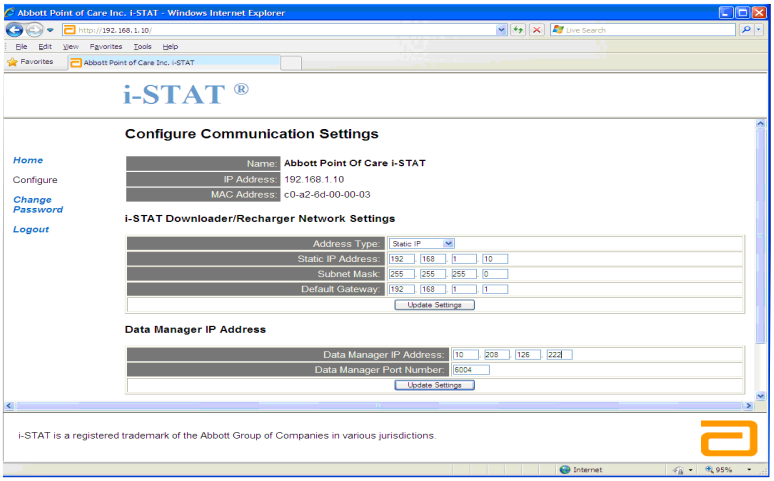
Note 10.2: The session will terminate after 15 minutes of inactivity, after which the user must re-enter their password.

Note 10.3: To change the configuration password, perform the following steps:

- Under “Current Settings”, click **Change Password.**
- Enter the existing password and the new password twice identically. Passwords must be 6 to 14 characters in length and contain only the letters a to z, A to Z, digits 0 to 9 and the characters ‘-‘ (hyphen) and ‘_’ (underscore).
- Click **Change Password.**

Note 10.4: If the new password is forgotten later, it can be temporarily reset to the factory default (i-STAT) by resetting the DRC-300 as described in Note 9.2. **However, please note that this will also reset the Downloader’s Internal settings.**

11. Under “Current Settings”, click **Configure.** The Configure Communication Settings page will appear.



12. Determine the following site-specific information for this DRC-300:
    - IP Address of the DRC-300.
    - Subnet Mask.
    - Default Gateway Address.
    - IP Address of the Data Manager.
    - Data Manager Port Number (Default is 6004).

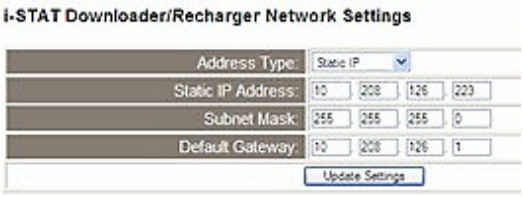
Note 12.1: You must configure the “Data Manager IP Address” first, followed by the “i-STAT Downloader/Recharger Network Settings” to maintain connection to the DRC-300 and complete configuration.

13. Scroll down to the “Data Manager IP Address” section, enter the Data Manager IP Address for this DRC-300 and the Data Manager Port Number (default is 6004), and click **Update Settings.**

Note 13.1: The “Data Manager IP Address” is the IP address of the PC where the i-STAT/DE software is installed.

14. Once back to the “Current Settings” screen, click **Configure.**

15. Scroll to the “i-STAT Downloader/Recharger Network Settings” section, and select the address type for assigning the IP Address of the DRC-300 being configured:



16. To configure for a **static IP address**, follow the instructions in **16A.** To configure for **DCHP**, follow **16B**.

Note 16.1: Static IP addresses are required when using handheld customization by Download Locations.

16A. If you want to configure the DRC-300 with a **static IP Address**, select **“Static IP”** from the **Address Type** drop down menu, and enter the assigned IP Address, Subnet Mask, and Default Gateway for the DRC-300 and click **Update Settings.**

16B. If you want to use the **DHCP** server, select **“DHCP”** from the **Address Type** drop down menu and click **Update Settings.**

After completion, the following screen will be displayed.

17. If additional DRC-300s require configuration, connect the next DRC-300 to the PC and apply power to the DRC-300 and repeat steps 9 through 16. Otherwise, proceed to step 18 to restore the PC's network configuration.

18. **Disconnect the Ethernet cable from the DRC-300 and connect to the network.**

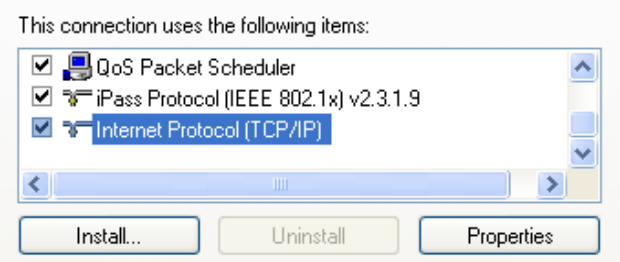
    Windows 10: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Change Adapter Options**.

    Windows 11: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Advanced Network Settings** → **More Network Adapter Options.**

19. Right click on **"Ethernet"** and select **"Properties"**.

20. Select the **"Internet Protocol (TCP/IP)"** connection and click the **"Properties"** button.

21. Restore Internet Protocol (TCP/IP) properties in the **General** tab to the network settings recorded in Step 6.



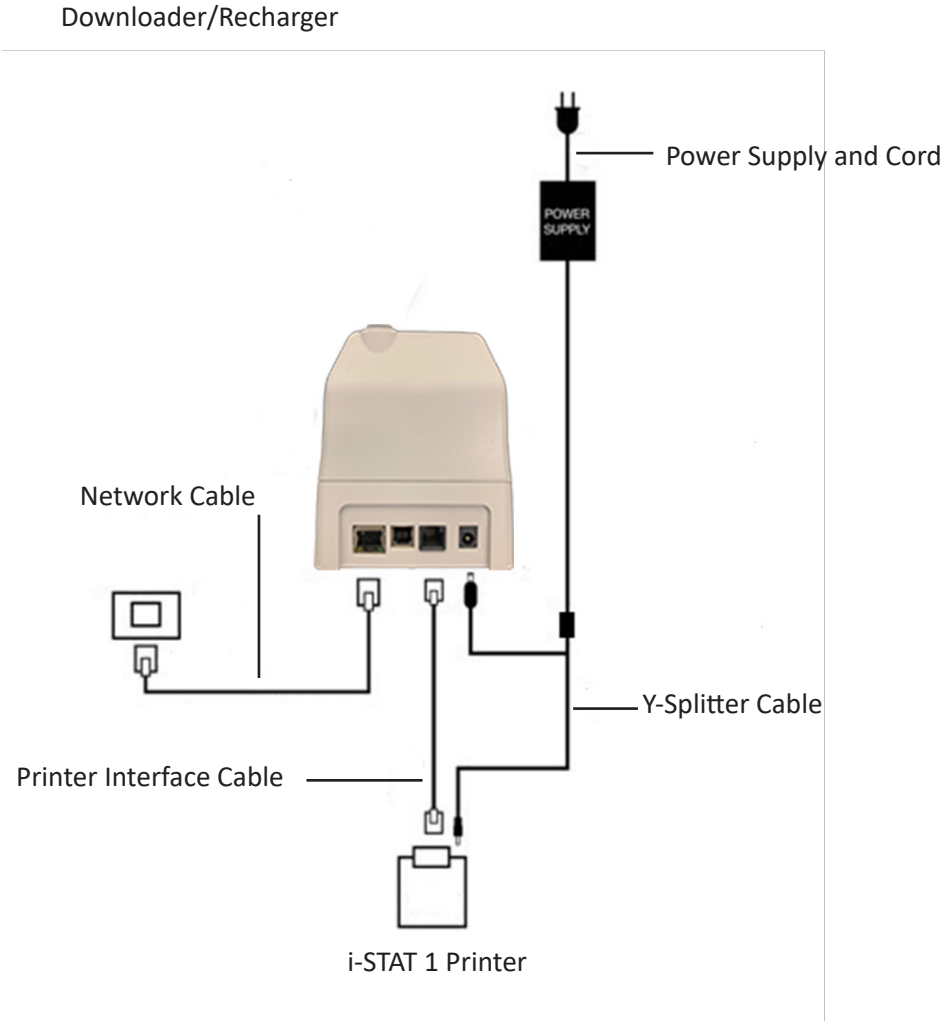
22. Check the additional internet protocol(s) previously unchecked in Step 5.

23. To connect the configured DRC-300 for transmission to the Data Manager, follow the instructions in the **Wiring the Downloader/Recharger** sections below.

CONNECTING AND WIRING THE DRC-300 FOR NETWORK COMMUNICATION

The following diagram shows how to connect the portable printer to the DRC-300 and the DRC-300 to the network for communication to the Data Manager. The parts are:

- Network Cable.
- Printer Interface Cable.
- Power Supply and Cord.
- Y-Splitter Cable (Optional).
- LAN Cable Filter (Abbott L/N 06F23-63) - For use only with the i-STAT 1 Wireless Analyzer containing Wireless Module FCC ID: P1405W (Firmware: 6.5.X.X/X.X)



Note: Once the DRC-300 has been configured and connected to the facility's network, you can view the DRC-300's configuration page by using Microsoft Edge or Google Chrome and navigating to the DRC-300's configured IP Address using any computer on the same node of the network.

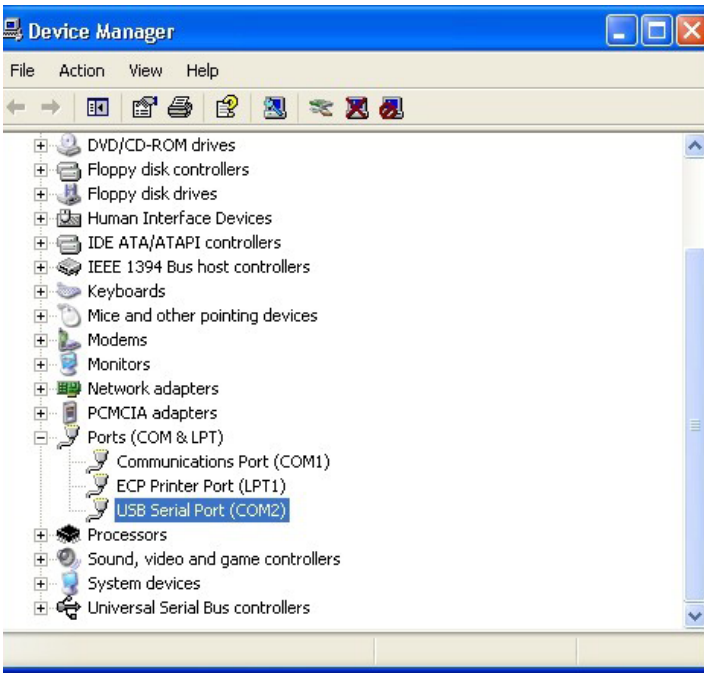
CONFIGURING THE i-STAT 1 DRC-300 FOR USB SERIAL OPERATION

To install the USB drivers for the DRC-300 for use with JammLite applications, it is necessary to be logged into a Windows PC with **Administrator rights**. Windows 10 and Windows 11 automatically installs drivers for devices that are connected to the PC.

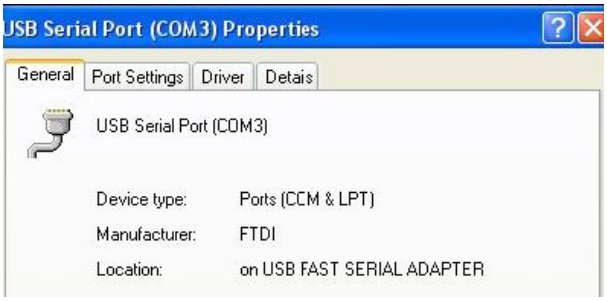
Note: i-STAT/DE does not support direct serial connection.

The following instructions require a PC connected to the Internet as well as Administrative rights to receive and install Windows Updates.

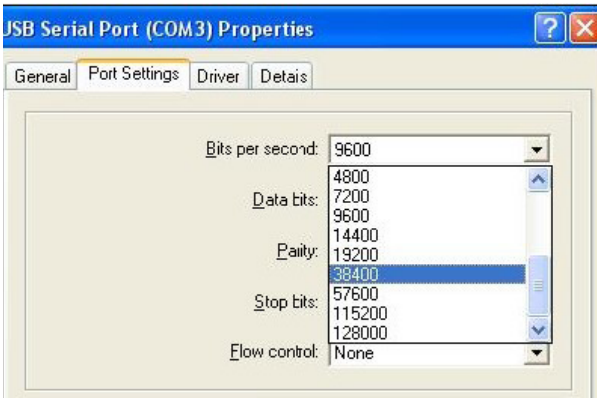
1. Apply power to the DRC-300. Connect the USB cable from the DRC-300 to the PC.
2. Wait while the "USB Serial Converter" driver (FT232R USB UART) installs. This may take a few minutes.
3. If the DRC-300 USB driver installs successfully, you may see a **"Device is Ready"** message appear on the PC Taskbar.
4. Click on the Windows Start icon, type in **"Device Manager"**, then select **"Device Manager"** to show a list of devices. Expand "Ports (COM & LPT)" to list all the COM Ports (as shown below). The newly installed DRC-300 port is named "USB Serial Port".



5. Right click on the **"USB Serial Port"** device entry and select **Properties.** A "USB Serial Port Properties" dialog box will open. Select the **Port Settings** tab.



6. Using the drop-down menu, set the **“Bits per second”** to 38400. Other dropdown menus should remain as the default.



7. Click the **“Advanced”** button. Using the drop-down menu, change the port number to the lowest available number. Determine availability by viewing the existing COM Ports in Device Manager. Click **OK** twice.

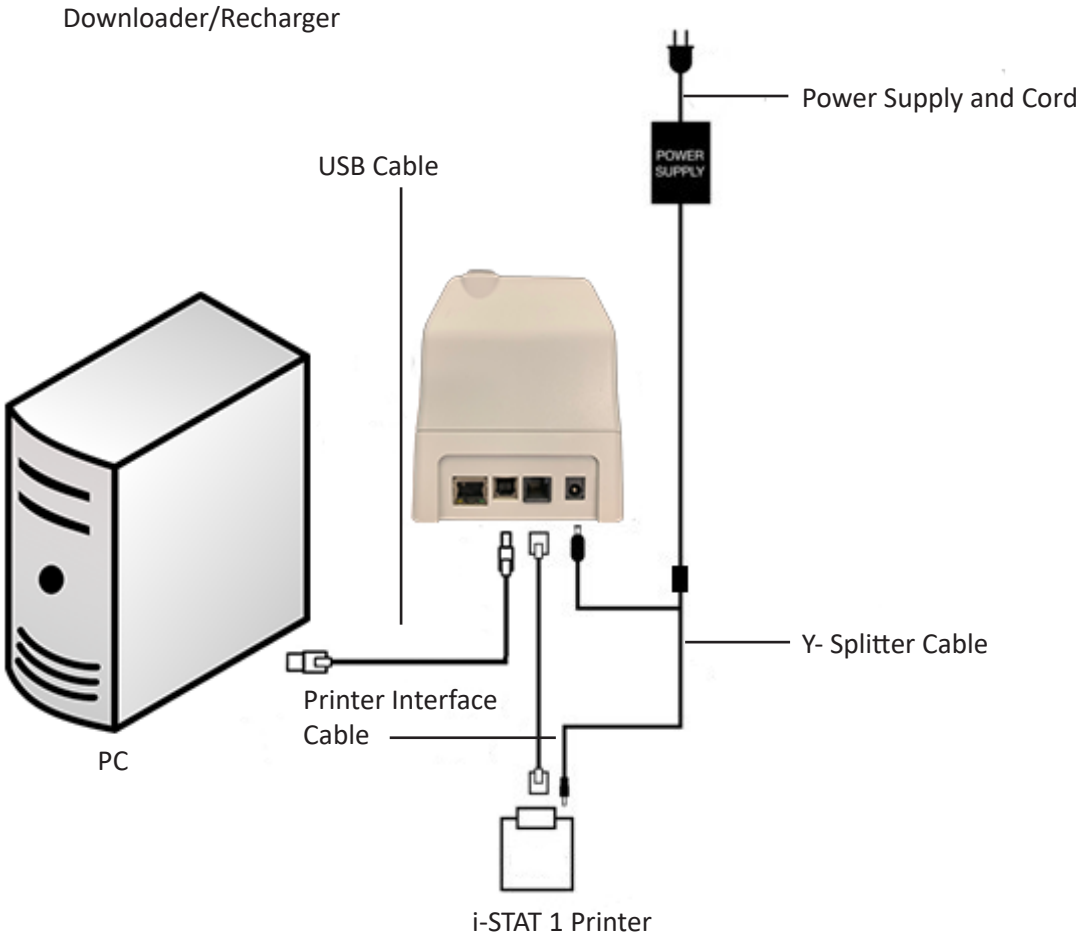
8. Close all **Control Panel** windows.

CONNECTING AND WIRING THE DRC-300 FOR USB SERIAL COMMUNICATION

Note: For successful data transmission to occur, the USB cable should first be connected between the DRC-300 and the PC prior to installing or opening the JammLite applications.

The following diagram shows how to connect the DRC-300 to the computer, where the JammLite application is installed via USB connection and how to connect the portable printer to the DRC-300 for communication. The parts are:

- USB Cable.
- Printer Interface Cable.
- Power Supply and Cord.
- Y-Splitter Cable (Optional).



TROUBLESHOOTING THE ANALYZER 11

Introduction

When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem and the next step to be taken will be displayed. The Code number may be helpful to a technical support representative if a problem cannot be resolved. If a problem cannot be resolved by the procedures described in this section, refer to Support Services information in the Troubleshooting section.

Note: Troubleshooting for results and quality tests are covered in those sections of this manual.

Note: The Technical Bulletin "Analyzer Coded Messages" included in this manual lists the Quality Check Code numbers as well as additional troubleshooting details

Caution

DO NOT OPEN THE ANALYZER, or any other i-STAT product, or perform any unauthorized procedures. Opening any i-STAT product, including analyzer, Electronic Simulator, printer or communication device, in attempt to repair it or resolve a problem may cause erroneous results. If the troubleshooting procedures found in this manual or requested by an i-STAT support specialist do not resolve the problem, the product must be returned to i-STAT for repair.

Information Needed

Have the following pertinent information available for review with the representative:

- Description of problem
- When problem first occurred and what has been done so far to resolve the problem
- Serial number of component(s)
- Displayed message and code number
- Frequency of problem
- Software version
- Environmental conditions
- Result of last Electronic Simulator test
- Battery voltage from Analyzer Status page

STARTUP MESSAGES

Overview

Whenever the analyzer is turned on using the On/Off key, the analyzer performs self-checks. If a condition that should be corrected in the near future, but that will not affect results is detected, a warning is displayed. The operator presses the 1 key to continue with testing. If the analyzer has been customized to disable testing under any of these conditions, the condition must be corrected and the analyzer turned off and back on before testing will be enabled.

Message on Display	Explanation	How to Respond
Electronic Simulator Test Required	Analyzer customized to alert the operator that a scheduled simulator test is due.	Insert the external Electronic Simulator at the earliest convenient time.
Stored Memory Low	Memory space for 50 unsent test records available before the “Stored Memory Full” message is displayed.	Place the analyzer in a Downloader.
Stored Memory Full	The analyzer is customized to alert the operator that the memory for unsent records is full. If the operator does not transmit the test records to the Point-of-Care Central Workstation, the analyzer will either block further testing or will overwrite oldest records depending on how the analyzer is customized.	Place the analyzer in a Downloader.
Upload Required	The analyzer is customized to alert the operator that a scheduled transmission of test records to the Central Data Station is due.	Place the analyzer in a Downloader.
Battery Low	Battery voltage has dropped to 7.4 volts. There is sufficient power to test a few more cartridges, the number depending mainly on the types of cartridges in use. Under this condition, a flashing battery icon will also appear on the result page, the Test Menu screen, and the Administration Menu screen.	Change the disposable lithium batteries or recharge the rechargeable battery.
Software Expires DDMMMYY	Message appears 15 days before the software expires.	Update the analyzer before the expiration date.

TEST CYCLE MESSAGES AND QUALITY CHECK CODES

Overview

If a problem is detected during a testing cycle, the cycle will be stopped and a message will identify the problem and indicate the next step to be taken. If the problem causes testing to be disabled, the problem must be corrected and the analyzer must be turned off and back on before testing will be enabled.

Environmental Conditions

The following messages usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the the offending condition is corrected.

Message on Display	Cause	Action
Date Invalid, Check Clock	The analyzer will not allow a date that precedes or exceeds the six months lifetime of the CLEW software.	Press **Menu** once to go to the Test Menu and then again to go to the Administration Menu. Press 5 to go to the Set Clock screen and correct the date.
Dead Batteries, Replace Batteries	There is insufficient battery power to complete a test cycle.	Change the disposable lithium batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status Page	The analyzer makes a temperature measurement before initiating a test cycle.	Check the temperature reading on the Analyzer Status screen (under the Administration Menu). If below the operating range, move to a warmer area. If above the operating range, move to a cooler area. Allow time for the analyzer to equilibrate to the new temperature. Check the Analyzer Status screen periodically.
Expired Software, Update Required	The software has become corrupt or has expired. The Product Update for each software update includes the expiration date.	Verify that the date in the analyzer is correct. Change the software if expired. Update the software again if not expired. If the message is displayed again, refer to Support Services information at the end of this section.
Analyzer Interrupted, Use Another Cartridge	The analyzer detected that the last cartridge run was not completed. This can happen if battery voltage is low, or if batteries were removed or making poor contact while a cartridge was still in the analyzer.	Check that the battery pack is inserted properly. Turn the analyzer on and check for the Low Battery message; replace or recharge if needed.

Error in Cartridge or Fluid Movement

The following conditions usually indicate an error condition relating in some way to the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Message on Display	Cause	Action
Cartridge Error Use Another Cartridge	These codes can all be caused by a variety of reasons including sample-related problems, users, cartridges or analyzers. Single or sporadic errors are most likely a sample-related problem (an interferent), an aberrant cartridge, or a user-induced situation such as touching cartridge contacts, pressing on center of cartridge or bubbles in the sample ("frothy" samples).	Use another cartridge. If the same code repeats more than twice, there may be an analyzer problem. Try another analyzer if available.
Cartridge Preburst Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • Cartridges may have been frozen. • Calibrant pack, if applicable, may have been burst by operator exerting too much pressure on the center of the cartridge.	Try another cartridge. Make sure that the cartridges were not frozen.
Unable to Position Sample Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to: • not closing the snap closure on the cartridge. • a clot in the sample preventing movement of the sample. • an aberrant cartridge.	Use another cartridge.
Sample Positioned Short of Fill Mark Use Another Cartridge	The cartridge was under-filled.	The sample must reach the fill mark. Try another cartridge.
Sample Positioned Beyond Fill Mark Use Another Cartridge	The cartridge was overfilled.	The sample was past the fill mark. Try another cartridge.

Error in Cartridge or Fluid Movement (continued)

Message on Display	Cause	Action
Insufficient Sample Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample.	Try another cartridge.
Cartridge Not Inserted Properly Reinsert Cartridge	The code indicates the cartridge or external Electronic Simulator may not be pushed in all the way.	Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Refer to Support Services.
Test Cancelled by Operator	No response to mandatory prompt before analyzer time out.	No action required. Training may be required if a particular operator has a high rate of cancelled tests.

Electrical or Mechanical Failures

The following conditions are related to electronic or mechanical failures in the analyzer.

Message on Display	Cause	Action
Analyzer Error Use Electronic Simulator	The analyzer usually recovers from these errors when the Electronic Simulator is run. This error can occur if the cartridge or Electronic Simulator was “angled” when inserted.	Push cartridge or Simulator straight through the cartridge port. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?). Try another Simulator. If the analyzer passes the Electronic Simulator check, continue to use it. If not, or if the Quality Check Code is recurrent, the analyzer may need repair.
Analyzer Error See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover.	Use an external Electronic Simulator twice and use a cartridge with sample or control solution. If an error condition occurs, refer to Support Services. If not, continue to use the analyzer.
Cartridge Type Not Recognized Use Another Cartridge	This error could be due to: • The analyzer could not identify the cartridge or simulator • Insertion of an Electronic Simulator when performing a cartridge test • Insertion of a cartridge when performing an Electronic Simulator test	Insert the correct cartridge or simulator for the test. If the message continues to occur after inserting the correct cartridge or simulator, contact i-STAT Technical Services or your Support Services Representative, as the analyzer may need repair.

Internal Simulator Failure	This error can occur if poor contact is made between the handheld pins and the contact pads of the cartridge.	**Lockout Enabled:** Immediately rerun the cartridge in the same handheld. If the simulator test fails again, rerun the cartridge is another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator. **Lockout Not Enabled:** Immediately rerun the cartridge in another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator.

No Display

Symptom	Possible Cause	Action
The display screen remains blank, either after a cartridge has been properly inserted or after the On/Off key has been pressed.	Batteries dead. Keypad not responding. Internal Start switch broken.	Change or recharge batteries. If this does not fix the problem, reinstall the current software in the analyzer. If the problem persists, the analyzer should be returned for repair. If using the analyzer recharging function of the i-STAT 1 Downloader/Recharger, ensure that the Downloader/Recharger is working as intended. If experiencing an issue, contact your support representative and use disposable batteries for continued use of the analyzer.

"Cartridge Locked" Not Removed

Symptom	Possible Cause	Action
Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the "Cartridge Locked" message will remain on the screen.	Dead batteries. Mechanical problem.	Wait until the analyzer turns off or turn the analyzer off. Then turn the analyzer on. If it can reset, it will release the cartridge and remove the "Cartridge Locked" message. If the cartridge is not released, change or recharge the battery and turn the analyzer on. If the "Cartridge Locked" message does not disappear, do not attempt to remove the cartridge and refer to Support Services.

Alert Messages

Message on Display	Possible Cause	Action
Invalid Cart. See Admin.	Analyte action or reference range limit, customized using i-STAT/DE, is outside the analyte measurement range for the cartridge being tested.	Ensure that the action and reference range limits for analyte(s) are customized to values within the analyzer measurement range for the cartridge(s) being tested. Refer to the *Customizing Reference and Action Ranges* section in the i-STAT/DE User Guide.
	Barcode scanned from a cartridge that is not supported.	Scan the barcode from a supported cartridge that contains the analytes needed to perform testing.
Lot Expired	Cartridge lot being tested is expired.	Check the expiration date and repeat the test using a non-expired cartridge lot.

Analyzer Coded Messages

From the time it powers up until the time it powers down, the i-STAT Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause", an "action" message, and a code.

The Cause Message:

This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".

The Action Message:

This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.

The Cause Code:

This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting your local support organization for further assistance. The codes are stored in the analyzer's memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 Analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.

Code Number	Cause/Action Message on Display	Explanation
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
4, 8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Expired Software Update Required /** See Manual	The standardization software (CLEW) has expired. Download a valid CLEW. The date on the real-time clock in the analyzer exceeds the expiration date of the CLEW. Check the date on the real-time clock and adjust as necessary.
13	**Invalid CLEW Update Required /** See Manual	The standardization software (CLEW) is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the Data Manager, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Download analyzer to the data manager. If code 14 reoccurs, contact your local support organization for further assistance.
15	**Barcode Does Not Match Cartridge Type**	Cartridge identified via barcode does not match inserted cartridge. The user should run another cartridge, being careful to scan the barcode from the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may an analyzer problem.

Code Number	Cause/Action Message on Display	Explanation
17-19	**No Clot Detected** / See Manual	During the coagulation test cycle, no clot was detected. Run another cartridge. If the code reappears, run the sample on an alternate methodology.
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact your local support organization.
26	**Cartridge Error** / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.

Code Number	Cause/Action Message on Display	Explanation
20, 27-29, 32, 33, 40, 41, 45, 87	**Cartridge Error** / Use Another Cartridge	These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.
42, 43	**Cartridge Error** / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.

Code Number	Cause/Action Message on Display	Explanation
35, 36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample** / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been “cocked” when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact your local support organization for further assistance.
23, 49	**Poor Contact Detected** / See Manual	Code 23 may be caused by poor contact between the analyzer contact pins and the cartridge sensor contact pads. Code 49 may be caused by poor contact between the analyzer contact pins and the cartridge identification chip contact pads. These quality check codes can sometimes be corrected by conditioning the analyzer contact pins using the ceramic conditioning cartridge. The conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact your local support organization for assistance.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact your local support organization for assistance. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact your local support organization for further assistance.
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact your local support organization for further assistance.
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
53, 55-57, 63, 65-68, 72-74, 82, 83-85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover. Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzer. If these codes persist, contact your local support organization for further assistance. Codes 83 and 84 indicate an underlying hardware failure in the i-STAT 1 Wireless Analyzer. If these codes persist, contact your local support organization for further assistance. The rate of quality check code 55 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature. Code 56 occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned. Code 86 can occur when an i-STAT Analyzer is stored in an i-STAT Downloader/Recharger without adequate ventilation. This problem can usually be resolved by moving the Downloader/Recharger to an open location which is free of obstructions and external heat sources such as heater vents or other electronic equipment. If this code persists, or if code 86 occurs with the i-STAT 1 Analyzer without a Downloader/Recharger, contact your local support organization for further assistance. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
69	**Cartridge Type Not Recognized** / Use Another Cartridge	This condition may be due to: • Analyzer could not identify the cartridge or simulator • Insertion of an Electronic Simulator when performing a cartridge test • Insertion of a cartridge when performing an Electronic Simulator test Insert the correct cartridge or simulator for the test. If the message continues to occur after inserting the correct cartridge or simulator, contact i-STAT Technical Services or your Support Services Representative, as the analyzer may need repair.

Codes in the range of 120 to 138 and 142 to 151 indicate a failure during an immuno cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144, 148	**Cartridge Error /** Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. However, this code can also be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact your local support organization for assistance. Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.
127	**Cartridge Error /** Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.

Code Number	Cause/Action Message on Display	Explanation
128, 131, 132, 134, 135 - 138	**Cartridge Error /** Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. **Discard** (always) 1 drop from delivery device to clear unseen bubbles. 2. **Hang** single drop slightly larger than round target well. 3. **Touch** 1 drop (only) to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of fill mark. 5. **Close** cartridge. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge for insertion. • Original thumbwell design: grasp the closure between your thumb and first finger. There is a recess for your thumb on the closure. • Large thumbwell cartridge: grasp the thumbwell between your thumb and first finger. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error /** Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error /** Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.

Code Number	Cause/Action Message on Display	Explanation
145	**Cartridge Error /** Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • cartridge leak. • failure to close the cartridge completely. Ensure that the closure is fully engaged before inserting the cartridge into the analyzer. • underfilled cartridge. Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the fill mark and then close the cartridge.
146	**Cartridge Error /** Use Another Cartridge	Overfilled cartridge. Repeat the test.
147	**Analyzer Error /** See Manual	In order to run an immunoassay cartridge, the i-STAT 1 Analyzer must: • bear the i immuno symbol
149 - 151	**Cartridge Error** / Use Another Cartridge	The analyzer detected an atypical data stream from the cartridge. Try another cartridge. For BNP, if code 150 is encountered when running a whole blood sample, it is recommended that the sample be centrifuged and the test be repeated with the resulting plasma.

A code in the range 165–175 indicates a failure during a coagulation cartridge cycle. In all cases, the cartridge is spent and another cartridge should be used.

Code Number	Cause/Action Message on Display	Explanation
165	**Cartridge Error /** Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: user is attempting to run a used cartridge or user did not allow the cartridge to equilibrate to room temperature before opening the cartridge pouch. (Individual cartridges should equilibrate for 5 minutes at room temperature or a box of cartridges for 1 hour before opening the cartridge pouch.)
166	**Cartridge Error /** Use Another Cartridge	The sample arrived at the sensors too late. This may indicate that the cartridge was underfilled or that there was a bubble in the sample. Try another cartridge.

Code Number	Cause/Action Message on Display	Explanation
167	**Cartridge Error /** Use Another Cartridge	The sample arrived at the sensors too early. This may indicate that the cartridge was overfilled. Try another cartridge.
170	**Cartridge Error /** Use Another Cartridge	A resistance value detected during the testing cycle was too high. Try another cartridge.
171-175	**Cartridge Error /** Use Another Cartridge	The analyzer detected a bubble on or near the sensors. Try another cartridge.

The following conditions are related to the Electronic Simulator

Code	Explanation	How to Respond
Numerical Code	See under Analyzer Coded Messages.	See under Analyzer Coded Messages.
L	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.	Contact your local support organization for further assistance.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Contact your local support organization for further assistance.
R, r	Resistance reading on conductometric channel out of limits.	Contact your local support organization for further assistance.
t	Thermal probe failure.	Contact your local support organization for further assistance.
B	Potentiometric channel out of limits.	Contact your local support organization for further assistance.

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact your local support organization for further assistance.

PROCEDURE FOR USING AN i-STAT CERAMIC CONDITIONING CARTRIDGE (CCC) FOR ANALYZER PIN CONDITIONING

Step Number	Explanation
1. Run an external Electronic Simulator.	If the analyzer is configured with the internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the internal Simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.
2. Run the CCC two times.	Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. 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.	The log is located on page 3 of the Technical Bulletin entitled “Instructions for Restoring Analyzers That Produce *** for Hematocrit and Quality Check Code 23”, which is shipped with the CCC. Updating the log allows the user to keep track of the number of pin conditioning cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use.
4. Return the analyzer to service.	

QUALITY CONTROL 12

OVERVIEW

The Manufacturer's Quality System Instructions (MQSI) represent information necessary to ensure quality results (accurate, precise, and reliable) based upon the specific characteristics of the i STAT System.

Three key technological characteristics of the i-STAT System underlie the MQSI:

1. The unit-use cartridges are stable when stored properly.
2. The system has been designed so that any user influence on the analytical process is detected and flagged.
3. The performance of the handheld reader is verified by a combination of automated quality checks and procedural controls during each test event, supplemented by electronic quality control.

MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS

Perform Daily Quality Control with Electronic Simulator

Check each Handheld reader with the Electronic Simulator, using either the internal or external simulator, once on each day of use.

Check New or Replacement Handheld Readers with the Electronic Simulator

Use the Electronic Simulator, internal or external, to verify operation of a new or replacement handheld reader before use.

The internal Electronic Simulator will automatically activate the first time a new or replacement handheld is used and after every 24 hours of use thereafter. The handheld can be customized to remind the operator to perform the simulator test (i-STAT 1 Analyzer) or automatically run the simulator (i-STAT 1 Analyzer) more frequently as required or desired.

Check Temperature Strip for a New Shipment of Cartridges

Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.

Ensure Proper Cartridge Storage

- Ensure that refrigerator storage conditions for stored cartridges are between 2–8 °C (35–46 °F).
- Ensure that cartridges are not exposed to temperatures exceeding 30 °C (86 °F).
- Ensure that cartridges are not used after the expiration date printed on the individual package and box.
- Ensure that cartridges are not outside the refrigerator for longer than the time frame indicated on the cartridge box.
- Ensure that a cartridge is used immediately after it is removed from its package.
- Ensure that a cartridge taken from refrigerated storage is allowed to stand in its package at room temperature for 5 minutes before use, or that a box of cartridges stands at room temperature for one hour before use.

Ensure Thermal Probe Check is Performed

Ensure the thermal probe check is performed every 6 months on each handheld reader. This check may be performed in conjunction with the analyzer software updates. See *Thermal Probe Check—Procedure for Handheld* in this section.

Train Staff

Avoidance of Pre- and Post-analytical Errors:
Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).

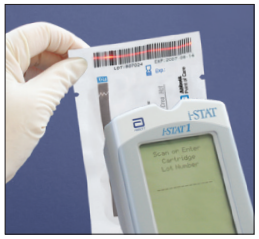
Update Software

1. Update the i-STAT System software as provided by Abbott Point of Care (APOC).
2. Check the handheld with the external Electronic Simulator after software updates.
3. Verify thermal probe reading.

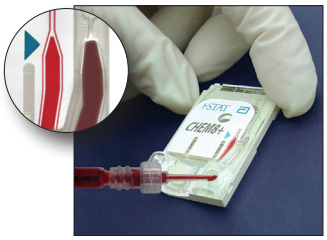
PROCEDURE FOR TESTING CONTROLS

Prerequisites

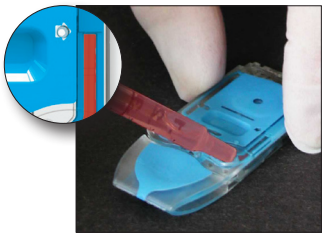
- Ensure that quality control testing is performed from the Quality Test Menu for the purpose of documentation and review.
- Scan the cartridge barcode before opening cartridge pouch.
- Ensure controls, cartridges, and handhelds are at the same room temperature.



1. Press ⏻ to turn on handheld.
2. Press MENU → 3 → 1 for Control Samples.
3. Follow handheld prompts.
4. Scan the lot number on the cartridge pouch.
   - Position barcode 3–9 inches (8–23 cm) from scanner window on the handheld.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The handheld will beep when it reads the barcode successfully.



5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.



6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT, INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing.
7. Review results.

TROUBLESHOOTING OUT-OF-RANGE CONTROL OR CALIBRATION VERIFICATION RESULTS ON CARTRIDGES

Troubleshooting

Verify that the following conditions are met and then repeat the test:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly–see the directions for use.
- The analyzer being used passes the Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or cartridges. If the results are still out of range, refer to Support Services information in the Technical Bulletins section.

PERFORMING ELECTRONIC SIMULATOR TEST

Procedure for Internal Electronic Simulator

The internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays "ELECTRONIC SIMULATOR FAIL." If the analyzer is customized to block testing when it fails the simulator test, the same cartridge can be re-inserted immediately after the FAIL message is displayed. If the analyzer fails the simulator test again, see the Troubleshooting section that follows the Procedure. If less than three minutes has elapsed, the cartridge can be inserted into another analyzer. If the analyzer is not customized to block testing after a failed simulator test, the internal simulator test will not repeat until the programmed interval has elapsed.

PROCEDURE FOR EXTERNAL ELECTRONIC SIMULATOR

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key to turn the analyzer on.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests Menu	Press **4** to select Simulator.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID and press **Enter**.	If enabled, the analyzer will validate ID and/or ask for the ID to be repeated.
Scan or Enter Simulator ID	Press **Scan** to scan the Simulator ID or manually enter the Simulator ID and press **Enter**.	The simulator serial number can be used as an ID. If the simulator does not have a barcode, one can be made on-site and affixed to the simulator (not near contact pads).
INSERT SIMULATOR	Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.	Inserting the simulator at an angle may cause a Quality Check message to be displayed.
Contacting Simulator Please wait… Time to Results bar Simulator Locked	Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.	
Result screen: ID of Simulator Date and Time ELECTRONIC SIMULATOR PASS or FAIL 1- Test Options	Test Options Simulator 1- Next Simulator 2- Same Simulator 3- History	If **PASS** is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case. If **FAIL** is displayed, see the Troubleshooting in this section of the manual.

Caution The analyzer will continue to initialize test cycles when the analyzer is customized to warn, but not block testing when a scheduled external Electronic Simulator test is missed, when a FAIL result for the external Electronic Simulator test is ignored, and when the analyzer fails the internal Electronic Simulator test and the lockout feature is not enabled.

TROUBLESHOOTING FAILED ELECTRONIC SIMULATOR TEST

Introduction With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.

External Simulator Run the test again or try another simulator, as it is possible that the test will pass on a second try. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped.

Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the electronic test and the failure code "L" will be displayed. Allow the analyzer to sit for half an hour to allow the moisture to evaporate, then insert the Electronic Simulator again. If the analyzer passes the second electronic test, continue using it. If the analyzer fails the second time, record the letter or Quality Check Code displayed with the FAIL message and refer to Support Services information in the Troubleshooting section.

Internal Simulator The cartridge or an external Electronic Simulator should be rerun to confirm the failure. The analyzer's connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can fail if the contact pads have been contaminated in some way.

Lockout Enabled: Rerun the cartridge in the same analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. If the cartridge fails in more than one analyzer, use another cartridge. When Lockout is enabled, the analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.

Lockout Not Enabled: Rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When Lockout is not enabled, the analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed. Verify the analyzer using an external Electronic Simulator.

THERMAL PROBE CHECK

Overview

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature ± 0.15°C.

A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, APOC recommends that the thermal probe check be verified every six months.

Procedure for Handheld

Check the thermal probes on the i-STAT 1 Analyzer as follows:

1. If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3 °C (5 °F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. Insert the simulator into the analyzer.
3. When results are displayed, press the period key to view the difference between the thermal probes.
4. Interpretation of the thermal probe check value:
   - Acceptable: a value from -0.1 to +0.1, inclusive.
   - Repeat the procedure if a FAIL message with a “t” Quality Check Code or a value less than -0.1 or greater than 0.1 is displayed.
   - Repeat the procedure if “--.--” is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.
   - Contact your Technical Support representative if the **repeat** thermal check value is greater than 0.1 or less than -0.1 or if a Quality Check Code is displayed.

Documentation of Results

The results of the thermal probe check are stored in a data manager. If a data manager is not available, use the form included in this section of the manual to record the results.

Central Data Station Customers

To view results with CDS:

1. Click on Data Viewer, then on Simulator.
2. Look under the Probe Delta column.
3. Check that there is a value from -0.1 to +0.1, inclusive, listed for each analyzer in use in the last 30 days.
4. A value of “--.--" indicates that the conditions to complete the thermal probe check were not met—repeat the procedure.

PREPARATION OF CONTROLS

Visit www.globalpointofcare.abbott for instructions for use (IFU) related to products not listed in this section.

I-STAT CONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Control Solutions

Aqueous assayed control fluids are available for verifying the integrity of newly received cartridges. i-STAT Level 1, 2 and 3 Controls are formulated at three clinically relevant levels with known pH and with known concentrations of:

Sodium	***P***CO_2	Glucose
Potassium	***P***O_2	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box of 10 ampules. Control solutions are contained in 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	108	127	141	169	187
K (mmol/L)	2.3	3.1	4.0	6.8	8.5
Cl (mmol/L)	71	85	100	122	133
Glu (mmol/L)	1.8	2.5	7.3	17	35
Urea (mmol/L)	44.6	18	4	2.7	1.8
iCa (mmol/L)	2.5	1.6	1.3	0.8	0.2
Lac (mmol/L)	19.5	8.4	2.3	1	0.6
Crea (µmol/L)	1486	386	155	46	17
PO_2 (mmHg)	43	61	100	140	400
PCO_2 (mmHg)	95	66	30	22	18
H^+ (pH)	6.81	7.15	7.41	7.60	7.95

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and analyzer should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and 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, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

Before Use

i-STAT control solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.

Procedure

STEP	ACTION
1	Access the i-STAT Cartridge Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results. **Note**: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringe with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.globalpointofcare.abbott.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the target value table matches the software revision in the analyzer.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls.

Target Values are specific to the i-STAT System. Results obtained from these aqueous controls with other methods may differ due to sample matrix effects.

Correction of PO_2 for Barometric Pressure

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of red blood cells containing hemoglobin which binds oxygen molecules. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration which occurs in the cartridges at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values in the value assignment sheet included with each box of i-STAT controls.

Equations:

For PO_2 values below 150 mmHg:

PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

For PO_2 value 150 mmHg and above:

PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

I-STAT TRICONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Control Solutions

Aqueous-based control fluids are available for verifying the integrity of newly received cartridges. i-STAT TriControls Level 1, 2 and 3 are formulated at three clinically relevant levels with defined pH and hematocrit values and with known concentrations of:

Sodium	***P***CO_2	Glucose
Potassium	***P***O_2	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box containing 10 individual 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
PCO_2 (mmHg)	96	65	40	26	12
PO_2 (mmHg)	40	63	120	163	500
H^+ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 °C (35-46 °F) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 °C; 64-86 °F) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and handhelds should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not ***P***O_2 is to be measured. If ***P***O_2 is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If ***P***O_2 is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

STEP	ACTION
1	Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into a handheld – it is important not to expose the solution to room air since this will alter the results. **Note:** Since aqueous based solutions such as control materials lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes (fresh 1 cc or 3 cc sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous control solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Ensure that the lot number printed on the Value Assignment Sheet matches the lot number on the label of the ampule and that the software full version above the target value table matches the software version in the handheld.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual.

Target Values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Correction of *P*O_2 for Barometric Pressure

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. ***P***O_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed ***P***O_2 values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Equations:

For ***P***O_2 values below 150 mmHg:

PO_2 corrected = ***P***O_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For ***P***O_2 values 150 mmHg and above:

PO_2 corrected = ***P***O_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

Precision

The additive used in the aqueous-based TriControls to simulate the effect of hematocrit in blood samples results in reduced precision in repeat measurement of electrolytes relative to the precision obtained when assaying with either standard control/calibration verification materials or whole blood. The imprecision is related to the concentration of additive. The increase is pronounced at higher levels of indicated hematocrit.

Internal testing of non-Abbott aqueous control materials on the i-STAT System which have hematocrit, blood gas and chemistry functionalities exhibit similar precision to that observed for TriControls.

The acceptance limits which have been established for these control solutions are wider than analogous limits established for the current i-STAT control and calibration verification solutions, reflecting the precision effect highlighted above.

The situation where better precision will be obtained in clinical samples than in control solutions is not unusual. A similar effect is observed in control solutions for the i-STAT measurement of ***P***O_2.

The precision data shown below, including results for TriControls solutions, were collected during studies at an Abbott Point of Care facility. SD and %CV are typical of performance; current Value Assignment Sheets should be referenced for applicable mean data. Refer to the value assignment sheets posted on the APOC website at www.globalpointofcare.abbott.

Analyte	Level 1			Level 3		
	Mean	**SD**	**%CV**	**Mean**	**SD**	**%CV**
Na (mmol/L)	120	0.46	0.4%	158	1.39	0.9%
K (mmol/L)	2.85	0.038	1.3%	6.15	0.058	0.9%
Cl (mmol/L)	72.9	0.63	0.9%	113.6	2.30	2.0%
Glu (mg/dL)	289	2.4	0.8%	41.8	0.68	1.6%
Urea (mg/dL)	69.7	0.94	1.3%	5.5	0.45	8.2%
iCa (mmol/L)	0.84	0.012	1.4%	1.51	0.030	2.0%
Lac (mmol/L)	6.35	0.08	1.3%	0.810	0.03	3.7%
Crea (mg/dL)	4.16	0.123	3.0%	0.50	0.046	9.1%
***P*CO_2 (mmHg)**	63.8	1.57	2.5%	19.6	0.40	2.0%
***P*O_2 (mmHg)**	65.1	3.12	4.8%	146.5	6.00	4.1%
H^+ (pH)	7.165	0.005	0.07%	7.674	0.003	0.04%
Hct (%)	17.6	0.40	2.3%	57.1	1.00	1.75%
TCO_2 (mmol/L)	17.4	0.62	3.6%	30.4	0.70	2.3%

ACT CONTROLS

Intended Use

The i-STAT ACT Control Level 1 and ACT Control Level 2 are intended for use to verify the integrity of newly received i-STAT ACT cartridges. The controls produce clotting times expected for moderate and high level heparinization to indicate that the cartridges are functioning properly.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage

i-STAT ACT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature (18 - 30 °C or 64 - 86 °F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.globalpointofcare.abbott. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

PT/INR CONTROLS

Intended Use

The i-STAT PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used to verify the integrity of newly received PT/INR cartridges (List Number 03P89-24).

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage

i-STAT PT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature 18-30 °C (64-86 °F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT/INR cartridge.
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional PT/INR cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.globalpointofcare.abbott. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

I-STAT CTNI, BNP, AND CK-MB CONTROLS

Intended Use

i-STAT cTnI, BNP, and CK-MB Control Levels 1, 2, and 3 are intended for use as an assayed quality control material which can be used to verify the integrity of newly received i-STAT cTnI, BNP, and CK-MB cartridges.

Product Description

6 bottles, 1 mL each

Notes:

- These controls contain ≤ 0.09% sodium azide as a preservative.
- These controls do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Control material is a ready-to-use liquid control requiring no reconstitution or frozen storage. The controls are stable until the expiration date on the vial label when stored unopened at 2-8 °C (35-46 °F). Once opened, these controls are stable for 30 days when stored tightly capped at 2-8 °C (35-46 °F).

Procedure

1. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.

3. Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8 °C (35-46 °F).
4. Seal the cartridge and immediately insert it into the i-STAT 1 handheld.

Control Target Values and Ranges

See Value Assignment Sheets posted on the APOC website at www.globalpointofcare.abbott. The Value Assignment Sheet displays target values and ranges expected when cartridges, controls, and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the handheld.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

See Troubleshooting section below for procedures to follow if control results are out of range.

I-STAT TOTAL B-HCG CONTROLS

Intended Use

The i-STAT Total β-hCG Controls are used to monitor performance of the i-STAT Total β-hCG test.

Product Description

6 Bottles (1 mL each) of i-STAT control fluid prepared in human serum.

Note: These controls contain < 0.09% sodium azide as a preservative.

Warnings and Precautions

Handle the products using the same safety precautions used when handling any potentially infectious material. The human serum used in the preparation of these products has been tested by FDA approved test methods and found negative/non-reactive for HBsAg, anti-HIV 1 /2, anti-HCV, and HIV 1 Ag. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Do not use control material if it is received uncapped.

Bacterial contamination of the control material can cause an increase in turbidity. Do not use the materials if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

i-STAT Total β-hCG control materials are ready-to-use liquids requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2–8 °C. Once opened, these control fluids are stable for 30 days when stored tightly capped at 2–8 °C.

Procedure

1. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of fluid into the i-STAT Total β-hCG cartridge using the vial dropper tip. Tightly recap the control vial and store it at 2–8 °C.
4. Seal the cartridge and immediately insert into the handheld.

Target Values and Ranges

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT 1 analyzers that pass the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott. The Value Assignment Sheet displays target values and ranges expected when controls and equipment are performing properly. See Troubleshooting section below for procedures to follow if control results are out of range.

Always ensure that the control material lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software full version in the handheld.

Target values are specific to the i-STAT System. The values assigned to the control material are traceable to *WHO 5th International Standard for Chorionic Gonadotropin (NIBSC Code 07/364)*. Results may differ if used with other methods.

Analyze the control material in the Control pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration menu.

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i-STAT System Incoming Cartridge QC Log

Cartridge Type:____________ **Lot No.:**____________ **Rec'd Date:**____________ **Exp. Date:**____________ **Quant:**____________ **Temp. Strip:**____________

Control Name: ________________ **Level:** __________ **Lot No.:** ____________ **Exp. Date:** __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ________________ **Level:** __________ **Lot No.:** ____________ **Exp. Date:** __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ________________ **Level:** __________ **Lot No.:** ____________ **Exp. Date:** __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ________________ **Level:** __________ **Lot No.:** ____________ **Exp. Date:** __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

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i-STAT System QC Log: Expiration Date and Storage Conditions

				REFRIGERATED 2 TO 8° C (35 TO 46° F)			ROOM TEMPERATURE 18 TO 30° C (64 TO 86° F)				
DATE	LOCATION	CARTRIDGE TYPE	LOT #	QTY	EXP. DATE	TEMP	QTY	EXP. DATE	TEMP	ACTIONS	INSP.

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i-STAT Cartridge Quality Control Action Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	CARTRIDGE LOT	PROBLEM	CORRECTIVE ACTION	OPERATOR

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i-STAT Electronic Simulator Log for Analyzer Serial Number:_____ Year:_____

DATE	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR

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i-STAT Electronic Simulator Action Log

DATE	TIME	ANALYZER	FAILURE CODE OR LETTER	SIMULATOR ID	ACTION	OPERATOR

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i-STAT Analyzer Thermal Probe Check

Year: ________

Analyzer Serial No.: ____________________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

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CALIBRATION VERIFICATION 13

NOTE: CALIBRATION VERIFICATION MATERIALS SHIPPED WITH GEL PACKS WILL INCLUDE A FOUR-WINDOW INDICATOR TO MONITOR AND VERIFY TEMPERATURE DURING TRANSIT.

CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure is not a manufacturer's system instruction. However, it may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure

APOC recommends that each sensor type be included in the Calibration Verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	***P***CO_2	Lactate
Chloride	***P***O_2	BUN/Urea
Ionized Calcium	TCO_2	Creatinine

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients

See the table on page 12-8 of the Quality Control section for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels. Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

If stored refrigerated, the calibration verification material should be equilibrated to room temperature for at least four (4) hours prior to testing.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

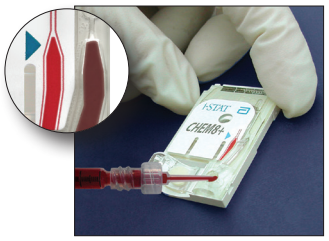
PROCEDURE FOR TESTING CALIBRATION VERIFICATION

Prerequisites

- Ensure that calibration verification testing is performed from the Quality Test Menu for the purpose of documentation and review.
- Scan the cartridge barcode before opening the cartridge pouch.
- Ensure calibration verification ampules, cartridges and analyzers are at room temperature.
- Measurement limits are not applied to results in the calibration verification test path. Results above and below the measurement ranges will be reported.

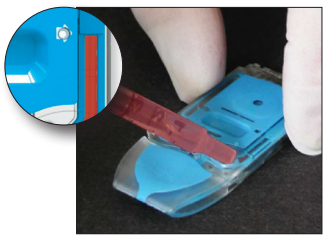
1. Press ⏻ to turn on handheld.
2. Press MENU → 3 → 3 for Cal Ver Samples.

3. Follow handheld prompts.
4. Scan the lot number on the cartridge pouch.
   - Position barcode 3 - 9 inches from scanner window on the handheld.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The handheld will beep when it reads the barcode successfully.



5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT, INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.



7. Review results.

Troubleshooting Cartridge Tests

See Troubleshooting Out-of-Range Results for Cartridges paragraph in the Performing Control Tests on Cartridges section of this manual.

PREPARATION OF CALIBRATION VERIFICATION MATERIALS

Visit www.globalpointofcare.abbott for instructions for use (IFU) related to products not listed in this section.

i-STAT CALIBRATION VERIFICATION SET

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 12. Target values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

If testing at extreme altitude refer to Correction of ***P***O_2 at Extreme Altitude under Controls for Blood Gas/Electrolyte/Metabolite Cartridges in the Quality Control section of the manual.

i-STAT CHEM8+ CALIBRATION VERIFICATION LEVEL 1B

Overview of Procedure

i-STAT recommends that each sensor type be included in the Calibration Verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solution for CHEM8+ Cartridges

i-STAT CHEM8+ Calibration Verification Level 1b is available for purchase to verify the calibration of the i-STAT CHEM8+ TCO_2 at the low end of the reportable range.

There are ten 1.7 mL glass ampules in each box.

Note: For testing all CHEM8+ cartridge analytes, use either the i-STAT TriControls Calibration Verification Set (includes hematocrit) or the i-STAT Calibration Verification Set (does not include hematocrit).

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels. i-STAT CHEM8+ Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

A separate ampule must be used for each cartridge being tested.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

Equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 12. Target values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

CALIBRATION VERIFICATION FOR BLOOD GAS/ ELECTROLYTE/ METABOLITE CARTRIDGES (i-STAT TRICONTROLS)

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure

It is recommended that each sensor type be included in the Calibration Verification procedure using a selection of handhelds that have passed the Electronic Simulator check.

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	***P***CO_2	Glucose
Potassium	***P***O_2	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium	Hematocrit	Creatinine
pH		

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
PCO_2 (mmHg)	96	65	40	26	12
PO_2 (mmHg)	40	63	120	163	500
H^+ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 °C (35-46 °F) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 °C; 64-86 °F) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and handhelds should be at the same temperature.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not ***P***O_2 is to be measured. If ***P***O_2 is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If ***P***O_2 is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into a handheld – it is important not to expose the solution to room air since this will alter the results. **Note:** Since aqueous based solutions such as control materials lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous calibration verification solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes (fresh 1 mL or 3 mL sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous calibration verification solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 12. Target values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

VERIFICATION PROCEDURE FOR HEMATOCRIT

Preparation of Hematocrit Sample

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.
2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.
3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.
4. Transfer all of the plasma from tube 4 to tube 1.
5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.
6. Gently invert tubes 1, 2 and 3 to resuspend the cells.
7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 15%. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75%.

Measurement

1. Gently invert tubes 1, 2, and 3 to resuspend the cells.
2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.
3. Inspect the data for outliers. Repeat a measurement if necessary.
4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results

The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K_3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.
2. The adjusted i-STAT hematocrit mean should be within ±3%PCV of the microhematocrit mean.

   For example: the microhematocrit method mean for the mid level sample is 36%PCV. The i-STAT method mean is 34%PCV. 34 x 1.0425 = 35.445. Acceptable range for the adjusted i-STAT mean: 33 - 39%PCV.

Note: If your analyzers are customized for K_2EDTA/Heparin/None, the above calculation is unneccessary.

Notes on the Procedure

1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.
2. The highest hematocrit that should be tested on the i-STAT System is 75%. Whole blood samples with hematocrit values greater than 75% will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 15%. Whole blood samples with hematocrit values less than 15% will be flagged as <15.

Using Another Comparative Method

Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:

- Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.
- Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method

CLSI recommends that the blood samples anticoagulated with Na_2EDTA or K_2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.

* CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard– Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

VERIFICATION PROCEDURE FOR ACT

See Technical Bulletin "i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure."

CALIBRATION VERIFICATION FOR i-STAT cTnI, BNP, AND CK-MB CARTRIDGES

Intended Use:

The i-STAT cTnI, BNP, and CK-MB Calibration Verification Sets are intended for use as an assayed plasma material to verify the greater portion of the Reportable Range for i-STAT cTnI, BNP, and CK-MB cartridges.

There are two 1.0 mL plastic vials of each of the three levels in the set.

Notes:

- These calibration verification materials contain ≤ 0.09% sodium azide as a preservative.
- These calibration verification materials do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Calibration Verification material is ready to use and requires no reconstitution or frozen storage. The calibration verification materials are stable until the expiration date on the vial label when stored unopened at 2-8 °C (35-46 °F). Once opened, these calibration verification materials are stable for 30 days when stored tightly capped at 2-8 °C (35-46 °F).

Procedure

1. Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. Immediately before use, gently mix the contents of the vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the vial and store it at 2-8 °C (35-46 °F).
4. Seal the cartridge and immediately insert it into the i-STAT 1 handheld.

Acceptable Criteria

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

The Value Assignment Sheet displays target values and ranges expected when cartridges, calibration verification materials and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

If a result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, see the Troubleshooting section that follows the Procedure for Testing Controls in Section 12 of the System Manual.

CUSTOMIZATION 15

Overview

This section describes the parameters that can be customized for site-specific testing requirements and the factory default settings. For the procedure to customize using i-STAT/DE see the *i-STAT/DE User Guide* located at www.globalpointofcare.abbott. For the procedure to customize the analyzer directly through the keypad, see the i-STAT 1 Analyzer section of the manual.

Caution

Handhelds that have been repaired and returned or replaced will have the factory settings as indicated by the DEFAULT0 customization profile name on the Customization screen (under the Administration Menu) of the handheld. These handhelds must be customized, if applicable, before being put into use. These handhelds will also have the current standard CLEW and application software (JAMS). If a different version of CLEW or application software is in use, it must be downloaded to these handhelds.

If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB Adjustment: Always" or "CPB Adjustment: Never" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery. If a handheld customized for the CVOR as "CPB Adjustment: Always" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If a handheld customized as "CPB Adjustment: Never" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

ANALYZER CUSTOMIZATION OPTIONS AND DEFAULT SETTINGS

Option	Description	Default
LANGUAGE WINDOW	Language for text: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, and Finnish	English
UNIT SET WINDOW	Reporting units for results. Selected from predefined sets or by analyte. See table below with 17 predefined unit sets. Unit Set 99 allows the name and units for each test to be defined individually. Note: Reference Ranges, Action Ranges, and Custom Reportable Ranges (if applicable) in the Preferences Window must be changed when changing units.	Unit Set 00
i-STAT 1 ANALYZER AND PHILIPS BAM CLEW WINDOWS	Standardization data. All non-expired versions listed. The CLEW software has an expiration date. If an expired CLEW remains in a customization profile, a warning will be displayed.	
i-STAT 1 SOFTWARE WINDOW	JAMS functionality data.	
PREFERENCES WINDOW	Options and default settings are listed under six headings: Instrument, ID Entry, Test, Cartridge QC, Results, and Analyte Enable.	
STATNotes	Feature allows users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings. See the "i-STAT/DE User Guide" for more details.	CHART0
USE eVAS	This Feature can automatically determine if the results of a liquid QC test run on an i-STAT cartridge are within APOC's published quality control ranges. See the "i-STAT/DE User Guide" for more details.	Not enabled
USE OPERATOR LIST	4000 operator IDs can be stored in the analyzer along with certification start and end dates for cartridge testing. See the "i-STAT/DE User Guide" for more details.	Not enabled (no information stored)

FOR INSTRUMENT OPTIONS

Option	Description	Default
PASSWORD	0-5 digit password to access Set Clock, the Change function in Customization, and Utility under the Administration Menu. Password protection for the Set Clock function can be enabled or disabled. See below.	No password
DATE FORMAT	mm/dd/yy or dd/mm/yy For Clock Set function only.	mm/dd/yy
INACTIVITY TIMEOUT	Number of seconds after a result is displayed and no operator intervention that an analyzer will turn off. Allowable range is 45 to 1620 seconds.	120 seconds
SOUND	If enabled, the analyzer will emit a beep after each successful key press, when results are ready or when a Quality Check message is displayed.	Beep enabled
ENABLE WIRELESS CUMMUNICATION (U.S. CUSTOMER USE ONLY)	Enable the wireless functionality in an i-STAT 1 Wireless handheld See the "Procedure for Using the i-STAT 1 Wireless Analyzer" Technical Bulletin for full details.	Not Enabled
AUTO TRANSMIT	Handheld transmits results when placed in Downloader or Downloader/Recharger.	Enabled
MEMORY FULL ACTION	Not enabled: over-write the oldest record without warning. Enabled: Warn user (start-up warning) or Lockout (testing disabled until upload occurs). Memory Full refers to when the unsent records as recorded on the Analyzer Status screen reaches 1000. Uploading does not erase the data from the handheld's memory.	Not enabled
BATCH MODE TIMEOUT	Not active at this time.	
DISPLAY PASSWORD FOR CLOCK PAGE	The default setting is enabled. However it may be useful to disable password protection for the clock page in the Spring and Fall when clocks are set forward and backward one hour.	Enabled
SYNCHRONIZE CLOCK TO CDS	Will synchronize or update the real time clock in the i-STAT 1 handheld to the Central Data Station's clock at the time of each download. See the "i-STAT/DE User Guide" for more details.	Not Enabled
APPLY OPERATOR LIST TO VIEWING STORED PATIENT RECORDS	Requires operator to enter their operator ID number to access stored patient results on the i-STAT 1 handheld. See the "i-STAT/DE User Guide" for more details.	Not Enabled
LIMIT NUMBER OF RECORDS IN TRANSMIT ALL	Allows the user to apply a date range limit to the Transmit All function in the i-STAT 1 handheld See the "i-STAT/DE User Guide" for more details.	Not Enabled
UPLOAD SCHEDULE	Options are Off, or every X hours, where X can be 1 to 65535 hours. If enabled, the behavior of the analyzer if the schedule is not met can be specified. Behavior Options are: Warn User (start-up warning message) or Lockout (testing disabled until upload occurs). See the "i-STAT/DE User Guide" for more details.	Off: no warning or lockout.

FOR OPERATOR AND PATIENT ID OPTIONS

Option	Description	Default
OPERATOR ID	Minimum and maximum allowed operator ID length (scanned or manually entered) If operator IDs are a fixed length, the min. and max. settings should both be equal to the ID length. See the "i-STAT/DE User Guide" for more details.	Min = 0 Max = 15
REPEAT ID ENTRY	Operator must enter ID twice. Handheld prompts operator to start again if IDs do not match. This option can be set for manual and/or scanned ID Entry. See the "i-STAT/DE User Guide" for more details.	Enabled: repeat required
INCLUDE ID ON PRINTOUT	Enables/Disables printing of operator IDs on printouts from the Martel or i-STAT printer. Disabling the printing of operator IDs can prevent uncertified operators from learning the IDs of certified operators.	Enabled
BARCODE OPTIONS	The type of barcodes used for Operator ID. See table below.	All barcode types
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check. Check digit algorithms are given in HL7 Specification, Section 2.9.5.3	None
INVALID OPERATOR	Behavior of handheld when Operator ID not in stored list or certification date expired Options are: Not enabled (continue without warning), Warn User (prompt to continue), and Lockout (block testing until a valid Operator ID is scanned/entered). This option should not be enabled if the Use Operator List option is disabled. Separate Actions can be chosen for Certification Expired or Operator Not On List. See the "i-STAT/DE User Guide" for more details.	Continue without warning
EXPIRATION NOTIFICATION	Allows a System Administrator to define a time period (1-255 days) in which the operator will be notified by a message on the i-STAT 1 handheld display of their competency expiration date. See the "i-STAT/DE User Guide" for more details.	Off
PATIENT ID	Minimum and maximum allowed patient ID length (scanned or manually entered) If ID numbers are a fixed length, the min. and max. settings should both be equal to the ID length.	Min = 0 Max = 15
REPEAT ID ENTRY	Operator must enter patient ID twice. Analyzer prompts operator to start again if IDs do not match. This option can be set for manual and/or scanned ID entry.	Repeat ID enabled
PATIENT ID RECALL	Operator can recall last patient ID when analyzer prompts for Patient ID. The most recent patient ID is recalled by pressing the → key.	Enabled
BARCODE OPTIONS	The type of barcodes used for Patient ID. See table below.	All barcode types
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check. Check digit algorithms are given in HL7 Specification, Section 2.9.5.3	None

FOR TEST OPTIONS

Option	Description	Default
AUTO-CHART PRESENTATION	If enabled, the Chart Page will be displayed automatically. If any information on the Chart Page is mandatory for the site, Auto-Chart Presentation is recommended.	Not enabled: operator must press the → key to display the Chart Page.
CARTRIDGE PATIENT TEST	The behavior for the following features is set by the analyzer firmware and no longer requires customization: • Require Information before Running Cartridge • Enter Lot Number • Scan Cartridge Barcode Third Party Result Output and Require Analyzer to be in Downloader: These two options were instituted for the release of the RIBS data integration feature. Please see the "The RIBS (Results Integration at the Bedside) Feature for the i-STAT System" Technical Bulletin for full details. **These options SHOULD NOT be activated by users until the data integration process is complete, as misconfiguring your analyzers using these features can cause testing to be disabled.**	Not enabled
PATIENT TEST COMMENT CODE	Options are: No prompt or prompt as follows: • Prompt for Comment Code, All Results in Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • Prompt for Comment Code, Any Result out of Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • A comment code of up to 3 characters is allowed. Care should be taken to select combinations that make sense. In the case of a missed required Comment Code, the results will be stored and "_ _ _" will be entered as the Comment Code.	No prompt
SAMPLE TYPES FOR CARTRIDGE	Drop down menus for each sample type allow the six sample types to be re-ordered or changed. Up to 4 user-definable characters are allowed for each sample type. The sample type is stored with the test record and is included on the printout from the portable printer and in the record in the Central Data Station.	1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR
CHART PAGE	Any item on the Chart Page can be deleted by clicking off the check mark in the Display column or be made mandatory by clicking a check mark in the Mandatory column. If any item is set as mandatory, the Chart Page will be displayed automatically after the Patient ID is entered. The items on the Chart page can also be rearranged by holding down the left mouse button and dragging the item to another location. See the "i-STAT/DE User Guide" for more details.	All items set to not mandatory.

FOR CARTRIDGE QC – ELECTRONIC QC SETTINGS

For the quality control of i-STAT analyzers, i-STAT recommends the use of the Electronic Simulator.

i-STAT's recommendation for the frequency of the Electronic Simulator is once every 24 hours. More frequent use or use according to number of patient tests may be required by accreditation and regulatory bodies.

Option	Description	Default
EXTERNAL SIMULATOR SCHEDULE	Options are Off (no prompt), an interval of specified hours (1 to 65535 hours), or an interval of specified patient tests (up to 99999). The behavior of the analyzer if the schedule is not met can also be specified: Warn or Lockout (testing disabled until Simulator used).	No prompt
INTERNAL SIMULATOR SCHEDULE	Time interval when the internal Electronic Simulator test will be run. Options are Off; an interval of specified hours (1 to 65535 hours); 8/24 (every 8 hours for blood gases, coagulation, hematocrit and immunoassays, and every 24 hours for other tests); an interval of specified patient tests (up to 99999). The behavior of the analyzer if the simulator test fails can also be specified. If the Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display "FAIL" on subsequent cartridges until the test passes. If Lockout is not selected, the simulator test will not be initiated again until next scheduled time.	Interval 24 hours. Lockout

FOR CARTRIDGE QC – LIQUID QC SETTINGS

Option	Description	Default
CONTROL PASS/FAIL DETERMINATION	Describes the way in which the System Administrator will determine the acceptability of liquid QC results. Options are: None: Disables the QC Pass/Fail and QC Schedule feature. Automatic via EVAS: Choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld. Manual: The user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at www.globalpointofcare.abbott/valsheets and indicate on the handheld whether the QC run passed or failed. See the "i-STAT/DE User Guide" for more details.	None
CONTROL TEST SETTINGS	If the System Administrator wants users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, they would check the appropriate box and then use the drop down menu to select whether entering the comment code is optional (Allow no comment) or Required (Require Comment). Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected. See the "i-STAT/DE User Guide" for more details.	Disabled
CONTROL RESULTS DISPLAY FORMAT	Options are: Numeric: liquid QC results are displayed in numeric format. Suppressed: the following symbol “<>” is displayed next to each liquid QC test name in place of the quantitative (numeric) results. The “Suppressed” option should only be chosen if “Automatic via EVAS” is chosen for the liquid QC Pass/Fail Determination. See the "i-STAT/DE User Guide" for more details.	Numeric
APOC FLUID LOT ENTRY METHOD	Options are: Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld, or scanning it from the barcode on the quality control vial being tested. Scan only: the fluid lot information must be entered by scanning the barcode on the vial being tested.	Scan or Enter
SCHEDULE STATUS	Displays the status of previously defined Liquid QC Schedules See the "i-STAT/DE User Guide" for more details.	Off

FOR CARTRIDGE QC - LIQUID QC SCHEDULE (1, 2, OR 3)

Option	Description	Default
QC FREQUENCY	Describes the frequency at which the System Administrator wants the liquid QC run under this schedule. Options are: Off: Disables the selected QC Schedule Daily Weekly: A particular day of the week (e.g. every Monday) Monthly: A particular day of the month (e.g. the second Tuesday of the month See the "i-STAT/DE User Guide" for more details.)	Off
QC TIME	The QC Time sets the time when the QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become “due to start”. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out. See the "i-STAT/DE User Guide" for more details.	Disabled
APPLY QC SCHEDULE TO	The months of the year to which this schedule will apply. Options are: All months Selected Months: Check the box next to the months to which this schedule will apply. See the "i-STAT/DE User Guide" for more details.	All months
CARTRIDGE QC PROFILE	The System Administrator defines a QC cartridge set consisting of: A QC cartridge type (i.e. the cartridge type to be test with specified liquid QC fluids during the QC procedure), as well as any number of dependent cartridge types (i.e. associated cartridge types that will be enabled by the handheld if the QC requirements for a given cartridge set are met on that handheld). The System Administrator then associates the defined cartridge set with up to six (6) specific QC fluids. A Cartridge QC Profile can only be edited or created if QC Frequency has been activated. See the "i-STAT/DE User Guide" for more details.	Disabled

FOR RESULTS REPORTING OPTIONS

Option	Description	Default
REFERENCE RANGES	Reference ranges can be defined for each test. The ranges will be depicted as tic marks on the bar graphs on the result pages. There are no bar graphs for blood gas, coagulation, and immunoassay tests.	Ranges are listed in the Cartridge and Test Information sheets.
ACTION RANGES	High and low action ranges can be defined for each test. See the "i-STAT/DE User Guide" for more details.	Disabled (-99999.9 to 99999.9)
CUSTOM REPORTABLE RANGES	High and low custom Reportable Ranges can be defined for each analyte (except ACT). See the "i-STAT/DE User Guide" for more details.	Disabled (-99999.9 to 99999.9)
PRINT REFERENCE RANGES	Reference Ranges can be printed with results. Ranges will print only if the record to be printed is stored with the active Preference set in the handheld.	Disabled
OPERATOR TEST SELECTION	Requires the operator to select tests to be reported from a cartridge test panel.	Disabled
ACT OPTIONS (i-STAT 1 Analyzer Only)	The user can select between the current 37° (PREWRM) result calibration and a new "NON-PREWARM" (ambient temperature) result calibration for both Celite ACT and Kaolin ACT cartridges.	PREWRM for both cartridge types.
HEMATOCRIT OPTIONS	Reference anticoagulant used to calculate hematocrit result: K3EDTA or K2EDTA/Heparin/None. (NaEDTA is included in this option and None means no anticoagulant.) CPB options are: 1. **Prompt:** asks user whether to apply CPB compensation when cartridge includes hematocrit sensor. 2. **Never:** CPB correction is never applied when running a cartridge with a hematocrit sensor.. 3. **Always:** apply CPB correction every time it runs a cartridge with a hematocrit sensor. See Theory section in this manual for explanation of CPB. Analyzers can be customized by location. Analyzers customized for "CPB: Always" should not be used for reporting Proficiency Testing results..	K3EDTA Prompt CPB
DECIMAL SEPARATOR	Select comma (,) or period (.)	Period
BASE EXCESS CALCULATION	Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb). See i-STAT Cartridge Instructions for User for **P**CO_2 for formulas.	BEecf

FOR ANALYTE ENABLE

Option	Description	Default
APPLY GLOBALLY	Test(s) can be disabled for all cartridge types. To enable/disable a particular analyte on all cartridge types, simply check/uncheck the box next to the analyte name in the Apply Globally section. The global selection takes precedence over the cartridge type selection.	All tests enabled.
APPLY BY PANEL	Test(s) can be disabled for individual cartridge types. To enable/disable a particular analyte on a specific cartridge type, make sure the analyte is first checked under the Apply Globally section. Then click on the cartridge type under the Apply by Panel section, and then check/uncheck the box next to the analyte name.	All tests enabled for all cartridge types.

FOR BARCODES

Option	Description	Default
ID BARCODES *	The user can select any or all of the following as valid barcode formats for both the operator and patient ID: • I2 of 5 • Code 128 • Codabar • Code 93 • Code 39 • EAN 8, EAN 13 Barcode type Code 128 will support USS 128 and UCC/EAN 128, but not ISBT 128.	All barcode types
I2 OF 5 OPTIONS	No Check Digit USS Check Digit OPCC Check Digit	USS Check Digit
CODE 39 OPTIONS	Check Digit or No Check Digit Alphanumeric or Full ASCII	Check Digit, Full ASCII
TRUNCATE DIGITS	User can select how to truncate digits from a scanned operator and/or patient ID: First: enter number of leading characters to be stripped from the barcode. Last: enter number of trailing characters to be stripped from the barcode. The analyzer will accept up to 15 characters for operator and patient IDs.	No truncation

*** Note:** For fields other than Operator and Patient ID, only the default setting for the barcode type can be scanned. These are:

- Code I2 of 5 with USS Check Digit
- Code 39 Full ASCII with Check Digit

UNIT SETS

17 PREDEFINED UNIT SETS ARE AVAILABLE IN THE UNIT SET WINDOW. THERE IS ALSO A UNIT SET 99 THAT CAN BE USED TO SELECT THE NAME AND UNIT FOR EACH TEST. THE DEFAULT UNIT SET IS 00

RESULT	0	1	2	3	4	5	6	7	8	9
Na/K/Cl *	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
BUN	mg/dL									
Urea		mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L
Crea	mg/dL	µmol/L	µmol/L	mg/dL	mg/dL	mg/dL	mg/dL	µmol/L	µmol/L	µmol/L
Glu	mg/dL	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH										
PCO2/PO2	mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg	kPa	mmHg	mmHg
Hct	%PCV		%PCV	%PCV	%PCV	%PCV	%PCV	%PCV		
Hb	g/dL	g/L	g/L	g/dL	g/dL	g/dL	g/dL	mmol/L	g/L	g/dL
HCO3/BE	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L
iCa	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
sO2	%	%	%	%	%	%	%	%	%	%

RESULT	10	11	12	13	14	15	16
Na/K/Cl	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
BUN			mg/dL			mg/dL	
Urea	mmol/L	mmol/L		mmol/L	mmol/L		g/L
Crea	µmol/L	µmol/L	mg/dL	µmol/L	µmol/L	mg/dL	µmol/L
Glu	mmol/L	mmol/L	mg/dL	mmol/L	mmol/L	mg/dL	g/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH							
PCO2/PO2	kPa	kPa	mmHg	mmHg	mmHg	mmHg	mmHg
Hct			%PCV	%PCV	%PCV	%PCV	%PCV
Hb	g/dL	g/dL	g/dL	g/dL	mmol/L	g/dL	g/dL
HCO3/BE	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
iCa	mmol/L	mg/dL	mg/dL	mmol/L	mmol/L	mEq/L	mmol/L
sO2	%	%	%	%	%	%	%

* Also, TCO2 and Anion Gap, except:

03 TCO2 mEq/L

04 TCO2, Anion Gap mmol/L

06 Anion Gap, HCO3, BE mEq/L

Note: There are no units for pH or for hematocrit when reported as decimal fraction

Note: See Cartridge and Test Information sheets for ACT Celite, PT/INR, cTnI, CK-MB, ß-hCG, and BNP units. See Instructions for Use for ACT Kaolin.

Celite is a trademark of Celite Corporation, Santa Barbara, CA for its diatomaceous earth products.

PROCEDURES FOR CUSTOMIZATION USING THE ANALYZER KEYPAD

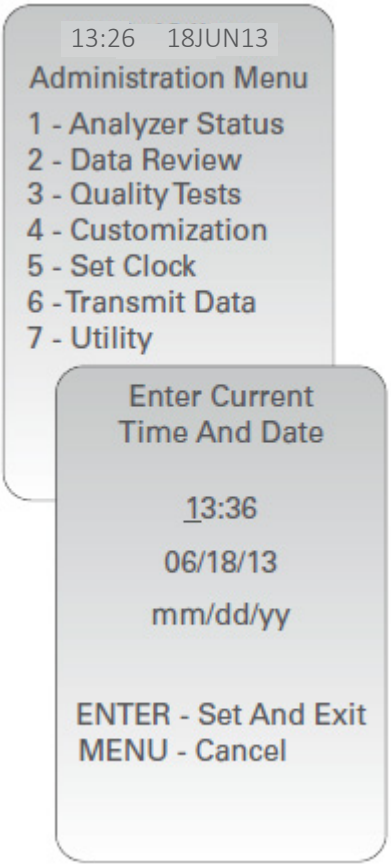
To change the customization profile via the analyzer keypad see “Customization” under “Administration Menu” in Section 3.

To change the Date and Time:

1. Press  to turn on the analyzer.
2. Press  to change to the Administration Menu
3. Press  (Set Clock)
4. Press 

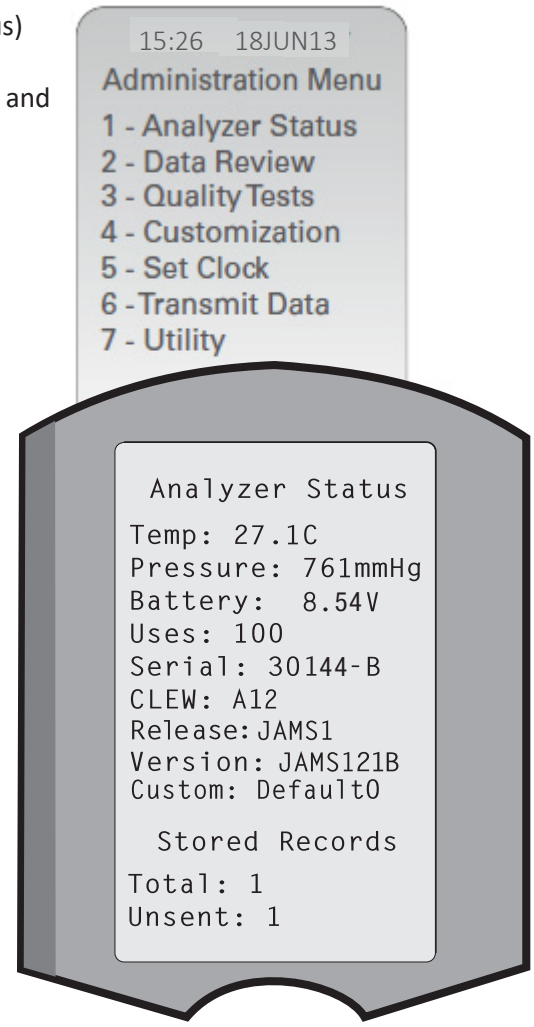
If the handheld has already been customized with a password, enter the password.

5. Use the arrrow keys to move the cursor to the digit to be changed. Use the numberkey to change the digit.
6. Press the *Enter* key to accept changes, or the *Menu* key to cancel changes.



Check Software

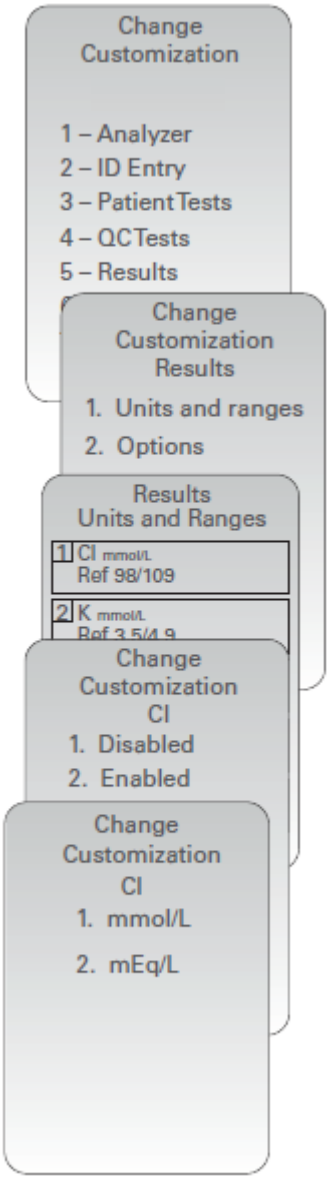
1. From the Administration Menu, 1 (Analyzer Status)
2. Check the analyzer status page for the installed CLEW and Application Software.



Change Units and Ranges

New analyzers or replacement analyzers will have standard unit sets installed and all analytes enabled.To disable or set a different unit of measurement for a particular analyte follow these steps:

1. Press  to turn on the analyzer.
2. Press  to change to the Administration Menu
3. Press  (Customization)
4. Press  (Change)
5. Press  (when enabled, enter password)
6. Press  (Results)
7. Press  (Units and Ranges)
8. To change a setting, select the item, then select the setting.
9. After all the items, have been set, turn the handheld off to save.



Change Test Selection

1. Press ⏻ to turn on the analyzer.
2. Press MENU to change to the Administration Menu
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (when enabled, enter password)
6. Press 5 (Results)
7. Press 2 (Options)
8. Press 2 (Test Selection)
9. To change a setting, select the item, then select the setting.
10. Turn the handheld off to save.