i-STAT 1
User Guide

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INTRODUCTION

CONTENTS

INTENDED USE

The i-STAT 1 Analyzer is intended for use in the *in vitro* quantification of various analytes in whole blood or plasma in point of care or clinical laboratory settings.

SCOPE

This User Guide provides instructions for use for the i-STAT 1 Analyzer.

Analyzers and cartridges should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

i-STAT 1 software expires periodically. Refer to the ANALYZER SETUP section of this guide for steps to check the software status.

To access our APOC website for additional information regarding software updates, use of the i-STAT 1 Analyzer and i-STAT test cartridges, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

Images and illustrations provided in this user guide are for representational purposes only.

Not all products are available in all markets. Contact your local Abbott Point of Care representative for information on available products.

To obtain additional product information and technical support, refer to the Abbott company website at www.globalpointofcare.abbott.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on *In vitro* Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

RELEASE NOTES

Art:714254-00AD 20-MAR-2024 - User Guide updated to Instructions For Use format.

SECTION 1

Before using the analyzer install batteries, check or change the date and time, check or update customization, check or update software, set language, set unit set, set date format and set decimal separator. For details on additional options for customization and available features, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

ANALYZER POWER OPTIONS

The analyzer requires two Ultralife 9-Volt lithium batteries. The analyzer may also be powered by an i-STAT 1 9-Volt NiMH Rechargeable Battery; see additional information in this section.

DISPOSABLE BATTERIES

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.

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.

CAUTIONS:

- Skin irritation, including caustic burns/injury, may occur following exposure to a leaking battery. Always wear gloves when handling a leaking battery, and do not permit a leaking battery to contact skin.
- A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

INSTALLING DISPOSABLE BATTERIES

1. Slide the battery compartment door off and tilt the analyzer slightly to slide out the battery carrier.
2. Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient the new battery so it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the battery inward. The terminals of the battery should be underneath the protective bar on the carrier. Repeat for the second battery on the other side of the carrier.
3. Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the analyzer first. Insert the carrier into the analyzer as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.
4. Slide the battery compartment door back into place.

REMOVING AND REPLACING DISPOSABLE BATTERIES

NOTE: Wait until any test in progress is completed, and turn off the analyzer before replacing the batteries or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

1. Slide the battery compartment door off.
2. Tilt the analyzer slightly to slide out the battery carrier which contains the two Ultralife 9-Volt Lithium batteries.
3. Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
4. Install the replacement batteries as per Steps 2, 3 and 4 in the procedure for INSTALLING DISPOSABLE BATTERIES above.

SECTION 1

i-STAT 1 9-VOLT NiMH RECHARGEABLE BATTERY (OPTIONAL)

If an i-STAT 1 9-Volt NiMH rechargeable battery is to be used, the Ultralife 9-Volt Lithium disposable batteries can be used while the i-STAT 1 9-Volt NiMH rechargeable battery is charging in the i-STAT 1 Downloader/Recharger.

When using a rechargeable battery, store the disposable battery carrier for possible future use.

CAUTIONS:

- If you are using the i-STAT 1 9-Volt NiMH rechargeable battery, use only the i-STAT 1 9-Volt NiMH rechargeable battery and i-STAT 1 Downloader/Recharger supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients.
- Skin irritation, including caustic burns/injury, may occur following exposure to a leaking battery. Always wear gloves when handling a leaking battery, and do not permit a leaking battery to contact skin.
- A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.
- Do not short circuit, incinerate or mutilate the rechargeable batteries.

INSTALLING THE i-STAT 1 9-VOLT NiMH RECHARGEABLE BATTERY

1. Slide the battery compartment door off and tilt the analyzer slightly to slide out the disposable battery carrier. Store the disposable battery carrier for possible future use.
2. The i-STAT 1 9-Volt NiMH Rechargeable Battery has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the i-STAT 1 9-Volt Rechargeable Battery into the analyzer as shown on the label. If the i-STAT 1 9-Volt Rechargeable Battery is inserted incorrectly, the battery door will not close.
3. Slide the battery compartment door back into place.
4. Proceed below to CHARGING USING THE ANALYZER**.**

CHARGING THE i-STAT 1 9-VOLT NiMH RECHARGEABLE BATTERY

The i-STAT 1 Downloader/Recharger must be used to charge or recharge the i-STAT 1 9-Volt NiMH Rechargeable Battery. Charge rechargeable battery fully before use. Full recharge from a discharged state takes approximately 40 hours. See the i-STAT 1 DOWNLOADER/RECHARGER SETUP section in this guide for information on indicator LED's related to charging.

CHARGING USING THE ANALYZER

Placing an analyzer that has an i-STAT 1 9-Volt NiMH rechargeable battery installed into an i-STAT 1 Downloader/Recharger will automatically initiate charging or recharging of the i-STAT 1 9-Volt NiMH Rechargeable Battery.

CHARGING USING THE i-STAT 1 DOWNLOADER/RECHARGER RECHARGING COMPARTMENT

Placing an i-STAT 1 9-Volt NiMH Rechargeable Battery into the recharging compartment will automatically initiate trickle charging or recharging of the i-STAT 1 9-Volt NiMH Rechargeable Battery, if needed.

REPLACING THE i-STAT 1 9-VOLT NiMH RECHARGEABLE BATTERY

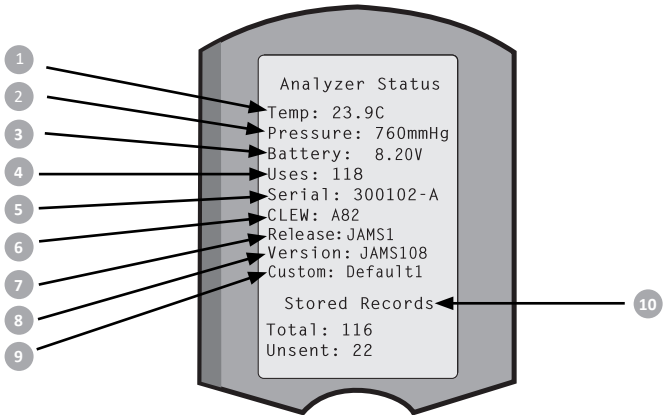
NOTE: Wait until any test in progress is completed, and turn off the analyzer before replacing the rechargeable battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

1. Slide the battery compartment door off.
2. Tilt the analyzer slightly to slide out the i-STAT 1 9-Volt Rechargeable Battery.
3. Install the replacement i-STAT 1 9-Volt Rechargeable Battery per Steps 2, 3 and 4 in the procedure for INSTALLING THE i-STAT 1 9-VOLT NiMH RECHARGEABLE BATTERY above.

SECTION 1

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.



1. **(Temp):** Room Temperature
2. **(Pressure):** Barometric pressure
3. **(Battery):** Battery voltage
4. **(Uses):** Total number of cartridge and simulator test cycles (whether or not results reported).
5. **(Serial):** Serial number of the analyzer.
6. **(CLEW):** Version of standardization data installed in the analyzer.
7. **(Release):** The current release version of application software installed in the analyzer.
8. **(Version):** The full version of application software installed in the analyzer.
9. **(Custom):** Customization profile name.
10. **(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. Transmission to i-STAT/DE is optional and requires network connectivity with Data Management software. For more information on i-STAT/DE and Connectivity Options, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

CAUTION:

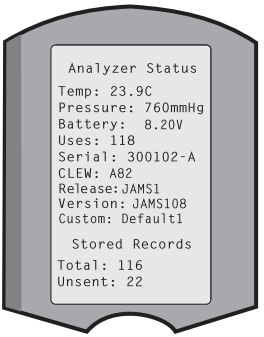
Analyzers that have been repaired and returned or replaced will have the factory settings.

- These analyzers must be customized, if applicable, before being put into use. See information in this section for setting Language, Date Format, Units and Ranges, and Decimal Separator. For additional customization options, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.
- These analyzers 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 analyzers. For more details on performing the Software Update to download the CLEW and application software to the analyzer, see HOW TO PERFORM A SOFTWARE UPDATE section in this guide.

SECTION 1

CHECKING THE BATTERY VOLTAGE

1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 1 (Analyzer Status)
4. Voltage is noted in (**Battery**).



CHECKING THE SOFTWARE VERSION

1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 1 (Analyzer Status)
4. Software version is noted in (**CLEW)** and (**Version** (JAMS))**.**

CHECKING THE CUSTOMIZATION PROFILE

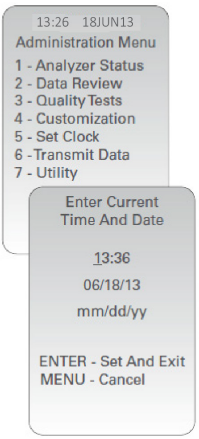
1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 1 (Analyzer Status)
4. Customization Profile is noted in (**Custom**)**.**

ANALYZER DATE AND TIME

Check the Analyzer date and time prior to use. Power on the analyzer and check that the date and time at the top of the display are correct. To change, see procedure below.

CHANGE DATE/TIME

1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 5 (Set Clock)
4. Press ENT (Password)



Note: Abbott Point of Care recommends setting a password to protect access to the Set Clock, the Change Function in customization, and Utility under the Administration Menu. For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

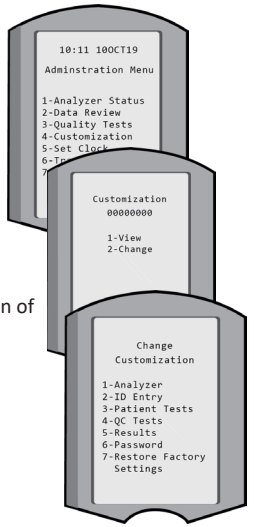
5. Use ⬅ ➡ arrow key, to move the cursor to the digit to be changed.
6. Press 0 - 9 number key, to change the digit.
7. Press ENT (Set and Exit)
   MENU (Cancel)

SECTION 1

ANALYZER LANGUAGE OPTIONS AND DATE FORMAT

The analyzer may be set with the following languages for text: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, and Finnish. There are two options available for date format: mm/dd/yy or dd/mm/yy.

SET LANGUAGE



1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (Password)

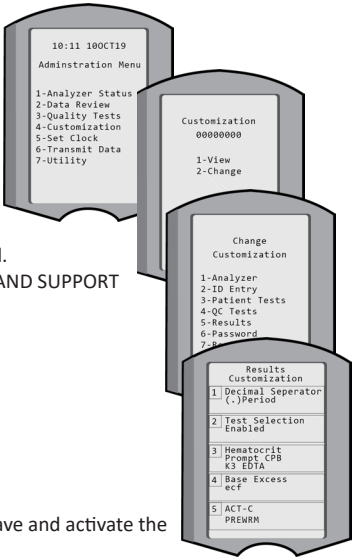
Note: Abbott Point of Care recommends setting a password. For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORRT section of this guide.

6. Press 1 (Analyzer)
7. Press 2 (Language)
8. Use ⬅ ➡ arrow Key to move to the next screen, if needed.
9. Press 1 - 9 number Key to select langauge.
10. Press 2 (Date Format) and select the corresponding number key to set the format.
11. After all items have been set, turn the analyzer off to save and activate the settings.

DECIMAL SEPARATOR

Customizes the analyzer keypad "." key to enter a decimal point or a comma separator.

To change the decimal separator, follow the steps below:



1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (Password)

Note: Abbott Point of Care recommends setting a password.
For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

6. Press 5 (Results)
7. Press 2 (Options)
8. Press 1 (Decimal Separator)
9. Select corresponding number key to set the format.
10. After all items have been set, turn the analyzer off to save and activate the settings.

SECTION 1

UNITS AND RANGES

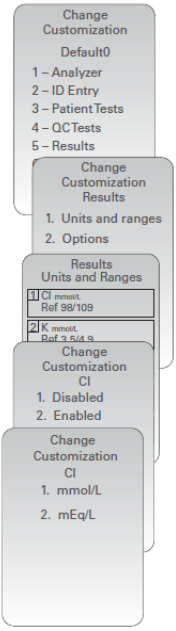
New analyzers, repaired analyzers, or replacement analyzers will have standard unit sets installed and all analytes enabled. To disable or set a different unit of measurement for a particular analyte, follow these steps:

1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (Password)

Note: Abbott Point of Care recommends setting a password. For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

6. Press 5 (Results)
7. Press 1 (Units and Ranges)
8. Press the number key corresponding to the analyte you wish to disable or change units for.
9. Press 1 (Disabled), to disable the analyte OR

   Press 2 (Enabled) to change the units.
10. When changing units, press the number key corresponding to the units in which you would like the analyte reported.
11. After all items have been set, turn the analyzer off to save and activate the settings.



Note: When an analyte is disabled, units and ranges will not be displayed on the Results Units and Ranges screen.

SECTION 1

SAMPLE TYPE CUSTOMIZATION

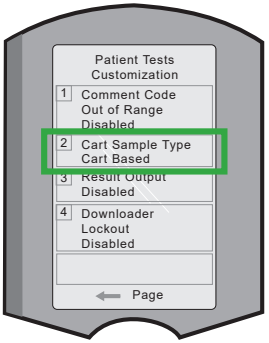
Customization Using the Analyzer Keypad

Prior to placing the analyzers into use, ensure preferred customization of the sample-type selection list.

1. Press ⏻ to turn on the analyzer.
2. Press MENU to go to the Administration Menu.
3. Press 4 to access the Customization screen.
4. Press 2 (Change).
5. Press ENT (when enabled, enter password).
6. Press 3 (Patient Tests), then press the → to go to the next page.
7. Press 2 (Cart Sample Type).
8. Press 1 (Cart Based) to display a sample-type selection list for the cartridge scanned.

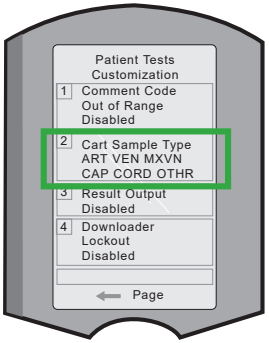
   OR

   2 (Custom) if a custom sample-type selection list is preferred based on your facility's policies and procedures.
9. Once the selection has been made, press MENU twice to save and return to the Main Menu.



Step 8:
Patient Tests Customization Screen Cart Based Selection (DEFAULT)

OR



Step 8:
Patient Tests Customization Screen Custom Selection. Custom Selection will display sample types as in the image above.

Note: Cart Based Selection will display sample types that are noted in the Instructions for Use or Cartridge Test Information Sheet for the cartridge.

SECTION 2

SYSTEM COMPONENTS

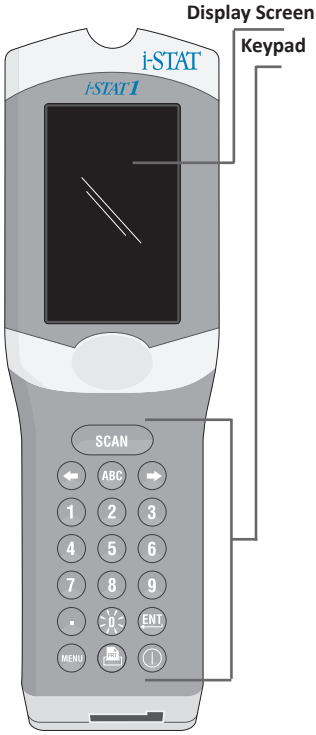
1. **i-STAT 1 Analyzer:** Used to perform cartridge testing, review test results, and conduct quality control (QC) testing. Optional ability to transmit results with network connectivity configuration via the i-STAT 1 Downloader/Recharger.
2. **i-STAT 1 Downloader/Recharger (DRC-300):** Used to perform analyzer software updates. Can recharge the i-STAT 1 9-Volt NiMH Rechargeable Battery installed in the analyzer or in the recharging compartment of the DRC-300. Optional ability to transmit results with network connectivity configuration.
3. **i-STAT Cartridges:** Contains sensors and reagents for testing patient samples and quality control fluids.
4. **Disposable Batteries and the i-STAT 1 Battery Carrier:** The analyzer requires two Ultralife 9-Volt lithium batteries as its main power source for use with the i-STAT 1 Battery Carrier.
5. **i-STAT 1 9-Volt NiMH Rechargeable Battery (Optional):** provides alternate power source that can be charged using the i-STAT 1 Downloader/Recharger.
6. **i-STAT Electronic Simulator:** A quality control device for the analyzer's cartridge signal-reading function.
7. **i-STAT 1 Printer:** Portable printer used to print records from the analyzer.

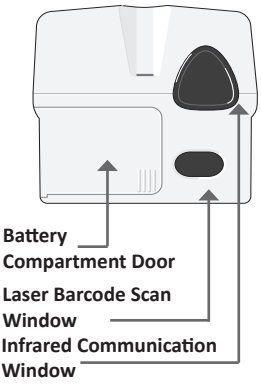
NOTE REGARDING SYSTEM RELIABILITY

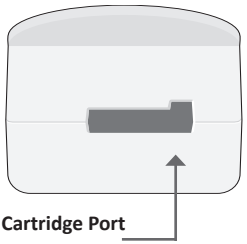
The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Theory section in the i-STAT 1 System Manual for detailed information). To minimize the probability of delivering a result with medically significant error, the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If, however, the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup i-STAT 1 Analyzer and cartridges from an alternate lot number.**

SECTION 3

ANATOMY OF THE ANALYZER







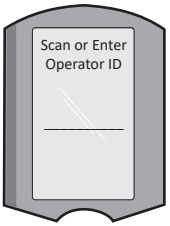
Key	Description & Function
SCAN	Activates the barcode scanner. Information that can be entered into the analyzer via the scanner includes: Operator ID, Patient ID , control, and cartridge lot number.
⬅ ➡	Arrow Keys. Used to move the cursor on the Set Clock Screen and to move up and down the alphabet when the ABC key is pressed.
➡	The right arrow key is used as a page key to move from one screen to the next.
⬅	The left arrow key is used to backspace and clear keypad entries, and to move backward through the screens menu.
ABC	ABC Key. 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.
0-9	Numbered Key. Used to enter a number or digits on data entry screen and to select menu options and stored records.
.	Period Key. Enters a decimal point or a comma separator according to the analyzer customization.
0	The back-light for the display is turned on and off by pressing the 0 key for one second. The back-light will automatically turn off after ninety seconds and when the analyzer powers down or is turned off. The back-light cannot be turned on while data entry screens are displayed.
ENT	Enter Key. 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.
PRT	Print Key. Used to print either directly to the i-STAT 1 Printer or to the i-STAT 1 Printer attached to the i-STAT 1 Downloader/Recharger.
⏻	On/Off Key. 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.

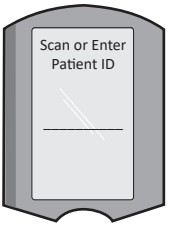
SECTION 4

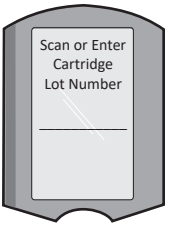
PROMPTS

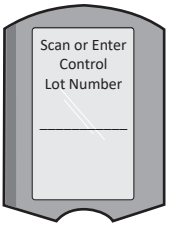
Either before or during the testing cycle, the analyzer will display prompts that require operator action or keypad entry, such as “Enter Operator ID.” Prompts for the following information are mandatory:

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





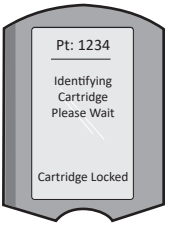


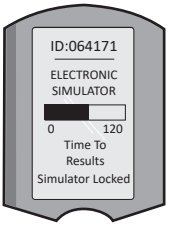


ATTENTION:

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.





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.

ALERT MESSAGES

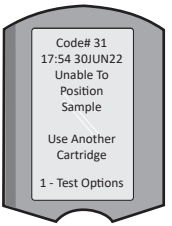
An Alert message may occur during cartridge testing.

- **“Lot Expired”** is an example of an alert that will appear when a cartridge barcode is scanned from an expired lot.

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.

- “**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.



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

Startup, Alert, and Quality Check messages are described in the Troubleshooting and Support section of this user guide.

SECTION 5

MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS

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 analyzer is verified by a combination of automated quality checks and procedural controls during each test event, supplemented by electronic quality control.

PERFORM DAILY QUALITY CONTROL WITH ELECTRONIC SIMULATOR

Check each Analyzer with the Electronic Simulator, using either the internal or external simulator, once on each day of use. To perform the test, see PROCEDURE FOR THE i-STAT ELECTRONIC SIMULATOR in this Section of the user guide.

CHECK NEW OR REPLACEMENT ANALYZERS WITH THE ELECTRONIC SIMULATOR

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

The internal Electronic Simulator will automatically activate the first time a new or replacement analyzer is used and after every 24 hours of use thereafter. Optional customization settings are available, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide for more details.

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 analyzer. This check may be performed in conjunction with the analyzer software updates. See HOW TO PERFORM A SOFTWARE UPDATE section of this guide for procedure.

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

Perform software updates; see HOW TO PERFORM A SOFTWARE UPDATE section of this guide.

SECTION 5

HOW TO PERFORM QUALITY CONTROL TESTING

THE ELECTRONIC SIMULATOR

The Electronic Simulator, external (i-STAT Electronic Simulator) and internal (i-STAT Cartridge), is a quality control device for the analyzer's cartridge signal-reading function. It simulates two levels of electrical signals that stress the analyzer's cartridge signal detection function both below and above measurement ranges.

While the analyzer performs internal electronic checks and calibration during each test cycle, the Electronic Simulator test provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. An analyzer will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the analyzer software.

The schedule for the Electronic Simulator can be customized. For Optional customization settings for the electronic simulator, external and internal, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

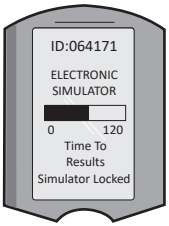
PROCEDURE FOR THE i-STAT ELECTRONIC SIMULATOR

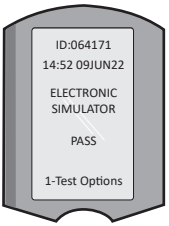
The i-STAT Electronic Simulator is a stable electronic device, which is inserted into the cartridge port. The test cycle for the i-STAT Electronic Simulator is about 60 seconds.

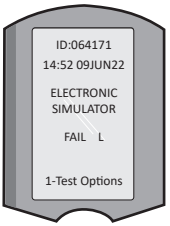
When 24 hours has elapsed since the last Electronic Simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted. If the test passes, the analyzer proceeds with the measurement of the patient sample. If the test fails, the analyzer displays a FAIL message. The analyzer cannot be used until the simulator test passes. The i-STAT Electronic Simulator can be used to verify the failure.

1. Press ⏻ to turn on analyzer.
2. Press MENU (Administration Menu)
3. Press 3 (Quality Tests)
4. Press 4 (Simulator)

5. Scan or Enter Operator ID and press the enter key. If ID numbers are not required, just press the enter key to continue.
6. If prompted, Scan or Enter Operator ID number again and press the Enter key.
7. Remove the i-STAT Electronic Simulator from its box. Remove protective cap. Take care not to touch gold contact pads.
8. Enter serial number found on label of the i-STAT Electronic Simulator.
9. Insert Electronic Simulator into analyzer with gold contact pads facing up and forward. When inserted properly, analyzer will display "Contacting Simulator". **DO NOT remove simulator until "Simulator Locked" message is removed and the result is displayed.**
10. If "PASS" is displayed, analyzer may be used. If "FAIL" is displayed, do not use analyzer. Record the letter or number below the result box on display and see Troubleshooting and Support section of this guide.
11. Replace the cap and return the i-STAT Electronic Simulator to its box.







SECTION 5

LIQUID QUALITY CONTROLS

Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing 2 levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets.* Any analyzer that has passed the Electronic Simulator test may be used in the verification.

* This information is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory.

See SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide for how to accces the i-STAT 1 System Manual for additional information on quality control.

i-STAT Cartridges	i-STAT Controls
G, Crea, G3+, CG4+	i-STAT TriControls or i-STAT controls
CHEM8+, 6+, EC8+, EG6+, EG7+, CG8+	i-STAT TriControls
ACTk, ACTc	i-STAT ACT controls
PT*Plus*	i-STAT PT*Plus* Controls
PT/INR	i-STAT PT/INR controls
cTnI	i-STAT cTnI controls
CK-MB	i-STAT CK-MB controls
BNP	i-STAT BNP controls
Total ß-hCG	i-STAT Total ß-hCG control

PROCEDURE FOR LIQUID QUALITY CONTROL

1. Press ⏻ to turn on analyzer.
2. Press MENU (Administration Menu)
3. Press 3 (Quality Tests)
4. Press 1 (Control)
5. Press 1 (i-STAT Cartridge), if prompted.
6. Scan or enter Operator ID. Repeat if prompted.
7. Scan or enter control lot number.
8. Scan the lot number on the cartridge pouch or portion pack.
9. Fill a cartridge with the control and close the cover.
10. Insert the cartridge into the cartridge port.
11. Enter chart page information if applicable.
12. View results on analyzer's display.
13. Remove and discard cartridge when Cartridge Locked message disappears.
14. Press 1 for Test Options on the results page and
15. Press 1 for Next Level if testing another level of control.

CALIBRATION VERIFICATION (OPTIONAL)

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. For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

SECTION 6

HOW TO PERFORM PATIENT TESTING

IDENTIFYING THE i-STAT CARTRIDGE

Labeling on the box and pouch or portion pack identify:

- the cartridge name.
- the tests included in the cartridge.
- the lot number.
- the expiration date of the cartridge.

i-STAT CARTRIDGE LIMITATIONS

Interfering substances in the patient's sample may cause an increase or decrease in a result. See SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide for how to access i-STAT Cartridge and Test Information Sheets, Instructions for Use and Technical Bulletins for information on substances and/or conditions that may interfere with cartridge tests.

BLOOD COLLECTION

The sample used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status. Samples should be collected according to the facility's policies and procedures.

See the Cartridge and Test Information sheets and the cartridge Instructions For Use on the APOC website for further information.

i-STAT blue CG4+ Cartridge Only

- Arterial: whole blood collected in balanced heparin or lithium heparin syringes.
- Venous: whole blood collected in balanced heparin or lithium heparin syringes or; whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity.
- Capillary: Not recommended. This cartridge has not been evaluated with capillary samples.

Other Chemistry and Blood Gas cartridges (including CHEM8+) can use:

- Arterial: Plain syringe, heparinized syringe labeled for analytes to be tested and filled to capacity, or syringe with minimum volume of heparin to prevent clotting (10 U/mL of blood). For ionized calcium, use balanced heparin syringes.
    - Avoid drawing air into syringes for blood gas and ionized calcium tests.
    - If not tested immediately, remix and discard 2 drops of blood before filling cartridge.
    - Do not use iced samples.
- Venous: Plain syringe, heparinized syringe (for ionized calcium, use balanced heparin syringes) or; whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity.
    - Do not leave tourniquet on for more than 2 minutes.
    - Do not draw above an I.V.
- Capillary (except CHEM8+): Lithium heparin capillary tubes for testing all analytes except ionized calcium. For all analytes, including ionized calcium, use a balanced heparin capillary tube.
    - Allow alcohol to dry over puncture site before collecting sample.
    - Do not "milk" finger or heel while collecting sample.

Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas cartridges:

- Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringes for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds. Test immediately, if collected in capillary tube.
- Test for lactate immediately. Samples for pH, PCO_2, PO_2, TCO_2 and ionized calcium should be tested within 10 minutes. Test other analytes within 30 minutes.

SECTION 6

Coagulation cartridges: ACT, PT/INR and PT*Plus*

- The ACT test may be performed using venous or arterial samples, while the PT/INR and PT*Plus* test may be performed using capillary or venous samples.
- Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators.
- Test sample immediately upon draw.
- For venipuncture, some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing samples for coagulation testing.
- If a second measurement is needed, draw a fresh sample.
- For indwelling line testing for ACT:
  a. Fluid drip through the line must be discontinued.
  b. If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.
  c. Withdraw the sample into a fresh plastic syringe with no anticoagulant and test immediately.
- For extracorporeal line testing for ACT:
  a. Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
  b. Withdraw the sample into a fresh plastic syringe with no anticoagulant and test immediately.

Troponin I/cTnI and CK-MB Tests

- cTnI or CK-MB cartridges require the use of either:
  a. Heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin and filled to capacity, or;
  b. Non-heparinized whole blood or plasma samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.
- The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB readings.
- Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the cTnI or CK-MB cartridges.

BNP Tests

- BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA and filled to capacity.
- The use of whole blood or plasma samples containing other anticoagulants such as oxalate and citrate is not recommended.
- Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the BNP cartridge.

Total ß-hCG Tests

- Total ß-hCG cartridges require the use of heparinized whole blood or plasma samples collected in plastic syringes or evacuated tubes containing lithium or sodium heparin and filled to capacity.
- The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased Total ß-hCG readings.
- Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the Total ß-hCG cartridge.

SECTION 6

PREPARATION FOR USE

GENERAL PRECAUTIONS

Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.

To protect yourself and others from infection:

- Do not perform blood or control fluid testing in areas where food and drink are stored or consumed.
- Wash hands after handling blood or blood soiled items.
- Do not use a cartridge if blood is spilled on it.
- Discard contaminated (blood soiled) items in a bio-hazard waste container.
- Decontaminate analyzer or work surface if blood is spilled on it.
- Since blood spots may not be noticeable on the analyzer and since a cartridge could contaminate the inside of the analyzer, treat the analyzer as capable of transmitting infection.

PREPARING TO USE THE i-STAT 1 ANALYZER

Before using the analyzer:

- Check the battery status, Date and time, Software and customization.
- See HOW TO PERFORM QUALITY CONTROL TESTING section in this guide for details on performing a quality control check.

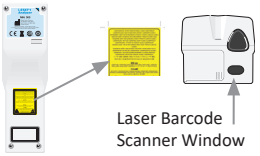
CAUTIONS FOR THE ANALYZER

- A falling analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.
- **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.

ANALYZER WARNING LABELS

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.



SECTION 6

PREPARING TO USE THE i-STAT CARTRIDGE

RECEIVING i-STAT CARTRIDGE SHIPMENT

- Immediately check temperature strip enclosed with each shipment of i-STAT Cartridges. Follow the instructions on the card.
- Verify the integrity of cartridges, included in every shipment, upon receipt. See the HOW TO PERFORM QUALITY CONTROL TESTING section of this user guide for additional details.

HANDLING THE i-STAT CARTRIDGE

While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling and Quality Check failures.

- A cartridge should not be removed from its protective pouch or portion pack.
- For best results, the cartridge and analyzer should be at the temperature of the room where they are to be used. Condensation on a cold cartridge may prevent proper contact with the analyzer.
- Equilibrate a single cartridge for 5 minutes or a box of cartridges for 1 hour at room temperature before opening pouch or portion pack.
- Use a cartridge immediately after removing it from its protective pouch or portion pack — prolonged exposure may cause a cartridge to fail a Quality Check.
- If the pouch or portion pack has been punctured, the cartridge should not be used.
- Once cartridges have been brought to room temperature, they should not be returned to the refrigerator.

CAUTIONS FOR HANDLING THE i-STAT CARTRIDGE

- Avoid touching the contact pads, as this may cause contamination and prevent the analyzer from making proper contact with the cartridge. Avoid touching the sensors on the top.
- Do not apply pressure to the central area of the Cartridge.
- To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled.
- Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.

SECTION 6

PROCEDURE FOR PATIENT TESTING

CAUTIONS:

- Ensure cartridges and analyzers are at room temperature
- Scan the cartridge barcode before opening cartridge pouch or portion pack.
- Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent eye damage.
- Use a cartridge immediately after removing it from its protective pouch or portion pack or portion pack. Prolonged exposure may cause a cartridge to fail a Quality Check.
- Do not attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the analyzer. The message "Cartridge Locked" will remain on the screen until the analyzer unlocks the cartridge.
- Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.
- To protect from nosocomial infections, decontaminate analyzers periodically and whenever blood is spilled or transferred to an analyzer. See CLEANING AND DISINFECTING section of this guide.
- A falling analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.
- The analyzer may be rendered inoperative by damage due to mishandling, such as dropping, by exhausting the batteries or by other causes. Clinical settings that demand fail-safe testing should reduce this risk by having a backup analyzer or test source available.
- The analyzer and its peripherals are not listed by any authority with respect to suitability for use in oxygen enriched atmospheres.
- Proper procedure must be used to ensure correct manual entry of patient ID, operator ID, sample type and other data that may affect the clinician's interpretation of results.

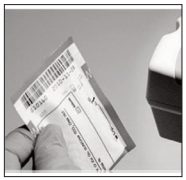
1. Press ⏻ to turn on the analyzer.

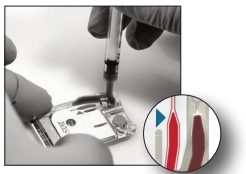
   Note: The analyzer will turn off after 2 minutes of inactivity (no keys pressed). For more information on analyzer time out, refer to the i-STAT 1 System Manual.

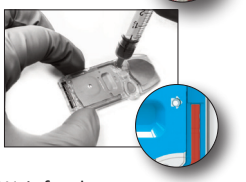
2. Press 2 (i-STAT cartridge).
3. Follow the analyzer prompts.
4. Scan the lot number on the cartridge pouch or portion pack.
   - Position barcode 3-9 inches from scanner window on the analyzer.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The analyzer will beep when it reads the barcode successfully.

   Laser Radiation – Do not stare into beam. Class 2 laser product. Laser Diode 650 nm Maximum Output 1.0 mW.

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







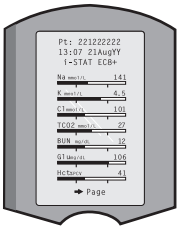
6. Push the sealed cartridge into the cartridge port until it clicks into place. Wait for the test to complete.

   Note: (1) For ACT, PT, INR, Hct, and immunoassay testing, the analyzer must remain on a level surface with the display facing up during testing. A level surface includes running the analyzer in the i-STAT 1 downloader/recharger.
   (2) During testing, do not remove the rechargeable battery or the battery carrier.

7. Review results.

SECTION 6

REVIEWING TEST RESULTS



- The 0 key can be used to backlight the display to view results in dim lighting. (The back light turns off after 90 seconds or when the 0 key is pressed again.)
- Test results are displayed numerically and with bar graphs. Tick marks indicate the reference ranges on the bar graphs. (Blood gas, coagulation, and immunoassay results are not displayed with bar graphs and reference ranges.)
- Test results are displayed for 2 minutes or a customized time. To recall the last set of results to the screen, turn the analyzer on and press 1 for Last Result.
- To review results from the same patient, when results are displayed, press 1 for Test Options and then 3 for History. Scroll through test records using the 1 and 2 keys.
- To review another patient's results, turn the analyzer on and press the Menu key followed by the 2 key for Data Review and the 1 key for patient. Scan or enter the Patient's ID number. Use the 1 and 2 keys to scroll through the test records. Or, press the Menu key followed by the 7 key for List. Select the test record(s) to be reviewed and press the Enter key.

REPORTABLE AND REFERENCE RANGES

REPORTABLE RANGE

The reportable range (sometimes referred to as the linear range) is the concentration range over which test results are valid. Reportable ranges programmed into the analyzer are listed in the Cartridge and Test Information (CTI) Sheets/Instructions for Use (IFU) on the APOC website at www.globalpointofcare.abbott.

REFERENCE RANGE

Reference ranges (sometimes referred to as normal ranges) in the default Customization profile are derived from the literature and are listed in the Cartridge and Test Information (CTI) Sheets/ Instructions for Use (IFU) on the APOC website at www.globalpointofcare.abbott. Variables such as sex, age, heritage and other demographic factors of a population may cause a shift in these ranges. Therefore, it is usually recommended that each facility determine its own reference ranges.

TEST FLAGS AND OPERATOR ACTION

When the analyzer detects an out-of-range result or an uncharacteristic sensor signal, the condition is indicated by a flag. See below for flags and symbols used with results.

- *******: (Starouts) Results that are not reportable due to sensor errors or interfering substances. Draw a fresh sample and repeat test. If results are flagged again, send sample to the lab.
- **< , > and < >**: Results that are below or above the reportable range or dependent on results that are outside the reportable range. Send sample to the lab if necessary.
- **↑ and ↓:** Results that are above or below the action range. Follow facility procedure for samples with critical values.

SECTION 6

HOW TO PRINT RESULTS

PRINTING WITHOUT i-STAT 1 DOWNLOADER/RECHARGER

1. Turn printer on if green power light is not on.
2. Align IR windows of analyzer and printer.
3. Display results.
4. Press PRT .
5. Do not move analyzer or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

PRINTING WITH i-STAT 1 DOWNLOADER/RECHARGER

1. Place analyzer in Downloader or Downloader/Recharger that is wired to printer.
2. Display results.
3. Press PRT . Do not move analyzer or printer until printing is complete.
4. If printer is not powered from a wall unit using the AC adapter, turn printer off.

PRINTING MORE THAN ONE RESULT

1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 2 (Data Review)
4. Press 7 (List)
5. Scroll through the test records using the ← and → keys.
6. Press the numbered key for the test record(s) to be printed. (Press the numbered key again to deselect a record.)
7. Align analyzer and printer IR window or place in Downloader/Recharger attached to printer.
8. Press PRT .
9. Do not move analyzer or printer until printing is complete.
10. If printer is not powered from a wall unit using the AC adapter, turn printer off.

HOW TO TRANSMIT RESULTS (OPTIONAL)

Abbott Point of Care offers optional connectivity and data management capabilities to ensure that blood analysis results obtained at the patient bedside may be integrated into various healthcare information systems. For more information, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

TRANSMITTING RESULTS WITH THE i-STAT 1 DOWNLOADER/RECHARGER

1. Place analyzer in the i-STAT 1 Downloader/Recharger. A “Communication in Progress” message will appear on the analyzer display.
2. Do not move analyzer until “Communication in Progress” message disappears. Once the message disappears, the transmission is successful.

SECTION 6

STORAGE CONDITIONS

i-STAT 1 ANALYZER STORAGE CONDITIONS

- Storage/Transport temperature: -10 to 46 °C (14-115 °F).
- Operating temperature range: 16 to 30 °C (61-86 °F).
- Store analyzers near the testing location or in an area close to the temperature of the testing area. Do not store analyzers near equipment that gives off heat or in direct sunlight.
- The disposable lithium batteries should be removed from the analyzer **when long periods, such as six months, of no use are anticipated.**

i-STAT 1 RECHARGEABLE BATTERY (OPTIONAL)

- Store the i-STAT 1 9-Volt NiMH Rechargeable Battery in a cool dry place when not in use.
- Storage/Transport temperature: -20 to 46 °C (-4 to 115 °F).

i-STAT ELECTRONIC SIMULATOR STORAGE CONDITIONS

- The i-STAT Electronic Simulator should be stored in the box in which it is shipped and the blue cap should be replaced after each use to protect the contact pads.

i-STAT 1 PRINTER STORAGE CONDITIONS

When the Printer is not in use for an extended period:

- Keep the AC adapter connected to wall outlet and Printer, if possible.
- If AC power is unavailable, disconnect the i-STAT Printer Rechargeable Battery from the i-STAT 1 Printer. Failure to remove the battery may result in the inability for the battery to be charged following storage.

i-STAT CARTRIDGE STORAGE CONDITIONS

- Store at temperatures between 2 and 8 °C (35-46 °F). Do not use after expiration date on cartridge pouch or portion pack or box.
- Store cartridges at room temperature for the time frame indicated on the cartridge box. Mark the cartridge box or cartridge pouch or portion pack with the room temperature expiration date.
- Do not expose to temperatures above 30 °C (86 °F). Do not return cartridges to the refrigerator after room temperature equilibration.
- Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage.

DISPOSAL

Dispose of analyzer, peripheral electronics, and batteries according to local, state, and/or national guidelines.

The analyzer contains a separate internal lithium battery that is not intended to be replaced by the user.

SECTION 7

CLEANING AND DISINFECTING

CAUTIONS:

- **Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.**
- **The use of any unapproved product to clean the i-STAT System may result in damage to system components.**
- The analyzer and downloader/recharger are **NOT** designed to be autoclaved or sterilized by any other method, including high heat, irradiation, or gaseous chemical processes.
- The analyzer and downloader/recharger **MUST NOT** be immersed in any liquid.
- DO NOT IMMERSE THE SIMULATOR IN ANY FLUID, AT ANY TIME.
- DO NOT IMMERSE THE PRINTER IN ANY FLUID, AT ANY TIME.
- Wash hands throughly with soap and water after handling an analyzer or downloader.

DRYING A WET ANALYZER OR DOWNLOADER/RECHARGER

If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged:

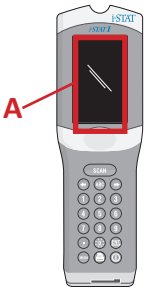
- The electronics compartment
- The battery compartment
- The cartridge port

The downloader/recharger may also be damaged by liquid contamination. Unplug the power supply from the outlet and dry the downloader/recharger completely.

CLEANING THE ANALYZER AND DOWNLOADER/RECHARGER

Avoid getting excess fluids in the seam (A) between the display screen and the case.

Avoid getting cleaning fluid on the analyzer contact pads, the battery compartment and the charging pins on the downloader/recharger.



Clean with any of the following:

- A gauze pad moistened with:
  - Isopropyl alcohol (IPA) or
  - 10% bleach solution
- A PDI® Super Sani-Cloth®

1. Clean the display screen and the case.
2. Rinse the case using another gauze pad moistened with water and dry.

CLEANING THE i-STAT ELECTRONIC SIMULATOR

Clean the simulator with any of the cleaning agents approved for the analyzer and listed above under the heading Cleaning the Analyzer and Downloader/Recharger.

1. Before cleaning, cover the connector area with the blue rubber boot. This will minimize the possibility of any cleaning fluid getting into the simulator housing, thus contaminating the internal circuitry.
2. Rinse the simulator using another gauze pad moistened with water and dry.

CLEANING THE i-STAT 1 PRINTER

Clean the external casing of the i-STAT 1 Printer with any of the following:

- A gauze pad moistened with:
  - Isopropyl alcohol (IPA) or
  - 10% bleach solution
- A PDI® Super Sani-Cloth®

SECTION 7

DECONTAMINATE THE ANALYZER OR DOWNLOADER/RECHARGER

Decontaminate the analyzer or downloader/recharger whenever a specimen is spilled onto it or if the item is to be returned to APOC for repair. Wear gloves while performing the following procedure.

1. Prepare a 10% solution of household bleach by mixing one part of bleach with nine parts of tap water.
2. Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
3. Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
4. Clean the entire surface of the device twice with gauze pads soaked in the bleach solution.
5. Rinse the surface of the device with gauze pads moistened with tap water and dry. If the device is to be shipped, place it in a plastic bag.

DECONTAMINATE THE i-STAT ELECTRONIC SIMULATOR

If the connector itself is contaminated, the user should contact their Support Representative and arrange to have the simulator returned.

SECTION 8

TROUBLESHOOTING AND SUPPORT

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 Downloader/Recharger, in an attempt to repair it or resolve a problem may cause erroneous results. If the troubleshooting procedures found in this guide or requested by an APOC support specialist do not resolve the problem, the product must be returned to APOC for repair.

TEST CYCLE MESSAGES

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.

Symptom	Possible Cause	Action
No display	Disposable Ultralife 9-Volt Lithium batteries dead or i-STAT 1 Rechargeable battery fully discharged. Keypad not responding. Start switch broken.	Change disposable Ultralife 9-Volt Lithium batteries or recharge i-STAT 1 Rechargeable battery. If still no display, contact Support Services.
"Cartridge Locked" not removed. 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 battery(s). 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.

SECTION 8

STARTUP MESSAGES

The analyzer performs self-checks when it is turned on. 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 access the Test Menu. The analyzer can be customized to lock out the operator until the corrective action is taken.

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 i-STAT 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 the downloader/recharger or delete stored records.
Stored Memory Full	The analyzer can be customized to display a Memory Full prompt. Otherwise, the oldest data is overwritten when the memory becomes full.	Place the analyzer in the downloader/recharger.
Upload Required	The analyzer is customized to alert the operator that a scheduled transmission of test records to the Data Management is due.	Place the analyzer in a downloader/recharger.
Battery Low	Battery voltage has dropped to 7.4 volts.	Change the disposable Ultralife 9-Volt lithium batteries or recharge the i-STAT 1 rechargeable battery.
Software Expires DDMMMYY	Message appears 15 days before the software expires.	Update the analyzer before the expiration date.

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 the 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.

SECTION 8

QUALITY CHECK CODE MESSAGES (QCC)

From the time it powers up until the time it powers down, the i-STAT 1 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 i-STAT Technical Services or your local support organization for further assistance.

See SUPPORT in this section on how to access additional details for Quality Check Codes found the i-STAT 1 System Manual or the Analyzer Coded Messages Technical Bulletin.

ELECTRONIC SIMULATOR QCC'S

The following messages are related to the electronic simulator (internal or external).

Code	Explanation	How to Respond
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 the i-STAT Electronic 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.	
B	Potentiometric channel out of limits.	

SECTION 8

ANALYZER AND CARTRIDGE TESTING QCC'S

The following conditions are related to the environment, state of the analyzer, or with the i-STAT Cartridge or fluid movement within the cartridge.

Message	Cause	Action
Date Invalid, Check Clock	Date outside six month lifetime of software.	Select 5-Clock Set from Administration Menu. (Password protected.)
Dead Batteries, Replace Batteries	Insufficient power to complete a test cycle.	Replace disposable batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status page	Temperature outside operating range of 16 to 30 °C.	Check analyzer temperature by pressing 1 for Analyzer Status under the Administration Menu. Move analyzer to warmer area if below operating range or to cooler area if above the range.
Expired Software, Update Required	Software expired or corrupt.	Verify that the analyzer's date is correct. Change software if expired. Update software again if not expired.
Analyzer Interrupted, Use Another Cartridge	Last cartridge run not completed.	Check that the battery pack is inserted properly. Check for Low Battery startup warning.
Cartridge Error	Usually problem with sample or cartridge filling.	Use another cartridge. If same code repeats more than twice, try another analyzer.
Cartridge Preburst	Calibrant pack burst before cartridge inserted into analyzer.	Use another cartridge - do not press on center of cartridge. Check that cartridges have not been frozen.
Unable to Position Sample	Cartridge not sealed. Clot in sample. Aberrant cartridge.	Use another cartridge.
Sample Positioned Short of Fill Mark	Cartridge underfilled.	Use another cartridge - fill to Fill Mark.
Sample Positioned Beyond Fill Mark	Cartridge overfilled.	Use another cartridge - do not fill beyond Fill Mark.
Test Cancelled by Operator	User did not respond to mandatory prompt before analyzer time out.	No action required.
Cartridge Type Not Recognized	Software does not recognize cartridge.	Update software. Check to see if cartridges are expired.
Analyzer Error, Use Electronic Simulator	Analyzer detects problem from which it is likely to recover.	Insert the i-STAT Electronic Simulator. If PASS, continue to use analyzer.
Analyzer Error, See Manual	Analyzer detects problem from which it may not recover.	Insert i-STAT Electronic Simulator. If PASS, insert a cartridge with sample or control. If the code does not reappear, continue to use analyzer.

SECTION 8

TROUBLESHOOTING UNEXPECTED RESULTS

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Instructions for Use or the Cartridge and Test Information sheets for the test in question. Test by another method to verify the result. If the controls are out of range there may be a problem with that particular cartridge lot. Use another lot number or repeat the test using another method, and refer to SUPPORT information below.

SUPPORT

PRODUCT DOCUMENTATION AND RESOURCES

Additional information related to configuration, customization, features and product documentation can be found at www.globalpointofcare.abbott.

- Value Assignment Sheets
- Product Software
- Administration Documentation
- Operator Documentation

ADDITIONAL SUPPORT

If a problem cannot be resolved by the procedures described in this section, contact your local APOC Support representative.

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)
- Lot number of cartridges
- Lot number of i-STAT liquid quality controls or calibration verification materials
- Displayed message and code number
- Frequency of problem
- Software version
- Environmental conditions
- Result of last i-STAT Electronic Simulator test
- Battery voltage from Analyzer Status page

SECTION 9

HOW TO PERFORM A SOFTWARE UPDATE

The i-STAT System is designed to eliminate operator influence on delivered results. Due to the continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance.

These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer. New CLEW software—delivered twice a year—re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the analyzer to recognize any newly launched cartridge types and to perform any newly launched features.

JAMMLITE PROCESS OVERVIEW

The JammLite procedure must be used to update the analyzer. It's best to update all analyzers via JammLite if they are readily available and near the computer you will use to run JammLite.

GATHER THE EQUIPMENT

Before starting the process make sure you have access to a computer with Windows 10, a user account on the computer with administrative rights to obtain and run the JAMMLITE Utility software and the following i-STAT 1 System equipment is available and has been setup. To setup the i-STAT 1 Downloader/Recharger for the software update, see i-STAT 1 DOWNLOADER/RECHARGER SETUP section in this guide.

1. i-STAT 1 Analyzer
2. i-STAT Electronic Simulator
3. i-STAT 1 Downloader/Recharger (DRC-300)
4. Power Cord
5. Power Supply
6. USB cable

SECTION 9

CONFIRM THE BATTERY VOLTAGE ON THE ANALYZER

Ensure that your analyzer has enough battery power (7.5 volts or higher). To verify the battery voltage on the analyzer, perform the following steps:

1. Press  to turn on the analyzer.
2. Press  (Administration Menu)
3. Press  (Analyzer Status)
4. Voltage is noted in (**Battery**).

CONNECTING AND SETTING UP EQUIPMENT

Ensure that the i-STAT 1 Downloader/Recharger has been setup. See **i-STAT 1 Downloader/ Recharger Setup** Section of this guide for details on setting up the DRC-300 for software updates.

1. Connect the DRC-300 to the back of the computer with the **USB** cable.
2. Connect the power supply with cord to the back of the downloader/recharger and to a wall outlet or power strip.

NOTE: When power is supplied to the downloader/recharger, it will look as it did before power was supplied.

LOADING JAMS/CLEW

1. Close all open programs on the computer.
2. Navigate to www.globalpointofcare.abbott website to download the latest i-STAT 1 software update file.
3. Click on “Download SUXXXXXX.ZIP” and save the zip file to the Desktop.
4. Close the “Download Complete” window.
5. Navigate to the saved zip file location. Right click on the zip file and select Extract All and Extract to the Desktop.
6. Navigate to the Desktop and click on the folder SUXXXXXX to open.
7. Double click the software file “ SUXXXXXX.exe.” to run.

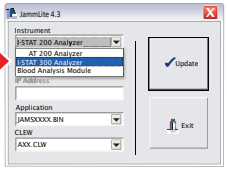
   If a Command window opens prompting to overwrite, answer “Y” and then press Enter. Continue answering “Y” to all prompts that appear until the Command window closes. From among the icons that appear, double click “JAMMLITE.exe” to launch the JammLite Utility.

   NOTE: If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to launch the JammLite Utility.

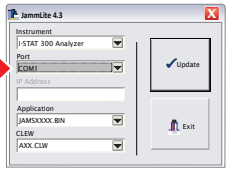
SECTION 9

UPDATING THE ANALYZER WITH THE JAMMLITE UTILITY

1. In the JammLite utility, select the i-STAT 300 Analyzer within the **Instrument** dropdown menu.



2. Select the com port within the **Port** dropdown menu. By default, the lowest numbered COM port will automatically be selected. If the DRC-300 is connected to a different COM port, change the selection to that COM port now.



NOTES:

- **If no ports are displayed, close all open programs including JammLite, and then re-launch JammLite.**
- **If JammLite still has no available COM ports listed, call your Support Services representative for assistance.**

3. Check that the **Application** and **CLEW** listings match those in the Product Update. Click the **Update** button.

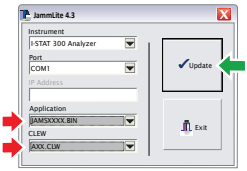


Image Note:
Application and CLEW numbers are for example only.
The "numbers" have been replaced with X's in the example to the left and will change with each software update.

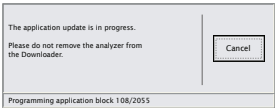
NOTES:

- If an error occurs, check the serial connection between the downloader/recharger and the PC, as well as the power connection to the downloader.
- If connected correctly, select a different COM port (Do not select TCP/IP) within the dropdown menu and click Update.
- If errors persist after trying each of the COM ports listed in JammLite, verify the serial number of your downloader and call your Support Services representative for assistance.

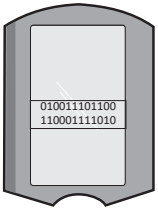
4. Follow the on-screen instructions.

When using the i-STAT 1 Downloader/Recharger, a blue light will illuminate when the analyzer is placed correctly within it.

5. When the update is in progress, the following screen will appear.

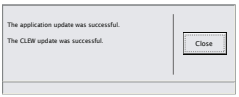


NOTE: If you do not see the screen shown on the left, acknowledge the error message(s) and click OK, then return to STEP 3.



The receiving analyzer will have 1's and 0's streaming across the screen signifying that it is receiving the software.

6. **DO NOT MOVE THE ANALYZER until the success screen is displayed. Software update has been completed,** proceed to **Perform the Electronic Simulator Test and Check Thermal Probes.**



SECTION 9

PERFORM THE ELECTRONIC SIMULATOR TEST AND CHECK THERMAL PROBES

APOC recommends that the thermal probe check be verified every six months.

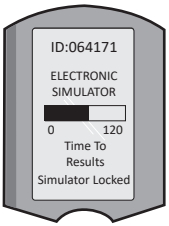
CAUTIONS:

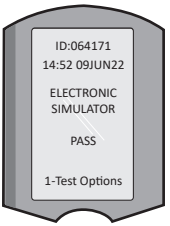
- If the analyzer and i-STAT Electronic Simulator have been stored separately in areas where the ambient temperature differs by more than 3 °C (5 °F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer.
- Handle the i-STAT Electronic Simulator as little as possible to maintain its thermal uniformity and stability.

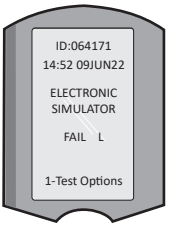
PROCEDURE TO CHECK THE THERMAL PROBES

1. Press ⏻ to turn on analyzer.
2. Press MENU to change screen to Administration Menu.
3. Press 3 Quality Tests
4. Press 4 Simulator
5. Enter Operator ID number using number keys. If ID numbers are not required, just press the enter key to continue.
6. If prompted, enter Operator ID number again and press the enter key.
7. Remove i-STAT Electronic Simulator from its box. Remove protective cap. Take care not to touch gold contact pads.
8. Enter serial number found on label of i-STAT Electronic Simulator.
9. Insert the i-STAT Electronic Simulator into analyzer with gold contact pads facing up and forward. When inserted properly, analyzer will display “Contacting Simulator”. DO NOT remove simulator until “Simulator Locked” message is removed and result is displayed.
10. When a PASS result is displayed, press the period key to view the difference between the thermal probes.

    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 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. Replace the cap and return the i-STAT Electronic Simulator to its box.



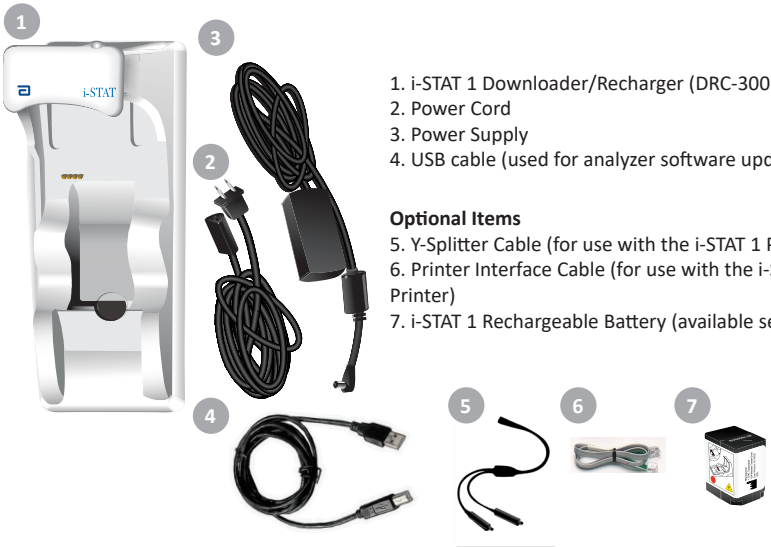




SECTION 10

i-STAT 1 DOWNLOADER/RECHARGER SETUP

GATHER EQUIPMENT



1. i-STAT 1 Downloader/Recharger (DRC-300)
2. Power Cord
3. Power Supply
4. USB cable (used for analyzer software updates)

Optional Items

5. Y-Splitter Cable (for use with the i-STAT 1 Printer)
6. Printer Interface Cable (for use with the i-STAT 1 Printer)
7. i-STAT 1 Rechargeable Battery (available separately)

CAUTIONS FOR THE i-STAT 1 DOWNLOADER/RECHARGER

- 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.
- A network cable and USB cable may NOT be connected to the downloader/recharger (DRC) at the same time.
- Only APOC approved printers may be connected to the DRC-300 printer port.
- If using rechargeable batteries to power the analyzer, 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 analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.

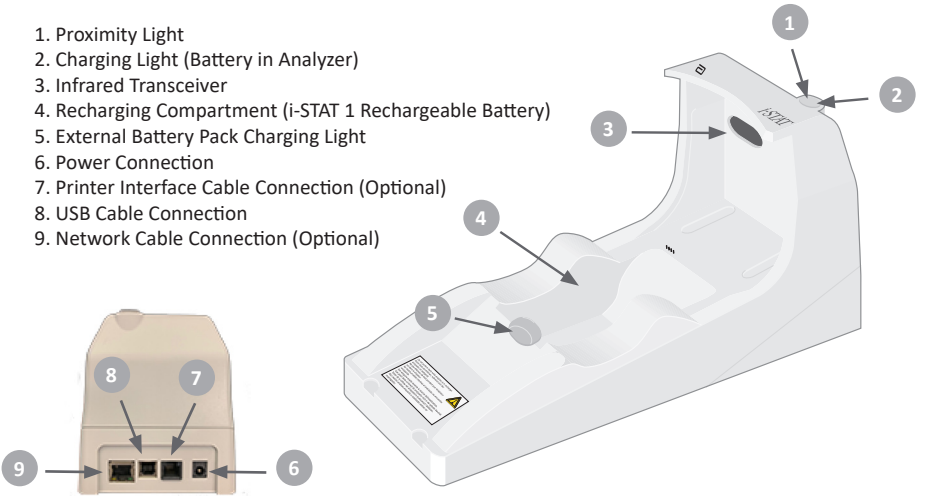
POWER REQUIREMENTS

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 1 Printer (Model Number PR-300), which reduces the number of power outlets required in the downloading and printing area.

SECTION 10

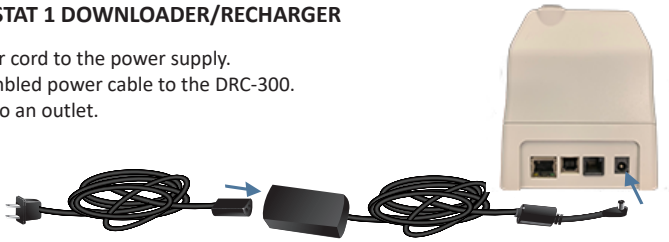
ANATOMY OF THE i-STAT 1 DOWNLOADER/RECHARGER

1. Proximity Light
2. Charging Light (Battery in Analyzer)
3. Infrared Transceiver
4. Recharging Compartment (i-STAT 1 Rechargeable Battery)
5. External Battery Pack Charging Light
6. Power Connection
7. Printer Interface Cable Connection (Optional)
8. USB Cable Connection
9. Network Cable Connection (Optional)



POWERING THE i-STAT 1 DOWNLOADER/RECHARGER

1. Connect the power cord to the power supply.
2. Connect the assembled power cable to the DRC-300.
3. Connect the plug to an outlet.



INDICATOR LEDs ON THE i-STAT 1 DOWNLOADER/RECHARGER

Analyzer Battery LED (near the 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

SECTION 10

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

The DRC-300 utilizes a Virtual COM Port (VCP) driver that enables the USB device to appear as an additional COM port available to the PC. 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 or 11 automatically installs drivers for devices that are connected to the PC. If your operating system does not automatically detect the driver for the DRC-300, the driver is available from FTDIchip.com.

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

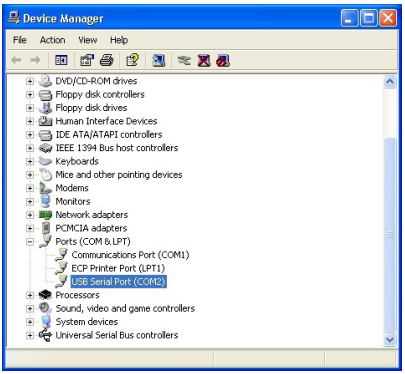
The following instructions require a PC connected to the Internet as well as Administrative rights to receive and install Windows Updates.

1. Apply power to the DRC-300. Connect the USB cable from the DRC-300 to the PC.

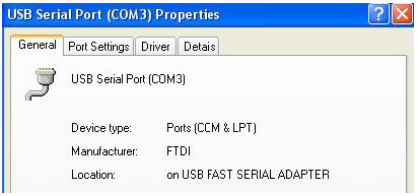
2. Wait while the "USB Serial Converter" driver (FT232R USB UART) installs. This may take a few minutes.

3. If the DRC-300 USB driver installs successfully, you may see a **"Device is Ready"** message appear on the PC Taskbar.

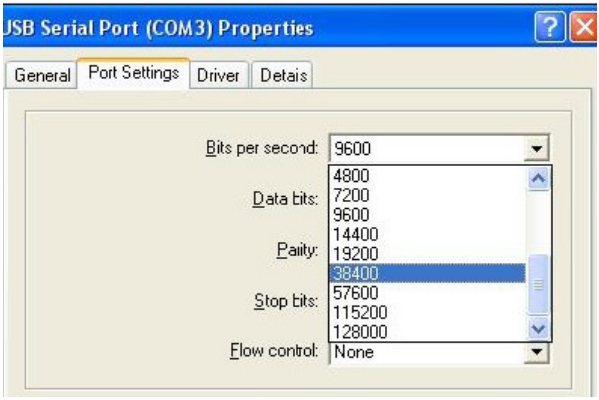
4. Click on the Windows Start icon, type in **"Device Manager"**, then select **"Device Manager"** to show a list of devices. Expand "Ports (COM & LPT)" to list all the COM Ports (as shown below). The newly installed DRC-300 port is named "USB Serial Port".



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.

SECTION 11

i-STAT 1 PRINTER SETUP

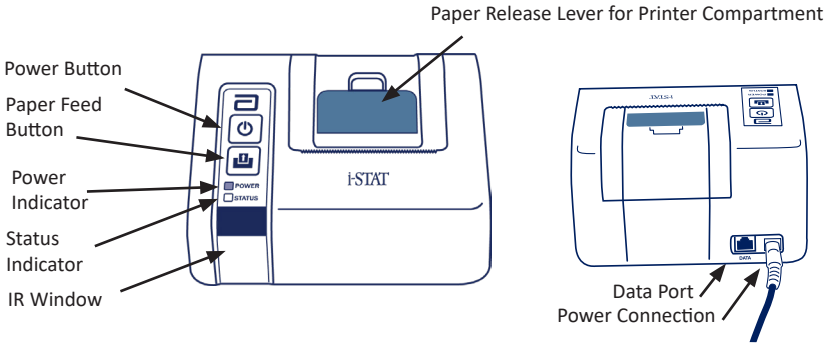
GATHER EQUIPMENT

1. i-STAT 1 Printer
2. Rechargeable Battery
3. AC Adapter
4. Power Cord
5. One roll of printer paper (not shown)

CAUTIONS FOR THE i-STAT PRINTER

- Use only a Rechargeable Battery pack purchased from Abbott Point of Care (List Number 04P74-03). Rechargeable battery packs not recommended by or purchased from Abbott Point of Care may be susceptible to overheating and could lead to a potential fire or burn hazard.
- Use only power adapter and power supply provided with the i-STAT 1 Printer kit.
- Do not operate the printer without paper.
- Do not disturb the analyzer or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and analyzer or replace the analyzer in the downloader/recharger to resume printing. **Note:** If significant time has elapsed, some results may be missing from the printout. Reprint the results.
- Do not allow the power supply to become a trip hazard.
- Only APOC provided printers may be connected to the printer port on the i-STAT 1 Downloader/Recharger (DRC-300).
- Fluorescent light sources can cause interference with communications sent to the i-STAT 1 Printer. When light from a fluorescent source of sufficient proximity or brightness has a direct path into the IR (Infrared Radiation) window of the i-STAT 1 Printer, the printer may fail to respond when records are sent for printing over a serial (wired) connection to a Downloader/Recharger.
- A falling analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.

ANATOMY OF THE i-STAT 1 PRINTER



POWER REQUIREMENTS

There are three options for powering the i-STAT 1 Printer:

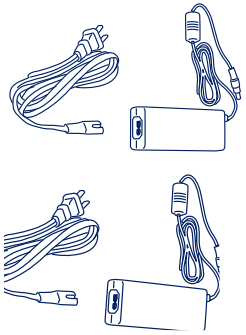
- Using the AC adapter and power cord only,
- Using the Rechargeable Battery only, and
- Using the Rechargeable Battery with the AC adapter and power cord.

SECTION 11

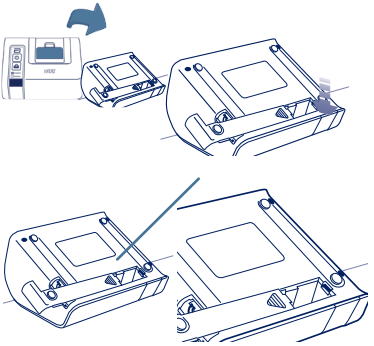
PERFORM PRINTER SETUP

This section describes the instructions for setting up the i-STAT 1 Printer.

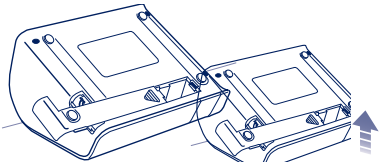
1. Connect Power Cord to AC Adapter



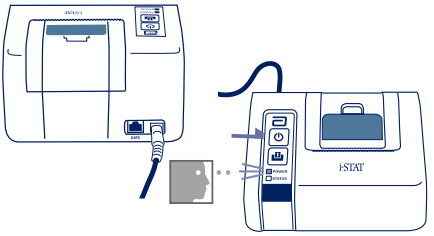
2. Open and Connect Rechargeable Battery



3. Insert Rechargeable Battery and Close

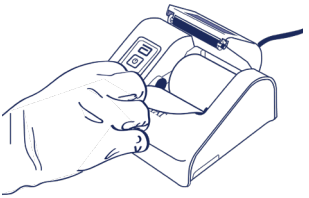


4. Attach Power Cord and Power On

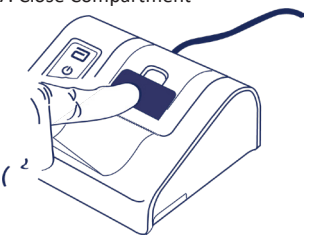


5. Open Printer Compartment

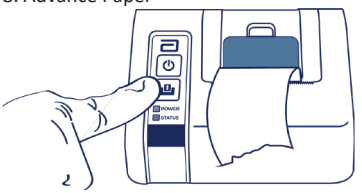
6. Load Paper



7. Close Compartment



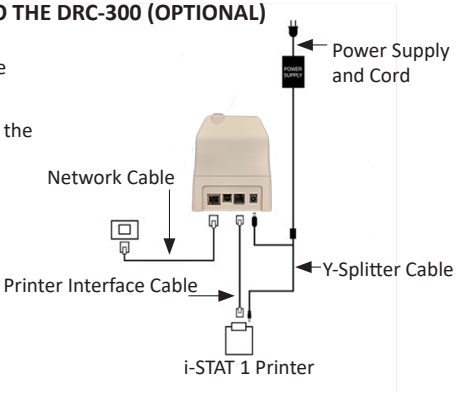
8. Advance Paper



SECTION 11

CONNECTING THE i-STAT 1 PRINTER TO THE DRC-300 (OPTIONAL)

1. Connect the printer interface cable to the i-STAT 1 Printer and DRC-300.
2. Ensure that both the i-STAT 1 Printer and the DRC-300 have power.
3. Power on the i-STAT 1 Printer.



INDICATOR LEDS ON i-STAT PRINTER

POWER INDICATOR LED

When the printer is on, the POWER indicator will be illuminated:

Power OK	**Green**	●
Battery Low	**Orange**	●
Battery Empty	**Red**	●

If the printer is inactive for >60 seconds, it will automatically enter the power-saving mode. When in the power-saving mode, the POWER indicator will change from a solid color light to pulsed illumination.

The printer's rechargeable battery needs to be recharged when the POWER indicator turns orange. If the battery becomes exhausted, the POWER indicator will turn red and printing will be disabled.

The printer's battery can be recharged using the supplied AC power adapter. The socket for the AC power adapter is located on the rear of the printer.

Note: Charging only occurs when the printer is switched off or is in the power-saving mode. A full charge takes approximately 3 hours.

Symptoms Indicating that the Rechargeable Battery Requires Replacement:

1. A steady Orange or Red POWER indicator light on the printer, even after charging it for the recommended 3 hours.
2. Loss of battery capacity, indicated by a shorter interval between charges.

STATUS INDICATOR LED

The STATUS indicator will illuminate to indicate the print status:

Ready	**Green**	●
Out of Paper	**Orange**	●
Error	**Red**	●

Note 1: Should the paper become creased or misaligned, simply reload the paper as described above ensuring that the paper has a clean, straight edge.

Note 2: When removing a printout from the printer, pull the printout toward the front of the printer and tear from one side to the other across the serrated edge.

APPENDIX 1: SYMBOLS

SYMBOL	DEFINITION
	i/immuno: Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.
	Consult instructions for use or see System Manual for instructions.
	Attention: See instructions for use.
	Caution: Risk of electrical shock.
	Laser radiation hazard symbol.
	Biological Risks.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Upper limit of temperature. The upper limit for storage is adjacent to the upper arm.
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used. An expiration date expressed as YYYY-MM means the product cannot be used past the last day of the month specified.
	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
	Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.
	Serial number. The serial number will appear adjacent to this symbol.
MN OR #	Model number. The model number will appear adjacent to this symbol.
	Date of manufacture.
	Manufacturer.
	*In vitro* diagnostic medical device.
	For prescription use only.
	Authorized Representative for Regulatory Affairs in the European Community.
	Importer in the European Community.
	Control.
	Contains sufficient for < n > tests.
$\overline{X}$	Mean
R	Range

APPENDIX 1: SYMBOLS

SYMBOL	DEFINITION
CE	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) with respect to safety, health, environment and consumer protection.
⎓	Direct Current (DC).
~	Alternating Current (AC).
⧈	Class II Construction.
c ETL US LISTED Intertek	Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010-1: 3rd Ed; Am.1 CAN/CSA C22.2 No. 61010-1-12 3rd Ed. (R2017) +U1;U2
	Note concerning batteries: The following information is applicable to EEA (European Economic Area) countries: The directive 2006/66/EC requires separate collection of spent batteries. You are requested to dispose those batteries referred to in Section 6 of this user guide, in accordance with local regulations. This product also contains a separate internal lithium battery that is not intended to be replaced by the user.
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
	Do not reuse.
	This symbol is used for compliance with the China RoHS regulation(s). It indicates in years the Environmentally Friendly Use Period (EFUP) for the labeled electronic medical device product.
FC	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.
14 d	14 days room temperature storage at 18-30 °C
2 m	2 months room temperature storage at 18-30 °C
BC	Packaging contains cartridges with barcoded pouch or portion pack.
	Battery: i-STAT 1 Analyzer low battery icon (flashes on lower left side of display screen).
BODYYYY-MM-DD	Born On Date: the label BODYYYY-MM-DD defines year, month and day of manufacture.
	The near-patient testing symbol illustrates that a device can only be used in a near-patient setting by a health worker, professional or trainee.

APPENDIX 1: TERMINOLOGY

TERM OR ACRONYM	DEFINITION
300-G	i-STAT 1 Analyzer
300W	i-STAT 1 Wireless Analyzer
APOC	Abbott Point of Care
BOD	Born on Date
CalVer	Calibration Verification
CLEW	Standardization software
CPB	Cardiopulmonary Bypass Surgery Setting. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery.
CTI	Cartridge and Test Information
DRC-300	i-STAT 1 Downloader/Recharger Combination
eVAS	Electronic Value Assignment Sheet
EDTA	Ethylenediamine tetraacetic acid
IFU	Instructions for Use
JAMS	i-STAT 1 Analyzer Software
LED	Light emitting diode
MAC	Media Access Control
MQSI	Manufacturer's Quality System Instruction
POC	Point of Care
PR-300	i-STAT 1 Printer for the i-STAT 1 Analyzer
QC	Quality Control
QCC	Quality Check Code
ReVAS	Rilibak Electronic Value Assignment Sheet for customers in Germany.
SU	Software Update
UG	User Guide
USB	Universal Serial Bus
VAS	Value Assignment Sheet

APPENDIX 1: TEST ABBREVIATIONS

ABBREVIATION	DEFINITION
Na	Sodium
K	Potassium
Cl	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
pH	pH
***P*CO$_2$**	Partial pressure of carbon dioxide
***P*O$_2$**	Partial pressure of oxygen
iCa	Ionized Calcium
BUN/UREA	Urea nitrogen/Urea
Hct	Hematocrit
ACTc **Celite ACT**	Activated Clotting Time with Celite® activator
ACTk **Kaolin ACT**	Activated Clotting Time with Kaolin activator
PT	Prothrombin Time
INR	International Normalized Ratio
Hb	Hemoglobin
TCO$_2$	Total carbon dioxide concentration
HCO$_3$	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extracellular fluid)
AnGap	Anion Gap
sO$_2$	Oxygen saturation
cTnI	Cardiac Troponin I
CK-MB	Creatine Kinase MB Isoenzyme
BNP	B-type Natriuretic Peptide
Total β-hCG	Total Beta-Human Chorionic Gonadotropin

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