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This section has its own table of contents about a wide range of information that may be useful as a reference, although only applicable or needed in waived test settings on an occasional basis.

Regulatory Guide

This section has its own table of contents and provides regulatory information regarding waived testing with the i-STAT 1 System.

Contact Information

To place an order for cartridges, supplies or equipment, contact Abbott Point of Care Inc. at 800-284-0702 – Option 2, or order through your distributor.

Cartridges and controls are shipped Monday through Thursday and delivered within 24 hours.

For Technical Support: Phone: 800.284.0702, Option 1
Fax: 609.452.1905
e-mail: techsvc@apoc.abbott.com

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Overview of the i-STAT System

The i-STAT System incorporates components needed to perform blood analysis at the patient's side. A portable handheld, a cartridge with the required tests, and 1 to 3 drops of blood will allow the caregiver to view quantitative results for tests commonly needed in physician offices, nursing homes, and clinics. A portable printer allows test records to be printed.

To perform a test, the operator fills a cartridge with sample, seals the cartridge with its closure, and inserts the cartridge into the handheld. The unit-use cartridge contains all components needed to perform the tests. The handheld automatically controls all steps in the testing cycle including: fluid movement, reagent mixing, calibration and temperature control. Quality checks are performed continuously throughout the testing cycle. Operator and patient identification and other patient information can be entered into the test record. When the test cycle is complete, results are displayed and the test record is stored. This degree of automation, along with the ability to test fresh whole blood, eliminates many sources of error as well as time-consuming and costly steps inherent in other methods.

Fill and seal cartridge with patient sample.

Insert into handheld.

Review, report and record results in minutes.

Note Regarding System Reliability: The i-STAT System automatically runs a comprehensive set of quality checks of handheld and cartridge performance each time a sample is tested. This internal quality system will suppress results if the handheld or cartridge does not meet certain internal specifications. 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 handheld 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 handhelds or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup i-STAT System handheld and cartridges from an alternate lot number.**

Preparing the Handheld

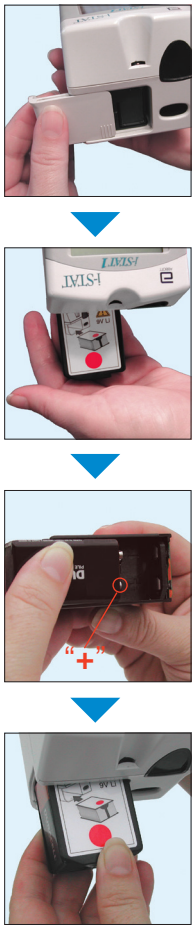
Before using a new or replacement handheld, complete these simple procedures:

- Install batteries
- Check the handheld's date and time
- Check the handheld's software and status
- Customize handheld

Install/Change Batteries

The handheld requires two 9-volt lithium batteries. Before using a new handheld, or when battery replacement is indicated, install batteries as follows:

1. Slide the battery compartment door off.
2. Tilt the handheld to slide out battery carrier.
3. Locate two (2) 9 volt lithium batteries. Insert a battery into each side of battery carrier, matching + and - marks on batteries to the + and - marks on battery carrier.
4. Slide battery carrier into handheld as shown (label facing up).
5. Slide battery door back into place.



Note:

Two 9 volt lithium batteries will provide power for approximately 400 chemistry cartridges. The handheld will display a "BATTERY LOW" message when the On/Off key is pressed, and a flashing battery icon will appear when battery replacement is needed. Stored results are not lost when batteries are fully discharged or removed. Stored results and clock settings are maintained by an internal lithium battery that should last for seven years.

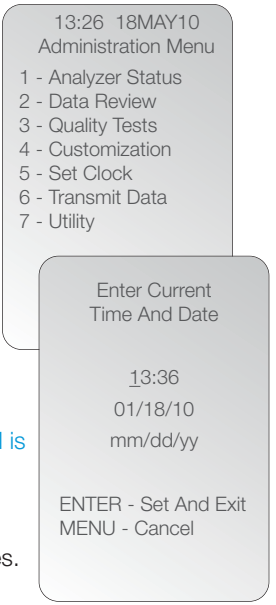
Remove the batteries if the handheld is not to be used for an extended period of time.

Check/Change Date and Time

1. Press ⏻ to turn on handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 5 (Set Clock).
4. Press ENT (No password is required).
5. Use ← or → to move the cursor to a digit if it needs to be changed. Use number keys to change digit.

   Note: Handheld uses a 24 hour clock. Therefore, 1:00 PM is displayed as 13:00.

6. Press ENT to accept changes, or MENU to cancel changes.



Check Software and Status

1. From the Administration Menu, press 1
2. Check that software (CLEW & Version) in a newly received handheld is the same as software in other handhelds in your facility (if applicable).

Temp: Handheld's reading of room temperature. Handheld will function between 16-30 ˚C.

Pressure: Handheld's reading of barometric pressure. Handheld will function between 300-850 mmHg.

Battery: Handheld's reading of battery voltage.

Uses: Total number of cartridge runs on handheld.

Serial: Serial number of handheld.

CLEW: Standardization software installed on handheld. Maintains accuracy of tests.

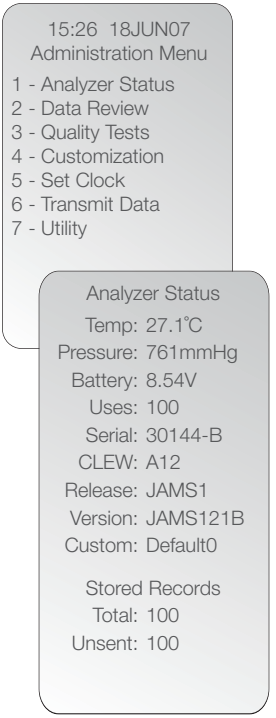
Release: The current released version of application software installed in the analyzer.

Version: The full version of application software installed on handheld.

Custom: Name of customization profile in handheld. Default0 indicates default settings. Handheld can be customized for certain site-specific and cartridge testing characteristics.

Total: Total number of test records stored in memory.

Unsent: Number of records that have not been sent to a data management system.



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Entering Information into the Handheld

Instructions for performing a patient and control test can be found in the Testing Procedures section for each cartridge type. Information entered into the handheld during the testing process is stored with results in a patient record that can be accessed and printed at any time.

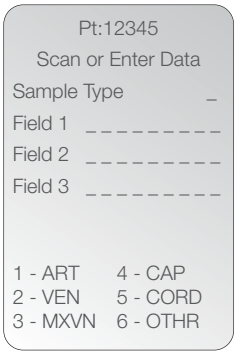
- After Operator and Patient ID are entered (up to 15 characters each), additional information can be entered on the Chart Page, which is accessed by pressing the ➡ key. Press ENT to move from field to field on the Chart Page.

Sample Type:

1. ART (arterial)
2. VEN (venous)
3. MXVN (mixed venous)
4. CAP (capillary)
5. CORD (umbilical cord)
6. Other

Note: In waived testing environments,

- Venous whole blood collected in lithium or sodium heparin tubes is the only acceptable sample type.



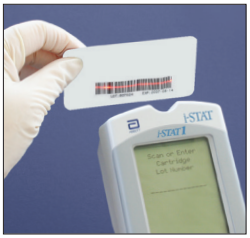
Fields 1, 2 and 3: up to 9 characters can be entered

Note: To enter letters, press the ABC key. The letter A is automatically entered. Use the arrow keys to move up and down the alphabet until the desired letter appears. Press the ABC key again to advance to the next position (To erase a letter, press the ABC key to move to the next position, then press ⬅ to erase the letter). Once all desired characters have been input, press ENT to advance to the next field.

- Operator ID numbers, Patient ID numbers and information for Fields 1, 2 and 3 on the Chart Page can be also be entered by scanning a barcode.

Caution: DO NOT stare into the laser aperture or the laser beam, or point the laser beam at other persons.

Press and hold SCAN to activate laser barcode scanner. Align the red laser light so it covers the entire barcode being scanned. The handheld will beep when it reads the barcode successfully. Try again if the “Scan or Enter” message is still displayed.



Reviewing Stored Results

A maximum of 1000 test result records are stored by the handheld, and can be reviewed by accessing the Data Review Function:

1. Press ⏻ to turn on handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 2 (Data Review).
4. At the Data Review screen, choose the category of results for review. Use 2 to move from the most recent record to additional records.

Data Review Definitions

Patient: Records for patients are recalled by scanning or manually entering a patient ID number. If no patient ID is entered, all patient test records are recalled when ENT is pressed. Not all tests may be displayed on first screen. Press handheld's arrow keys to page through all screens.

Control: All quality control test records.

Proficiency: Proficiency testing is a type of Quality Test. Not required for testing under a Certificate of Waiver.

Cal Ver: Calibration Verification is a type of Quality Test. Not required for testing under a Certificate of Waiver.

Simulator: All external and internal Electronic Simulator records.

All: All test records in the handheld's memory.

List: Records are listed with cartridge type, date and time of test, and patient or control ID (lot number). Records can be selected for viewing or printing using the numbered keys. Pressing the number key corresponding to a record selects the record; pressing the number key a second time deselects the record. To view one or more records, select the records and press the ENT key.

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Printing Results

A small thermal printer is available (purchased separately through Abbott Point of Care Inc.) for obtaining printouts of test records.

To print a test record shown on the display, point the handheld's Infrared Communication Window at the printer's IR LED window (on the left side of the front) and press the  key on the handheld. The printer must be within 1 to 5 in (2.5 to 12.7 cm) of the handheld. Do not move handheld or printer until printing is complete. To print a stored result, recall the result to the display using the procedure in "Reviewing Stored Results".

To print a selection of different stored records and for information on set-up, use and maintenance of the printer, see the System Resources section of this Manual.

Quality Control

Quality control procedures are used to ensure the continued accuracy of a test system. The quality control program for the i-STAT System includes:

- Automatic quality checks: A series of automatic quality checks are performed during each test cycle. When there is a quality check failure, a message is displayed with the cause and corrective action. A complete list of quality check messages can be found in the System Resources section of this manual. The quality checks detect improper environmental conditions, handheld function, cartridge filling, cartridge function and sensor function.

- Electronic Simulator check: An independent check of the handheld's ability to take accurate and precise readings from the sensors is performed automatically every 24 hours when cartridges are being tested. An external Electronic Simulator is used to verify an internal Electronic Simulator failure and perform the twice yearly Thermal Probe check described in the System Resources section. Both the internal and external simulator results are stored in the handheld's memory.

  Both the internal and external Electronic Simulator send signals that simulate those of a cartridge to the handheld's signal detection system. The signals are below and above the measurement ranges of the tests and the acceptance limits are tighter than those for liquid control samples. Therefore, the simulator test is more sensitive to an out-of-specification condition than liquid control samples.

  The internal simulator check is triggered by the insertion of a cartridge once every 24 hours. If the check passes, the cartridge test cycle continues. If the check fails, "FAIL" and a failure code are displayed. A cartridge test cannot be performed until the handheld passes the simulator check. If the FAIL message is observed when it occurs, the cartridge can be re-inserted. If FAIL is displayed a second time, the external simulator can be used to verify that the failure is being caused by the handheld and not by a faulty cartridge. Note that if there is a delay between the time the cartridge is inserted and the time the display is read, use a fresh cartridge and sample or the external simulator rather than re-inserting the original cartridge.

- Liquid control samples: Used to perform independent checks of system performance. Their use is an accepted way of verifying performance with traditional quantitative tests. Although this is a unit use test system, the waived status categorization for this product requires laboratories to test controls. Control testing frequency: test one cartridge from each lot in each shipment upon receipt and test a single cartridge from the refrigerator monthly. Select cartridges in the order as specified in the Testing Procedures section.

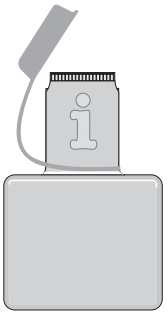
- Cartridge storage: Proper cartridge storage conditions as described in the cartridge Testing Procedures section are required for reliable results.

Checking Handheld with the Electronic Simulator

The external Electronic Simulator is stored at room temperature in its box.

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 handheld proceeds with the measurement of the patient sample. If the test fails, the handheld displays a FAIL message. The handheld cannot be used until the simulator test passes. The external Electronic Simulator can be used to verify the failure.

1. Place handheld on a flat surface.
2. Press ⏻ to turn on handheld.
3. Press MENU to change screen to Administration Menu.
4. Press 3 for the Quality Tests menu.
5. Press 4 for Simulator.
6. Enter Operator ID number using number keys.
   If ID numbers are not required, just press ENT to continue.
7. Enter Operator ID number again, if prompted, and press ENT.
8. Remove Simulator from its box. Remove protective cap. Take care not to touch gold contact pads.
9. Enter serial number found on label of Electronic Simulator.
10. Insert Electronic Simulator into handheld with gold contact pads facing up and forward. When inserted properly, handheld will display “Contacting Simulator”. DO NOT remove simulator until “Do Not Remove Simulator - Simulator Locked” message is removed and result is displayed.
11. If “PASS” is displayed, handheld may be used. If “FAIL” is displayed, do not use handheld. Record the letter or number below the result box on display and call Technical Support.
12. Replace the cap and return the simulator to its box.
13. Record result in “Electronic Simulator Check” log found in System Resources section of this Manual.



Cleaning and Decontaminating the Handheld

Drying a Wet Handheld

If the handheld is placed on a wet surface or if any liquid is spilled on it, dry immediately. The handheld may be damaged if liquid enters the battery compartment, cartridge port or case.

Cleaning the Handheld

Clean the display screen and case using a gauze pad moistened by any of the following:

- Alcohol
- 10% bleach solution

Avoid getting excess fluids in the seam between the display screen and the case. Rinse using another gauze pad moistened with water and dry.

Decontaminating the Handheld and Work Space

The handheld must not be sterilized or autoclaved by any method. If blood gets on the handheld, decontaminate it using a 10% bleach solution. Wear gloves to protect yourself from bloodborne pathogens while performing this procedure.

1. Prepare a 10% solution of household bleach by mixing one part of bleach with 9 parts of tap water. This solution will retain its strength for one week.
2. Thoroughly wet two paper towels in the bleach solution.
3. Squeeze the excess fluid out of the towels.
4. Clean handheld's surface twice using the two towels. Make sure the towels are not dripping wet or the bleach solution may enter the seams of the handheld case.
   - If the blood has already dried, do not scrape it off the surface, but gently remove it with a paper towel moistened with the bleach solution.
5. Moisten a paper towel with tap water and rinse bleach solution from the surface.
6. Dry the surface with a dry paper towel.

To decontaminate the work space, cover the area with the bleach solution and allow to stand for 10 minutes. Then wipe dry and rinse the area with tap water.

Customizing the Handheld Settings

The handheld has a variety of settings that can be customized to make data management and compliance with laboratory regulations easier in large hospital settings. However, in waived testing environments, nearly all default settings are appropriate and do not need to be changed. If handheld customization is desired, refer to the customization information in the System Resources section of this Manual.

Updating the Handheld Software

The handheld's software must be updated twice a year. The software expires in June and December. About six weeks before the current software expires, your facility will get a software update packet with complete instructions on how to perform the update.

15 days before the software expires, the handheld will display "Software Expires DDMMMYY". If you see this message and you have not received the update packet, call Technical Support.

Software updates require an i-STAT Serial Downloader or Downloader/Recharger and a PC with Windows 2000 or higher.

Thermal Probe Check

The handheld's thermal probes should be checked every six months. The procedure can be found in the System Resources section of this manual.

Warranty

Abbott Point of Care Inc. warrants this medical product (excluding disposables and consumable supplies) against defects in materials and workmanship for one year from the date of shipment. If Abbott receives notice of such defects during the warranty period, it shall, at its option, either repair or replace products which prove to be defective. With respect to software or firmware, if Abbott receives notice of defects in these products during the warranty period, it shall repair or replace software media and firmware which do not execute their programming instructions due to such defects. Abbott does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free. If Abbott is unable, within a reasonable time, to repair or replace any product to a condition as warranted, Buyer shall be entitled to a refund or the purchase price upon return of the product to Abbott Point of Care Inc.

The warranty for the 9V rechargeable battery remains in effect for one year following the Born on Date (BODYYYY-MM-DD) noted on the battery's label (pictured below).

Limitations of the Warranty

The foregoing warranty shall not apply to defects resulting from:

1. Improper or inadequate maintenance by Buyer or an unauthorized person,
2. Using accessories and/or consumables that are not approved by Abbott Point of Care Inc.,
3. Unauthorized repair, modifications, misuse, or damage caused by disposable batteries, or
4. Operating outside of the environmental specifications of the product.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED. ABBOTT SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.