System Resources

This section has 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.

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

For Technical Support, contact Abbott Point of Care Inc. at 800-284-0702 – Option 1, by fax at 609-419-9371, or by e-mail at: techsvc@apoc.abbott.com

Symbols

The following symbols may be found on components of the i-STAT System.

	Definition
	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. Date shown as YYYY-MM-DD means last day product can be used. YYYY-MM means it cannot be used past last day of 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	Model number. The model number will appear adjacent to this symbol.
	Manufacturer
	*In vitro* diagnostic medical device.
	Contains sufficient for < n > tests.
	Consult instructions for use or see System Manual for instructions.
	Control
	Signifies that product bearing ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010A-1, CAN/CSA C22.2 No. 1010.1-92.
	i/immuno: Cartridges bearing this symbol must be run on i-STAT handhelds that also bear this symbol.
	Authorized representative in European Community.

Do not reuse.

Battery: Low battery icon (flashes on lower left side of display screen).

BODxxxx-xx Born On Date: the label BODxxxx-xx defines year and month of manufacture.

14 14 days room temperature storage at 18-30°C.

2 2 months room temperature storage at 18-30°C.

BC Packaging contains cartridges with barcoded pouches.

Specifications

Dimensions	*Width 7.68 cm (3.035 in.)* *Length 23.48 cm (9.245 in.)* *Depth 7.24 cm (2.85 in.)*
Weight	*635 grams (22.4 oz.)*
Power	*Two 9-volt lithium batteries*
Calibration	*Factory: electronic, mechanical, thermal, pressure*
Memory/Clock Backup Power	*Lithium Battery*
Display	*Dot matrix supertwist liquid crystal*
Communication Link	*Infrared light-emitting diode (LED)*
Operating Temperature	*16-30°C (61-86°F)*
Transport Temperature	*-10-46°C (14-115°F)*
Relative Humidity	*90% (maximum) non-condensing*
Barometric Pressure	*300-850 mmHg*
Laser Scanner	*Complies with U.S. 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No. 50, dated July 26, 2001. EN 60825-1:1994 + A1:2002 + A2:2001; IEC 60825-1:1993 + A1:1997 + A2:2001*
Barcodes	*The barcode scanner is used to scan bar coded information into the handheld. The following barcodes are recognized:* • *I2 of 5* • *Code 128* • *Codabar* • *Code 93* • *Code 39* • *EAN 8, EAN 13*

Laser Caution

Do not open the handheld. The handheld 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.

The warning label is shown below. The warning label is located on the back or underside of the handheld. The location of the laser window from where the handheld emits the laser beam is also shown below.

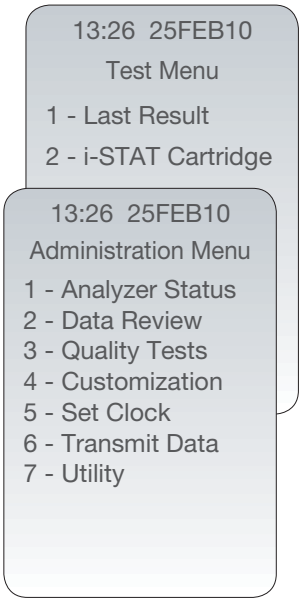
Test and Administration Menus

The handheld has two menus. When the handheld is turned on using the On/Off key, the Test Menu is displayed.

- Pressing 1 will recall the last set of results to the screen.
- Pressing 2 will display prompts for cartridge testing.

The Administration Menu is accessed by pressing the MENU key when the Test Menu is displayed. Selections are made from the main Administration Menu and submenus by pressing the appropriate numbered keys.

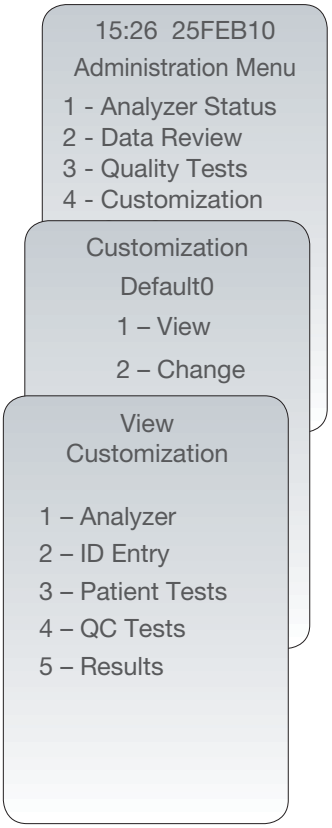
References to functions can be found in sections of the i-STAT 1 System Manual for Waived Tests as noted below.



Function	Options	Location in Manual
Analyzer Status		Start-Up
Data Review	1. Patient	Start-Up
	2. Control	"
	3. Proficency	"
	4. Cal Ver	"
	5. Simulator	"
	6. All	"
	7. List	"
Quality Tests	1. Control	Testing Procedures section
	2. Proficiency	System Resources
	3. Cal Ver	Not applicable
	4. Simulator	Start-Up
Customization	1. View	System Resources
	2. Change	"
	1. Analyzer	"
	2. ID Entry	"
	3. Patient Test	"
	4. QC Tests	"
	5. Results	"
	6. Password	"
	7. Restore Factory Settings	"
Set Clock		Start-Up
Transmit Data	1. Most Recent	Requires a data management system. This function is not described in this Manual.
	2. This Month	
	3. Last Month	
	4. All	
Utility	1. Send Software	Software update package
	2. Clear Memory	System Resources
	3. Receive Software	Not applicable

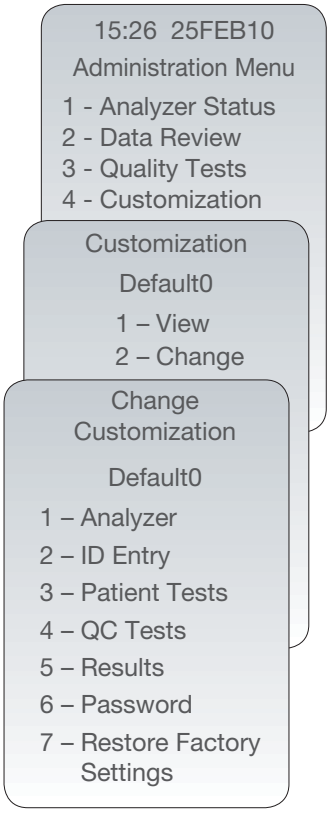
Customizing the Handheld

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. Customization options that may be useful to the smaller hospital or physician's office using the i-STAT System under a CLIA Certificate of Waiver are included below.



To view the active Customization Profile:

1. Press ⏻ to turn on handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 4 (Customization).
4. Press 1 (View).
5. Select the category to view (1 - 5).
6. Use ← or → to scroll the options in each category.
   Use ← to return to the Customization menu.



To change the active Customization Profile:

1. Press ⏻ to turn on handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 4 (Customization).
4. Press 2 (Change).
5. Press ENT (Enter password if applicable).
6. Select the category to change (1 - 7).
7. To change a setting, select the item by pressing the number key corresponding to the item, then select the setting. Use arrow keys to scroll through all items.
8. Turn handheld off to save new setting(s).

Art: 720660-00H, Rev. Date: 26-Aug-13

Highlights of Customization Menu

Menu Item	Highlights	Of interest to the smaller facility
Analyzer	Many of these options are applicable only in conjunction with a data management system.	Language used by the handheld can be changed.
ID Entry	Allows you to: • Specify the number of digits in an operator and/or patient ID to prevent operators from skipping ID entry. • Disable the repeat ID prompt. • Specify the type of barcode for operator and/or patient ID entry. • Disable the printout of operator ID with results.	If operator and or patient IDs are important to your record keeping, specify the minimum and maximum number of digits required in the ID number. If incorrect ID entry is not an issue, the handheld can be customized for single entry of operator and/or patient IDs.
Patient Tests	Allows you to: • View the Chart Page automatically (rather than having to press ➡). • Enter comment codes with results. • Prepare handheld for cartridges that require their package barcode to be scanned.	The Start-up section indicates how the handheld must be customized.
QC Tests	Allows you to customize certain behaviors associated with the internal and external Electronic Simulator.	The default settings must not be changed when using the i-STAT System under a CLIA Certificate of Waiver.
Results	Allows you to: • Change units, i.e. mmol/L to mg/dL. • Select which test results will be reported each time a cartridge is inserted. • Print default reference ranges along with patient results.	"CPB never" may be selected, as CPB is only used when a patient is on cardiovascular bypass. Other characteristics for hematocrit should not be i-STAT System under a Certificate of Waiver.
Password	A password up to 5 characters can be enabled.	The password limits access to Clockset, Customization and Utility functions.
Restore Factory Settings	Restores default settings.	

Proficiency Testing

Proficiency Testing is not a CLIA requirement for waived tests, but may be required by state regulations or if your laboratory is accredited by the College of American Pathologists (CAP). Before participating in a Proficiency Testing program, request a copy of the Technical Bulletin, "Proficiency Testing and the i-STAT System" from i-STAT Technical Support. When enrolled in a Proficiency Testing program, the program provider will ship from two to five samples, two to three times a year. You will test these samples and send your results to the program provider. The program provider will grade your results and send you a report on your results and a summary of all participant results.

Handheld Procedure

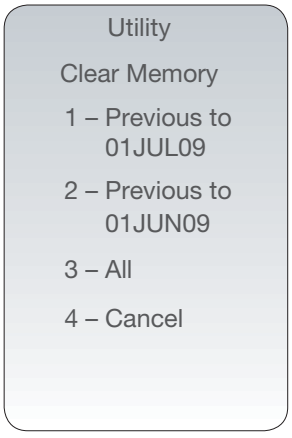
1. Press ⏻ to turn on handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 3 (Quality Tests).
4. Press 2 (Proficiency).
5. Enter information requested by the prompts.
6. Insert cartridge filled with proficiency sample when prompted. Note: the handheld will wait only 5 minutes for the cartridge before turning off.

Deleting Results From Handheld

The Utility Function is used to delete stored results. This function can be password protected using the Customization function.

To delete stored results:

1. Press ⏻ to turn on handheld.
2. Press MENU to change screen to Administration Menu.
3. Press 3 (Utility).
4. When prompted for Password, press the Enter key or the enter the password.
5. Press 2 (Clear Memory).
6. Select from the Clear Memory menu:
   1. Previous to current month and year *(as shown)*
   2. Previous to previous month and year *(as shown)*
   3. All
   4. Cancel



Thermal Probe Check

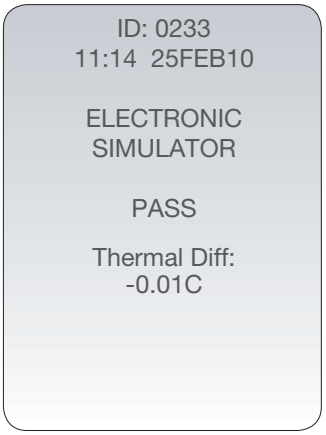
Two thermal probes in the handheld maintain the cartridges at the correct temperature during the testing cycle. This check should be performed every six months.

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

1. Follow the procedure Checking Handheld with Electronic Simulator, located in the the Start-Up section of this Manual.

2. When results are displayed, press the period key on the handheld to display the thermal difference.

   - If the value is between -0.1 and +0.1, continue to use the handheld.
   - If a FAIL message with a “t”, Quality Check Code, “--.--”, or if the value is outside the range of -0.1 to +0.1, repeat the procedure. Contact Technical Support if the test fails a second time.



Printing Results

Results can be transmitted from the handheld to either an i-STAT Printer or a Martel Printer. The printer can be recharged from a power adapter connected to an outlet.

i-STAT Printer Specifications

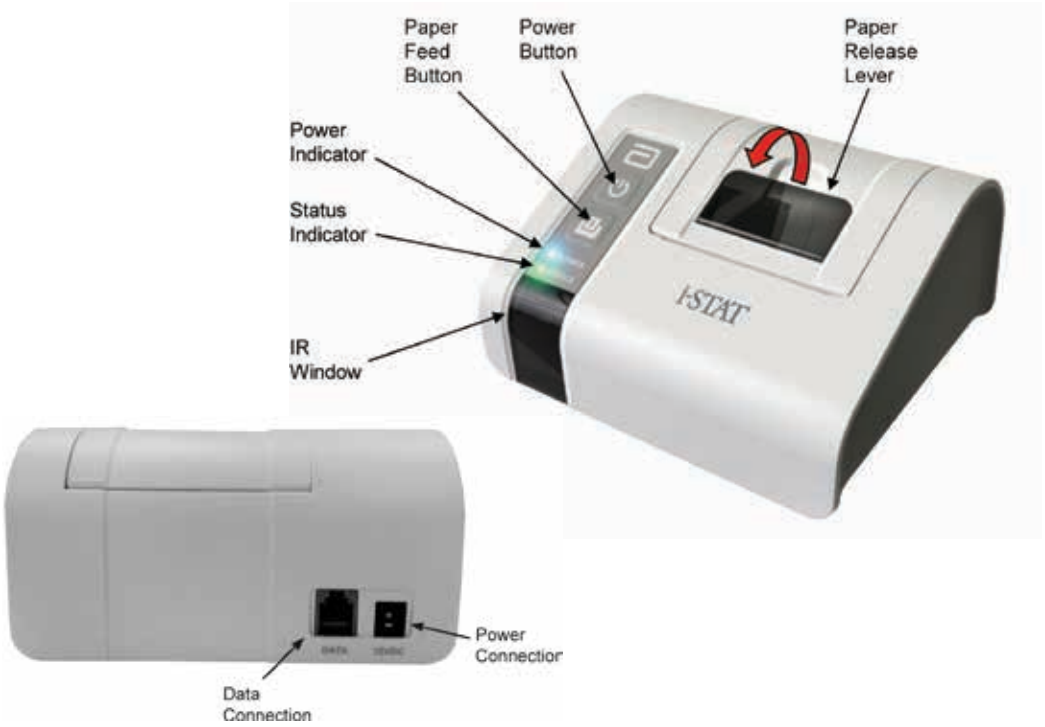
Height: 72.5mm

Width: 136mm

Depth: 120mm

Weight: 500g (Approx.)

Power	1. 4.8V NiMH rechargeable battery pack 2. Power adapter for AC outlet
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Switch	On/Off
LED Indicator Lights	POWER: Green/Orange/Red STATUS: Green/Orange/Red
Printing method	Thermal line printing
Printing speed	Up to 10 lines per second (battery) or up to 2.5 lines per second (AC Adapter)
Temperature Operating:	15 °C to 40 °C
Storage:	-20 °C to 50 °C
Power Requirements:	12Vdc, 1.5A max, 18W
External Power Supply Unit:	100-240Vac, 50-60Hz



Power

There are three options for powering the i-STAT 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.

The i-STAT Printer can be turned on and off by pressing the POWER button. 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 in the power-saving mode. A full charge takes approximately 3 hours.

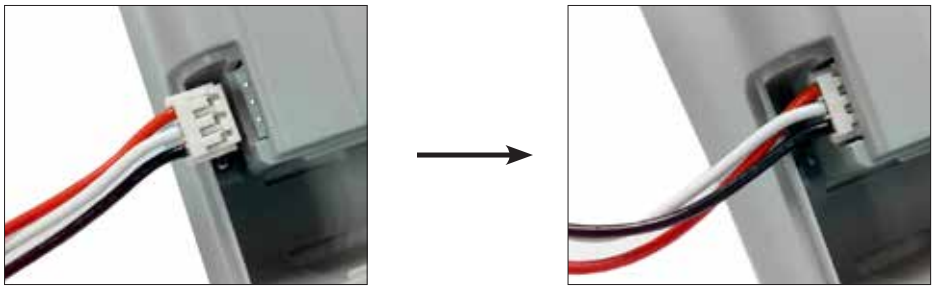
Symptoms Indicating that the Rechargeable Battery Requires Replacement:

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.

Installing or Replacing the Rechargeable Battery in the i-STAT Printer:

1. Disconnect the printer from the AC adapter.
2. Turn the i-STAT Printer upside down and place it on a flat surface. Remove the battery door by sliding it off while pressing on the grooved section. Set the door aside.

3. If replacing an existing rechargeable battery in the printer, disconnect the existing battery by gently pulling up on the red/white/black wires until the connector releases from the three metal pins. Once the battery is disconnected, remove it completely from the battery compartment.
4. Remove the new rechargeable battery from its packaging. With the thumb and index finger of one hand, grasp the connector at the end of the red/white/black battery wires.
5. Assure proper connector alignment as shown, then slide the connector onto the three metal connector pins.



7. Once the wires are connected, place the battery portion of the pack into the rectangular compartment. Make sure the wires are not under the battery or projecting out of the opening. The correct positioning is shown below.

8. Slide the battery door back onto the compartment until it closes and locks into place.
9. Turn the printer over, plug it back into the AC power adapter, and charge the new battery in the printer for a minimum of 3 hours before use.

   Note: If the rechargeable battery is removed or becomes exhausted, it is still possible to print at reduced speed using the AC power adapter.

Powering the i-STAT Printer Using the AC Adapter and Power Cord:

1. Connect the power cord to the AC adapter as shown.
2. Plug the round connector from the AC adapter into the 12VDC port on the back of the i-STAT Printer.
3. Plug the power cord into a wall outlet.

Paper

Printer paper may be ordered along with other supplies for the i-STAT System unit Abbott List # 06F17-11.

The STATUS indicator will illuminate to indicate the print status:

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

Paper for the i-STAT Printer can be installed or replaced as follows:

1. Open the paper compartment lid by pulling the release lever as shown in the printer illustration on page 1 and remove any remaining paper.
2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.
3. Sit the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.

4. Close the lid until it snaps into place.

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.

Printing with the i-STAT Printer

1. Ensure that the printer is turned on and that the POWER indicator is green.
2. Align the handheld's IR communication window with the printer's IR LED window. Generally, the printer must be within 1 to 5 inches (2.5 – 12.7 cm) of and not too close to the handheld.
3. Display the results to be printed on the handheld.
4. Press PRT on the handheld. Do not move handheld or printer until printing is complete.
5. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

Printing Many Results

1. Press ⏻ to turn on handheld.
2. Press MENU to access the Administration Menu.
3. Press 2 – Data Review.
4. Press 7 – List.
5. Scroll through the results using the ← and → keys.
6. Press the number key for the test record(s) to be printed. (Press the numbered key again to deselect a record.)
7. Align i-STAT 1 handheld and i-STAT Printer IR window. Press PRT on the handheld.
8. Do not move handheld or printer until printing is complete.
9. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

What is Printed:

Name of Test	i-STAT cartridge type.
Sample ID	Patient ID or type of quality test and lot number of solution.
Results	Results are printed with units as well as flags, reference ranges, and comment codes if applicable.
Sample Type	Sample type selected from Chart Page when sample is patient or proficiency test.
Free Fields	Information entered into the free fields on the Chart Page when sample is patient or proficiency test.
Time and Date	Time and Date when test was performed.
Operator ID	Operator ID
Lot Number	Lot number of cartridge
Serial	Serial number of the handheld
Version	Handheld application software
CLEW	Standardization software

Caution

- 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 overheading and could lead to a potential fire or burn hazard.
- Use only power adaptor and power supply (List Number 04P74-02) provided with the i-STAT Printer kit.
- Do not operate the printer without paper.
- Do not allow the power supply to become a trip hazard.
- Do not disturb the handheld or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and handheld or replace the handheld in the Downloader to resume printing. Note: if significant time has elapsed, some results may be missing from the printout. Reprint the results.
- If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the handheld. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the handheld data, the printer requires service and the printed results must not be used.
- 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. Should skin exposure to a leaking battery occur, follow the first aid measures outlined in the MSDS Sheet for the Novacell nickel metal hydride battery.
- 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 or Downloader/Recharger.

Troubleshooting

Printer not printing. POWER Indicator is green/orange and STATUS indicator is green:

- Check that results are displayed on the handheld, or that results have been selected from **List** under **Data Review**.
- If printing directly from the handheld, check that the distance between the handheld and printer is not too short or too long.
- Perform printer self test to ensure that printer is functioning. Turn the printer off. While pressing the Paper Feed button, press down on the Power button until the printout begins, and then let go of both buttons. Ensure that the resulting printout is clear and complete.

Printer is not printing over a wired connection to a Downloader or Downloader/Recharger. The POWER indicator light is green/orange and the STATUS indicator light is green.

If the printer is in close proximity to a fluorescent light:

- Reposition the printer or shield the IR window to prevent direct line-of-sight between the fluorescent light and the IR window.
- Relocate the printer or fluorescent lamp to a greater distance from each other.
- Turn off fluorescent lights within close proximity of the i-STAT 1 Printer when printing records via a serial connection.
- Print directly from the handheld via an IR connection.

Paper is feeding but nothing is printed: check that the paper is feeding from under roll.

Printer not printing and POWER indicator is red: battery needs to be recharged.

Printer POWER indicator does not illuminate when printer is turned on: battery needs to be recharged.

Printer not printing and STATUS indicator is orange: printer is out of paper.

Printer not printing and STATUS indicator is red: print head temperature is out of range. Printing will be inhibited until print head temperature returns to normal level.

Martel Printer Specifications

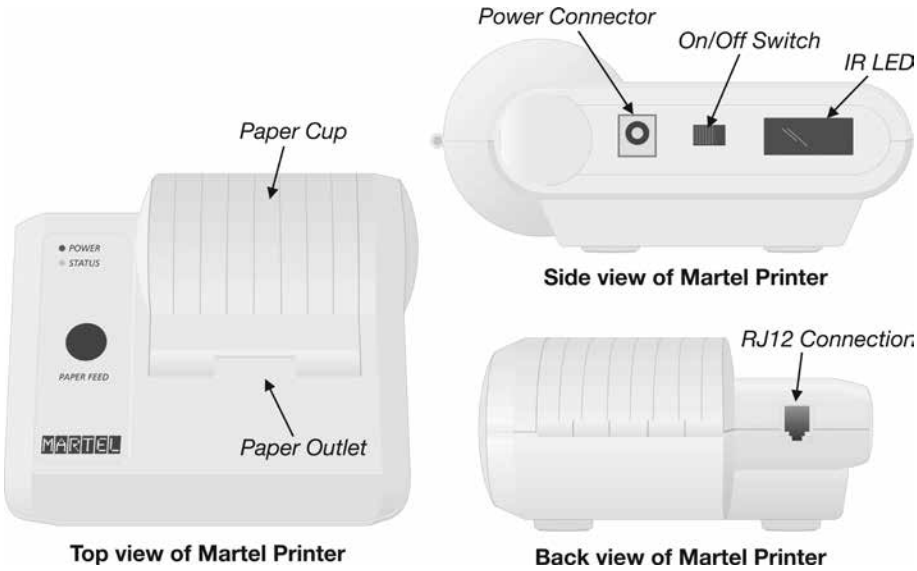
Height: 64mm

Width: 135mm

Depth: 130mm

Weight: 425g (Approx.)

Power	1. 4.8V Nickel Metal Hydride battery pack 2. Power adapter for AC outlet 3. Downloader
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Switch	On/Off
LED Indicator Lights	POWER: Green STATUS: Amber
Printing method	Thermal line printing
Printing speed	10 lines per second
Temperature Operating:	0 °C to 50 °C (32-122°F)
Storage:	-20 °C to 60 °C (-4-140°F)
Charging:	10 °C to 45 °C (50-113°F)



Side view of Martel Printer

Top view of Martel Printer

Back view of Martel Printer

Power

The Martel printer is turned on using the switch on its left side. When the printer is on, the Power LED will be green. The plug for the AC adaptor is also on the left side.

The power LED may flicker when connected to the power supply and the switch is in the OFF position. This flicker indicates that the printer is fast charging. Fast charging occurs only when the printer is turned off. Trickle charging occurs when these printers are plugged in and turned on, but not in use. Printer will charge to full capacity in 9 hours, if charged from a 12V supply with the power switch off.

The battery needs to be recharged when the Status LED lights continuously during printing. If the battery becomes exhausted, printing will become faint, erratic, or not possible at all. Should this happen, turn the printer off and allow to recharge for 1 hour before attempting printing again.

Paper

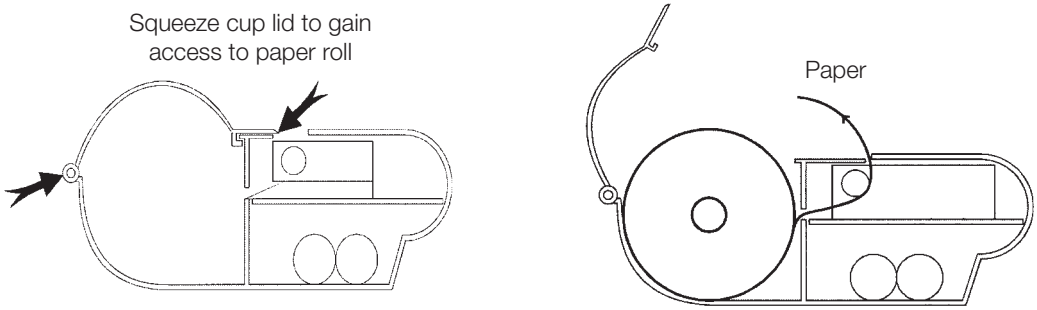
Paper may be ordered along with other supplies for the i-STAT System:

- Black print thermal paper
- 2.25” (5.7 cm) wide by 80’ (25 m) long
- Paper grade: TF50KS-E2C

The Status light will flash to indicate that the paper has run out. To replace the paper, open the paper cup lid by squeezing the lid as shown in the illustration and remove any remaining paper by pressing the Paper Feed button. Do not pull paper through the printer mechanism. Reel off a few centimeters from a new roll of paper and check that the end has a clean straight edge. Slide the leading edge of the paper through the paper entry slot, with the leading edge of the paper feeding forwards from the bottom of the roll, until you feel resistance. Press the paper feed button and feed the paper through the printer mechanism. Keep the paper feed button depressed until enough paper is fed through the printer mechanism to pass through the paper exit slot. Sit the new paper roll in the paper cup and close the lid.

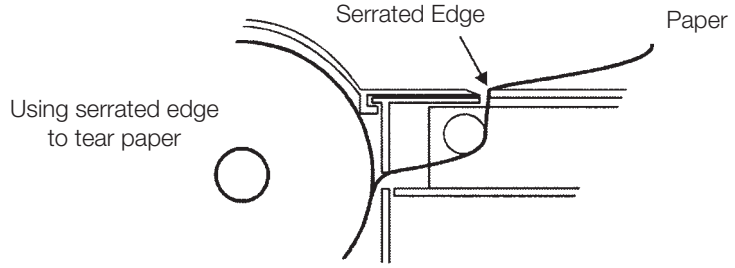
Should the paper become creased or out of line when feeding a new roll, cut the end off the paper roll, feed out the creased paper using the Paper Feed button, and reload ensuring the paper has a clear straight edge.

Before use, open the paper cup lid and ensure that the paper roll is present. Close the lid, ensuring that the paper passes through the paper exit slot. Turn the printer on. The Power indicator will light and the printer mechanism will reset.

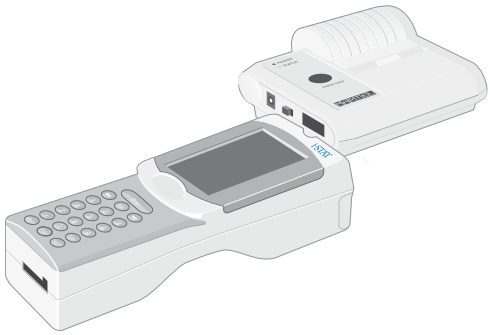


Position of paper roll in printer

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.



Printing with the Martel Printer



1. Ensure that the printer is turned on and that the POWER indicator is green.
2. Align the handheld's IR communication window with the printer's IR LED window. Generally, the printer must be within 1 to 5 inches (2.5 – 12.7 cm) of and not too close to the handheld.
3. Display the results to be printed on the handheld.
4. Press PRT on the handheld. Do not move handheld or printer until printing is complete.
5. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

Printing Many Results

1. Press ⏻ to turn on handheld.
2. Press MENU to access the Administration Menu.
3. Press 2 – Data Review.
4. Press 7 – List.
5. Scroll through the results using the ← and → keys.
6. Press the number key for the test record(s) to be printed. (Press the numbered key again to deselect a record.)
7. Align i-STAT 1 handheld and Martel Printer IR window. Press PRT on the handheld.
8. Do not move handheld or printer until printing is complete.
9. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

What is Printed:

Name of Test	i-STAT cartridge type.
Sample ID	Patient ID or type of quality test and lot number of solution.
Results	Results are printed with units as well as flags, comment codes, and/or reference ranges, if applicable.
Sample Type	Sample type selected from Chart Page when sample is patient or proficiency test.
Free Fields	Information entered into the free fields on the Chart Page when sample is patient or proficiency test.
Time and Date	Time and Date when test was performed.
Operator ID	Operator ID

Lot Number	Lot number of cartridge
Serial	Serial number of the handheld
Version	Handheld application software
CLEW	Standardization software

Caution

- Use power supply provided with printer.
- Use only a rechargeable battery pack purchased from Abbott Point of Care.
- Do not operate the printer without paper.
- Do not allow the power supply to become a trip hazard.
- Do not disturb the handheld or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and handheld to resume printing. Note: If significant time has elapsed, some results may be missing from the printout. Reprint the results.
- If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the handheld. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the handheld data, the printer requires service and the printed results must not be used.

Troubleshooting

Printer not printing. Power LED on and Status LED off:

- Check that results are displayed or that results have been selected from List under Data Review.
- Check that the distance between handheld and printer, if printing directly from the handheld, is not too short or too long.
- Perform printer self test to ensure that printer is functioning. Turn the printer on while pressing the Paper Feed button, then release the Paper Feed button and ensure that the printout is clear.

Paper is feeding but nothing is printed: check that the paper is feeding from under roll.

Printer not printing and Status light on continuously: battery needs to be recharged.

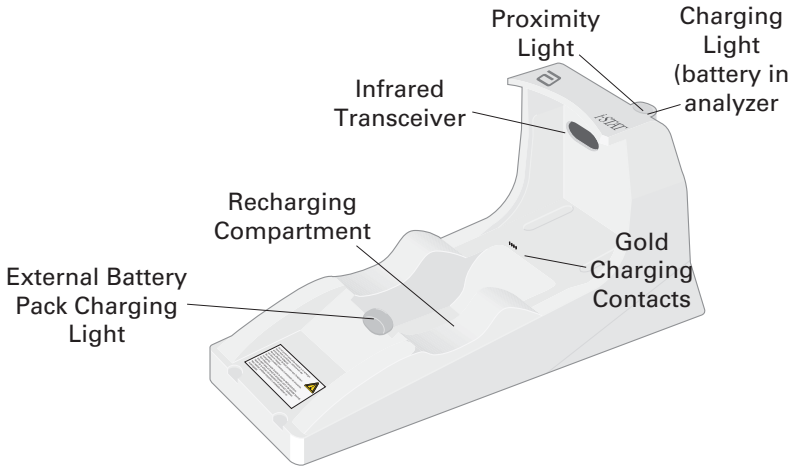
Printer Power LED does not come on when printer turned on: battery needs to be recharged. The power adapter cannot supply sufficient power for printing so the battery needs to be partially charged before printing is possible.

Printer not printing and Status light flashing at rate of 0.5 seconds: printer is out of paper.

Printer not printing and Status light flashing at rate of 0.25 seconds: print head temperature too hot. Printing will be suspended until print head temperature returns to normal level.

Downloader/Recharger

A Downloader/Recharger is needed to update the software in the handheld. This procedure is explained in the software update package. The Downloader/Recharger is also required if rechargeable batteries are being used. This section will explain how to use the Downloader/Recharger to recharge rechargeable batteries. Only rechargeable batteries supplied by Abbott Point of Care may be used.



The Downloader/Recharger will recharge a rechargeable battery in the handheld when the handheld is placed in the Downloader/Recharger. The Downloader/Recharger also has a Recharging Compartment for an additional rechargeable battery.

Power Requirements: The Downloader/Recharger requires one power outlet. The Downloader/Recharger must be used with the AC power supply adapter supplied with it.

Caution:

- 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 pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as the disconnect device for the Downloader/Recharger and therefore, the socket outlet must be located near the Downloader/Recharger and must be easily accessible.
- Only Abaxis provided printers may be connected to the Downloader printer port.
- Users should not connect the Downloader/Recharger to a medical electrical system.
- The Downloader/Recharger is not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).

Charging Batteries

- Put a new or fully discharged rechargeable battery in the Recharging Compartment for 40 hours. Battery will be 100% charged and ready for use.
- To keep batteries charged, either keep the handheld on the Downloader/Recharger when not in use, or store a rechargeable battery in the Recharging Compartment.
- The battery pack has two labels: one for orientation in the handheld and one for orientation in the Downloader/Recharger.
- A rechargeable battery is expected to last for 15 months from the date of manufacture, which appears on the battery.
- Indicator lights indicate the following when charging the battery in the analyzer:

Off	No Rechargable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging

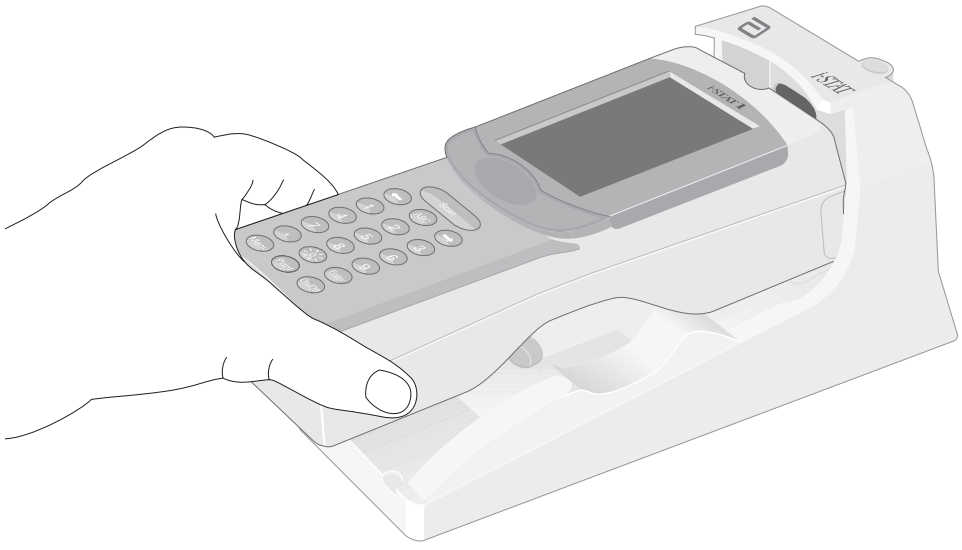
- Indicator lights indicate the following when charging a spare battery:

Off	No Rechargable Battery
Solid Green	Trickle Charging

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

Placing the Handheld in the Downloader/Recharger

- When the handheld is placed in the Downloader/Recharger, the proximity light on the Downloader/Recharger will turn blue. Also, the message "Waiting to Send" and two arrows will be displayed on the handheld. This message is relevant only if the Downloader/Recharger is connected to a data management system. The message will disappear from the analyzer display screen in a few seconds. .



Logs

A variety of logs may be useful for managing the i-STAT System:

- Receipt of New Cartridges
- Monthly Cartridge Check
- Storage Temperature
- Quality Check Codes
- Thermal Probe Check

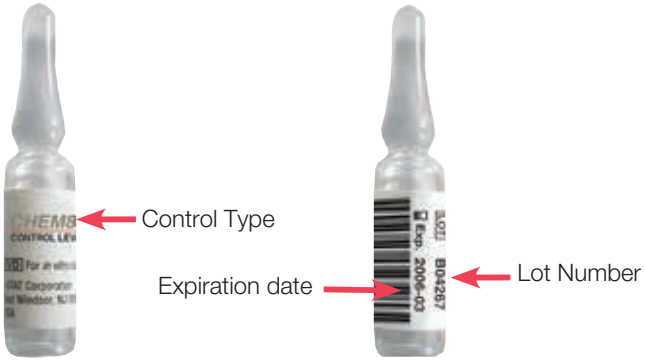
Reviewing and Recording Control Results

The following steps will guide you through recording control results on control logs.

You will need:

- A photocopy of the log. Do not write on the log in the manual.
- A printout of the control results. If a printout is not available, results can be read from the handheld result screen.
- The Value Assignment sheet from the APOC website www.abbottpointofcare.com – make sure to copy the sheet with the lot number you are using.
- The cartridge type, control lot number and control expiration date, which can be found on the individual control ampule, vial or bottle, or the control box.

- The control type, lot number and expiration date of the control, which can be found on the individual control or the control box.



- The CLEW from the handheld. See “Check Software and Status” in the Start-up section of the manual.

Maintain Value Assignment sheets and logs for two years in a file for quality control results.

Instructions for Receipt of New Cartridges Log

1. Enter the information in the top half of the log. Be sure that:
   - the lot number printed on the Value Assignment Sheet (VAS) matches the lot number on the label of the control.
   - the CLEW number on the VAS matches the CLEW listed on the Status Page of the handheld.
   - the letter preceeding the cartridge lot number on the VAS matches the cartridge lot being tested.
2. From the printout or from the handheld result screen, copy the Test names and Units into the table. For test names, you can use the test symbols (such as Na for sodium). The test units follow the test names on the printout or result screen (such as mmol/L for Na).

   Do not copy the following test names (The Value Assignment sheets do not list Hematocrit or calculated values and these results do not have to be recorded):
   - Hematocrit
   - Hemoglobin
   - TCO_2 for all cartridges except the CHEM8+ cartridge
   - Anion Gap
3. From the Value Assignment Sheet, locate the cartridge type you are testing and copy the Range for each test you have listed on the log. Make sure to copy the range appropriate for the test units.
4. From the printout or the handheld, copy the results into the log.
5. Check each result against its acceptable Range. If the result falls within Range, enter Yes. If not, enter No.
   - If a No is recorded, repeat the test and record these results
   - If a No is still recorded, do not use cartridges and contact Technical Support.

Instructions for Monthly Cartridge Check

Use the same cartridge type for this monthly check or create a new log when the cartridge type is changed.

1. Enter the date, cartridge lot number, control level, control lot number, your initials for Tested By, and the CLEW for this month's cartridge check on the log.
2. From the results printout or from the results screen on the handheld, enter the TEST names and Units into the top rows of the log.
3. From the Value Assignment sheet for the control, enter the Ranges on the log.
4. From the printout or the handheld's result screen, enter the results.
5. Check each result against its acceptable Range. If the result falls within Range, enter Yes. If not, enter No.
   - If a No is recorded, repeat the test and record these results in the next block on the log.
   - If a No is still recorded, do not use cartridges and contact Technical Support.

i-STAT System: Receipt of New Cartridges

Tested by: _____ **Test Date:** _____ **CLEW:** _____

Cartridge Type: _____ Lot: _____ Received Date: _____ Expiration Date: _____ Quantity: _____

Control Type: _____ Level: _____ Lot: _____ Expiration Date: _____

Temperature Strip: Circle any colored windows None Window 1 Window 2 Window 3 Window 4

Test Name								
Units of Measure								
Acceptable Range								
Results								
Results in Range?								
Results for Repeat Test								
Results in Range?								

Record any corrective actions taken.

i-STAT System: Monthly Cartridge Check

	TEST							
	UNITS							
Date: _____ Cartridge Lot: _____	Range:							
Tested by:_____ Control Level: _____	Results:							
CLEW: _____ Control Lot:_____	In Range?:							
Date: _____ Cartridge Lot: _____	Range:							
Tested by:_____ Control Level: _____	Results:							
CLEW: _____ Control Lot: _____	In Range?:							
Date: _____ Cartridge Lot: _____	Range:							
Tested by:_____ Control Level: _____	Results:							
CLEW: _____ Control Lot: _____	In Range?:							
Date: _____ Cartridge Lot: _____	Range:							
Tested by:_____ Control Level: _____	Results:							
CLEW: _____ Control Lot: _____	In Range?:							
Date: _____ Cartridge Lot: _____	Range:							
Tested by:_____ Control Level: _____	Results:							
CLEW:_____ Control Lot: _____	In Range?:							
Date: _____ Cartridge Lot: _____	Range:							
Tested by:_____ Control Level: _____	Results:							
CLEW: _____ Control Lot: _____	In Range?:							

i-STAT System: Storage Temperature Log (optional)

Date	Refrigerator (2-8°C / 35-46°F)	Room (Up to 30°C / 86°F)	Initials

i-STAT System: Quality Check Codes

Date	Operator	Analyzer SN	Code	Comment

i-STAT System: Thermal Probe Check

Date/Time	Handheld Serial Number	Result of Probe Check	Operator

Art: 720660-00H, Rev. Date: 26-Aug-13

i-STAT System: Electronic Simulator Log

Handheld Serial Number: _____ **Simulator ID:** _____

Date	Time	Operator	Pass/Fail	Failure Code (If applicable)	Action

Quality Checks

From the time it powers up until the time it powers down, the handheld performs numerous quality checks. The failure of any quality check causes the handheld to halt the test cycle and display a “cause” and “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 handheld will display “Sample Positioned Beyond Fill Mark”.

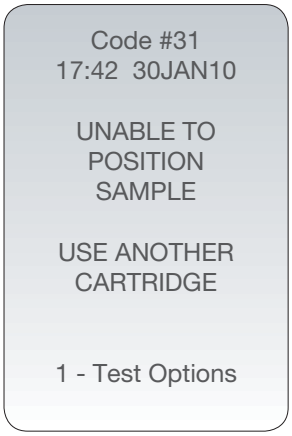
The Action Message:

This message indicates the appropriate action. For example, if the problem is related to an operator or a 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 Technical Support for assistance. The codes are stored in the handheld’s memory and can be viewed by selecting “All” from the “Data Review” function under the “Administration Menu.”

Codes below 16 usually indicate a condition related to the environment or state of the handheld. These conditions usually go away after the next cartridge is inserted or the condition is corrected.



If a Qualilty Check failure persists after taking the recommended action, call i-STAT Technical Support. Please have the following information available:

- When the problem first occurred
- Frequency of problem
- Handheld serial number
- The CLEW software version
- Any failure messages displayed on the handheld and the number or letter below the message box
- Battery voltage from Analyzer Status page
- Cartridge type and lot number

General Quality Check Codes

Cause Message	Action Message	Code	Comments
Dead Batteries	Replace Batteries	1	There is insufficient power to complete the testing cycle. Replace the batteries.
Temperature Out of Range	Check Status Page	2	Move the Handheld to an area within the operating temperature range: 16-30°C (61-86°F). Check the Status page to see when the temperature is within operating range.
Date Invalid	Check Clock on Status Page	11	Date in Handheld precedes release date programmed into the application software. Correct the date.
Invalid or Expired CLEW	See Manual	12	CLEW software has expired. Install most recent CLEW software. If CLEW has not expired, check date on Handheld.
Invalid or Expired CLEW	See Manual	13	CLEW software is corrupt or there is no CLEW software in Handheld. Install or re-install most recent CLEW software.
Cartridge Not Inserted Properly	Reinsert Cartridge	47	Push cartridge straight trough the cartridge door until it will go no further.
Analyzer Error	Use Electronic Simulator	50-52, 58-62	If the Handheld passes the simulator check, continue to use it. If not, contact Technical Support. Handheld may need to be replaced.
Analyzer error	See Manual	56	Interference from electronic noise from nearby power supply or power cord. Relocate Handheld.

General Quality Check Codes

Cause Message	Action Message	Code	Comments
Cartridge Type Not Recognized	Use Another Cartridge	69	Check that you are using the most recent software. Some cartridges require the most recent software. Make sure cartridges being used are not expired. During testing, this code will be displayed if incorrect information is entered in response to the prompt “Enter or Scan Cartridge Lot Number.” The Handheld expects the barcode on the individual cartridge pack to be scanned. It will not accept keypad entries of the cartridge lot number nor a scan of the barcode on the cartridge box.
Cartridge Error	Use Another Cartridge	79-81	This may be a cartridge problem, but if the failure persists it is likely due to damaged thermal probes in Handheld. Attempting to remove a cartridge or simulator before the “Cartridge Locked” or “Simulator Locked” message is removed or results are displayed will damage thermal probes.
Test Cancelled by Operator		95	This message will appear in the stored results if the Handheld powers down before mandatory information was entered.
Analyzer Error	See System Manual	Various Codes	Insert Electronic Simulator twice and test a control sample. If Handheld passes simulator checks and control is in range, continue to use it. If not, call Technical Support. Handheld may need to be replaced.
Electronic Simulator Fail		L	Allow Handheld to equilibrate in new environment for 30 minutes and repeat test. If code reoccurs, call Technical Support. Handheld may need to be replaced.
Electronic Simulator Fail		G	Reinsert simulator. If code reoccurs, call Technical Support. Handheld may need to be replaced.
Electronic Simulator Fail		R, r, t, B	Call Technical Support. Handheld may need to be replaced.

General Quality Check Codes

Cause Message	Action Message	Code	Comments
Cartridge Error	Use Another Cartridge	20, 23 27-29, 32, 33, 40-43, 45, 49, 87	If failure persists, contact Technical Support.
Cartridge Error	Use Another Cartridge	24	Run three additional cartridges with control or patient sample. If the failure persists, call Technical Support.
Cartridge Preburst	Use Another Cartridge	21	Take care not to press over the cartridge label area. Reinserting a used cartridge will also cause this quality check code and message.
Sample Positioned Short of Fill Mark	Use Another Cartridge	35, 36	Sample did not reach fill mark.
Sample Positioned Beyond Fill Mark	Use Another Cartridge	30, 37	Cartridge is overfilled.
Insufficient Sample	Use Another Cartridge	38, 39	Cartridge is underfilled or air bubbles were trapped in the sample.
Unable to Position Sample	Use Another Cartridge	31, 34, 44	Snap closure left open, sample overflowed well preventing adequate seal or sample clotted.
Cartridge Error	Use Another Cartridge	46	Snap closure left open, sample overflowed well preventing adequate seal or sample clotted.

General Quality Check Codes

Cause Message	Action Message	Code	Comments
Lot Expired		140	The Handheld detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
Analyzer Error	See Manual	147	The Handheld is not customized appropriately to run cartridges with barcoded pouches. See the Start-up section of this manual for instructions on customizing the Handheld for cartridge testing.

Cartridge and Test Information

Detailed information on each test can be found in the Cartridge and Test Information sheets. These sheets are available on the Abbott Point of Care Inc. website: www.abbottpointofcare.com. This information includes:

- Intended Use
- Methodology
- Contents of Cartridge
- Metrological Traceablity
- Expected Values
- Clinical Significance
- Performance Characteristics
- Factors Affecting Results
- References

Waived Status Studies for the i-STAT System

Abbott Point of Care Inc., in the course of application for Waived Status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), carried out clinical studies intended to demonstrate that users with no laboratory training, after viewing only the manufacturer's test instructions, can obtain accurate results with the i-STAT System. Accuracy of results was assessed in terms of agreement with a comparative method. The design and results of these studies are described in "Waived Test Data" folder on the Abbott Point of Care Inc. website: www.abbottpointofcare.com. Data from these studies showed that results from operators with no laboratory training or training on the i-STAT System were equivalent to operators with laboratory training and experience with the i-STAT System.