

i-STAT Alinity



Quick Reference Guide

Art: 731848-01 Rev. P Rev. Date: 20-Mar-2025

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INTENDED USE:

The i-STAT Alinity instrument 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:

The **Quick Reference Guide** contains information that describes several functional pathways of the **i-STAT Alinity** instrument.

Instrument 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 Alinity software expires periodically. Upon receipt of a new or replacement instrument, check the expiration date of the software by navigating to *More Options* > *Instrument Status*. Instructions for updating software are found in the HOW TO PERFORM SOFTWARE UPDATE 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.

Product problems and adverse events should be reported to Abbott through your Abbott Point of Care support service.

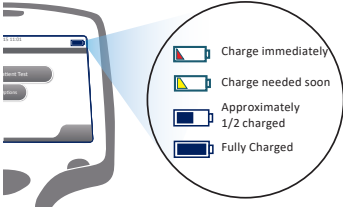
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to Abbott and its authorized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

INSTRUMENT SETUP (New Instruments)

1 ATTACH BATTERY AND POWER ON INSTRUMENT



2 CHECK FOR SUFFICIENT BATTERY CHARGE

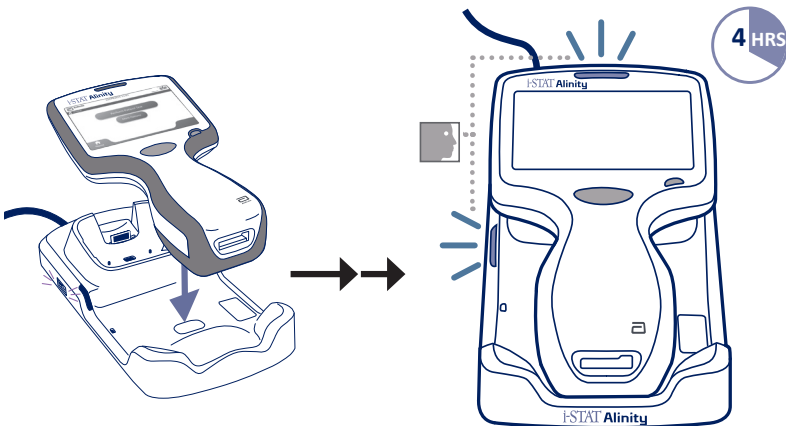


IF BATTERY SHOWS A YELLOW OR RED BAR, CONTINUE TO STEP 3.

IF BATTERY HAS SUFFICIENT CHARGE CONTINUE TO STEP 4.

An alert displays when the battery level approaches the level at which testing is disabled.

3 CHARGE BATTERY IF NEEDED OR MOVE TO STEP 4



INSTRUMENT SETUP (New Instruments) CONT.

If instrument displays *Set Region Code* screen, proceed to **STEP 4**.

If not, proceed to **STEP 6**.


4 LOCATE REGION BAR CODE

a



OR

b



INSTRUCTIONS FOR USE

ENGLISH


Alerts 1 of 1

Region Code Barcode Must Be Scanned
Before Instrument Use.

Locate region code barcode on i-STAT Alinity User Manual.

Touch the Region Code to begin set-up.

Set Region Code



FASI PER IMPOSTARE IL CODICE REGIONE

1. Caricare lo strumento i-STAT Alinity sulla Stazione base, come riportato nella Guida introduttiva.
2. Accendere lo strumento i-STAT Alinity. Verrà visualizzato l'avviso mostrato qui.
3. Toccare **Set Region Code** (Impr. codice reg.) e seguire le istruzioni sullo schermo.
4. Quando si visualizza la richiesta di scansionare il codice regione, utilizzare il codice a barre riportato su questa pagina.
5. Continuare a seguire le istruzioni sullo schermo.
6. Una volta acceso lo strumento, verificare che il messaggio **Region Code Barcode Must Be Scanned** (Codice a barre codice regione non scansionato) non venga più visualizzato. Dopo la verifica non è necessario ripetere le fasi qui descritte.

Per qualsiasi problema o domanda, contattare il Supporto tecnico all'indirizzo putectech@apoc.abott.com

STEPS TO SET REGION CODE

1. Charge the i-STAT Alinity instrument on the Base Station, per the Getting Started Guide.
2. Power on the i-STAT Alinity instrument. The alert shown here, will be displayed.
3. Touch **Set Region Code** and follow prompts on this page.
4. When prompted to scan the region code, use the barcode on this page.
5. Continue to follow prompts on the screen.
6. Once the instrument powers on, verify that the Region Code Barcode Must Be Scanned no longer displays. Once verified, these steps do not need to be repeated.

Contact Technical Services if you encounter any problems or have any questions: putectech@apoc.abott.com




SCHRITT ZUM EINSTELLEN DES REGIONSCODES

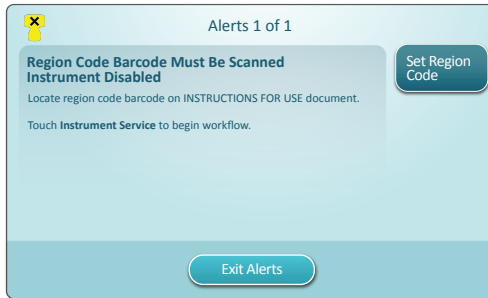
1. Laden Sie das i-STAT Alinity-Gerät gemäß dem Handbuch „Erste Schritte“ in der Basisstation auf.
2. Schalten Sie das i-STAT Alinity-Gerät ein. Der hier angezeigte Hinweis erscheint.
3. Tippen Sie auf **Set Region Code** (Regioncode einstellen) und befolgen Sie die Anweisungen auf dieser Seite.
4. Verwenden Sie bei Aufforderung, den Regioncode zu scannen, den Barcode auf dieser Seite.
5. Befolgen Sie die Anweisungen auf dem Bildschirm weiter.
6. Sobald das Gerät eingeschaltet ist, vergleichen Sie sich, dass die Meldung **Region Code Barcode Must Be Scanned** (Regioncode-Barcode muss gescannt werden) nicht mehr angezeigt wird. Sobald dies geprüft wurde, müssen diese Schritte nicht wiederholt werden.

Wenden Sie sich bei Problemen oder Fragen an den technischen Kundendienst: putectech@apoc.abott.com

i-STAT and Alinity are trademarks of the Abbott Group of Companies in various jurisdictions.

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INSTRUMENT SETUP (New Instruments) CONT.**5 TOUCH SET REGION CODE**

1. Touch **Set Region Code** and follow prompts on screen.
2. When prompted, scan Region Code on box or letter.
3. Continue to follow prompts on the screen.
4. Once the instrument powers on, the **Region Code Barcode** alert should no longer be displayed. Proceed to **STEP 6**.

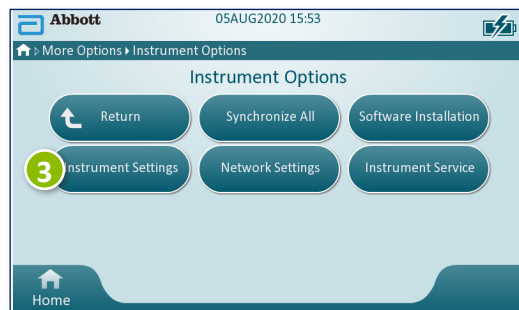
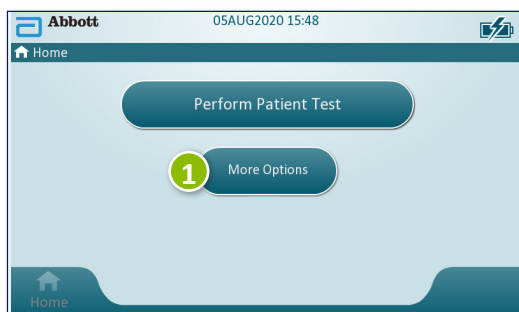
If Alert screen displays again, repeat **STEP 5**.

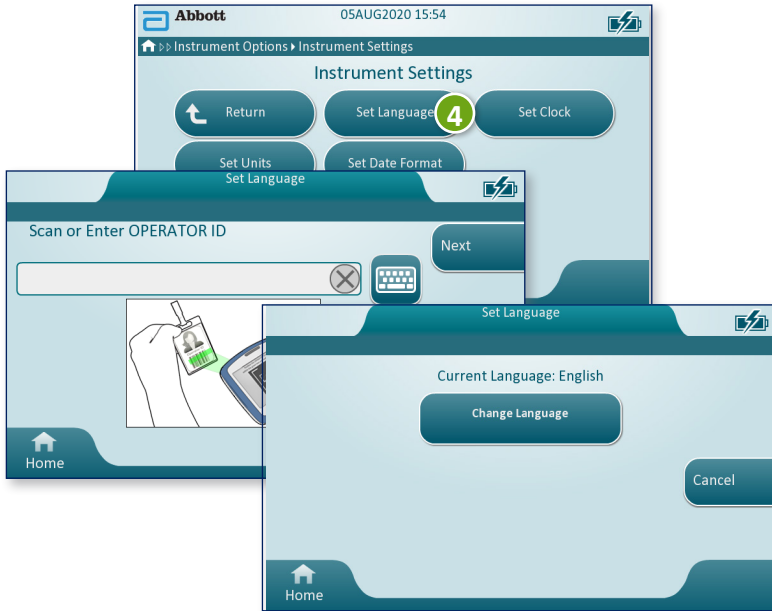
If the Alert screen displays again, contact your Abbott representative.

INSTRUMENT SETUP (New Instruments) CONT.

6 FINISH SETTING UP THE INSTRUMENT

Power instrument on, follow sequence and on-screen instructions.



INSTRUMENT SETUP (New Instruments) CONT.**6 FINISH SETTING UP THE INSTRUMENT CONT.****Set Language****Set Clock**

INSTRUMENT SETUP (New Instruments) CONT.

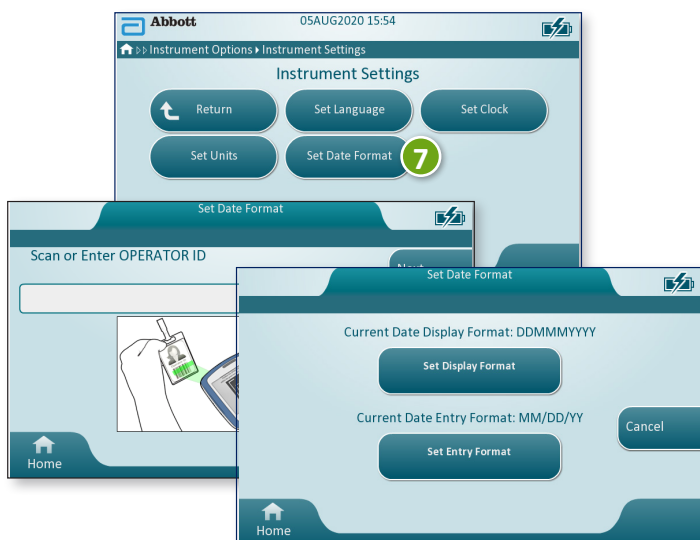
6 FINISH SETTING UP THE INSTRUMENT CONT.

Set Units



NOTE: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

Set Date Format

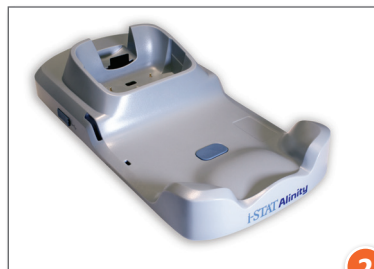


7 INSTRUMENT SETUP IS COMPLETE

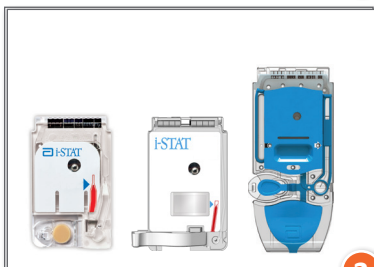
SYSTEM COMPONENTS



1



2



3



4



5



6

- 1 **i-STAT ALINITY INSTRUMENT:** Used to perform cartridge testing, reviewing test results, and conducting quality control (QC) testing.
- 2 **i-STAT ALINITY BASE STATION:** Used to recharge the battery installed in the i-STAT Alinity.
- 3 **i-STAT CARTRIDGES:** Contains sensors and reagents for testing patient samples and quality fluids.
- 4 **i-STAT ALINITY RECHARGEABLE BATTERY:** Provides main power source to the instrument.
- 5 **i-STAT ALINITY ELECTRONIC SIMULATOR:** Provides an independent check on the instrument's thermal controls and success of software updates.
- 6 **i-STAT ALINITY PRINTER:** Used to print records stored in the instrument.

SYSTEM COMPONENTS (CONT.)

PRECAUTIONS AND LIMITATIONS

i-STAT CARTRIDGE

See section HOW TO PERFORM PATIENT TESTING in this guide for details.

i-STAT ALINITY ELECTRONIC SIMULATOR

See section HOW TO PERFORM QUALITY TESTING in this guide for details.

i-STAT ALINITY INSTRUMENT

For best results, observe the following precautions to prevent damage to the instrument, to ensure the safety of the operator and the integrity of the results.

DO:

- use care when placing the instrument on a surface that is unstable, such as a patient bed. Placing the instrument on an unstable surface may cause the instrument to fall. Place the instrument on a tabletop or counter to minimize the likelihood of a fall.
- always place the instrument and peripherals on a stable surface or in a location where they will not cause injury if dropped.
- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- protect patients from nosocomial infections by disinfecting the instrument periodically and whenever blood is spilled or transferred to an instrument.
- follow site specific guidelines for integration of wireless devices into a hospital environment.
- keep the cartridge and the instrument at the temperature of the room where they are to be used. Condensation on a cold cartridge can prevent proper contact with the instrument.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the instrument. The message **Cartridge Locked in Instrument. Do Not Attempt to Remove the Cartridge.** remains on the screen until the instrument unlocks the cartridge.
- remove the rechargeable battery during the testing process. Prior to removing the rechargeable battery, ensure the instrument is powered off.
- use the instrument in environmental conditions that exceed the operating temperature and humidity specifications.
- make any unauthorized repairs or modifications to this product as this may cause personal injury or damage to the unit.

SYSTEM COMPONENTS (CONT.)

PRECAUTIONS AND LIMITATIONS (CONT.)

i-STAT ALINITY INSTRUMENT (CONT.)

NOTE:

- Protection provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- Operators should use standard precautions whenever handling the instrument, cartridge, and peripherals to protect themselves from blood-borne pathogens. Standard precautions, such as the wearing of gloves, are designed to protect personnel from blood-borne pathogens and pathogens from other body substances. These precautions are based on the assumption that blood, body fluids, and tissue can contain infectious agents and should therefore be treated as biohazardous materials.
- The instrument can be rendered inoperative by damage caused by mishandling - for example, dropping the instrument.
- Clinical settings that demand fail-safe testing should have a backup instrument or test source available.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- Synchronizing the instrument date/time to a data manager with an incorrect date/time could render the instrument unusable. To disable automatic date/time synchronization, run the **Set Clock** flow and uncheck the box **Synchronize Clock with Data Manager**. Then press **Set Date/Time** manually and set the correct date/time.

SYSTEM COMPONENTS (CONT.)

PRECAUTIONS AND LIMITATIONS (CONT.)

i-STAT ALINITY RECHARGEABLE BATTERY

Batteries have been designed to provide a safe, high-capacity power source in a relatively small lightweight package. However, if misused or abused, these batteries can be dangerous. Follow these guidelines for the safe handling, use and disposal of the rechargeable batteries.

DO:

- refer to the *Getting Started Guide* for proper charging instructions.
- charge a new rechargeable battery pack for 4 hours before initial use. A fully discharged battery will be 100% charged and ready for use after 4 hours.
- use only a rechargeable battery pack purchased from Abbott Point of Care.
- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- keep a spare, charged battery on hand at all times.
- store charged battery in the original packaging.
- check with authorities for local, state, and/or national requirements for disposal or recycling requirements for Lithium-Ion batteries.

DO NOT:

- dismantle, open or shred the battery.
- expose the battery to heat or fire. Avoid storage in direct sunlight.
- short circuit the battery. Do not store batteries in such a manner that they may short circuit each other, or allow metal objects to touch the battery contacts.
- subject the batteries to mechanical shock.
- open, disassemble, modify, crush, burn, shred, or expose to high temperatures. Toxic gases and liquids are present in batteries.
- place the battery in an oxygen-enriched atmosphere.
- make any unauthorized repairs or modifications to this product as this may cause personal injury or damage to the unit.

SYSTEM COMPONENTS (CONT.)**PRECAUTIONS AND LIMITATIONS (CONT.)****i-STAT ALINITY RECHARGEABLE BATTERY (CONT.)****NOTE:**

- A fully charged battery, if not periodically recharged, will self-discharge over time. Prevent self-discharge by keeping the rechargeable battery pack in an instrument that is on a powered Base Station.
- Protection provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- In the event of a battery leaking, do not allow any leakage to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

SYSTEM COMPONENTS (CONT.)

PRECAUTIONS AND LIMITATIONS (CONT.)

i-STAT ALINITY BASE STATION

For safety when using the Base Station:

DO:

- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- use only the power supply shipped in the box with the Base Station. Attempting to use a different type of manufacturer's adapter could damage the unit and cause fire or explosion hazards.
- 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.
- always use the Base Station for charging. Refer to the rechargeable battery *Getting Started Guide* on instructions for proper charging.
- connect only Abbott Point of Care provided printers to the Base Station printer port.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- try to connect any non-electrically isolated equipment to the Base Station.
- connect the Base Station to unauthorized medical devices or other equipment.
- place metal objects on or near the exposed battery charging contacts.
- place the instrument in an oxygen-enriched atmosphere.
- make any unauthorized repairs or modifications to this product, as it may cause personal injury or damage to the unit.

SYSTEM COMPONENTS (CONT.)**PRECAUTIONS AND LIMITATIONS (CONT.)****i-STAT ALINITY BASE STATION (CONT.)****NOTE:**

- The AC adapter power supply plug acts as a disconnect device for the Base Station and therefore, the AC socket outlet must be installed (or located) near the Base Station and must be easily accessible if the Base Station needs to be unplugged. When correctly connected to power, the blue light on the Base Station will be illuminated. After an instrument is docked, the blue light above the screen will be illuminated. This may take several seconds. If the blue light does not illuminate, check the power supply. Ensure that the Base Station is connected properly and that the instrument is seated correctly in the Base Station.
- Protection provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- The Base Station must be on a flat, level, horizontal surface such as a table top. Falling equipment may cause injury. Always place the equipment on a stable level surface in a location where it will not cause injury if dropped.

SYSTEM COMPONENTS (CONT.)

PRECAUTIONS AND LIMITATIONS (CONT.)

i-STAT ALINITY PRINTER

For best results, observe the following precautions when using the i-STAT Alinity printer.

DO:

- use only a rechargeable battery pack purchased from Abbott Point of Care.
- use only the power adapter and supply provided with the i-STAT Alinity printer kit.
- use an i-STAT Alinity printer when attempting to print from an i-STAT Alinity instrument.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- operate the printer without paper.
- pull paper through the paper mechanism. Damage to the printer can result. Use the paper feed button.
- allow the power supply to become a trip hazard.
- place the printer in an oxygen-enriched atmosphere.
- disturb the instrument or the printer until printing is complete, since this will interrupt the printout. If printing is interrupted, realign the instrument and the printer, or replace the instrument in the Base Station to resume printing.
- place printers side by side. Doing so may cause instrument to printer communication problems.

SYSTEM COMPONENTS (CONT.)**PRECAUTIONS AND LIMITATIONS (CONT.)****i-STAT ALINITY PRINTER (CONT.)****NOTE:**

- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- In the event of a battery leaking, do not allow any leakage to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- If a printout appears inconsistent with a patient's clinical assessment, verify that the correct patient record was selected (patient ID, date and time of test, etc.). If the record is not correct, select the correct record and print. If the printout still does not match the data in the instrument, the printer needs service and the printed results must not be used. If another printer is available, retry.
- Fluorescent light sources can cause interference with communications sent to the i-STAT Alinity printer. When light from a fluorescent source of sufficient proximity or brightness has a direct path into the printer's infrared radiation (IR) window, the printer might fail to respond when records are sent for printing over a serial (wired) connection to a Base Station.

ANATOMY OF THE INSTRUMENT



LED: Indicates status of the instrument.

GREEN: Instrument is starting up or test results are complete.

WHITE: Cartridge is processing.

RED: Requires immediate attention.

BLUE: Battery is charging.

YELLOW: Instrument printing.

DISPLAY SCREEN

POWER BUTTON: Press and hold button for 2 seconds to power up or power down the instrument.

BARCODE CAPTURE BUTTON: Press and hold button in order to capture a barcode. Audible cues indicate successful and unsuccessful barcode captures.

CARTRIDGE PORT: Cartridge or Electronic Simulator is inserted into the cartridge port to initiate testing.



CAMERA AND IR PORT: Camera is activated by pressing and holding the barcode capture button. The display screen displays the object within the cameras view. The IR port sends information from the instrument to the portable printer.



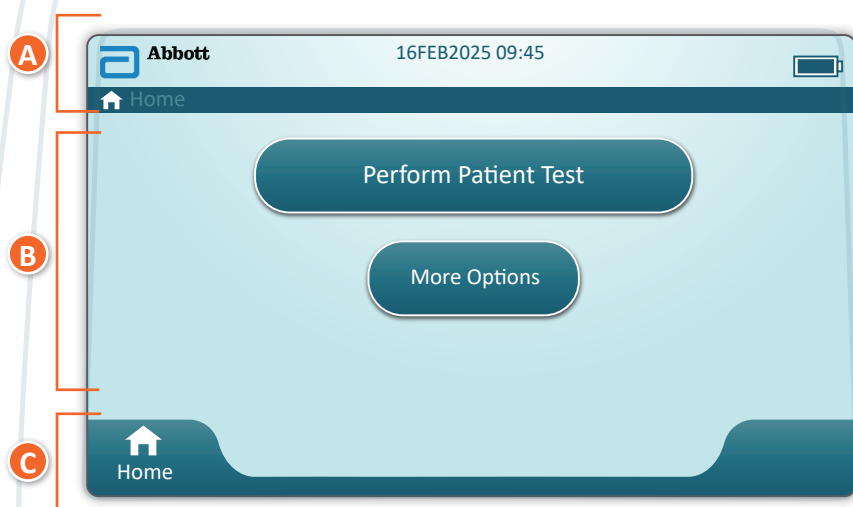
BATTERY: Rechargeable battery is the sole power source for the instrument.

SCREEN COMPONENTS AND THEIR MEANINGS



After the power button is pushed and the instrument starts the power-up sequence, the LED light will turn green, and i-STAT Alinity will appear briefly on the display screen. During the power-up sequence, the i-STAT Alinity instrument performs a series of self-checks.

SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



HOME SCREEN

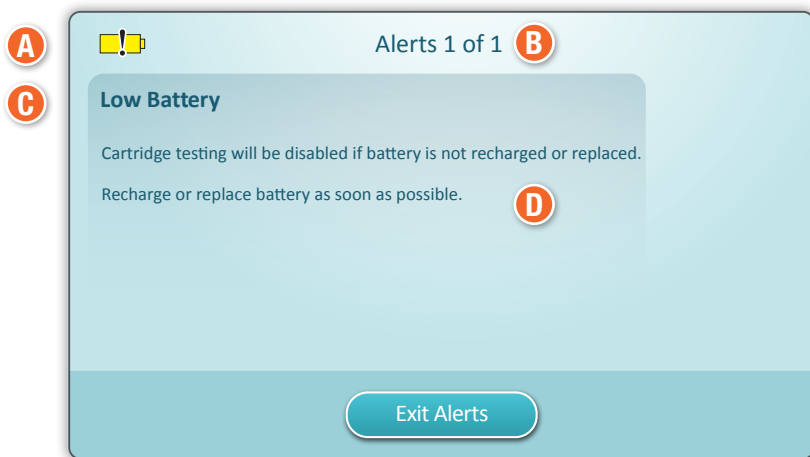
If all self-checks pass at startup, the instrument will display the *Home Screen*.

Anatomy of a Home Screen:

- A HEADER Area Contains:**
 - ◆ Date/Time
 - ◆ Wireless Status*
 - ◆ Battery Status*
- B BODY Area Contains:**
 - ◆ Buttons provide access to pathways
 - ◇ Perform Patient Test
 - ◇ More Options
- C FOOTER Area Contains:**
 - ◆ Home Button

* See Page 21 for screen icons and their meanings.

SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)

**ALERT SCREEN**

If one or more startup self-checks fail, the instrument will display the Alerts Screen as shown in the **example** above.

Anatomy of Alerts Screen:**A WARNING or LOCKOUT ICON:**

Indicates status of alert.



Instrument is locked until requirement is satisfied



or  Instrument warning

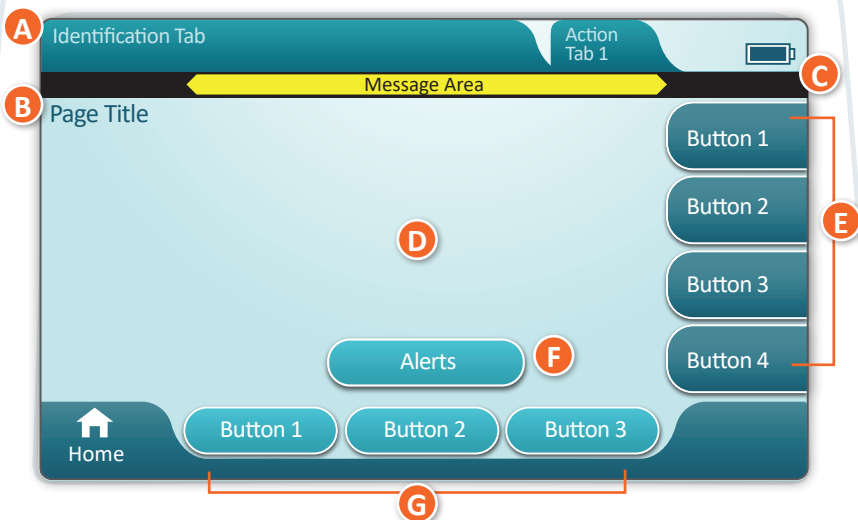
B ALERTS INDICATOR:

Displays number of alerts

C ALERT TITLE**D ALERT DESCRIPTION:**

Displays cause and resolution

SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



PATHWAY SCREEN

A generic pathway screen is shown in the **example** above.

ANATOMY OF A PATHWAY SCREEN

A HEADER:

- ◆ Identification Tab
 - ◇ Displays details such as patient ID, cartridge name, liquid quality control name
- ◆ Header Action Tabs
 - ◇ Provide options for screen navigation

B PAGE TITLE

C MESSAGE AREA

D BODY:

- ◆ Buttons in this area provide access to pathways, OR
- ◆ Location of details such as data entry field, help graphics, selection options

E SIDE ACTION TABS:

- ◆ Provide access to area or action indicated

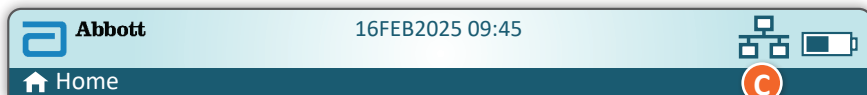
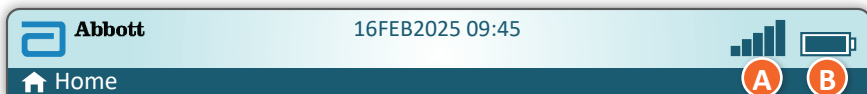
F ALERT BUTTON:


























- ◆ Provides access to Alerts description

G ACTION BUTTONS:

- ◆ Provide options for screen navigation

SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



| A Wireless Status | | B Battery Status | | C Network Status | |
|---|----------------------|---|-----------------------------------|---|-----------------------------------|
|  | Best |  | Fully charged |  | Connected |
|  | Very Good |  | Approximately 1/2 charged |  | Disabled |
|  | Good |  | Charge needed soon | Alert Icons | |
|  | Fair |  | Charge immediately | | |
|  | Poor | Battery Charging | |  | Pass |
|  | No Signal | | |  | Bolt indicates active-ly charging |
|  | No Connection |  | Bolt indicates active-ly charging |  | Warning |
|  | Wireless Disabled |  | Bolt indicates active-ly charging |  | Instrument locked |
|  | Wireless Connecting | | |  | Information |
|  | Wireless Not Allowed | | |  | Low Battery |
| Instructional Icons | | | | | |
|  | | Mandatory | | | |

CARTRIDGE INFORMATION

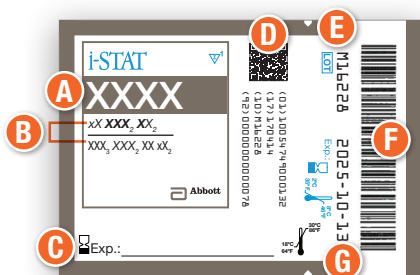


ANATOMY OF A BOX:

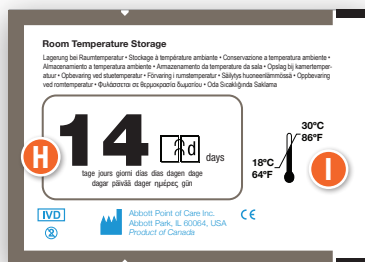
- A** Refrigerated storage temperature indicator: 2-8°C (35-46°F)
- B** Indicates shelf life when stored at room temperature
- C** Refrigerated storage expiration date
- D** Cartridge LOT number
- E** Location to record room temperature expiration date
- F** Cartridge List Number
- G** Unique Device Identifier (UDI) barcode

CARTRIDGE INFORMATION (CONT.)

Pouch Front

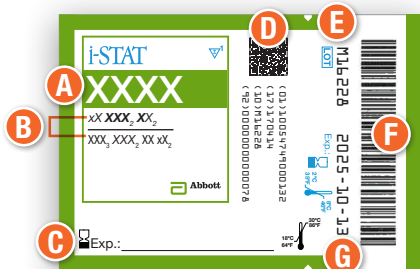


Pouch Back

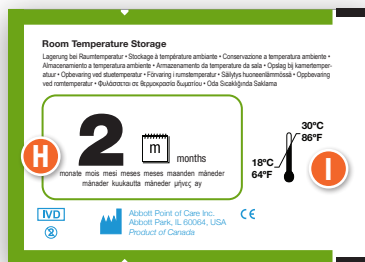


OR

Pouch Front



Pouch Back



ANATOMY OF A POUCH:

- A** Cartridge name
- B** Analytes – measured and calculated
- C** Location to record room temperature expiration date
- D** UDI (2D) barcode; not scannable by instrument
- E** Cartridge LOT number
- F** Cartridge pouch barcode, scan for test
- G** Refrigerated storage expiration date
- H** Indicates shelf life when stored at room temperature
- I** Room temperature storage range

CARTRIDGE INFORMATION (CONT.)

**Portion Pack
Front**



**Portion Pack
Back**



ANATOMY OF A PORTION PACK:

- A** Cartridge name
- B** Analytes – measured and calculated, if applicable
- C** UDI (2D) barcode; not scannable by instrument
- D** Cartridge LOT number
- E** Cartridge portion pack barcode, scan for test
- F** Refrigerated storage expiration date
- G** Refrigerated temperature storage range

HOW TO PERFORM QUALITY TESTING

MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS (MQSI)

The list below defines the i-STAT Alinity System MQSI components.

1. Check New or Replacement Instruments with the Electronic Simulator

Use the Electronic Simulator to verify operation of a new or replacement instrument before use.

2. Check Temperature Strip for a New Shipment of Cartridges

Verify that the temperature in transit was maintained by reading the temperature strip included in each shipping container.

3. Ensure Proper Cartridge Storage according to these criteria:

- Refrigerator storage conditions for stored cartridges range from 2 to 8°C (35 to 46°F).
- Cartridges are not exposed to temperatures exceeding 30°C (86°F).
- Cartridges are not used after the expiration date printed on the individual pouch and box.
- A cartridge taken from refrigerated storage must stand in its pouch at room temperature for 5 minutes before use.
- A box of pouched cartridges must stand at room temperature for one hour before use.
- A cartridge allowed to come to room temperature must be labeled with its new expiration date. See Cartridge Box Information.
- A cartridge is used immediately after it is removed from its pouch.

4. Ensure Thermal Probe Check is Performed

Ensure the thermal probe check is performed with the electronic simulator every 6 months on each instrument. This check can be performed in conjunction with the instrument's software updates.

5. Train Staff on 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).

There may be additional accreditation organization requirements and individual codes, statutes, or regulations which are not addressed here.

HOW TO PERFORM QUALITY TESTING (CONT.)

ELECTRONIC SIMULATOR

The i-STAT Alinity Electronic Simulator is a quality control device used to evaluate the i-STAT Alinity instrument's ability to read the electronic signal from a cartridge. The test cycle for the Electronic Simulator is approximately 60 seconds.

The i-STAT Alinity Electronic Simulator test provides an independent check on the ability of the instrument to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. The instrument will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the instrument software.



HOW TO PERFORM QUALITY TESTING (CONT.)

ELECTRONIC SIMULATOR (CONT.)

PRECAUTIONS AND LIMITATIONS

For best results, observe the following precautions:

DO:

- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- place the removable cap over the contacts when the Electronic Simulator is not in use or when cleaning or disinfecting.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- attempt to remove the Electronic Simulator while a test is being performed.
- drop the Electronic Simulator, as doing so can cause it to malfunction.
- place the Electronic Simulator in an oxygen-enriched atmosphere.
- make any unauthorized repairs or modifications to this product.
- use the Electronic Simulator with any instrument other than the i-STAT Alinity.
- touch the area under the cap.

NOTE:

- Function provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- The instrument can become contaminated with blood during use. Operators should use standard precautions whenever handling the instrument, cartridge, and peripherals to protect themselves from blood-borne pathogens and pathogens from other body substances. Standard precautions, such as the wearing of gloves, are designed to protect personnel from blood-borne pathogens and pathogens from other body substances. These precautions are based on the assumption that blood, body fluids, and tissue can contain infectious agents and should therefore be treated as biohazardous materials.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.

HOW TO PERFORM QUALITY TESTING (CONT.) ELECTRONIC SIMULATOR (CONT.)

Starting from the **Home Screen** touch **More Options** then **Quality Options**.



Next, touch the **Perform Electronic Simulator Test** button.



By carefully observing the text and graphic instruction, the user will be able to successfully complete an Electronic Simulator test. In the event that the test does not pass, follow the prompts on the screen.



Use care when handling the Electronic Simulator.
Avoid touching the sensor area. Replace cap after use.

HOW TO PERFORM QUALITY TESTING (CONT.)

LIQUID QUALITY CONTROL

Starting from the **Home Screen** touch **More Options** then **Quality Options** then **Quality Control**.



- For i-STAT ACT Control, i-STAT Control or i-STAT TriControl materials (controls and cal/ver), refer to the System Operations Manual for handling instructions.
- For i-STAT hs-Tnl and TBI Control materials (controls and cal/ver), refer to the instructions for use.
- When the instrument is customized by the System Administrator, the Quality Control Pathway may present screens not displayed in this guide.

- ◇ It is essential to follow the prompts on the instrument screen.
- ◇ On screen graphics and text are provided to assist the user.



NOTE: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

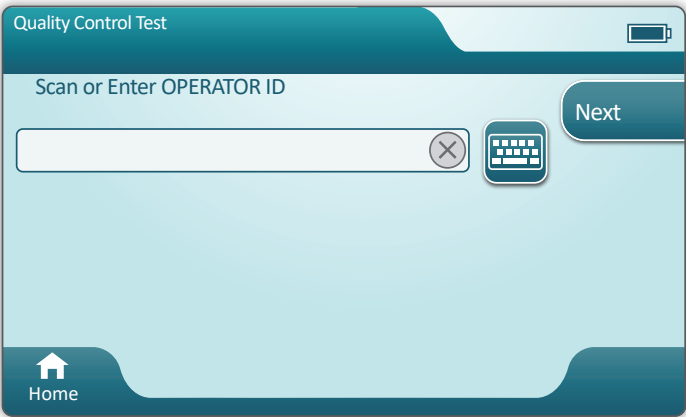
HOW TO PERFORM QUALITY CONTROL TESTING (CONT.)
LIQUID QUALITY CONTROL (CONT.)

The next step in the pathway is **Perform Unscheduled QC**



 **Scheduled QC** is only available when set by the System Administrator.

The next step in the pathway is **Scan or Enter OPERATOR ID**

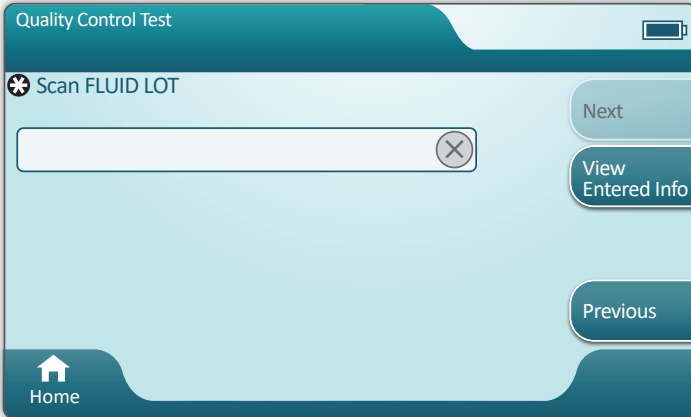


HOW TO PERFORM QUALITY TESTING (CONT.)


LIQUID QUALITY CONTROL (CONT.)

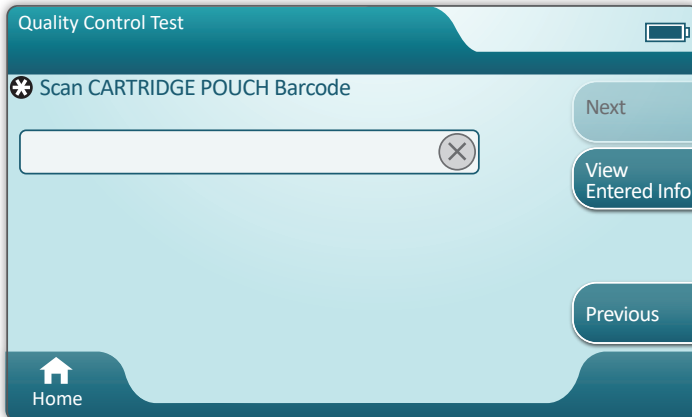
✱ **Scan FLUID LOT** barcode on i-STAT control material. Manual entry is not an option. Scanning is required.

 When the text is preceded by a ✱, the information is mandatory.



The screenshot shows the 'Quality Control Test' screen. At the top, there is a title bar with a battery icon. Below it, the instruction '✱ Scan FLUID LOT' is displayed. A text input field with a clear (X) button is provided for the barcode. On the right side, there are three buttons: 'Next', 'View Entered Info', and 'Previous'. At the bottom left, there is a 'Home' button with a house icon.

 When using i-STAT control material, the barcode is on the control material for the control level being tested.



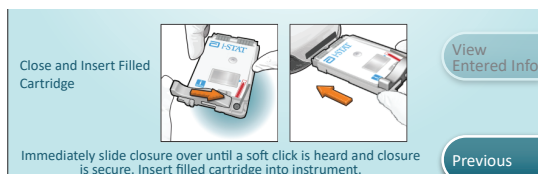
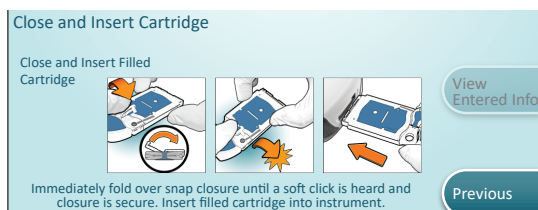
The screenshot shows the 'Quality Control Test' screen. At the top, there is a title bar with a battery icon. Below it, the instruction '✱ Scan CARTRIDGE POUCH Barcode' is displayed. A text input field with a clear (X) button is provided for the barcode. On the right side, there are three buttons: 'Next', 'View Entered Info', and 'Previous'. At the bottom left, there is a 'Home' button with a house icon.

✱ **Scan CARTRIDGE POUCH Barcode.** Manual entry is not an option. Scanning is required.


HOW TO PERFORM QUALITY TESTING (CONT.)

LIQUID QUALITY CONTROL (CONT.)

After the instrument successfully scans the barcode, help screens will be displayed. See examples below.



 **NOTE:** Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

 For experienced users, the help screens may be bypassed by inserting a filled cartridge.

Once the cartridge is inserted, **Contacting Cartridge** will display followed by the countdown bar. This allows the user to estimate the time to results. Alerts such as **Cartridge Locked and Instrument Must Remain Level** are also displayed.

HOW TO PERFORM QUALITY TESTING (CONT.)

LIQUID QUALITY CONTROL (CONT.)

i-STAT CHEM8+
i-STAT TriControl L1: 321055

Options Menu

View Second Page

| | | | |
|---------------------------|---------------------------|----------------------------|-------------------|
| Na, mmol/L 129 | BUN, mg/dL 119 | Glu, mg/dL 468 | Options Menu |
| K, mmol/L 3.0 | Crea, mg/dL 6.2 | iCa, mmol/L 1.2 | View Entered Info |
| Cl, mmol/L 79 | | AnGap, mmol/L 32 | Print |
| TCO2, mmol/L 19 | | | |

Home

Page →

RESULTS

Use Value Assignment Sheet to determine if results are in range. Follow hospital policy if results are outside the assigned range.

- ◆ An audible cue will be heard when results are ready. Touch **Silence** or remove cartridge to silence the audio.
- ◆ The result page shown here is the default. The system administrator must specify the ranges used in your facility.
- ◆ The blinking page button at the bottom of the screen appears when there is more than one page of results. All action tabs are inactive until the second page of results has been viewed.
- ◆ Occasionally numeric results will be replaced with the following symbols. When displayed, a new test must be performed.
 - <> – Instrument cannot calculate the result.
 - *** – (Starouts) Instrument is unable to determine a result.

A sample may also yield results that are preceded by a greater than (>) or less than (<) symbol. These results are outside the instrument's measurement range.

HOW TO PERFORM QUALITY TESTING (CONT.)

LIQUID QUALITY CONTROL (CONT.)

BEST PRACTICE EXAMPLE



Use AlinIQ CWi to customize for automatic pass/fail determination using eVAS.

Once customized, the results will appear as follows:

Numeric value with no arrow – In Range

Numeric value with ↑ arrow – Out of Range High

Numeric value with ↓ arrow – Out of Range Low

| i-STAT CHEM8+ 16FEB2025 11:01 i-STAT TriControl L2: 321068 PASS | | | Options Menu |
|---|--|---|--|
| Na, mmol/L 129 127 - 136 | BUN, mg/dL 10 8 - 14 | Glu, mg/dL 91 85 - 100 | Options Menu View Entered Info Print Transmit |
| K, mmol/L 3.8 3.5 - 4.1 | Crea, mg/dL 1.3 0.7 - 1.5 | iCa, mmol/L 1.33 1.24 - 1.42 | |
| Cl, mmol/L 92 85 - 98 | AnGap, mmol/L 34 | | |
| TCO2, mmol/L 18 16 - 29 | | | |
| Home | | | Page → |

| i-STAT CHEM8+ 16FEB2025 09:45 i-STAT TriControl L1: 321054 FAIL | | | Options Menu |
|---|--|---|--|
| Na, mmol/L 124 117 - 126 | BUN, mg/dL 66 ↑ 47 - 62 | Glu, mg/dL 280 228 - 312 | Options Menu View Entered Info Print Transmit |
| K, mmol/L 3.0 2.6 - 3.2 | Crea, mg/dL 3.7 3.0 - 4.6 | iCa, mmol/L 0.80 0.73 - 0.89 | |
| Cl, mmol/L 72 68 - 77 | AnGap, mmol/L 42 | | |
| TCO2, mmol/L 10 8 - 26 | | | |
| Home | | | Page → |

HOW TO PERFORM PATIENT TESTING

i-STAT CARTRIDGE PRECAUTIONS AND LIMITATIONS

Although cartridges are not fragile, they consist of sensors and other sensitive components that will alter the test results, or generate Quality Check Failure (QCF) Codes, if they are not properly filled and handled.

DO:

- dispose of the cartridge in a container for biohazardous waste, in accordance with your facility's policies and with local, state, and national regulatory guidelines.
- keep the cartridge and the instrument at the temperature of the room where they are to be used. Condensation on a cold cartridge can prevent proper contact with the instrument.

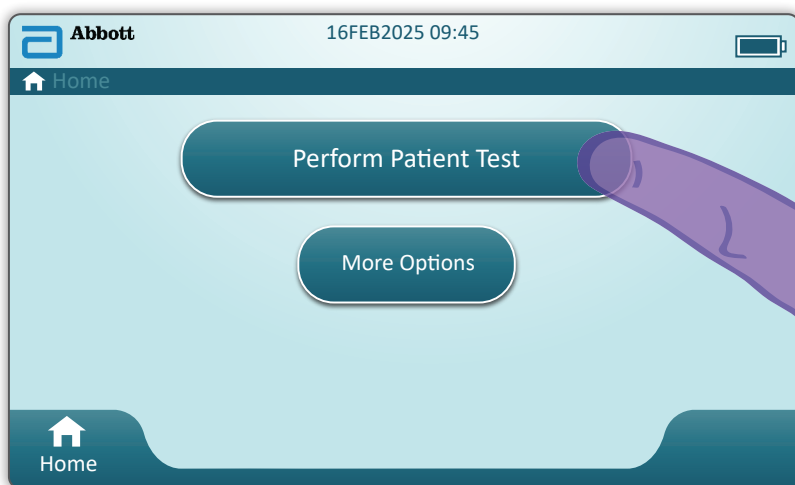
DO NOT:

- use a cartridge if either the refrigerated or room temperature dates have passed. Refer to the Cartridge Box Information.
- remove a cartridge from its protective pouch until it is at room temperature 18 to 30°C (or 64 to 86°F).
- return cartridges to the refrigerator after bringing them to room temperature.
- expose cartridges to temperatures above 30°C (86°F).
- use a cartridge that is expired or that shows signs of damage.
- use a cartridge if the foil pouch or clear plastic portion pack has been punctured.
- apply pressure to the central area of the label because the calibrant pack inside could burst prematurely.
- place the cartridges in an oxygen-enriched atmosphere.
- touch the sensors on the top of the cartridge.
- use a cartridge onto which blood or any other fluid has spilled. Avoid filling cartridges on surfaces where the cartridge could pick up fibers, fluid, debris, or other materials that could lodge in the instrument.
- attempt to remove the cartridge while the message **Cartridge Locked in instrument. Do not attempt to remove the cartridge.** remains on the screen.



NOTES:

- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- Follow manufacturers recommendations for handling and storing samples drawn into lithium or balanced heparin.
- For ACT, HcT, GFAP, UCH-L1, and cTnl (hs-Tnl) testing, the analyzer must remain on a level surface with the display facing up during testing. A level surface includes running the instrument in the Base Station.

HOW TO PERFORM PATIENT TESTING (CONT.)

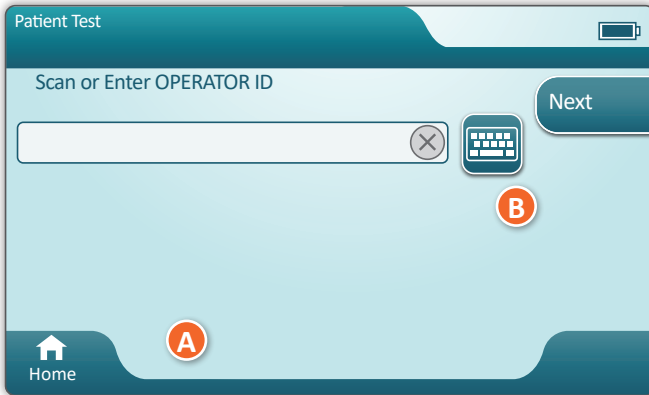


From the *Home* screen, touch **Perform Patient Test**.
This initiates the patient testing pathway.


- ◆ When the instrument is customized by the System Administrator, the pathways may present screens not displayed in this guide.
 - ◇ It is essential to follow the prompts on the instrument screen.
 - ◇ On-screen graphics and text are provided to assist the user.
 - ◆ This guide does not include instruction on blood collection. Follow facility-specific guidelines.
-  Standard precautions should be used when handling materials that may contain transmissible infectious agents.
-  Some regions have an alternate patient test flow. Always follow prompts on the screen.

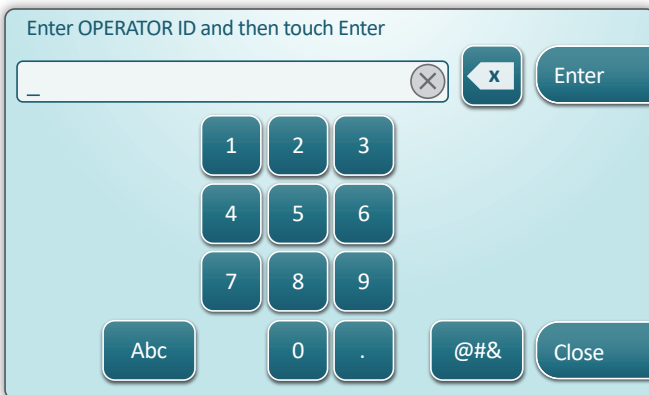
HOW TO PERFORM PATIENT TESTING (CONT.)

To begin: **Scan or Enter OPERATOR ID**



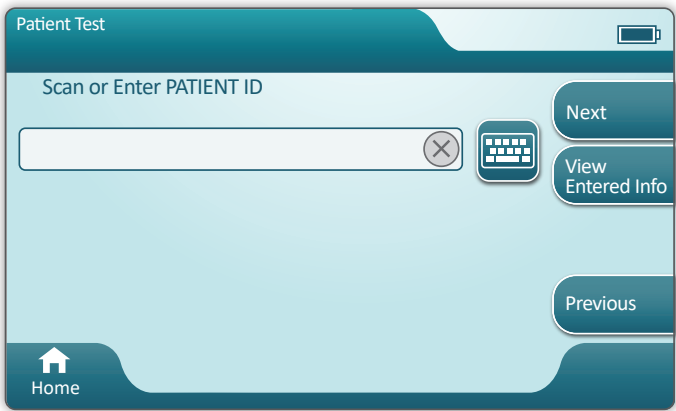
A On-screen graphic assists with scanning. After scanning is complete, the instrument will advance to the next step in the pathway.

B To enter information manually, touch  icon. A numeric keyboard displays automatically. For alpha, touch the **Abc** button. After entering the information, touch **Enter** and the instrument will advance to the next step in the pathway.



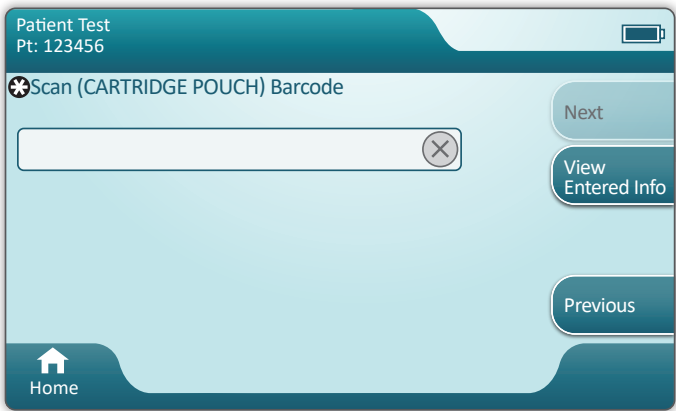
HOW TO PERFORM PATIENT TESTING (CONT.)

Scan or Enter PATIENT ID



The screens that follow represent a typical workflow. Continue to follow prompts on the screen if they differ from those shown here.

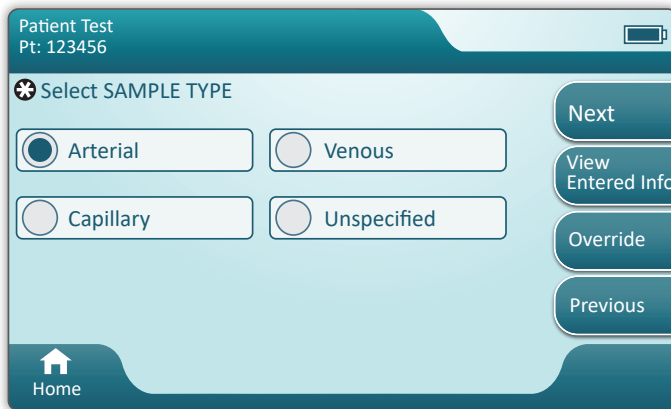
*** Scan (CARTRIDGE POUCH) Barcode.** Scanning is required. You must scan the barcode. This information cannot be entered manually.



? If an **Invalid Cartridge Type** window is displayed, contact the System Administrator.

HOW TO PERFORM PATIENT TESTING (CONT.)

This screen will display if more than one sample type is applicable.



Patient Test
Pt: 123456

Select SAMPLE TYPE

☒ Arterial ☐ Venous

☐ Capillary ☐ Unspecified

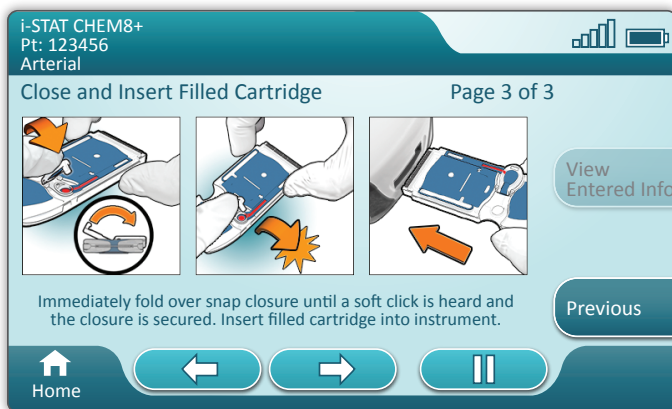
Next

View Entered Info

Override

Previous

Home



i-STAT CHEM8+
Pt: 123456
Arterial

Close and Insert Filled Cartridge

Page 3 of 3

View Entered Info

Previous

Home

← → ||

Immediately fold over snap closure until a soft click is heard and the closure is secured. Insert filled cartridge into instrument.

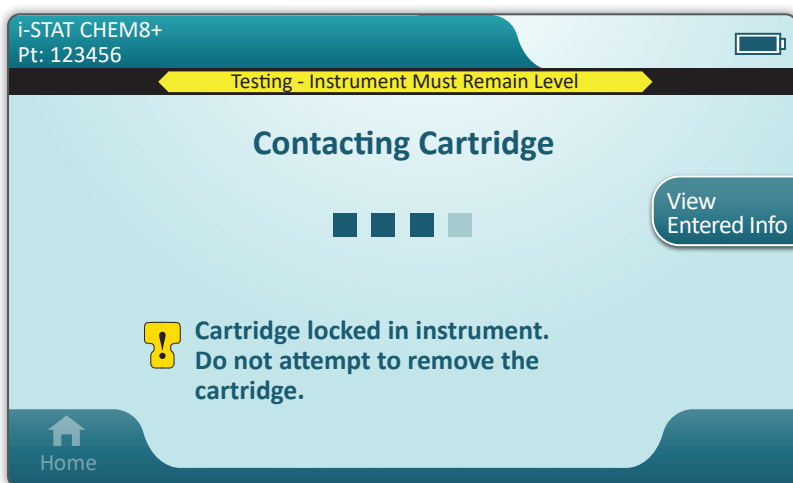
Below the Patient ID is the sample type selected from the previous screen or single sample type that is appropriate for the cartridge scanned. The action buttons at the bottom of the screen allow forward, backward and pause functionality.



For experienced users, the help screens may be bypassed by inserting a filled cartridge.

HOW TO PERFORM PATIENT TESTING (CONT.)

Once the cartridge is inserted, **Contacting Cartridge** will display followed by the countdown bar. This allows the user to estimate the time to results. Alerts such as **Cartridge Locked and Instrument Must Remain Level** are also displayed.



HOW TO PERFORM PATIENT TESTING (CONT.)

The screenshot displays the i-STAT CHEM8+ results screen. At the top, it shows the device name 'i-STAT CHEM8+', the date and time '16FEB2025 09:45', and the patient ID 'Pt: 123456'. There is an 'Options Menu' button and a battery status icon. A yellow banner with a right-pointing arrow says 'View Second Page'. Below this, test results are organized into boxes: Na, mmol/L (129), BUN, mg/dL (48), Glu, mg/dL (274), K, mmol/L (3.1), Crea, mg/dL (3.8), iCa, mmol/L (0.94), Cl, mmol/L (81), and AnGap, mmol/L (42). There is also a box for TCO2, mmol/L (9). On the right side, there are three buttons: 'Options Menu', 'View Entered Info', and 'Print'. At the bottom left, there is a bell icon with the word 'Silence' below it. At the bottom right, there is a 'Page' button with a right-pointing arrow.

| Test | Result |
|---------------|--------|
| Na, mmol/L | 129 |
| BUN, mg/dL | 48 |
| Glu, mg/dL | 274 |
| K, mmol/L | 3.1 |
| Crea, mg/dL | 3.8 |
| iCa, mmol/L | 0.94 |
| Cl, mmol/L | 81 |
| AnGap, mmol/L | 42 |
| TCO2, mmol/L | 9 |

When the test is complete, the test results are displayed as in the **example** above.

RESULTS

- ◆ An audible cue will be heard when results are ready. Touch **Silence** or remove cartridge to silence the audio.
- ◆ The result page shown here is the default. The system administrator must specify the ranges used in your facility.
- ◆ The blinking page button at the bottom of the screen appears when there is more than one page of results. All action tabs are inactive until the second page of results has been viewed.
- ◆ Occasionally, numeric results will be replaced with the following symbols. When displayed, a new test must be performed.
 - <> – Instrument cannot calculate the result.
 - *** – (Starouts) Instrument is unable to determine a result.

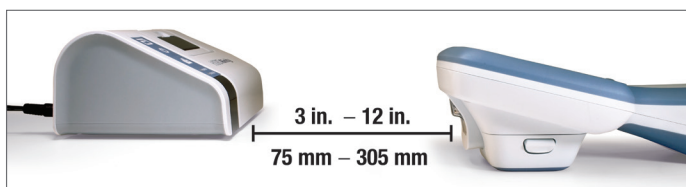
A sample may also yield results that are preceded by a greater than (>) or less than (<) symbol. These results are outside the instrument's measurement range. In order to determine the exact numeric result, the sample must be analyzed by a different method.

HOW TO PERFORM PATIENT TESTING (CONT.)

PRINTING

- A** Determine printing method:

Wireless

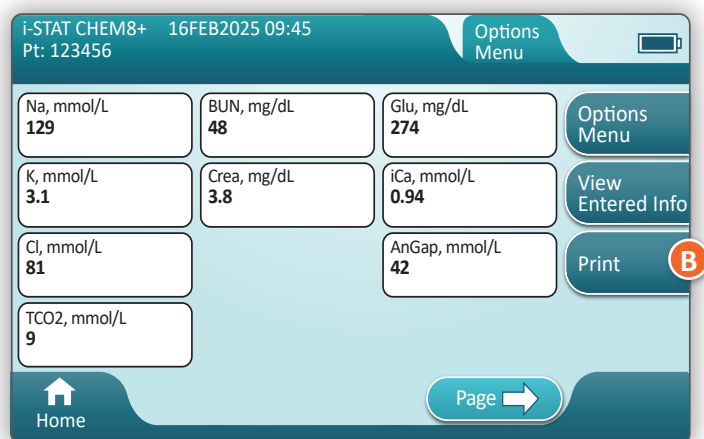


OR

Wired to Base Station



- B** With instrument and printer powered up, and the results on the screen, touch **Print**



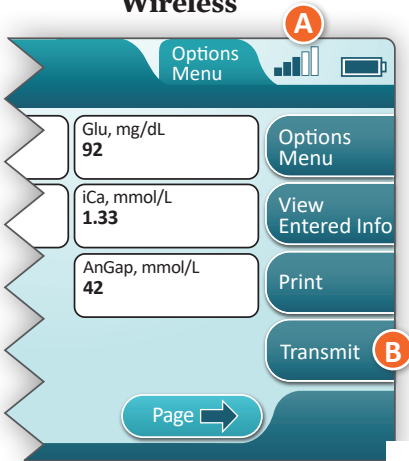
HOW TO PERFORM PATIENT TESTING (CONT.)

TRANSMITTING (OPTIONAL)

Transmission to a data manager is optional and requires network connectivity. For more information on network connectivity with AlinIQ NCI and customization with AlinIQ CWi, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

Determine transmission method:

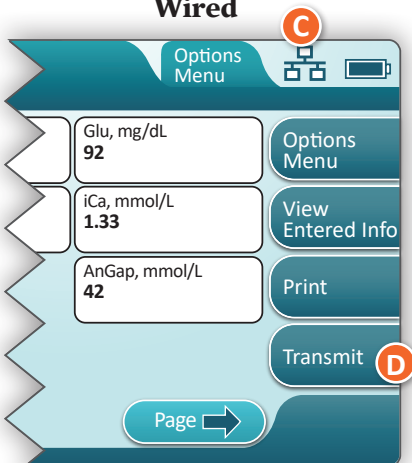
Wireless



- A** A signal strength of 3 bars or higher is recommended
- B** To initiate transmission, touch Transmit

OR

Wired



- C** Symbol indicates instrument is connected to the network
- D** To initiate transmission, touch Transmit

HOW TO PERFORM PATIENT TESTING (CONT.)

BEST PRACTICE EXAMPLE

i-STAT CHEM8+ 16FEB2025 09:45
Pt: 123456

Options Menu

View Second Page

| | | | |
|---|--|--|-------------------|
| Na, mmol/L 129 138 - 146 Ref ↓ | BUN, mg/dL 119 8 - 26 Ref ↑ | Glu, mg/dL 468 75 - 105 Ref ↑ | Options Menu |
| K, mmol/L 3.0 3.5 - 4.9 Ref ↓ | Crea, mg/dL 6.2 3.5 - 4.9 Ref ↑ | iCa, mmol/L 1.2 1.12 - 1.32 Ref | View Entered Info |
| Cl, mmol/L 79 98 - 109 Ref ↓ | AnGap, mmol/L 32 -10 - 99 Ref | | Print |
| TCO2, mmol/L 19 24 - 29 Ref ↓ | | | Transmit |

(()) Silence

Page →

Use AlinIQ CWi to set reference and action ranges.

RESULTS

- ◆ An audible cue will be heard when results are ready.
Touch **Silence** or remove cartridge to silence the audio.
- ◆ When the instrument is customized by the system administrator, reference ranges as well as action ranges may be assigned.
- ◆ When reference ranges are assigned, they appear under the analyte result followed by “Ref”.
- ◆ When action (critical) ranges are assigned, results within this range will be highlighted by both color and an arrow.
 - ◇ **Yellow** in the result area indicates that the result is outside of the reference range, but is not within the action range, sometimes known as an abnormal result. The arrow indicates if the result is high (↑) or low (↓).
 - ◇ **Red** in the result area indicates that the result is within the action (critical) range. The arrows indicate if the result is high (↑) or low (↓).
 - ◇ **Red arrow** in page button - indicates one or more results on second page are within the action (critical) range.
 - ◇ **Yellow arrow** in page button - indicates one or more results on second page are outside the reference range, but not in the action (critical) range.
 - ◇ **White arrow** in page button - indicates all results on second page are within the reference range.

CLEANING AND DISINFECTING

CLEANING

i-STAT Alinity Instrument, Base Station, Printer and Electronic Simulator

It is recommended that the i-STAT Alinity, base station, printer and electronic simulator be cleaned periodically or whenever visibly soiled. Standard precautions should be taken whenever working with blood or blood products.

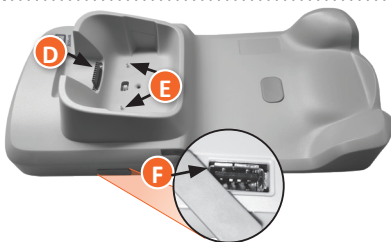
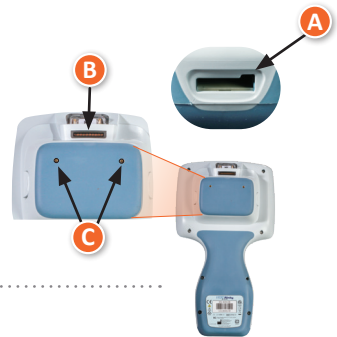
- ① When cleaning the i-STAT Alinity with CaviWipes, power off the instrument and place it on a level surface. Do not clean or disinfect the instrument while it is in the Base Station. The Base Station does not need to be unplugged when it is being cleaned.
- ② Remove a new disposable wipe from the container and squeeze to remove excess solution.
- ③ Gently wipe all outside surfaces (noting the **“Sensitive Areas”**) until all visible soil is removed.
- ④ Inspect all surfaces. If necessary, repeat until all visible soil is removed.
- ⑤ Wipe with dry gauze until dry.



SENSITIVE AREAS

Avoid forcing liquid into these areas:
i-STAT Alinity Instrument

- A** Cartridge Port
- B** 10-Pin Connector under the camera
- C** Gold contacts (2) on the outside of the battery

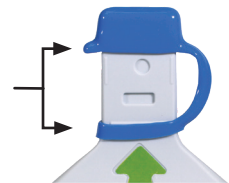


Base Station

- D** 10-Pin Connector
- E** Gold contact pins (2)
- F** USB Port

Electronic Simulator

Area between protective cap retaining ring and white sensor area



CLEANING AND DISINFECTING (CONT.)

DISINFECTING

i-STAT Alinity Instrument

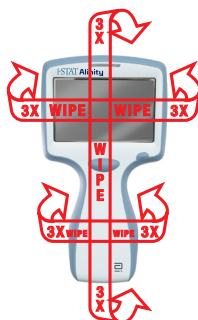
Disinfection is recommended between each patient. When instrument is dedicated to a single patient, disinfect at least once a day. The disinfection process must begin **IMMEDIATELY** after the cleaning procedure is complete. Standard precautions should be taken whenever working with blood or blood products.

1



Remove a wipe from the container and squeeze out any excess fluid before you begin to wipe the surface.

2



Wipe all surfaces three times. This includes front, back, sides, top and bottom.

3

Allow all surfaces to remain wet for **3** minutes.



4

Wipe with gauze until dry.

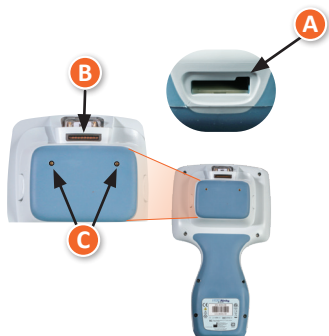


SENSITIVE AREAS

Avoid forcing liquid into these areas:

i-STAT Alinity Instrument

- A** Cartridge Port
- B** 10-Pin Connector under the camera
- C** Gold contacts (2) on the outside of the battery



CLEANING AND DISINFECTING (CONT.)

DISINFECTING (CONT.)

Base Station, Electronic Simulator and Printer

1



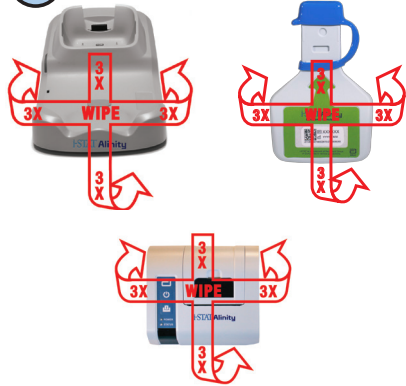
Remove a wipe from the container and squeeze out any excess fluid before you begin to wipe the surface.

3

Allow all surfaces to remain wet for **3 minutes**.



2



**WIPE 3X
LEFT & RIGHT**

**WIPE 3X
UP & DOWN**

Wipe the front as shown, flip products on back side and repeat.

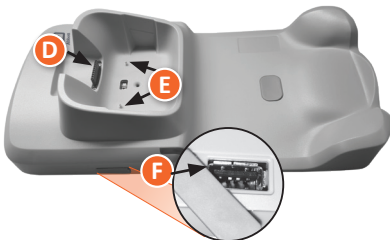
4

Wipe dry with gauze.



SENSITIVE AREAS

Avoid forcing liquid into these areas:

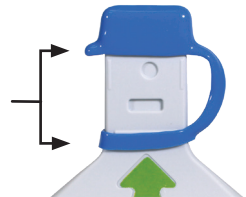


Base Station

- D** 10-Pin Connector
- E** Gold contact pins (2)
- F** USB Port

Electronic Simulator

Area between protective cap retaining ring and white sensor area



CLEANING AND DISINFECTING (CONT.)

- Due to the portability of the i-STAT Alinity Instrument, it may be subject to splatter or splash of bodily fluids when used in proximity of patients. Failure to wear clean gloves will result in contamination of the instrument.
- Instruments used with multiple patients may require more frequent cleaning and disinfecting. Cleaning is necessary for the removal of visible organic soil. Disinfecting is intended to kill microorganisms.
- Follow recommendations from the FDA and CDC and your facility’s policies and procedures for infection control.

APPROVED DISINFECTANT PRODUCTS

As the i-STAT Alinity instrument, electronic simulator, base station, and printer surfaces being cleaned/disinfected are non-porous, Abbott Point of Care recommends CaviWipes or equivalent for cleaning and disinfection.



CaviWipes
EPA #46781-8

The components of the CaviWipes tested and approved for use with the i-STAT Alinity instrument are shown in the table below.

| COMPONENT | CAS No. | AMOUNT |
|--|-----------|--------|
| Water | 7732-18-5 | 70-80% |
| Isopropanol | 67-63-0 | 17.2% |
| Ethylene Glycol Monobutyl Ether (2-Butoxyethanol) | 111-76-2 | 1-5% |
| Diisobutylphenoxyethoxyethyl dimethylbenzyl ammonium chloride | 121-54-0 | 0.28% |

TROUBLESHOOTING AND SUPPORT

TROUBLESHOOTING

The i-STAT Alinity is programmed to perform quality checks throughout the testing cycle.

The instrument has several methods of notifying operators of failed quality checks.

1. Quality Check Failures

- Are displayed when the instrument identifies a problem while running a cartridge or simulator
- There are 4 types of quality check failures:

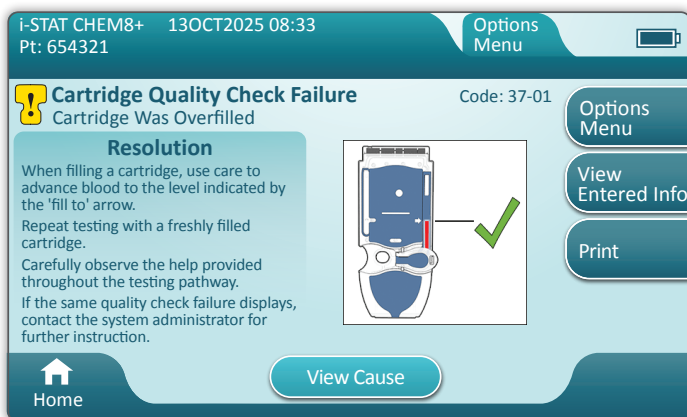
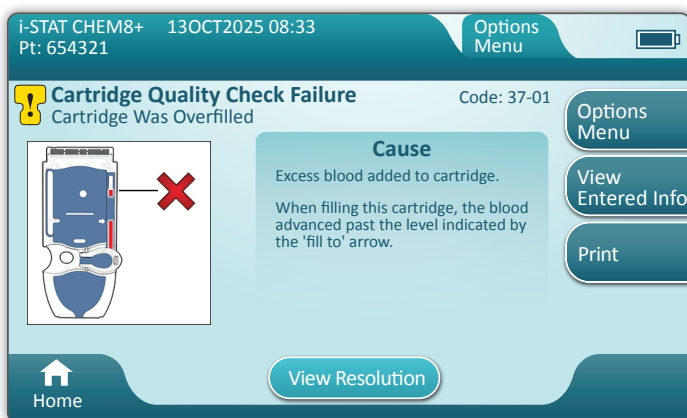
1. Instrument

2. Cartridge

3. Sample

4. Software

- Screen displays the type of failure and instructions for resolution.



TROUBLESHOOTING AND SUPPORT (CONT.)

TROUBLESHOOTING (CONT.)

2. Startup Alerts

- Displayed before the Home screen appears
- Screen displays instructions for resolution

3. Alerts

- Alert button provides access to Alerts description
- Indicates a change in instrument status during testing



For a full list of Quality Check Failure Codes and Alerts, see the i-STAT Alinity Instrument Section of the System Operations Manual.

SUPPORT

Product Documentation and Resources

Additional information related to configuration, customization, features and product documentation can be found in the Support area of www.globalpointofcare.abbott, in the i-STAT System Customers section.

ADDITIONAL SUPPORT

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

HOW TO PERFORM SOFTWARE UPDATE

Software updates to the i-STAT Alinity instrument are delivered twice a year. Each software update contains two elements in a single package: CLEW software and application software.



Note: Best practice is to enable use of an Operator List to protect the Update Software flows from being executed by unauthorized personnel.

SOFTWARE UPDATE AND INSTALLATION

Use this procedure to update the instrument software using a USB memory device via the base station.



Note: This procedure takes approximately 5 to 15 minutes to complete. Therefore, it is recommended this procedure be executed outside of the clinical work area.

Prerequisites:

Equipment:

- i-STAT Alinity instrument(s) to be updated
- Base Station with power cable connected to AC main power
- FAT-32 formatted USB memory device (not provided by Abbott Point of Care)
- PC with network connection to the Global Point of Care website, www.globalpointofcare.abbott. See SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide for navigation details.

Before attempting to update software from USB, prepare a USB memory device using the following steps:

1. Obtain a FAT32 formatted USB 2.0 memory device.
2. Remove any package files (.apkg file extension) from the top level of the directory structure of the memory device.
3. Retrieve the i-STAT Alinity instrument software package from the Global Point of Care website and follow instructions on webpage for downloading and unzipping the software package.
4. Copy the software package to the memory device
5. Safely remove the memory device from your PC and proceed to installation.

HOW TO PERFORM SOFTWARE UPDATE (CONT.)

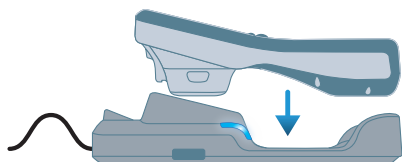
INSTALLATION

Ensure that the prerequisites, on the previous page have been completed.

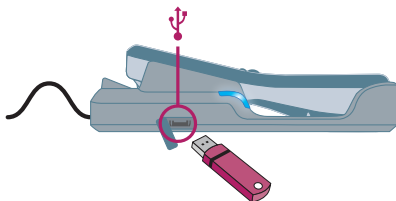


CAUTION: During the installation, do not remove the instrument or the USB memory device from the Base Station. When the installation is complete, the instrument will display a message indicating that new software has been installed. The display of this message is the indication that it is safe to remove the instrument and USB memory device from the Base Station.

- 1 Place instrument into the base station and power-up instrument.**

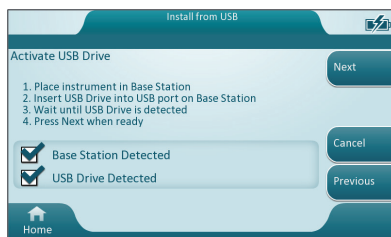


- 2 Insert USB into the USB port in the base station.**



- 3 From the Home Screen:**
- > More Options
 - > Instrument Options
 - > Software Installation
 - > Install from USB

- 4 Follow prompts until transfer is complete.**



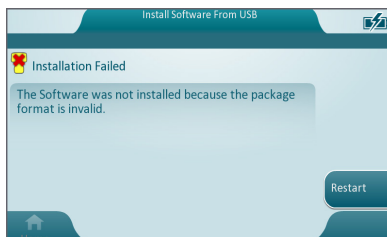
- 5 OSi Software Installation Results:**













The instrument automatically restarts upon successful installation!














Refer to onscreen details for cause and repeat procedure. If failure persists, contact your local Abbott representative.









SYMBOLS

| SYMBOL | DEFINITION |
|---|--|
|  | Consult instructions for use or see System Operations Manual for instructions. |
|  | Attention: See instructions for use. |
|  | Note the following information. |
|  | Electrical Hazard |
|  | Biological Risks. |
|  | Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms. |
|  | 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. |
| LOT | Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol. |
| REF | Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product. |
| SN | 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. |
| IVD | In vitro diagnostic medical device. |
| Rx ONLY | For prescription use only. |
| EC REP | Authorized Representative for Regulatory Affairs in the European Community. |
|  | Importer in the European Community. |
| CONTROL | Control. |

SYMBOLS (CONT.)

| SYMBOL | DEFINITION |
|---|---|
|  | 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. |
|  | Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010-1:2012 3rd Ed. +R:19Jul2019 CSA C22.2 No. 61010-1-12:2012 3rd Ed. +U1;U2;A1 UL 61010-2-101:2019 3rd Ed. CSA C22.2 No. 61010-2-101:2019 3rd Ed. |
|  | 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. |
|  | 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  | 14 days room temperature storage at 18-30 °C |
| 2  | 2 months room temperature storage at 18-30 °C |
|  | 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. |

SYMBOLS (CONT.)

| SYMBOL | DEFINITION |
|---|-------------------|
|  | Information |
|  | Instrument Locked |
|  | Low Battery |
|  | Pass |
|  | Warning |
|  | Fail |

TERMINOLOGY

| TERM OR ACRONYM | DEFINITION |
|-------------------|--|
| AlinIQ CWi | Customization Workspace for i-STAT |
| AlinIQ NCi | Network Connectivity for i-STAT |
| APOC | Abbott Point of Care |
| CLEW | Standardization software |
| CONT. | Continued |
| eVAS | Electronic Value Assignment Sheet |
| GSG | Getting Started Guide |
| IFU | Instructions for Use |
| IR | Infrared Radiation |
| LED | Light Emitting Diode |
| MQSI | Manufacturer's Quality System Instructions |
| OSi | Instrument Software |
| PC | Personal Computer |
| POC | Point of Care |
| QC | Quality Control |
| QCC | Quality Check Code |
| QCF | Quality Check Failure |
| QRG | Quick Reference Guide |
| R-VAS | Rilibak Value Assignment Sheet |
| ReVAS | Rilibak Electronic Value Assignment Sheet |
| SU | Software Update |
| TBI | Traumatic Brain Injury |
| USB | Universal Serial Bus |
| VAS | Value Assignment Sheet |

TEST ABBREVIATIONS

| ABBREVIATION | DEFINITION |
|------------------------|---|
| Na | Sodium |
| K | Potassium |
| Cl | Chloride |
| Glu | Glucose |
| Lac | Lactate |
| Crea | Creatinine |
| pH | pH |
| PCO₂ | Partial Pressure of Carbon Dioxide |
| PO₂ | Partial Pressure of Oxygen |
| iCa | Ionized Calcium |
| BUN/UREA | Urea nitrogen/Urea |
| Hct | Hematocrit |
| ACTk Kaolin ACT | Activated Clotting Time with Kaolin activator |
| 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 |
| eGFR | Estimated Glomerular Filtration Rate |
| eGFR-a | Black/African-American Estimated Glomerular Filtration Rate |
| GFAP | Glial Fibrillary Acidic Protein |
| UCH-L1 | Ubiquitin Carboxy-terminal Hydrolase L1 |
| cTnl (hs-Tnl) | Cardiac Troponin I (High Sensitivity Troponin I) |

RELEASE NOTES

The purpose of this APPENDIX is to provide customers with a summary of changes that have been performed with this revision of the User Guide. The changes are specific to the revision, and do not cover historical revision changes. The table below provides an overview of how the changes are identified when reviewing the User Guide.

| CHANGE TYPE | CHANGE INDICATION |
|---|---|
| Deletion (removal of content) | <p>Content that has been deleted will be identified in the release notes.</p> <ul style="list-style-type: none"> Items removed from a table will be noted, along with the reason for removal. Removal of a sentence and/or paragraph will be noted by providing the sentence or paragraph that has been removed, along with the reason for removal. Removal of an entire section, subsection and/or table will be noted, along with the reason for removal. |
| Addition (new content) | <p>New content will be highlighted and reason for addition of content will be provided in the release notes.</p> <ul style="list-style-type: none"> New table is indicated by highlight to the title of the table. Addition of a word, sentence or paragraph is indicated by highlighting the word, sentence, or paragraph. New section(s), sub-section(s), or appendix(es) are indicated by highlighting the titles of that section, sub-section or appendix. New appendix is indicated by highlighting the Appendix title. New image(s) is indicated by highlight of the title for the section, sub-section or table where the image is provided. |
| Update (modification of content) | <p>Content that has been updated is indicated as follows and will be identified in the release notes.</p> <ul style="list-style-type: none"> Substitution of a word for another, that is being made through out the document, i.e handheld to analyzer – will be discussed in the release notes. Update to a sentence will be indicated by highlighting the sentence, along with the reason for the update. Update to or re-organization of multiple sentences within a paragraph will be indicated by highlighting the paragraph, along with the reason for the update. Update to an image(s) will be indicated by highlighting the section, sub-section or the table where the image is provided, along with the reason for the update. |

RELEASE NOTES

Changes made to this revision of the Quick Reference Guide are identified in this section.

The following updates have been performed:

- **Section 5: Cartridge Information**

Updated descriptors for the Anatomy of a Box, Anatomy of a Pouch, and Anatomy of a Portion Pack.

- **Section 6: How to Perform Quality Testing**

Liquid Quality Control section updated to list hs-Tnl and TBI references to the instructions for use.

- **Section 7: How to Perform Patient Testing**

Note added instructing user to keep the analyzer on a level surface with the display facing up during testing specified analytes .

- **Appendix 1: Symbols, Terminology and Test Abbreviations**

Test Abbreviations table was updated to include “cTnl(hs-Tnl): Cardiac Troponin I (High Sensitivity Troponin I)”.

i-STAT ALINITY INSTRUMENT END USER LICENSE AGREEMENT

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