i-STAT Alinity

Quick Reference Guide

Abbott

This page left intentionally blank.

CONTENTS

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.

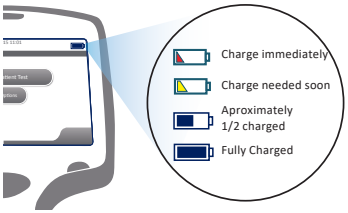
Product problems and adverse events should be reported to Abbott through your Abbott Point of Care support service.

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

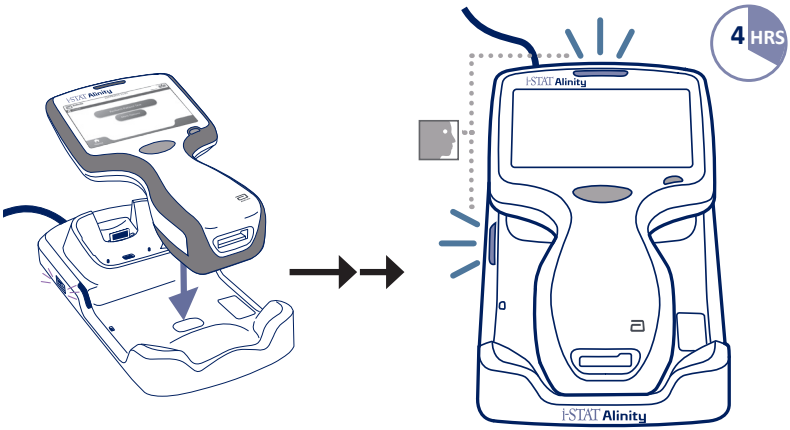


IF BATTERY SHOWS A YELLOW OR RED BAR, CONTINUE TO STEP 3.

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



Abbott

INSTRUMENT SETUP (New Instruments) CONT.

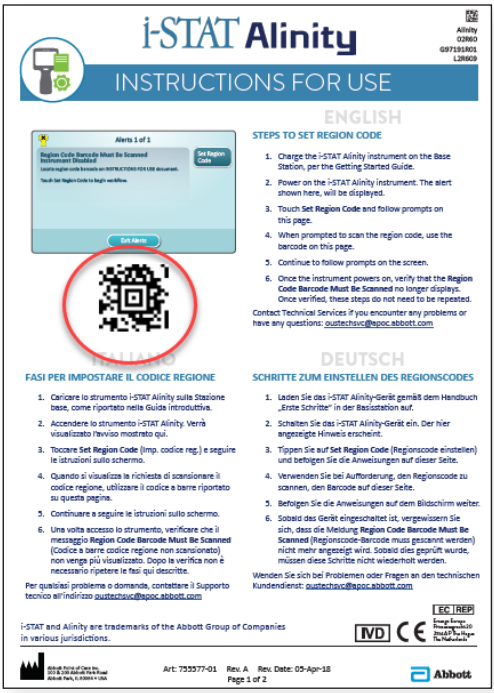
If instrument displays *Set Region Code* screen, proceed to **STEP** 4
If not, proceed to **STEP** 6.

4 LOCATE REGION BAR CODE

a

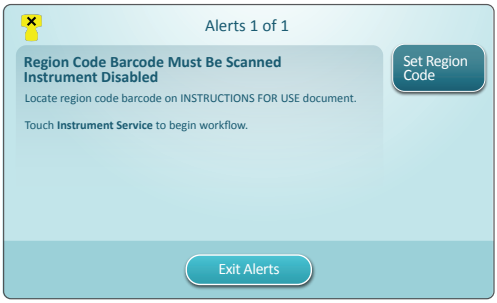
OR

b



INSTRUMENT SETUP (New Instruments) CONT.

5 TOUCH SET REGION CODE



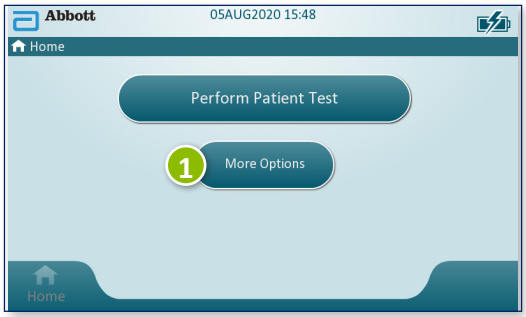
1. Touch **Set Region Code** and follow prompts on screen.
2. When prompted, scan Region Code on box or letter.
3. Continue to follow prompts on the screen.
4. Once the instrument powers on, the **Region Code Barcode** alert should no longer be displayed. Proceed to **STEP** 6.

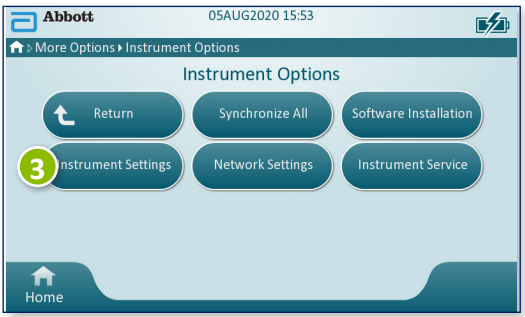
   If Alert screen displays again, repeat **STEP** 5.
   If the Alert screen displays again, contact your Abbott representative.

INSTRUMENT SETUP (New Instruments) CONT.

6 FINISH SETTING UP THE INSTRUMENT

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



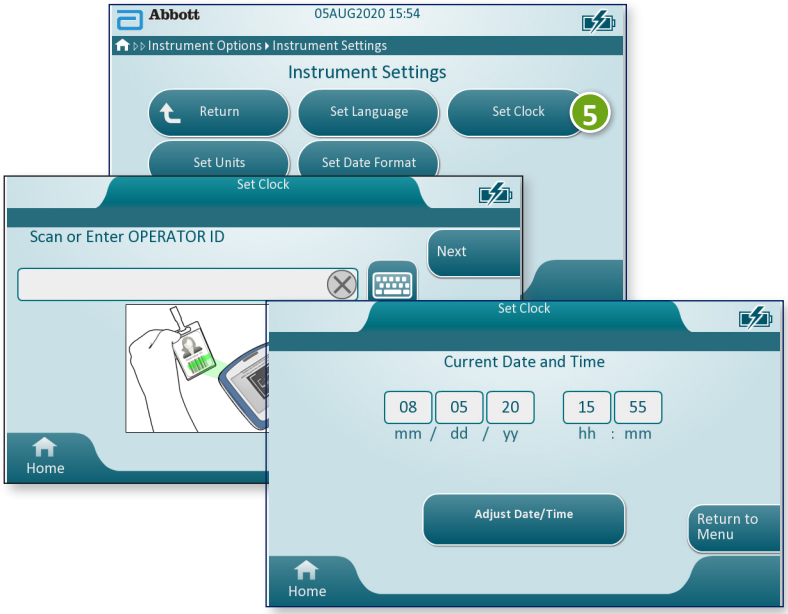


INSTRUMENT SETUP (New Instruments) CONT.

6 FINISH SETTING UP THE INSTRUMENT CONT.

Set Language

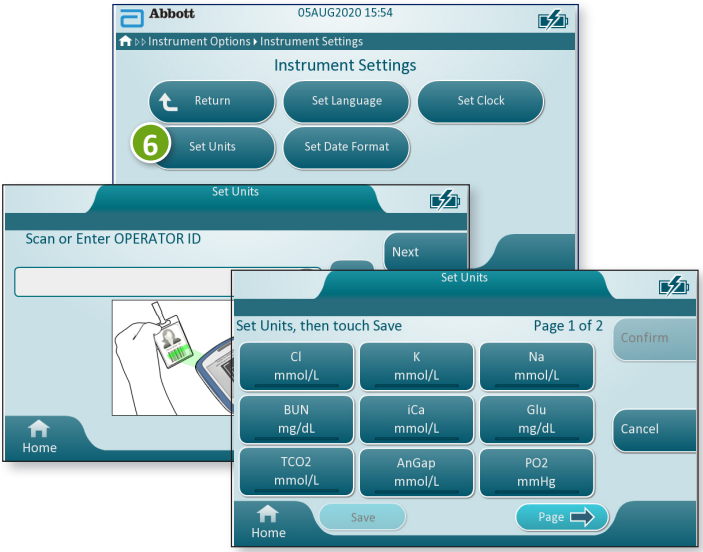
Set Clock



INSTRUMENT SETUP (New Instruments) CONT.

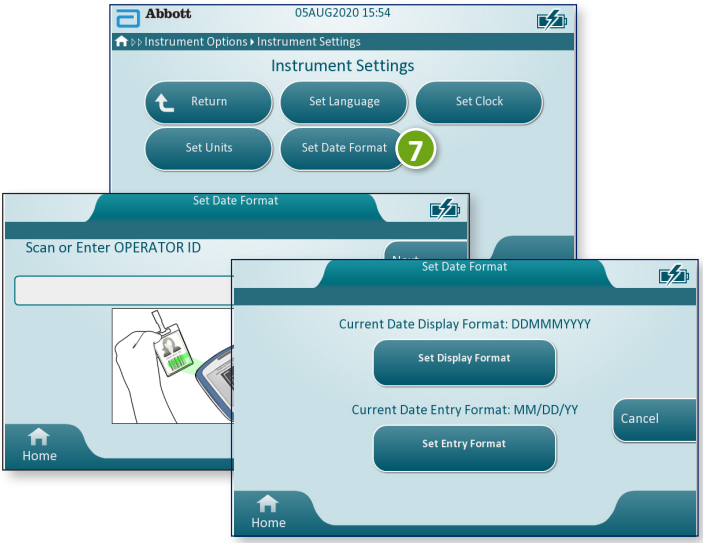
6 FINISH SETTING UP THE INSTRUMENT CONT.

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. **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 rechargable battery during the testing process. Prior to removing the rechargable 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.

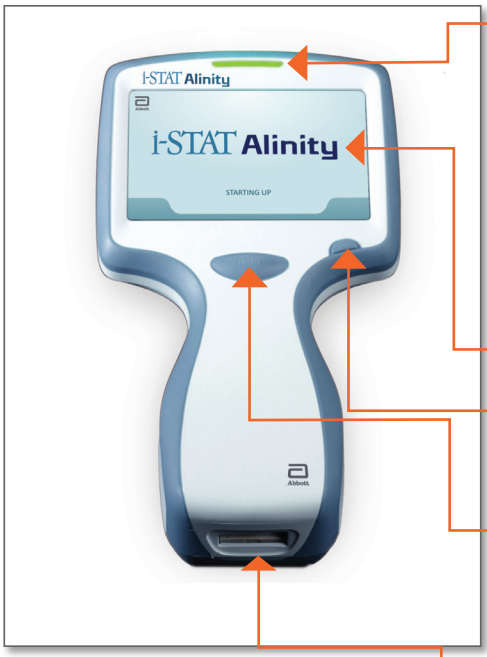
SYSTEM COMPONENTS (CONT.)
PRECAUTIONS AND LIMITATIONS (CONT.)

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.

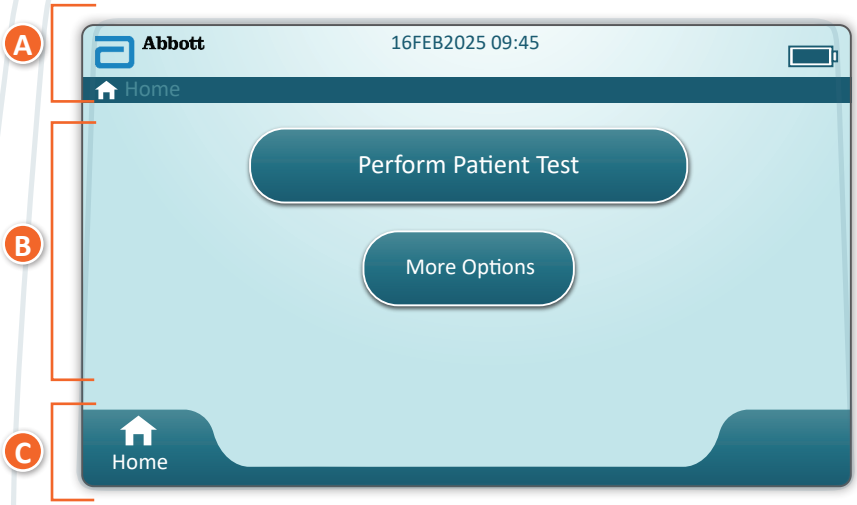
CAMERA AND IR PORT: Camera is activated by pressing and holding the barcode capture button. The display screen displays the object within the cameras view. The IR port sends information from the instrument to the portable printer.

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:

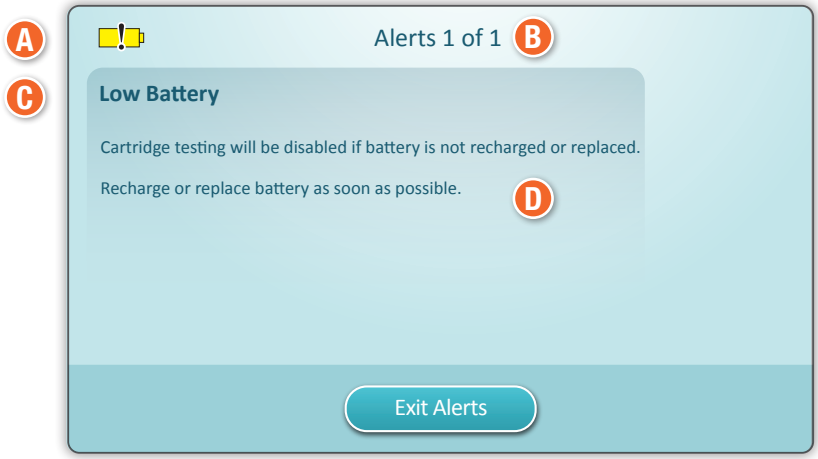
A HEADER Area Contains:
- Date/Time
- Wireless Status*
- Battery Status*

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

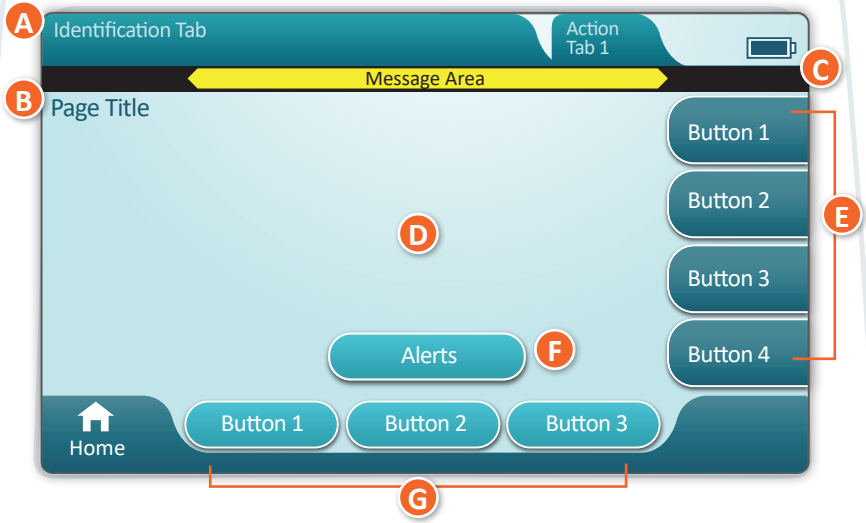
or Instrument warning

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

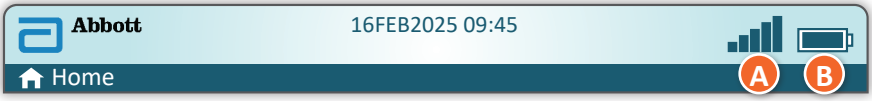
D BODY:
- Buttons in this area provide access to pathways, OR
- Location of details such as data entry field, help graphics, selection options

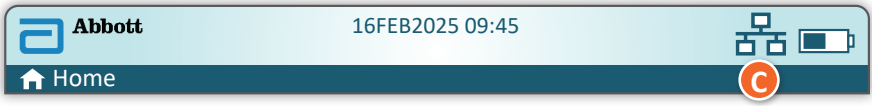
E SIDE ACTION TABS:
- Provide access to area or action indicated

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		Pass
	Poor	**Battery Charging**			Fail
	No Signal		Bolt indicates actively charging		Warning
	No Connection		Bolt indicates actively charging		Instrument locked
	Wireless Disabled		Bolt indicates actively charging		Information
	Wireless Connecting				Low Battery
	Wireless Not Allowed				
Instructional Icons					
	Mandatory				

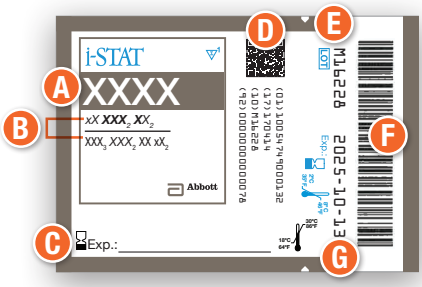
CARTRIDGE INFORMATION

ANATOMY OF A BOX:

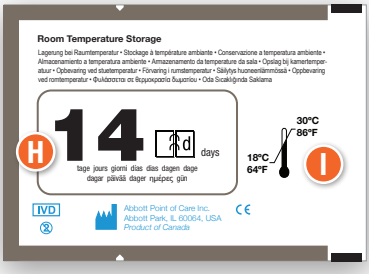
- **A** **Refrigerated storage temperature indicator:** 2-8°C (35-46°F)
- **B** **Indicates shelf life when stored at room temperature**
- **C** **Refrigerated storage expiration date**
- **D** **Cartridge LOT number**
- **E** **Location to record room temperature expiration date**

CARTRIDGE INFORMATION (CONT.)

Pouch Front

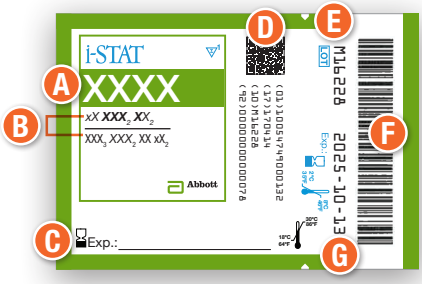


Pouch Back

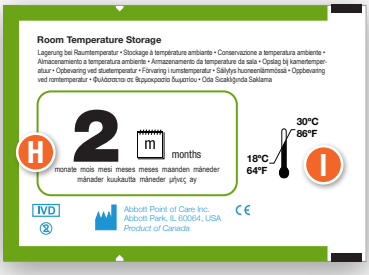


OR

Pouch Front



Pouch Back



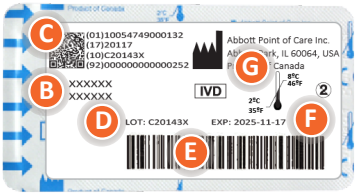
ANATOMY OF A POUCH:

- **A** Cartridge name
- **B** Analytes – measured and calculated
- **C** Location to record room temperature expiration date
- **D** 2D barcode for manufacturing quality control; not scannable
- **E** Cartridge LOT number
- **F** Cartridge pouch barcode
- **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** 2D barcode for manufacturing quality control; not scannable
- **D** Cartridge LOT number
- **E** Cartridge portion pack barcode
- **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**

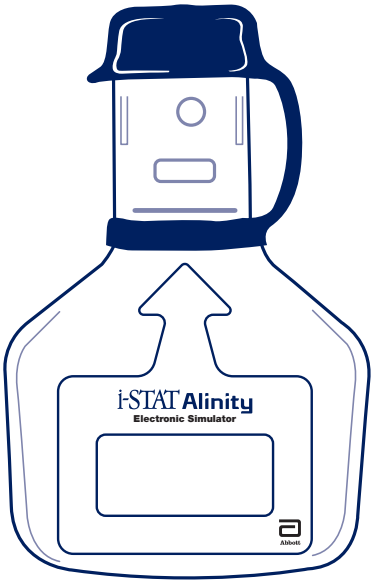
   Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).

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:

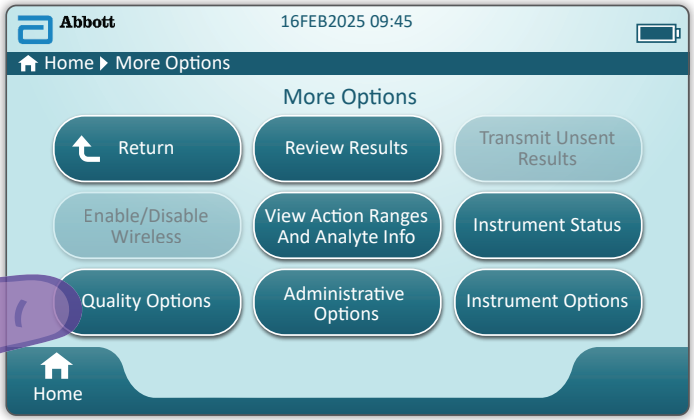
- attempt to remove the Electronic Simulator while a test is being performed.
- drop the Electronic Simulator, as doing so can cause it to malfunction.
- place the Electronic Simulator in an oxygen-enriched atmosphere.
- make any unauthorized repairs or modifications to this product.
- use the Electronic 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**.



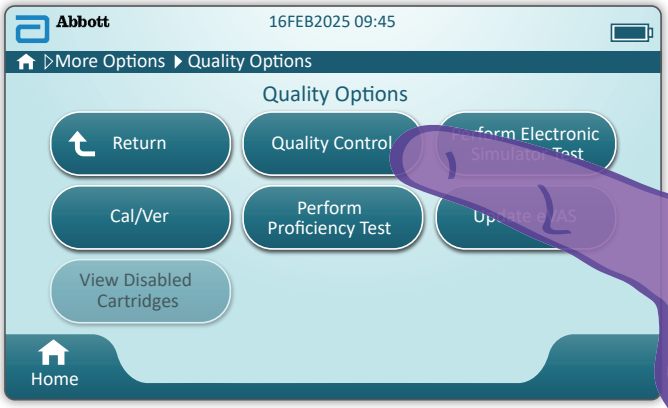
Next, touch the **Perform Electronic Simulator Test** button.

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 TBI Plasma 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.

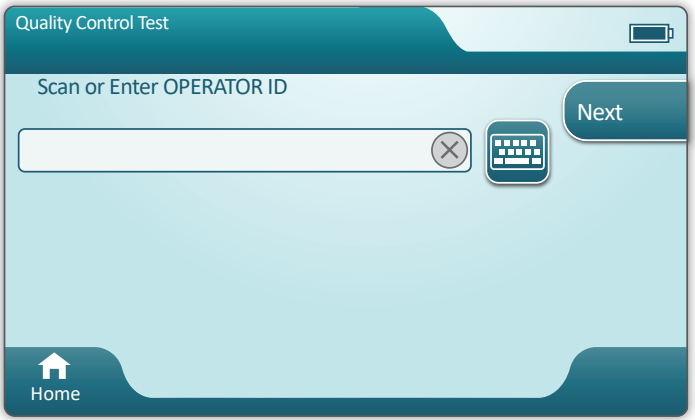
NOTE: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

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.

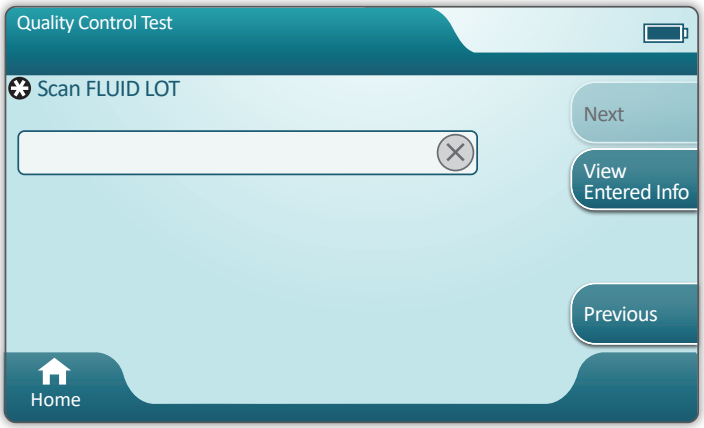
The next step in the pathway is **Scan or Enter OPERATOR ID**



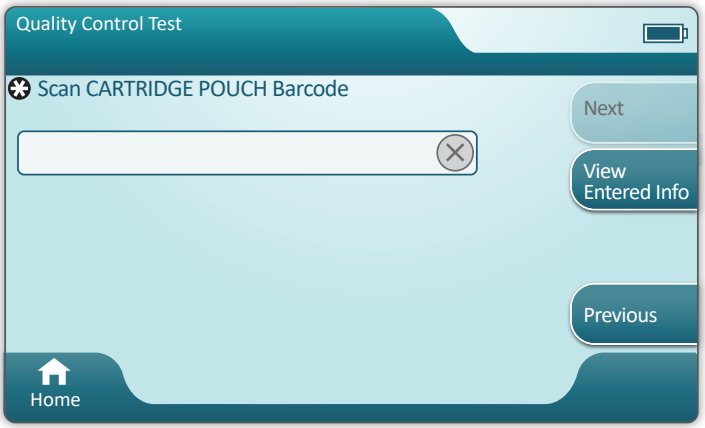
HOW TO PERFORM QUALITY TESTING (CONT.)
LIQUID QUALITY CONTROL (CONT.)

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.



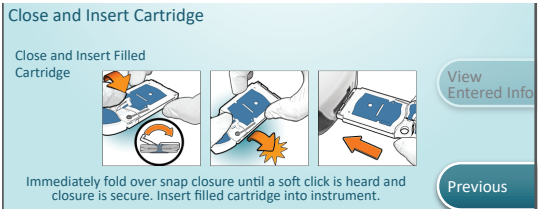
When using i-STAT control material, the barcode is on the control material for the control level being tested.

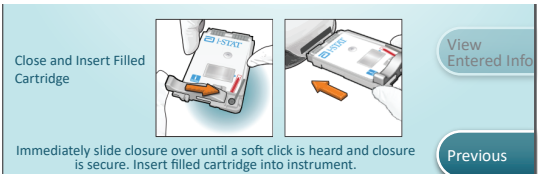


Scan CARTRIDGE POUCH Barcode. Manual entry is not an option. Scanning is required.

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.



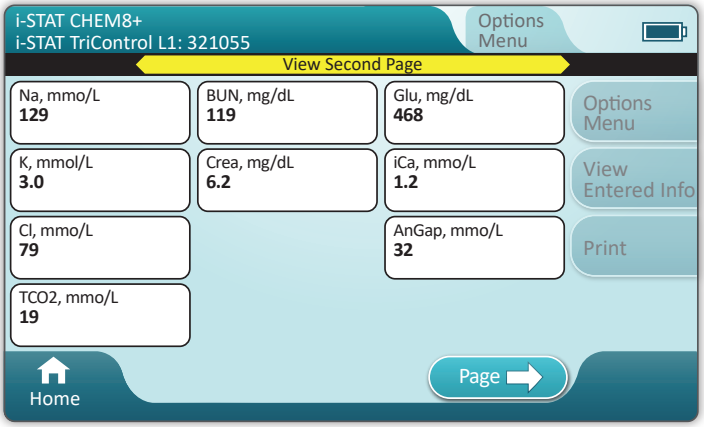


NOTE: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

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.)



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

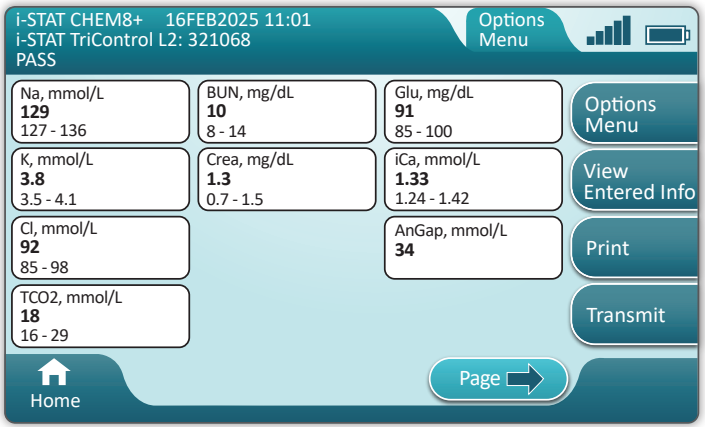
Use AlinIQ CWi to customize for automatic pass/fail determination using eVAS.

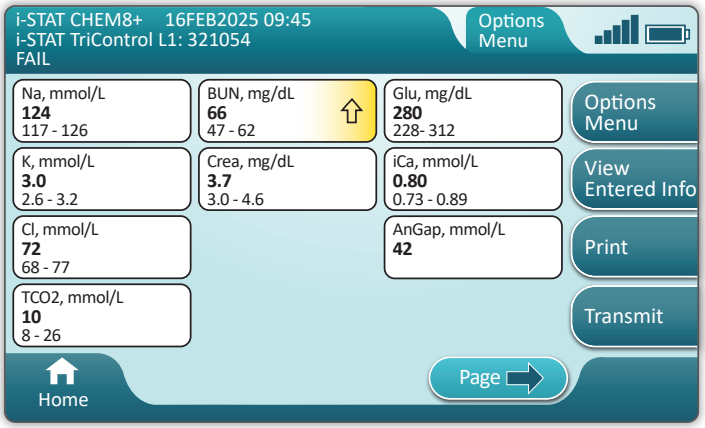
Once customized, the results will appear as follows:

Numeric value with no arrow – In Range

Numeric value with ⇧ arrow – Out of Range High

Numeric value with ⇩ arrow – Out of Range Low





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.

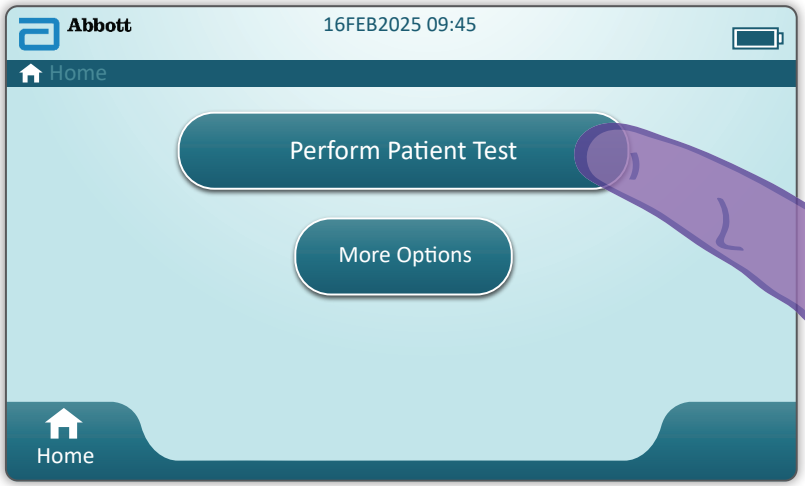
DO NOT:

- 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 manufacturer's recommendations for handling and storing samples drawn into lithium or balanced heparin.

HOW TO PERFORM PATIENT TESTING (CONT.)



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

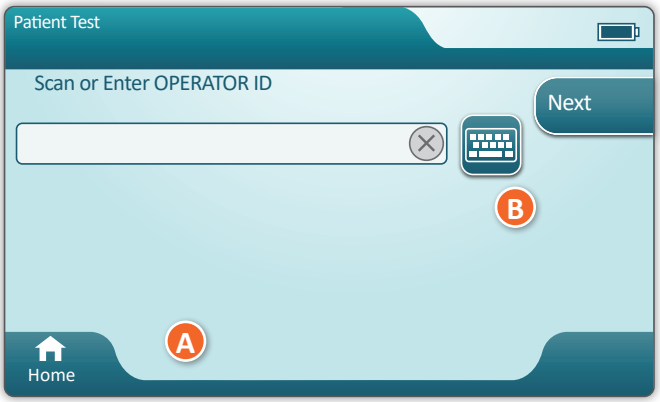
- When the instrument is customized by the System Administrator, the pathways may present screens not displayed in this guide.
  - ◇ It is essential to follow the prompts on the instrument screen.
  - ◇ On-screen graphics and text are provided to assist the user.
- This guide does not include instruction 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.

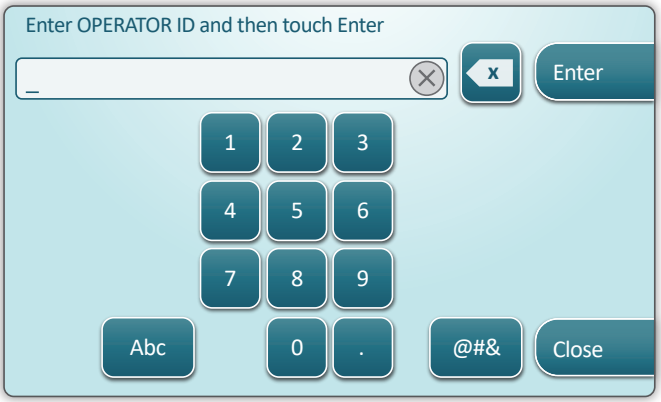
HOW TO PERFORM PATIENT TESTING (CONT.)

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



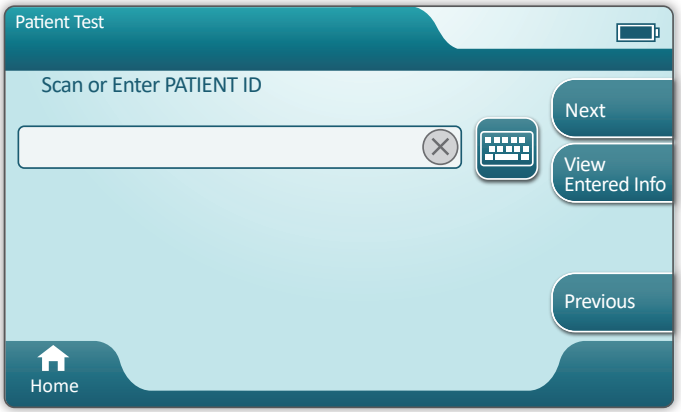
A On-screen graphic assists with scanning. After scanning is complete, the instrument will advance to the next step in the pathway.

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.



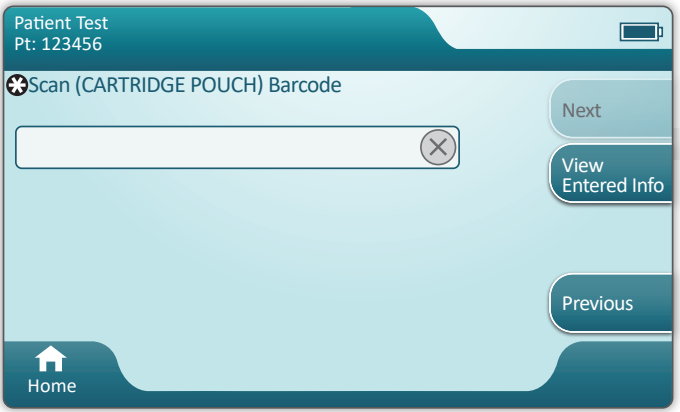
HOW TO PERFORM PATIENT TESTING (CONT.)

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.

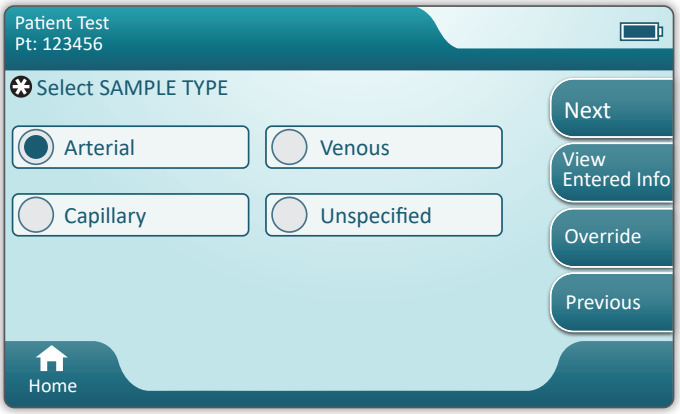
Scan (CARTRIDGE POUCH) Barcode. Scanning is required. You must scan the barcode. This information cannot be entered manually.

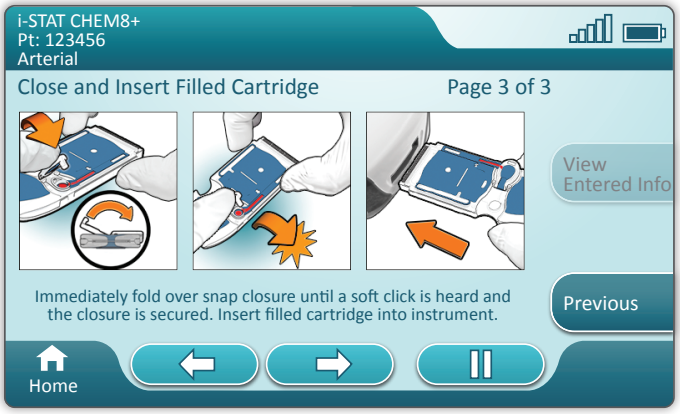


If an **Invalid Cartridge Type** window is displayed, contact the System Administrator.

HOW TO PERFORM PATIENT TESTING (CONT.)

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



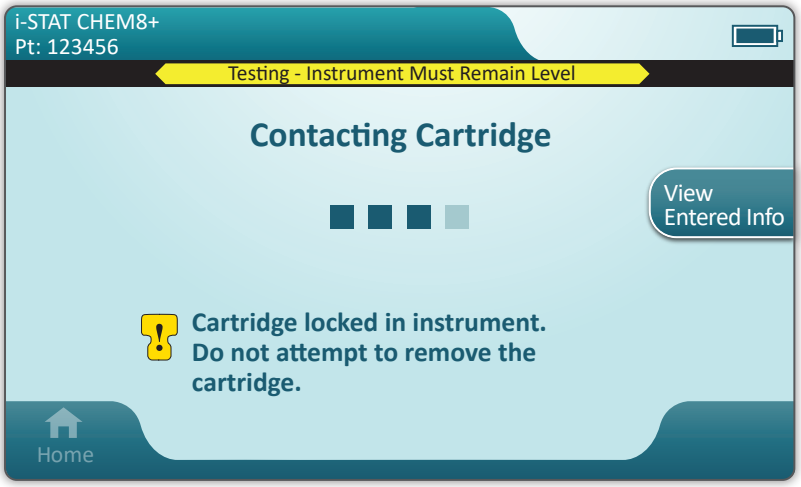


Below the Patient ID is the sample type selected from the previous screen or single sample type that is appropriate for the cartridge scanned. The action buttons at the bottom of the screen allow forward, backward and pause functionality.

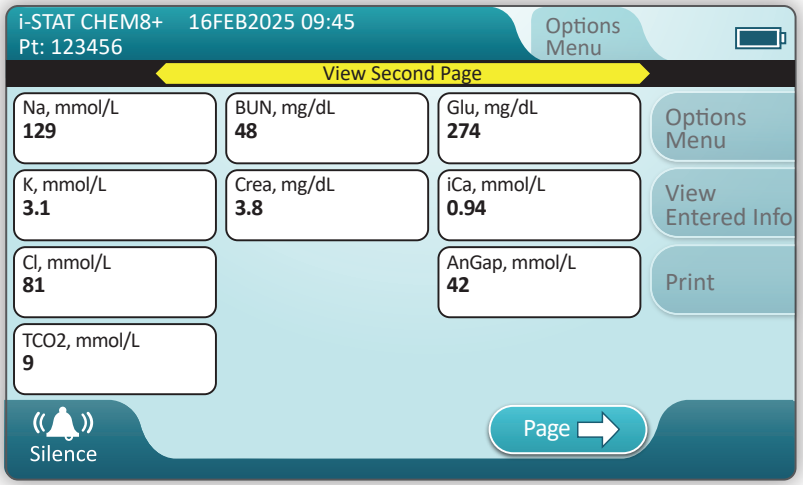
For experienced users, the help screens may be bypassed by inserting a filled cartridge.

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.)



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 here is more than one page of results. All action tabs are inactive until he 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.

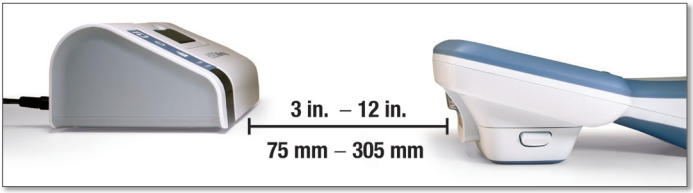
A sample may also yield results that are preceded by a greater than (>) or less than (<) symbol. These results are outside the instrument's measurement range. In order to determine the exact numeric result, the sample must be analyzed by a different method.

HOW TO PERFORM PATIENT TESTING (CONT.)

PRINTING

A **Determine printing method:**

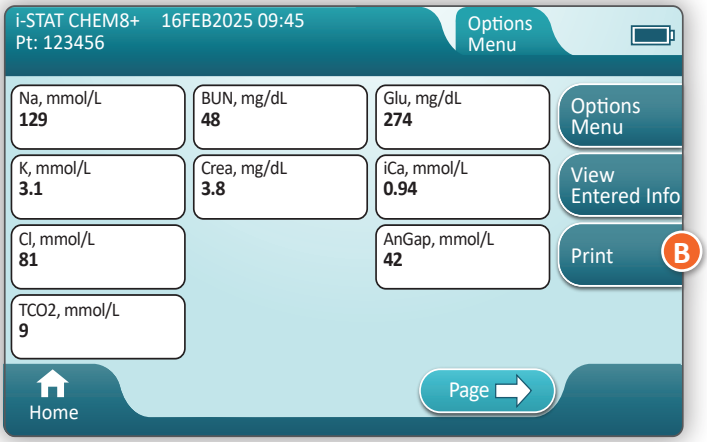
Wireless



OR

Wired to Base Station

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



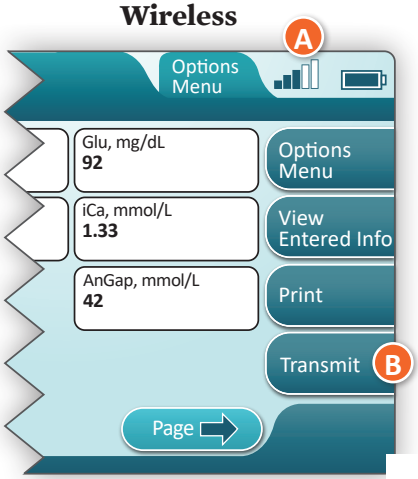
HOW TO PERFORM PATIENT TESTING (CONT.)

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

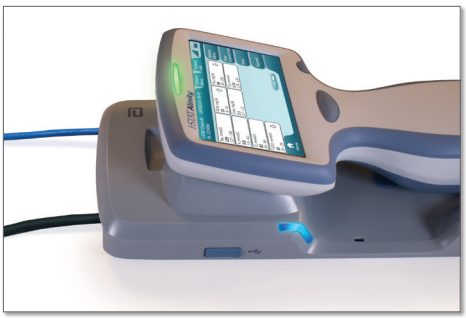


A A signal strength of 3 bars or higher is recommended

B To initiate transmission, touch Transmit

OR

Wired



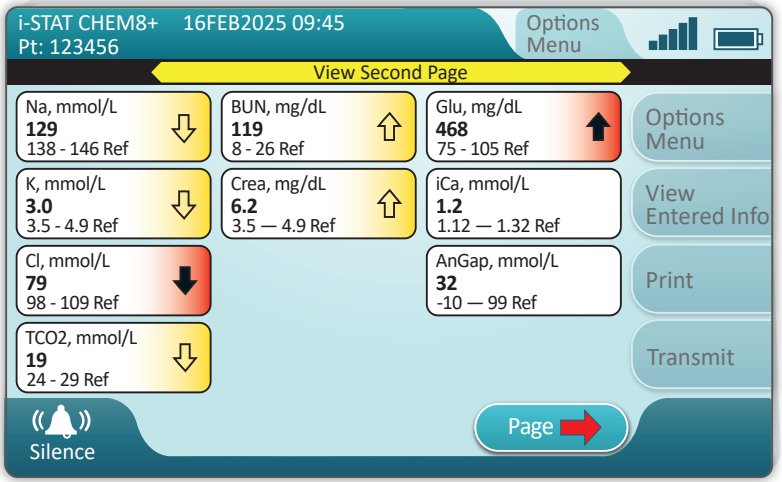
C Symbol indicates instrument is connected to the network

D To initiate transmission, touch Transmit

Abbott

HOW TO PERFORM PATIENT TESTING (CONT.)

BEST PRACTICE EXAMPLE



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

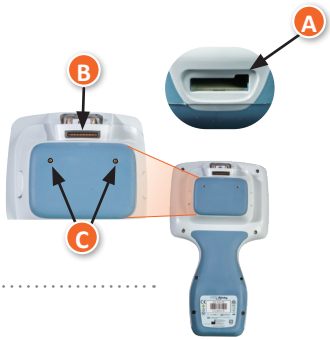
It is recommended that the i-STAT Alinity, base station, printer and electronic simulator be cleaned periodically or whenever visibly soiled. Standard precautions should be taken whenever working with blood or blood products.

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.

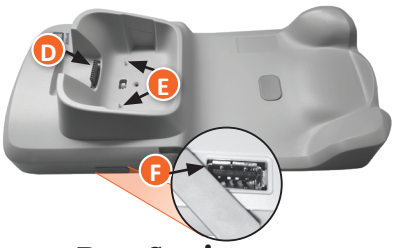
SENSITIVE AREAS

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

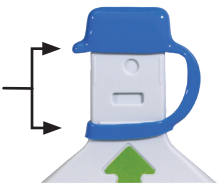


Base Station

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

Electronic Simulator

Area between protective cap retaining ring and white sensor area



Abbott

CLEANING AND DISINFECTING (CONT.)

DISINFECTING

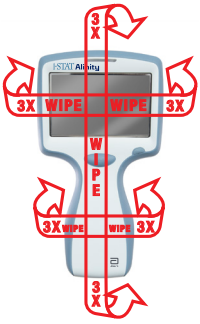
i-STAT ALINITY INSTRUMENT

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.

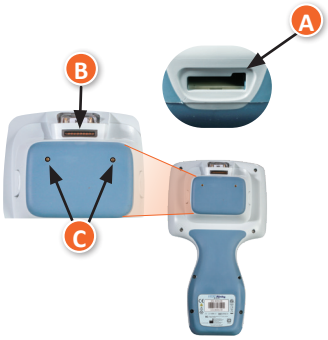
4 Wipe with gauze until dry.

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.)

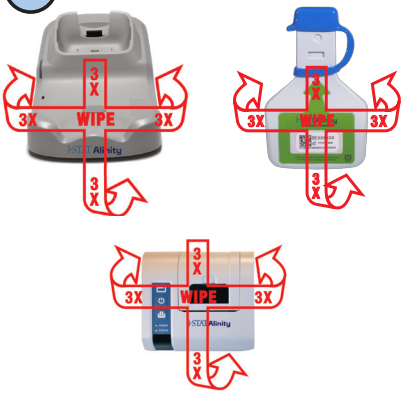
DISINFECTING (CONT.)

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.

2



WIPE 3X LEFT & RIGHT **WIPE 3X UP & DOWN**

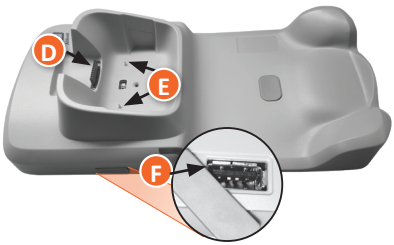
Wipe the front as shown, flip products on back side and repeat.

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

4 Wipe dry with gauze.

SENSITIVE AREAS

Avoid forcing liquid into these areas:

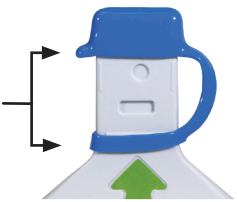


Base Station

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

Electronic Simulator

Area between protective cap retaining ring and white sensor area



Abbott

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 #46781-13

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)	11-76-2	1-5%
Disobutylphenoxyethoxyldimethylbenzyl ammonium chloride	121-54-0	0.28%

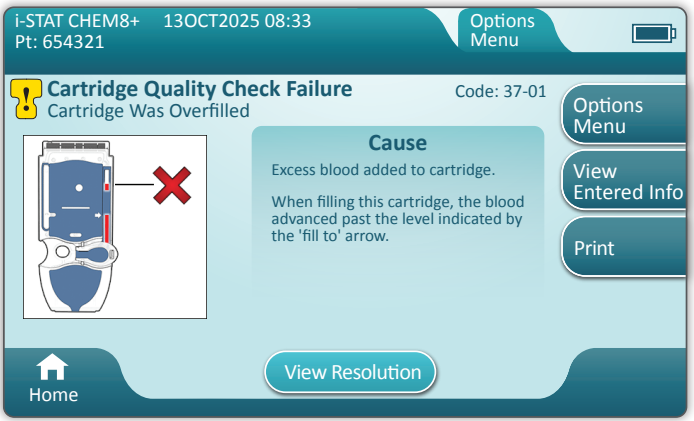
TROUBLESHOOTING AND SUPPORT

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 at www.globalpointofcare.abbott.

Once you have registered for access, login and navigate to SUPPORT > i-STAT 1 and i-STAT Alinity SUPPORT > CHOOSE YOUR PRODUCT > i-STAT ALINITY RESOURCES LOGIN and select from the following:

- Value Assignment Sheets
- Instrument Software
- Software Customization & Connectivity
- Administration Documentation
- Operator Documentation

ADDITIONAL SUPPORT

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

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 mains 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.)

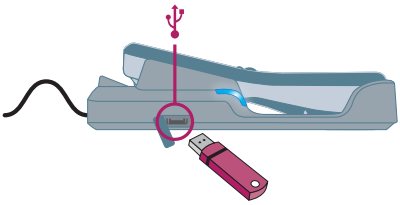
INSTALLATION

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.

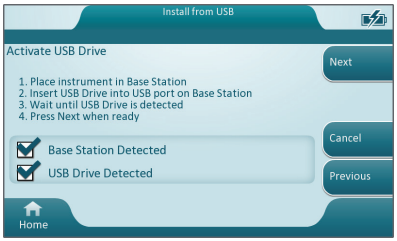
1 **Place instrument into the base station and power-up instrument.**

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

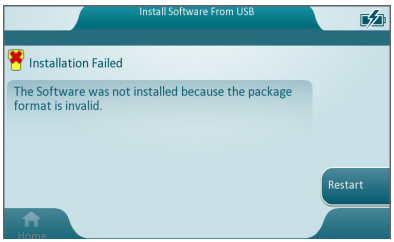
4 **Follow prompts until transfer is complete.**



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
CE	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) with respect to safety, health, environment and consumer protection.
⎓	Direct Current (DC).
~	Alternating Current (AC).
⧈	Class II Construction.
c ETL US LISTED Intertek	Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010-1: 3rd Ed; Am.1 CAN/CSA C22.2 No. 61010-1-12 3rd Ed. (R2017) +U1;U2
	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).
2	Do not reuse.
FC	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.
14	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
$\boldsymbol{P}CO_2$	Partial Pressure of Carbon Dioxide
$\boldsymbol{P}O_2$	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

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)	Content that has been deleted will be identified in the release notes. • 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)	New content will be highlighted and reason for addition of content will be provided in the release notes. • New table is indicated by highlight to the title of the table. • Addition of a word, sentence or paragraph is indicted 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)	Content that has been updated is indicated as follows and will be identified in the release notes. • 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 2: System Components**

  Addition of statement in the i-STAT Alinity Instrument DO NOT section instructing users to not remove the rechargeable battery during the testing process. This statement aligns with existing user documentation.

- **Section 8: Cleaning and Disinfecting**

  Addition of statement in the Approved Disinfectant Products section regarding cleaning/disinfecting instrument and peripherals surfaces with CaviWipes or equivalent. Tested and approved CaviWipes component breakdown provided for reference, for markets in which CaviWipes are not available.

- **Appendix 2: Release Notes**

  Addition of Release Notes summary

- **Back Cover:**

  Update to Emergo Europe address from "Prinsessegracht 20, 2514 AP The Hague" to "Westervoortsedijk 60, 6827 AT Arnhem".

i-STAT ALINITY INSTRUMENT
END USER LICENSE AGREEMENT

The full text of the end user license agreement ("EULA") for the Software (as defined in the EULA) can be found in the Systems Operations Manual. Please read the EULA prior to using this device. Any use of this device shall indicate your acceptance of the terms of the EULA. If you do not accept the terms of the EULA, do not use this device. The Software, and all intellectual property rights therein, is owned by APOC and its licensors. You may not (i) use the Software to access or attempt to access any other APOC systems, programs or data that are not made available for public use; (ii) copy, reproduce, alter, merge, modify, adapt, translate, republish, upload, post, transmit, resell or distribute in any way the Software (or the Devices) or decompile, reverse engineer, disassemble, or otherwise reduce the Software to a human perceivable form; (iii) permit any third party to benefit from the use or functionality of the Software via a rental, lease, timesharing, service bureau, or other arrangement; (iv) transfer any of the rights granted to you under this EULA; (v) work around any technical limitations in the Software, use any tool to enable features or functionalities that are otherwise disabled in the Software, or decompile, disassemble, or otherwise reverse engineer the Software except as otherwise permitted by applicable law; (vi) perform or attempt to perform any actions that would interfere with the proper working of the Software; or (vii) otherwise use the Software except as expressly allowed under the EULA.

The Software is provided "As Is" without warranty of any kind. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, APOC AND SUPPLIERS SHALL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES OR FOR ANY DAMAGES RELATING TO LOSS OF BUSINESS, TELECOMMUNICATION FAILURES, THE LOSS, CORRUPTION OR THEFT OF DATA, VIRUSES, SPYWARE, LOSS OF PROFITS OR INVESTMENT, USE OF THE SOFTWARE WITH HARDWARE OR OTHER SOFTWARE THAT DOES NOT MEET APOC'S SYSTEMS REQUIREMENTS OR THE LIKE, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), PRODUCT LIABILITY OR OTHERWISE, EVEN IF APOC AND/OR ITS SUPPLIERS, OR EITHER OF THEIR REPRESENTATIVES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND EVEN IF A REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. SOME STATES DO NOT ALLOW THE LIMITATION AND/OR EXCLUSION OF LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

This page left intentionally blank.

i-STAT is for *In Vitro* Diagnostic Use.

Printed in the USA.

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

Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

IVD

Rx ONLY

CE

EC REP

EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands