i-STAT Alinity

Quick Reference Guide

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CONTENTS

SCOPE:

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

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 **System Operations Manual at** www.pointofcare.abbott.

For additional information regarding the use of the **i-STAT Alinity** instrument and **i-STAT** test cartridges, refer to individual cartridge **Instructions for Use and Systems Operation Manual.**

IVD

CE

Rx ONLY

Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 USA
www.pointofcare.abbott

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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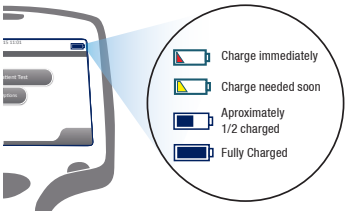
INSTRUMENT SETUP (New Instruments)

1 ATTACH BATTERY AND POWER ON INSTRUMENT

2 CHECK FOR SUFFICENT BATTERY CHARGE



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

IF BATTERY HAS SUFFICIENT CHARGE CONTINUE TO STEP 4

3 CHARGE BATTERY IF NEEDED OR MOVE TO STEP 4

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INSTRUMENT SETUP (New Instruments)

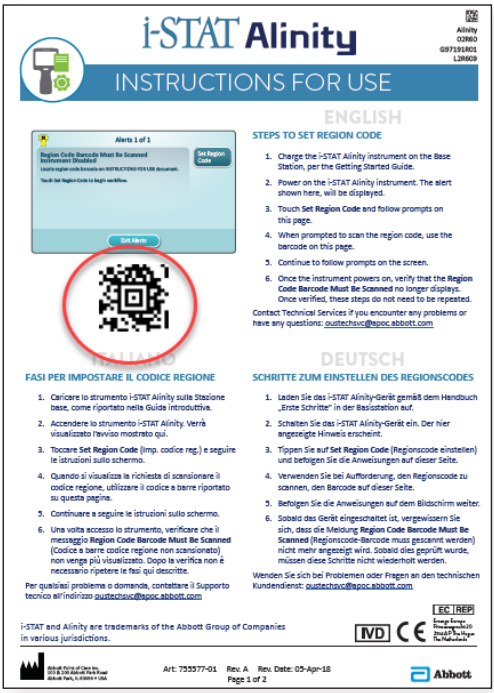
If instrument displays Set Region Code screen, proceed to **STEP** 4. If not, proceed to **STEP** 6.

4 LOCATE REGION BAR CODE

a

OR

b


i-STAT Alinity

INSTRUCTIONS FOR USE

Alinity
G97191R01
L2R609

ENGLISH

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: oustechsvc@epoc.abbott.com

ITALIANO

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** (Imp. 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 accesso 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 oustechsvc@epoc.abbott.com

DEUTSCH

SCHRITTE 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** (Regionscode einstellen) und befolgen Sie die Anweisungen auf dieser Seite.
4. Verwenden Sie bei Aufforderung, den Regionscode zu scannen, den Barcode auf dieser Seite.
5. Befolgen Sie die Anweisungen auf dem Bildschirm weiter.
6. Sobald das Gerät eingeschaltet ist, vergewissern Sie sich, dass die Meldung **Region Code Barcode Must Be Scanned** (Regionscode-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: oustechsvc@epoc.abbott.com

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IVD

Art: 755577-01 Rev. A Rev. Date: 05-Apr-18
Page 1 of 2

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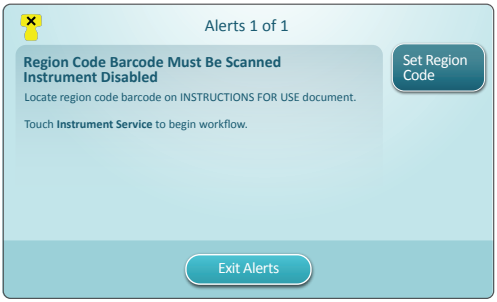
5 TOUCH SET REGION CODE

1. Touch **Set Region Code** and follow prompts on screen.

2. When prompted, scan Region Code on box or letter.

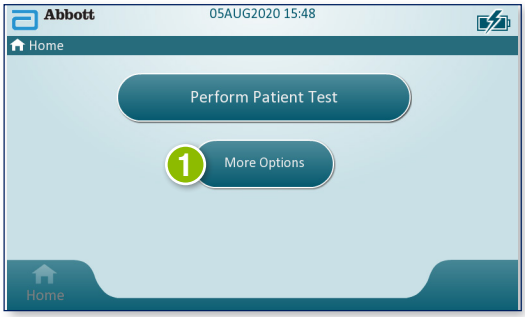
3. Continue to follow prompts on the screen.

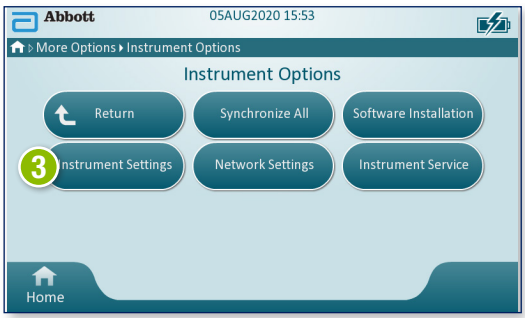


4. Once the instrument powers on, the **Region Code Barcode** alert should no longer be displayed. Proceed to **STEP** 6. If Alert screen displays again, repeat **STEP** 5. *If the Alert screen displays again, contact your Abbott representative.*

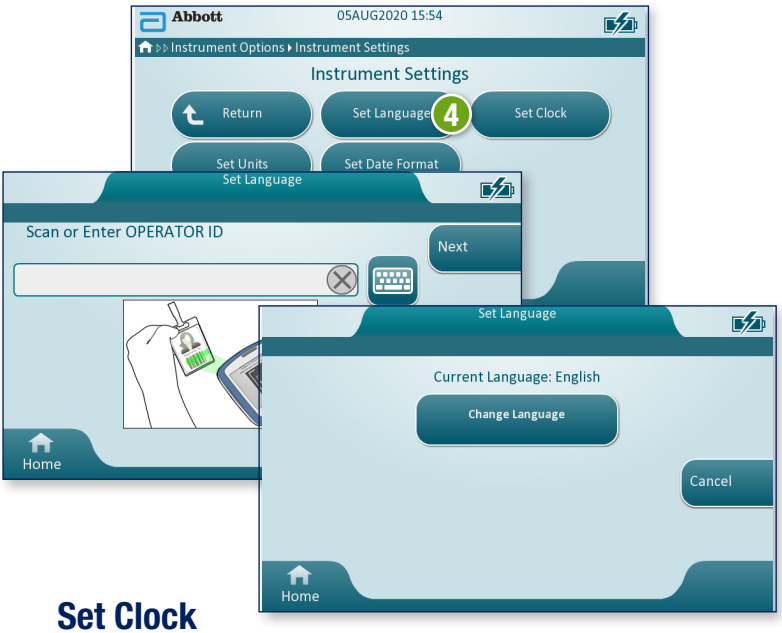
6 FINISH SETTING UP THE INSTRUMENT

Power instrument on and follow sequence.

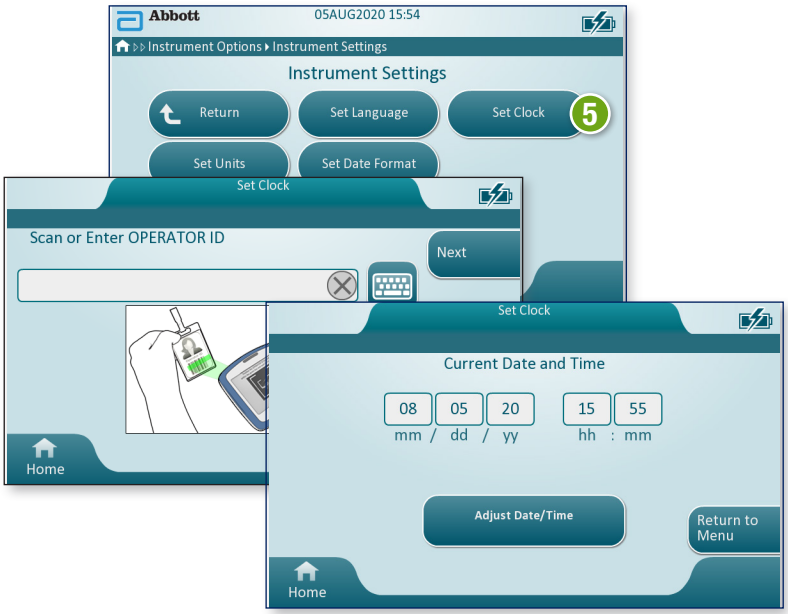




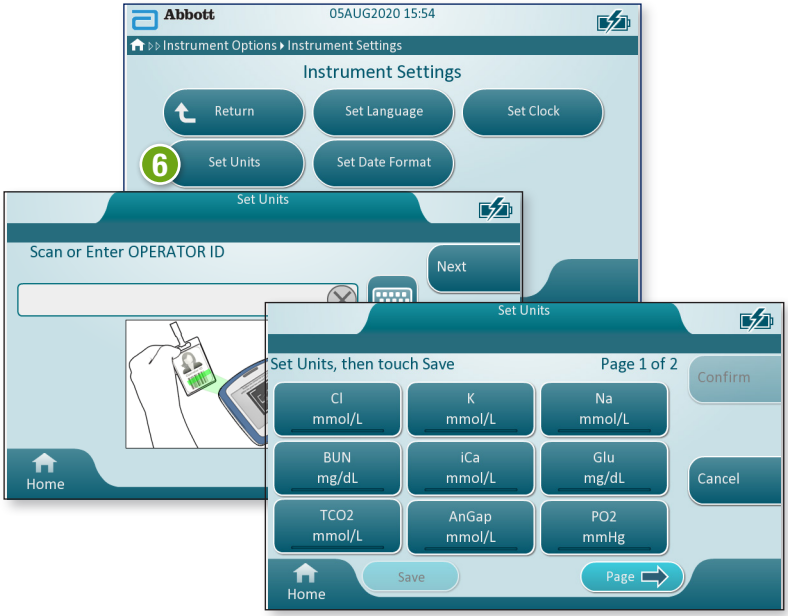
Set Language



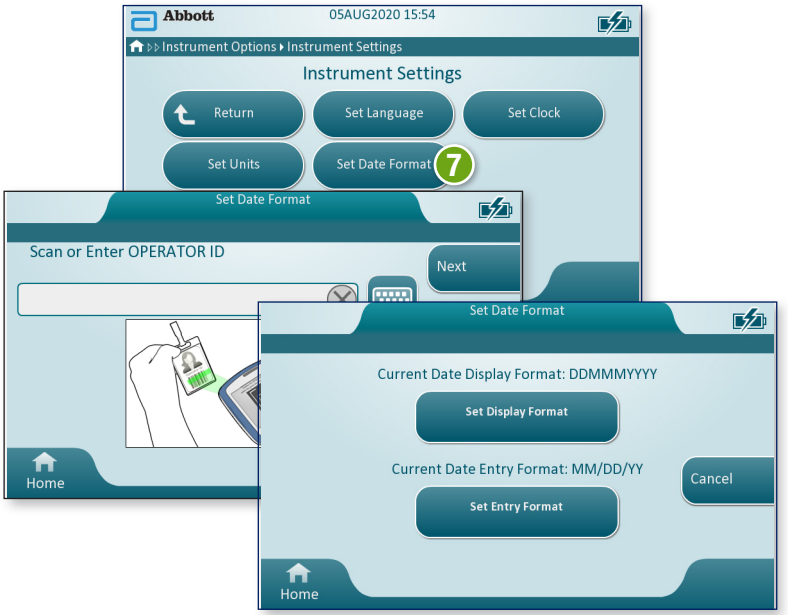
Set Clock



Set Units



Set Date Format



8 INSTRUMENT SETUP IS COMPLETE

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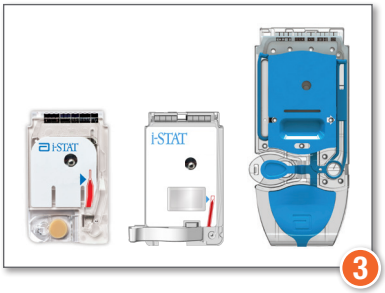
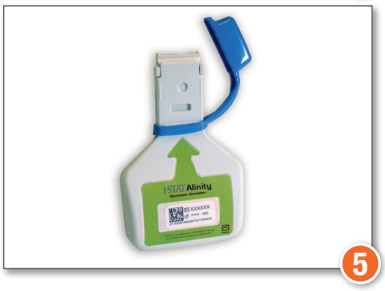
SYSTEM COMPONENTS





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 all patient and quality testing.
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 PORTABLE PRINTER:** Used to print records stored in the instrument.

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.

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SCREEN COMPONENTS AND THEIR MEANINGS

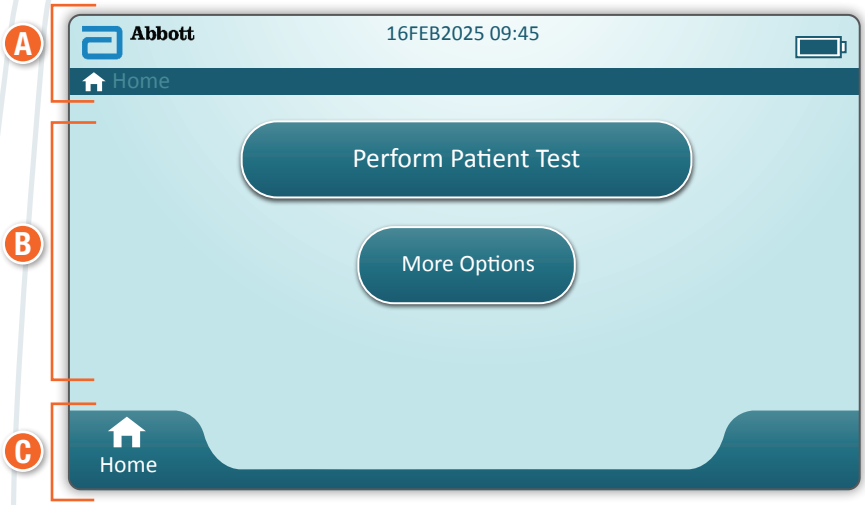
Home Screen

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.

If all the self-checks pass, the instrument will display the Home screen.

If one or more self-checks fail, the instrument will display the Alerts Screen.

SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



Home Screen

If all self-checks pass at start up, the instrument will display the Home screen.

Anatomy of a Home Screen:

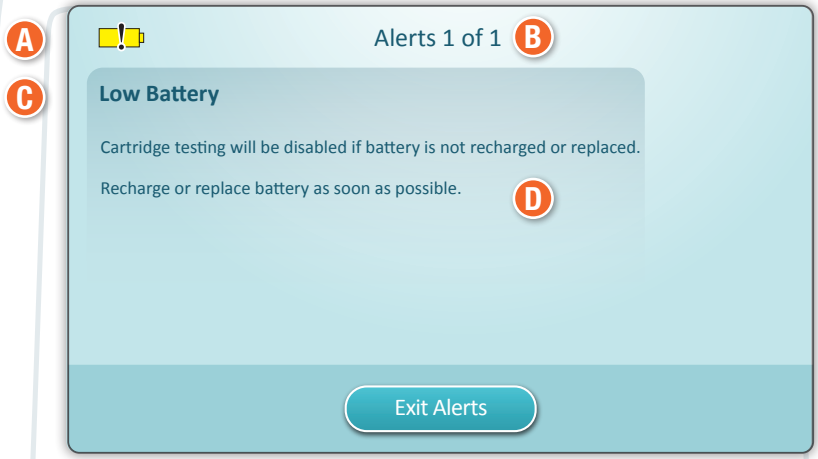
A HEADER Area Contains:
- Date/Time
- Wireless Status*
- Battery Status*

B BODY Area Contains:
- Buttons provide access to pathways
  - Perform Patient Test
  - More Options

C FOOTER Area Contains:
- Home Button

* See Page 13 for screen icons and their meanings.

SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



Alert Screen

If one or more start up 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

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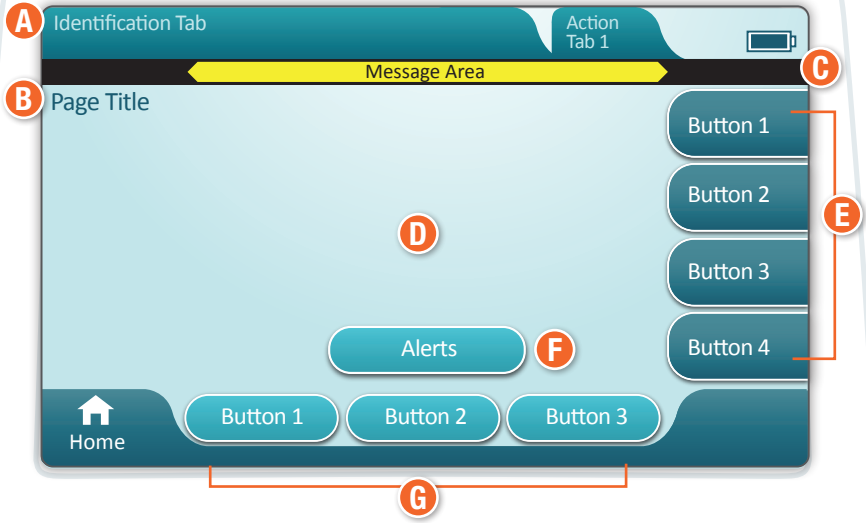
SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



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

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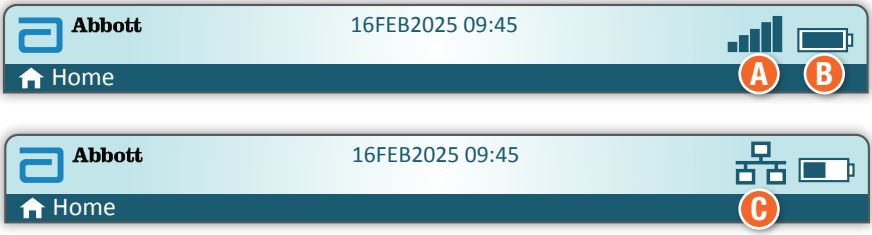
SCREEN COMPONENTS AND THEIR MEANINGS (CONT.)



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

*Disabled on instrument or via customization.
** Testing is disabled when the battery level is insufficient to perform a cartridge test.

CLEANING

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

It is recommended that the i-STAT Alinity, base station and electronic simulator be cleaned periodically or whenever visibly soiled.

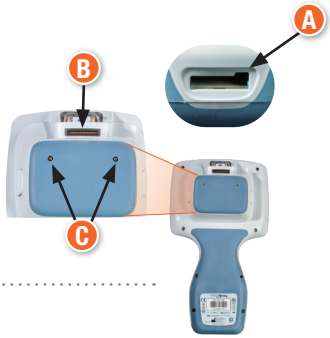
Standard precautions should be taken whenever working with blood or blood products.

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 nor the printer need to be unplugged when 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.

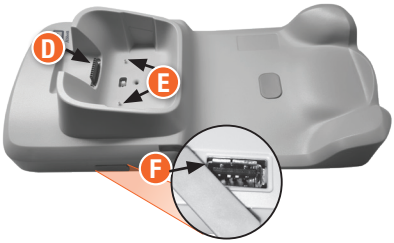
SENSITIVE AREAS

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

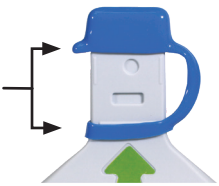


Base Station

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

G Electronic Simulator

Area between protective cap retaining ring and white sensor area



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DISINFECTING

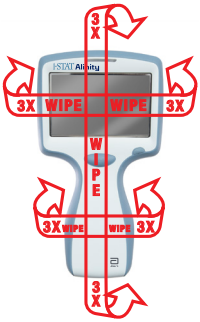
i-STAT Alinity Instrument

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.

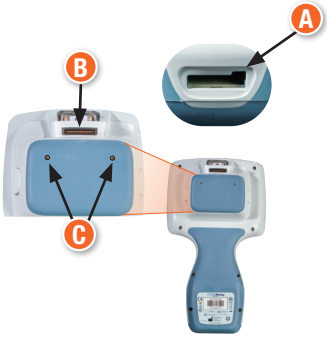
4 Wipe with gauze until dry.

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



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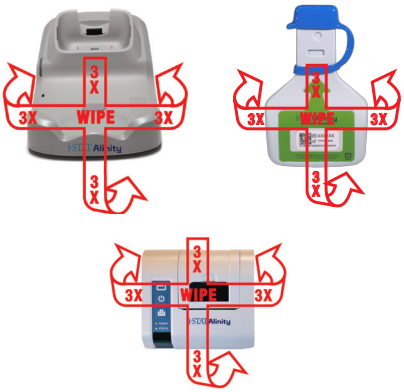
DISINFECTING

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**

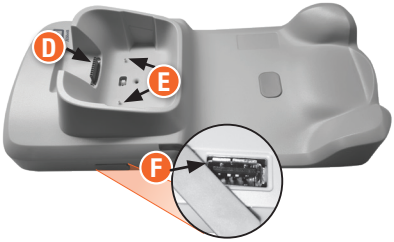
Wipe the front as shown, flip products on back side and repeat.

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

4 Wipe dry with gauze.

SENSITIVE AREAS

Avoid forcing liquid into these areas:

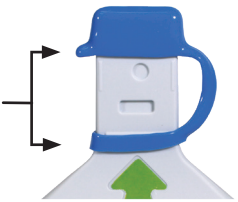


Base Station

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

G **Electronic Simulator**

Area between protective cap retaining ring and white sensor area



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- 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 microoganisms.
- Follow recommendations from the FDA and CDC and your facility's policies and procedures for infection control.

APPROVED DISINFECTANT PRODUCTS

CaviWipes
EPA #46781-13

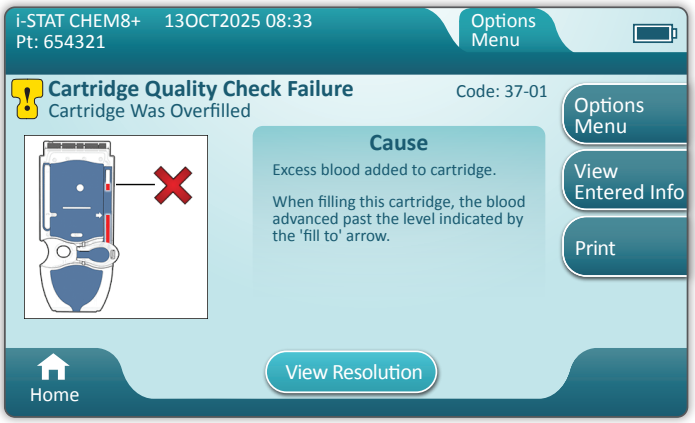
Note: Super-Sani Cloth is an acceptable disinfecting option for all markets except the United States.

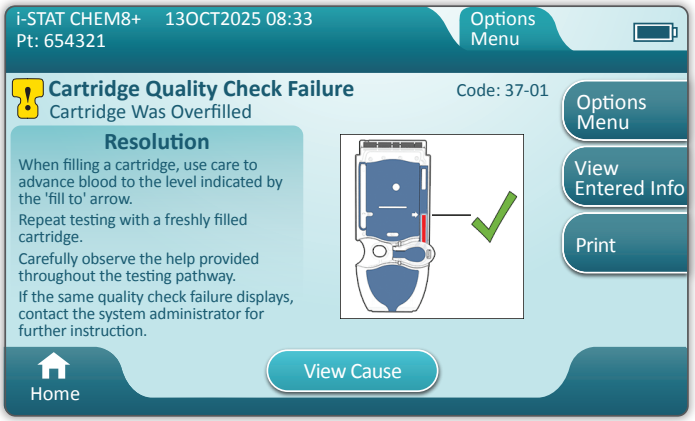
TROUBLESHOOTING

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 (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.

i-STAT ALINITY INSTRUMENT - END USER LICENSE AGREEMENT

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