

i-STAT[®] TECHNICAL BULLETIN

PROCEDURE FOR RUNNING CHEM8+ CARTRIDGES WITH BARCODED POUCH

OVERVIEW

In response to customer requests for barcoded packaging, starting in March 2010, Abbott Point of Care will begin shipping CHEM8+ cartridges with barcoded pouches. This simple addition will make it easier to comply with regulatory guidelines regarding the tracking of cartridge lot numbers to individual test results. The barcoding of pouches will also prevent the use of cartridges beyond the manufacturer's expiration date.



Use of these new barcoded CHEM8+ cartridges requires specific customization of the i-STAT 1 Handheld, plus new user testing procedures. **Users who previously started their testing process by inserting a filled cartridge into the Handheld must now follow these new procedures.** This Technical Bulletin has been created specifically to guide users through all these new processes in preparation for running barcoded CHEM8+ cartridges.

NOTE: NO ADDITIONAL STEPS ARE NECESSARY IF THE HANDHELD IS ALREADY USED TO TEST cTnI, CK-MB, or BNP CARTRIDGES.

If you have any questions regarding the information in this Technical Bulletin, please contact Abbott Point of Care Technical Support at 800-366-8020, option 1, or by e-mail at: techsvc@apoc.abbott.com

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CUSTOMIZING THE i-STAT 1 HANDHELD TO RUN BARCODED CHEM8+ CARTRIDGES

Before testing barcoded CHEM8+ cartridges, the i-STAT 1 Handheld must be customized for the following options:

- Cartridge Information First Required, AND
- Cartridge Lot Number Required

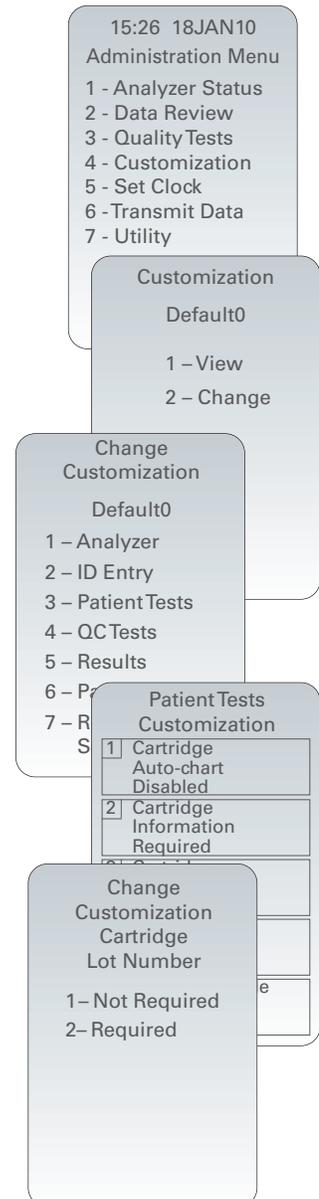
The procedure to customize the Handheld varies, depending on whether the customization is being done directly using the Handheld's keypad, or whether it is being done through the Customization Workspace in Central Data Station (CDS) Version 5 or i-STAT/DE.

- Users who do not have CDS Version 5 or i-STAT/DE → Proceed to Section A
- Users who have CDS Version 5 → Proceed to Section B
- Users who have i-STAT/DE → Proceed to Section C

A. Customizing the Handheld for Cartridge Testing Using the Handheld Keypad

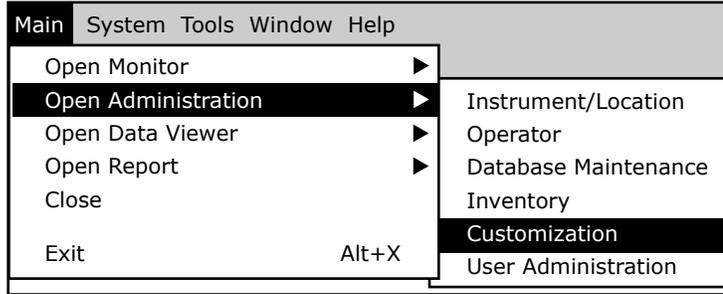
Cartridge use requires operators to turn on the Handheld, enter an Operator ID and Patient ID, and then scan the cartridge lot number before inserting a cartridge into the Handheld for testing. To customize the Handheld:

1. Press  to turn on the Handheld.
2. Press  to change screen to Administration Menu.
3. Press  (Customization).
4. Press  (Change).
5. Press  (No password is required).
6. Press  (Patient Tests).
7. Press  (Cartridge Information).
8. Press  to change setting to "Required".
9. Press  (Cartridge Lot Number).
10. Press  to change setting to "Required".
11. Both "Cartridge Information" and "Cartridge Lot Number" should be now appear on display as "Required".
12. Press  to turn Handheld off and save the settings. (If settings are not shown as "Required", return to Step 7).



B. Customizing the Handheld for Cartridge Testing Using CDS Version 5

1. Click on **Main → Open Administration Function → Customization**.



2. Type in your password and click OK. The default password is the word *istat*.



3. Make sure the “**Enable Customization**” box has a check mark in it.

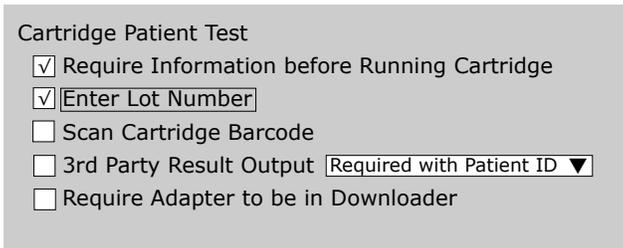


Also, make certain that the **Enable Updates** box is checked for the particular location to which this i-STAT 1 Handheld is assigned.

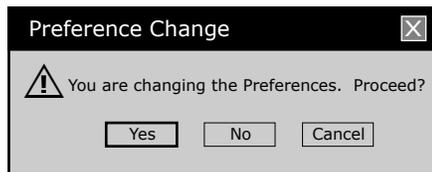
Location-based customization profiles:							
Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes
A_10.10.90.17	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0
A_10.10.90.24	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0
A_10.10.90.31	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0
A_10.10.90.32	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A18		DEFAULT0	CHART0

4. If the location where this Handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific location to which this Handheld is assigned.

- Once the **Preferences** screen opens, click on the **Test** tab.
- At the top of the **Test** tab screen, check the box next to **Require Information before Running Cartridge** and **Enter Lot Number**.



- Click **OK** and answer **YES** to the question about changing the preferences.



- Download the Handheld(s) to the CDS from a downloader in the location to which this Handheld is assigned. This action should upload the chosen customization features into the Handheld. Repeat step 8 for all Handhelds from this same location to be customized. To customize Handhelds from other locations for the same features, return to step 1.

C. Customizing the Handheld for Cartridge Testing Using i-STAT/DE

- Access the Customization Workspace

- RALS-Plus Users:
 - RALS-Plus application, pick i-STAT from the drop-down menu.
 - Click on **Device Customization**
- PrecisionWeb Users:
 - Double click on the desktop shortcut or Internet Explorer Favorites for **i-STAT Customization**.

- Make sure the “**Enable Customization**” box has a check mark in it.



Also, make certain that the **Enable Updates** box is checked for the particular location to which this i-STAT 1 Handheld is assigned.

Location	Enabled
ER	<input checked="" type="checkbox"/>
Lab	<input checked="" type="checkbox"/>

- If the location where this Handheld is assigned has a check mark under the **Use Default Profile** column, double click on the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click on the alphanumeric code under **Preferences** for the specific location to which this Handheld is assigned.
- Once the **Preferences** screen opens, click on the **Test** tab.

Instrument ID Entry **Test** QC Results Analyte Enable Strip Lots

Password Date Format Inactivity Timeout seconds

Sound
 Autotransmit
 Memory Full Action
 Batch Mode Timeout minutes
 Display Password for Clock Page
 Enable PCx Glucose
 Synchronize Clock to CDS
 Apply Operator List to Viewing Stored Patient Records
 Limit Number of Records in Transmit All to days

Upload Schedules Off Every hours Schedule Options

i-STAT Reserved Data

- At the top of the **Test** tab screen, check the box next to **Require Information before Running Cartridge** and **Enter Lot Number**.

Cartridge Patient Test

Require Information before Running Cartridge
 Enter Lot Number
 Scan Cartridge Barcode
 3rd Party Result Output
 Require Adapter to be in Downloader

- Click OK and answer YES to the question about changing the preferences.

Microsoft Internet Explorer

Do you want to change Preferences?

OK Cancel

- Download the Handheld(s) to the CDS from a downloader in the location to which this Handheld is assigned. This action should upload the chosen customization features into the Handheld. Repeat step 7 for all Handhelds from this same location to be customized. To customize Handhelds from other locations for the same features, return to step 1.

TESTING A SAMPLE USING THE NEW BARCODED CHEM8+ CARTRIDGES

- **DO NOT** insert cartridge to start test
- **DO NOT** open cartridge pouch before scanning the barcode (step 4 below)

The following procedure must be used when testing all samples using the barcoded CHEM8+ cartridges.

1. Press  to turn on Handheld.
2. Press the following, based upon the sample being tested:

Patient Samples: 

Control Samples:  →  → 

Cal Ver Samples:  →  → 

Proficiency Samples:  →  → 

3. Follow Handheld prompts.
4. Scan the lot number on the cartridge pouch.
 - Position barcode 3-9 inches from scanner window on the Handheld.
 - Press and hold  to activate the scanner.
 - Align the red laser light so it covers the entire barcode.
 - The Handheld will beep when it reads the barcode successfully.
5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.
6. Push the sealed cartridge into the Handheld port until it clicks into place. Wait about 2-3 minutes for the test to complete.
7. Review results.



QUALITY CHECK CODES

There are three additional quality check codes that users may encounter when running the new barcoded CHEM8+ cartridges. They are summarized in the table below.

Cause Message	Action Message	Code	Comments
Cartridge Type Not Recognized	Use Another Cartridge	69	The Handheld expects the barcode on the individual cartridge pouch to be scanned. It will not accept keypad entries of the cartridge lot number or a scan of the barcode on the cartridge box.
Lot Expired		140	The Handheld detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
Analyzer Error	See Manual	147	The Handheld is not customized appropriately to run cartridges with barcoded pouches. See the instructions in this Technical Bulletin following the Overview section for customizing i-STAT 1 Handhelds to run barcoded cartridges.