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Dear Abaxis Customer:

Enclosed you will find the December 2011 software update materials for your i-STAT<sup>®</sup> or i-STAT<sup>®</sup> 1 Analyzer(s).

It is necessary to update the Analyzer software to CLEW A23 in order to maintain long-term consistency and performance. **The CLEW A22 software currently installed on your analyzer will expire December 21, 2011.**

- A. Review the Update attached for information on the expiration date of CLEW A23
- B. Ensure that your PC contains the necessary serial and/or PS2 ports as described in the attached Update.
- C. Follow the attached Instructions document for your specific analyzer
  - Instructions for Updating Software on the i-STAT Portable Clinical Analyzer (P/N 610-7002 Rev. A)
  - Instructions for Updating i-STAT 1 Handheld Software (P/N 600-7055 Rev. A)

If you have any questions about performing this software upgrade, please contact Abaxis Technical Support at 800-822-2947.

Thank you for your continued support of the i-STAT System.

Sincerely,

Abaxis Technical Support

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## SOFTWARE AND CARTRIDGE TEST INFORMATION UPDATE FOR ABAXIS CUSTOMERS: December 2011

This update includes new software for the i-STAT and i-STAT 1 Analyzer. The appropriate materials required for your institution to perform the update are included.

This is a mandatory update. If you did not receive a disk or CD-ROM with the software for your analyzer, please call Abaxis Technical Support at 800-822-2947.

### ANALYZERS

The correct version of software and CLEW to install in your analyzers is listed below.

Standard Software	
<b>i-STAT Portable Clinical Analyzer</b>	<b>i-STAT 1 Analyzer</b>
JAMS064 & CLEW A23	JAMS131 & CLEW A23

#### Expiration Date

***Please note that the current software expires 21 December 2011.***

Fifteen days before the software expires, a message will be displayed to alert the user of the pending expiration date. If this update is not performed by 21 December 2011, the analyzer will display "INVALID OR EXPIRED CLEW – SEE MANUAL" (quality check code 12).

***The new software expires 20 June 2012.***

#### Value Assignment Sheets

Value Assignment Sheets for the new CLEW A23 can be downloaded or printed from <http://www.abbottpointofcare.com/valsheets>

#### MSDS Sheets

Updated MSDS Sheets for the following i-STAT System products are available for printing or downloading from <http://www.abbottpointofcare.com>

- i-STAT Controls and Calibration Verification material, plus the CHEM8+ Controls and Calibration Verification Material
- Cliniqa Cardiac Marker Controls and Tri-Level Control Set
- Novacell Nickel Metal Hybride Battery (for the i-STAT 1 Printer)
- Cryo – Gel Pack

## **Serial-to-USB and PS2-to-USB Adapters**

A serial port and PS2 (keyboard) port are required to update the i-STAT Portable Clinical Analyzer and a serial port is required to update the i-STAT 1 Analyzer (if customer does not have new i-STAT 1 USB Downloader/Recharger). If you do not have the required ports on your computer, you will need to purchase an adapter. Abaxis recommends the following adapters for both models which are available at most office supply distributors:

**Serial-to-USB Adapter:** Tripp Lite High Speed USB Serial Adapter Model #USA-19HS

**PS2-to-USB Adapter:** Belkin® USB to PS/2 Cable Adapter

## **STANDARDIZATION**

### **CLEW Update**

The i-STAT System is designed to eliminate operator influence on delivered results. With the exception of the immunoassay cartridges, the user is not required to enter lot-specific calibration information into the instrument. The micro-fabricated sensor technology produces very repeatable devices from lot to lot which allow the Analyzers to use the same set of standardizing values for extended periods of time.

Nevertheless, continuous manufacturing process improvements necessitate re-establishing standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. It has been our practice to accomplish this with periodic releases of software. This new CLEW re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

**Future shipments of cartridges may require the installation of this software prior to the use of the cartridges.** Failure to update prior to using these cartridges will result in quality check code 69, "CARTRIDGE TYPE NOT RECOGNIZED".

This software supports all current non-expired cartridges.



## INSTRUCTIONS FOR UPDATING SOFTWARE ON THE i-STAT<sup>®</sup> PORTABLE CLINICAL ANALYZER

### **1. OVERVIEW**

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These instructions are designed to guide customers through the process of updating the software in their i-STAT Portable Clinical Analyzer (Handheld).

### **2. WHY DO i-STAT HANDHELDS NEED SOFTWARE UPDATES?**

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The i-STAT System is designed to eliminate operator influence on delivered results.

Due to continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer.

New CLEW software -- delivered twice a year on a CD-ROM -- re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the i-STAT Handheld to recognize any newly launched cartridge types and to perform any newly launched features.

### **3. PROCEDURES FOR PERFORMING THE SOFTWARE UPDATE**

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There are two procedural options for the performing the software update on the i-STAT Handheld:

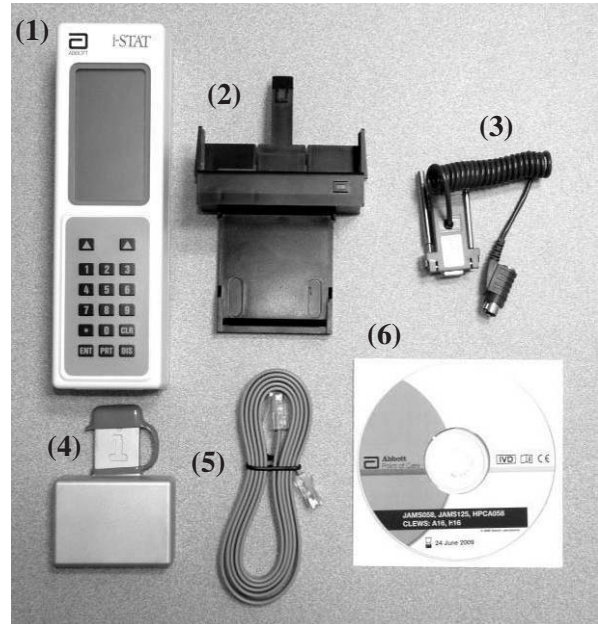
**JammLite Utility:** This utility must be used to update the first Handheld, and can be used to update all Handhelds, if desired. To use this utility, you must have a computer with Windows<sup>®</sup> 2000 or higher.

**Handheld to Handheld Update:** Once the first Handheld is updated using the JammLite utility, the remaining Handhelds may be updated using this procedure. This procedure is especially helpful for facilities where the Handhelds are located in multiple departments, or at large distances from each other. It allows the Handhelds to remain in their use areas, instead of having to bring them to the computer where the JammLite utility update is performed.

## **4. PERFORMING THE SOFTWARE UPDATE USING THE JAMMLITE UTILITY**

To perform the software update you will need:

- i-STAT Portable Clinical Analyzer (Handheld) (1)
- IR Link (2)
- Power Adapter with MiniDin Connector on one end and D-Connector on the other end (3)
- Electronic Simulator *optional* (4)
- RJ45 to RJ45 modular data cable (5)
- JAMS/CLEW software CD-ROM (6)
- Computer with Windows® 2000 or Windows® XP Operating System (not shown) that has a 9 Pin serial port and a CD drive.



### **4.1: Save Stored Results on Handheld**

All test records are erased in the Handheld when the application software is updated. If you are a Central Data Station (CDS) user, download each Handheld before proceeding.

### **4.2: Check Battery Voltage on Handheld**

Handhelds consume power during the software update. For the update, the voltage should be above 7.5 volts.

To check the Battery Voltage on the Handheld:

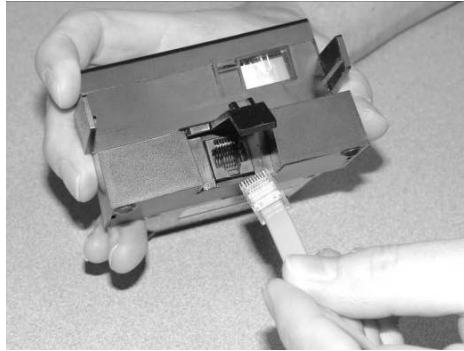
- Press DIS to activate the Handheld.
- Press the Right Arrow key to bring up the Menu.
- Press 1 to bring up the Analyzer Status page.
- Review the battery voltage.

If below 7.5 volts, install fresh batteries.

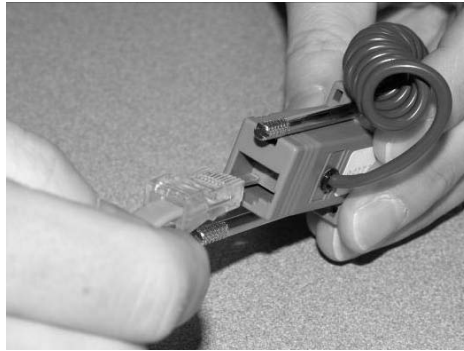
#### **4.3: Shut down all applications on the Computer being used for the Update**

#### **4.4: Connect the IR Link to the Computer being used for the Update**

- Connect one end of the modular data cable to the RJ45 port on the IR Link.



- Connect the other end of the modular data cable to the RJ45 port on the D-Connector portion of the Power Adapter



- Connect the other end of the D-Connector to the serial port on the computer being used for the update and hand-tighten the screws.



- Disconnect the keyboard cable from the computer and plug it into the back of the MiniDin connector portion of the Power Adapter.



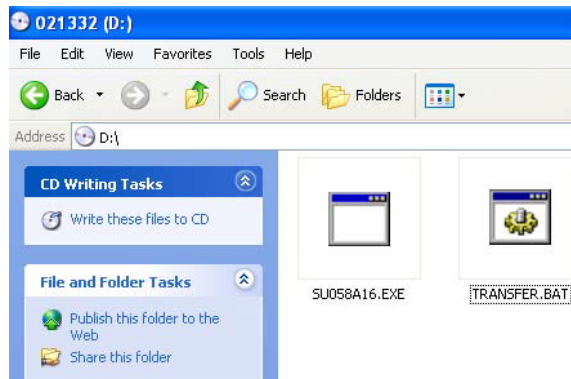
- Plug the MiniDin connector (with the keyboard cable attached) into the keyboard port on the computer being used for the update. The LED light on the IR Link should then turn red.



**4.5: Insert the JAMS/CLEW CD-ROM into the CD-ROM drive on the computer being used for the update**

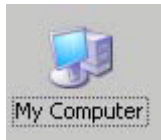


- If a screen appears within 30 seconds: double click **TRANSFER.BAT**.



Next, an additional window will open briefly, then close. Proceed to step **4.7**.

- If a window **does not** appear after inserting the Software update CD:
  - Double click My Computer



- Double click CD-ROM Drive



- Double click **TRANSFER.BAT**

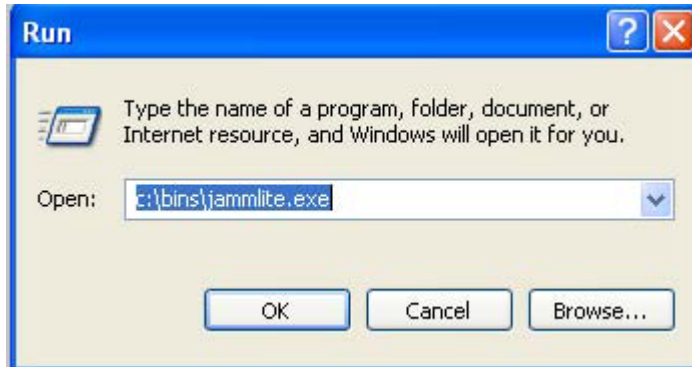


Next, an additional window will open briefly, then close.

**4.6: Close Windows Explorer by clicking on the  in the upper right corner.**

**4.7: Click Start → Run...**

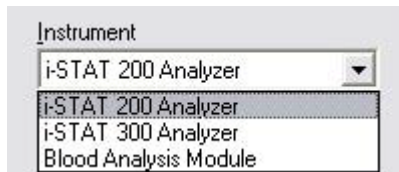
At the **Open:** prompt, type **c:\bins\jammlite.exe** and click **OK**.



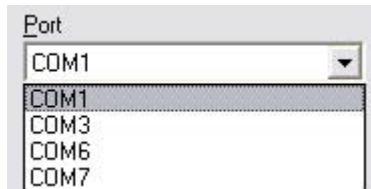
**Notes:**

- If you are unable to locate the “Run...” option, browse to c:\BINS via My Computer, and double click JammLite.
- If you are unable to reach the c:\BINS directory, call your IT support department and indicate the i-STAT Software Update process requires access to the c:\BINS directory. If you do not have internal IT support, contact Abaxis Technical Support at 1-800-822-2947 for assistance.
- If the JammLite program does not launch or you receive an error message, contact Abaxis Technical Support at 1-800-822-2947. Tell the support specialist you are unable to complete step **4.7** of this document.

**4.8: In the JammLite utility, select the i-STAT 200 Analyzer from the Instrument Drop-Down List**



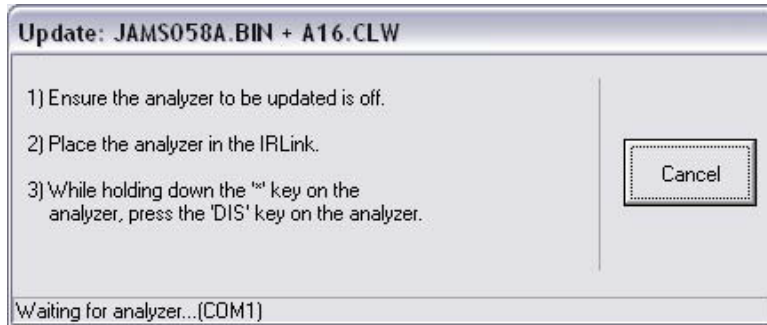
**4.9: Make sure there is at least one port number listed under the Port Drop-Down List**



**Note:** If the Port drop-down list says “None”, make certain the connection from the IR Link to the computer is tight. Then reboot the computer and return to step **4.3**.

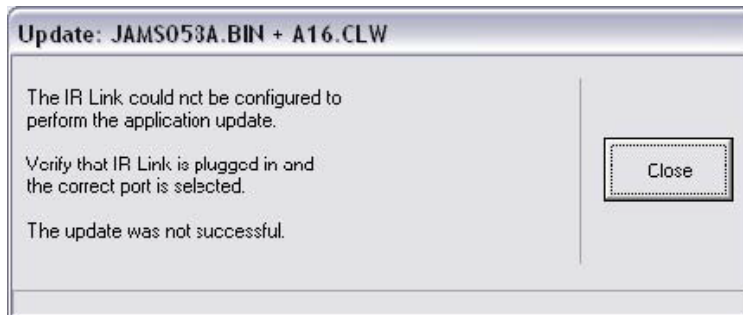
**4.10: Check that the Application and CLEW listings match those in the Product Update for the current software release. If the update is for CLEW only, select None for Application.**

**4.11: Click on the “Update” button. The LED light on the IR Link should turn green. If so, follow the instructions that appear on the screen.**

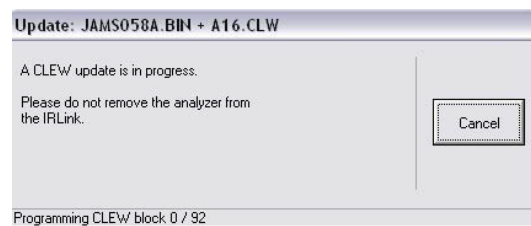
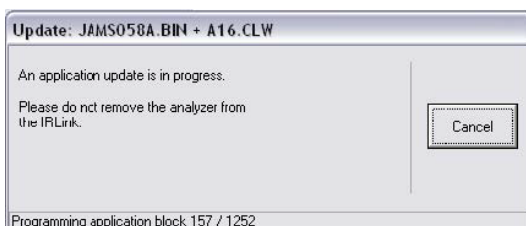


- Ensure the analyzer to be updated is off.
- Place the analyzer in the IR Link.
- While holding down the "\*" key on the analyzer, press the "DIS" key on the analyzer.

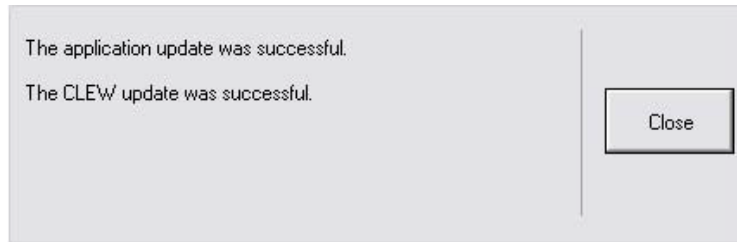
**Troubleshooting Note: If the LED light on the IR Link stays red and the following screen appears instead of the one above, click “Close”, select a different Port from the drop-down menu, and then click “Update” again. If the same message still appears after trying all available port numbers, contact Abaxis Technical Support at 1-800-822-2947 for assistance.**



The following two screens will appear on the computer display during the update process. The first indicates that an application update is in process, while the second indicates that a CLEW update is in process.



During the update, **DO NOT** move the Handheld until the following screen is displayed indicating the update was successful.




#### **4.12: Remove the Handheld from the IR Link and check to see that it has been properly updated.**

- If the display screen is blank, press DIS to activate the display. If the “NEW SOFTWARE INSTALLED. USE ELECTRONIC SIMULATOR. CODE 3” is displayed or “CODE 70” is displayed, ignore this message for now.
- Press the arrow key under the word MENU at the bottom of the screen. The analyzer’s menu options are displayed (1 STATUS, 2 STORED RESULTS).
- Press 1 to access the Status page.
- Check the numbers adjacent to VER and CLEW. VER should read “JAMSXXXX” and CLEW should read “AXX.” *VER and CLEW numbers are for example only. The “numbers” have been replaced with X’s in the example and will change with each software update.*
- Press \* (asterisk) to exit the page.
- If the JAMS and CLEW numbers are not correct, or if an error code is displayed other than CODE 3 or CODE 70, repeat the process. If the JAMS and CLEW are still not correct, call Abaxis Technical Support at 1-800-822-2947 for assistance.
- Check analyzer function by running a used cartridge to activate the Internal Electronic Simulator. Ignore any error messages that are due to the used cartridge (i.e., Code 21 Cartridge Preburst). Alternatively, you may also run a patient sample to activate the Simulator. If unexpected errors are encountered, call Abaxis Technical Support at 1-800-822-2947.

**Congratulations. The process for updating the first Handheld is complete.**

If there are no additional Handhelds to update, the process is complete:

- Click the 
- Close all open boxes
- Confirm all messages

If there are additional Handhelds to be updated via JammLite:

- Click **Close**
- Repeat steps **4.11 and 4.12.**

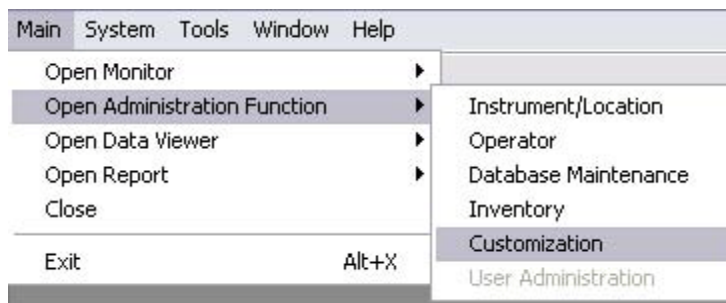
If there are additional Handhelds to be updated with the **Handheld-to-Handheld** process:

- Go to page 11

For users who do not have Central Data Station (CDS) Version 5, the update process is complete. CDS Version 5 users must proceed to step 4.13.

#### 4.13: Update the CLEW version in the Customization Workspace:

- Open the Central Data Station application.
- Click on **Main** → **Open Administration Function** → **Customization**



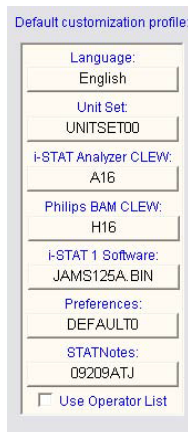
A Password box will then appear.



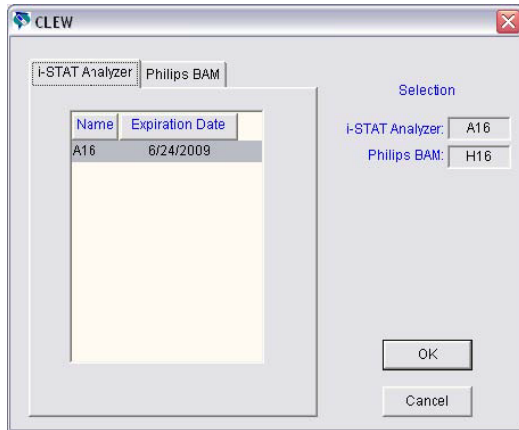
- Type in the Password and press Enter. The default password is **istat**.

**Note:** If you are unable to open CDS Customization, please contact Abaxis Technical Support at 1-800-822-2947 and indicate that your CDS Customization Password is unknown.

- Under the “Default customization profile:” column, double click on the “**i-STAT Analyzer CLEW**” button.



- The latest CLEW should be displayed in the CLEW window. Click the new version of **CLEW** and then click **OK**.



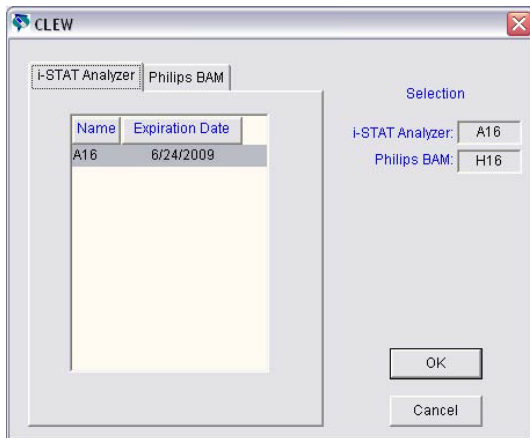
Answer Yes to the question that appears.

- If “Use Default Profile” is not checked beside any location-based customization profile, double click the box under the “**i-STAT Analyzer CLEW**” column.

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes
A_1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A16	H16	DEFAULT0	CHART0

- Click the new version of **CLEW**, and then click **OK**.



Answer Yes to the question that appears.

## **5. HANDHELD-TO-HANDHELD SOFTWARE UPDATES**

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The following procedure describes how to take any updated Handheld, and use it to update the software in another Handheld. In the instructions below, the Handheld that is already updated is referred to as the “Sending Handheld”, and the Handheld being updated is the “Receiving Handheld.”

### **5.1: Save Stored Results on Receiving Handheld**

All test records are erased in the Receiving Handheld when the application software is updated. Download each Handheld to your data management system before proceeding.

**5.2: Set both analyzers on a flat surface and align the IR LED windows so they directly face each other.**



**5.3: Run the External Electronic Simulator on the Sending Handheld.**



**5.4: With the Simulator test results showing on the display of the Sending Analyzer, press and hold down the DIS key, then with a second finger press the right arrow key for MENU. The Utility Menu will then appear on the Sending Handheld.**

**5.5: Press 3 – Send Software on the Sending Handheld.** The display will then show the JAMS version and the CLEW in this Handheld and the message “Waiting to Send”. Confirm that the JAMS and CLEW versions match those in the Product Update for the current software release.

**5.6: On the Receiving Handheld, make sure the display is off. With one finger, press and hold down the \* (asterisk) key on the Receiving Handheld, while pressing the DIS key with a second finger.**



**The display on the Sending Handheld will change from “Waiting to Send” to “Sending”, and a countdown bar will be displayed.**



**Note:** During the update, **DO NOT** move the Handhelds until the Sending Analyzer display screen returns to the Electronic Simulator result.

**5.7: Insert the Electronic Simulator in the Receiving Handheld.**



**5.8: To update software in another Handheld, return to 5.1.**

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