



i-STAT 1 System Mandatory Software Update Release Notes April 2023

This update includes information regarding new software for the i-STAT 1 analyzer. **This is a mandatory i-STAT 1 Software update.** The i-STAT 1 analyzer software may be downloaded directly from the Abbott Point of Care website: www.globalpointofcare.abbott.

REMINDER:

- Customers must have a user account at www.globalpointofcare.abbott to access software files.

UPDATES:

Note 1: Beginning October 2023, the i-STAT 1 analyzer software will no longer be provided on CD-ROM and will only be available in the Support section of the Abbott website www.globalpointofcare.abbott.

Note 2: For additional information pertaining to product support, see “Product Lifecycle Reminders and Notifications” in this document.

CAUTION FOR i-STAT/DE CUSTOMERS:

Prior to performing the software update, i-STAT/DE Customers must verify that the customized ranges in their customization profile(s) are at or within the analyte’s reportable range listed in the cartridge Instructions for Use (IFU) or Cartridge and Test Information (CTI) sheet.

Note 1: Failure to verify the customized ranges may impact the display of test results on the i-STAT 1 analyzer.

- An “Invalid Cart” message may appear, or
- The out-of-range flags (< or >) or the action range flags (↓ or ↑) may not display as expected.

Note 2: The rounding guidance previously provided in the i-STAT/DE User Guide is no longer applicable.

SOFTWARE VERSION

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

STANDARD SOFTWARE
JAMS155 & CLEW A46

Please note that the current software expires 21-JUNE-2023.

Expiration Date Fifteen days before the software expires, a message will be displayed on the analyzer screen to alert the user of the pending expiration date. If this update is not performed by 8:00am on 21-JUNE-2023, testing will be disabled and the analyzer will display “EXPIRED SOFTWARE – UPDATE REQUIRED – SEE MANUAL” (quality check code 12).

The new software expires 13-DECEMBER-2023.

VALUE ASSIGNMENT SHEETS (VAS and eVAS)

Value Assignment Sheets (VAS and eVAS) for the new CLEW A46 may be downloaded or printed from the Abbott Point of Care website: www.globalpointofcare.abbott.

STANDARDIZATION

CLEW Update The i-STAT 1 System is designed to eliminate operator influence on delivered results. The micro-fabricated sensor technology produces repeatable results 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 made by Abbott Point of Care 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.

This software supports all current non-expired cartridges.

TECHNICAL BULLETINS

Three Technical Bulletins have been updated.

- *Network Options for Updating the i-STAT 1 Analyzer Using www.globalpointofcare.abbott* was updated to remove unsupported operating systems and add Windows 10 and 11. Customers using RALs Remote Connection (RRC) can visit RALs.com for information related to RRC.
- *Instructions for Updating i-STAT 1 Analyzer Software Using www.globalpointofcare.abbott* was updated to remove unsupported operating systems and add Windows 10 and 11.
- The *Analyzer Coded Messages Technical Bulletin* has been updated to align with the software update for the analyzer identifying the cartridge via the scanned barcode and conditions that may occur during the testing process.
 - The following Quality Check codes will no longer be displayed: Codes 69, 140 and 141.
 - The information for Quality Check Code 15 has been updated to remove reference to immunoassay as this code will apply to all current cartridges.

i-STAT 1 SYSTEM MANUAL

The following Sections have been removed from the manual and all other sections have been reorganized and renumbered accordingly.

- Configuration Sheet
- Precision PCx and PCx Plus Blood Glucose Test Strips
- Data Management and Connectivity Options
- Procedures for Glucose Test Strip Testing

ADD/DELETE SHEETS

As numerous sections of the i-STAT 1 System Manual have been reorganized and renumbered, Add/Delete sheets and update packets will not be provided. Please download the entire manual from the APOC website and print or store electronically for reference.

CONTENT UPDATES

The following is a summary of the i-STAT 1 System Manual content changes:

The **System Manual Configuration Sheet** was updated to reflect the current revision for the artwork files contained in the i-STAT 1 System Manual and is only available in the Support section of the Abbott website, www.globalpointofcare.abbott.

Section 6: i-STAT 1 Downloader/Recharger was updated to remove content related to Windows XP and Windows 7. These operating systems are no longer supported by Microsoft. Windows 10 information has been provided for network configuration. For serial configuration via USB, Windows 10 detects connected devices and automatically installs the driver, based on your facility's computer permissions and policies.

Section 16: Proficiency Testing was renumbered to Section 14 and updated to remove the list of proficiency test providers. This information will be available in the Support section of the Abbott website www.globalpointofcare.abbott.

Section 19: Troubleshooting the Analyzer was renumbered to Section 11 and was updated to add the following alert messages: These updates support the changes that were made in the analyzer software's identification of i-STAT cartridges using the cartridge barcode found on the pouch and the portion pack.

- "Invalid Cart" message - is displayed during testing when:
 - o a barcode is scanned from a cartridge that is not supported.
 - o a cartridge is scanned, and the analyzer has been customized by i-STAT/DE to use a reference and/or action range that is outside the reportable range for the test(s) on that cartridge.
- "Lot Expired" message is displayed when the cartridge lot being tested is expired.

PERFORMING THE SOFTWARE UPDATE

Prior to performing the software update, please identify your system setup per the table below. Ensure that you have administrative rights on the computer being used for the software update.

If you are unsure of the method you use to perform the software update or whether you have administrative rights, please contact your point-of-care program administrator for guidance.

IF you have a Computer with:	IF you have i-STAT/DE with:
<ul style="list-style-type: none"> a connected Serial <i>i-STAT 1 Downloader</i> (DS-300) or <i>i-STAT 1 Downloader/Recharger</i> (DRS-300) using a DB9 to DB9 cable with a USB-Serial adapter* <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> an <i>i-STAT 1 Downloader/Recharger Combination</i> (DRC-300) with USB Cable** 	<ul style="list-style-type: none"> a Network <i>i-STAT 1 Downloader</i> (DN-300) or <i>i-STAT 1 Downloader/Recharger</i> (DRN-300) <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> an <i>i-STAT 1 Downloader/Recharger Combination</i> (DRC-300)
<ul style="list-style-type: none"> a downloaded Software File (CLEW/JAMS) from the CD-ROM or Abbott Point of Care website, www.globalpointofcare.abbott. 	<ul style="list-style-type: none"> access to Customization Workspace. a downloaded Software File (CLEW/JAMS) from the CD-ROM or Abbott Point of Care website, www.globalpointofcare.abbott.
THEN	THEN
<p>follow these instructions located at www.globalpointofcare.abbott:</p> <ul style="list-style-type: none"> <i>Instructions for Updating i-STAT 1 Analyzer Software Using www.globalpointofcare.abbott, Art:731335</i> 	<p>follow these instructions located at www.globalpointofcare.abbott:</p> <ul style="list-style-type: none"> <i>Network Options for Updating the i-STAT 1 Analyzer Using www.globalpointofcare.abbott, Art:731336</i>

* Follow the USB-Serial adapter manufacturer's instructions for installation. Abbott Point of Care does not provide USB-Serial adapters for use with the DB9 to DB9 (9-pin connector) cable.

**For the i-STAT 1 Downloader/Recharger Combination (DRC-300), the Windows operating system will detect and apply the appropriate driver. See *Section 6* of the *i-STAT 1 System Manual* for more details.

i-STAT/DE

i-STAT/DE USER GUIDE CONTENT UPDATES

Changes have been performed to align with recent changes to the i-STAT 1 analyzer software and clean up related to content that was incorporated previously into the i-STAT/DE User Guide.

The following items have been removed:

1. References to the following technical bulletins that are no longer available:

- Positive Patient Identification (PPID) on the i-STAT 1 Handheld*
- Liquid Quality Control Schedule and Lockout Customization on the i-STAT 1 Handheld*
- Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld*
- Operator Competency Notification on the i-STAT 1 Handheld*
- The RIBS (Results Integration at the Bedside) Feature for the i-STAT System*
- Hematocrit Determination in the i-STAT System*
- Proficiency Testing on the i-STAT System*

2. Reportable, Action and Reference Range Customization

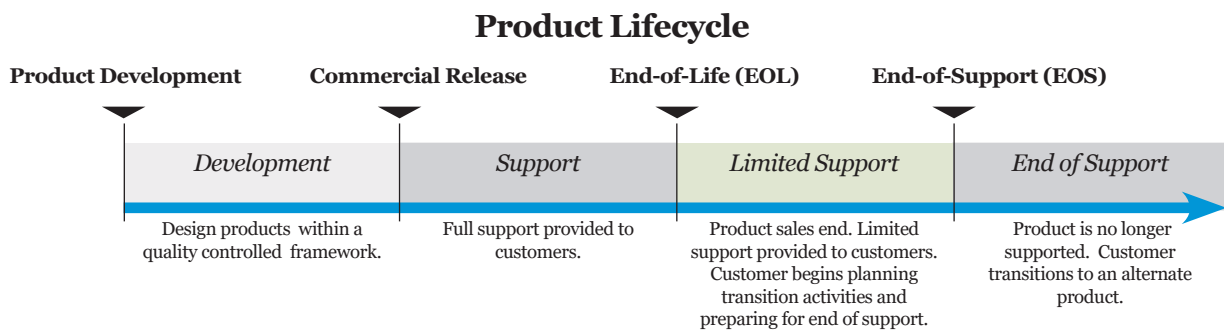
- The Rounding Table provided in Section 3.3 has been removed. With the analyzer software update to CLEW A46/JAMS155, customized ranges must be within the analyte reportable range for the i-STAT Cartridge in use. See the i-STAT/DE User Guide for more details.
- Notes have been updated to provide additional guidance when customizing ranges for the following sections:
 - o 3.13 Custom Reportable Range Feature
 - o 3.14 Customizing Reference and Action Ranges

3. Quality Check Codes (QCC) Report Categorization

- QCC codes 69, 140 and 141 have been removed from the Appendix, A.1 Quality Check Code Report Categorization. With the analyzer software update to CLEW A46/JAMS155, those quality check codes will be removed.

PRODUCT LIFECYCLE REMINDERS AND NOTIFICATIONS

Abbott is committed to maintaining the highest standards for the products we design, develop, and maintain. As part of this commitment, it is necessary to transition products through their product lifecycle.



END-OF-SUPPORT REMINDER(S)

The following products have reached end of support. Please contact your Abbott Representative with any questions or to transition to an alternate product.

- Central Data Station (CDS) reached end of support November 2020.
- i-STAT/DE versions less than 2.8.0.1 reached end of support December 2022
- i-STAT E3+ and EC4+ cartridges reached end of life May 2020. End of Support is May 2023 with the i-STAT 1 analyzer software release. Product information will be removed from the i-STAT 1 System user documentation by November 2024.

END-OF-LIFE NOTIFICATION(S)

The following products have reached end-of-life and limited support will be provided as indicated below:

i-STAT 1 Wireless Analyzers:

- **i-STAT 1 Wireless analyzers with the P1405W (Laird) Module:** The Laird wireless module has reached end-of-life and no new cybersecurity updates will be available. The i-STAT 1 Wireless analyzer with the Laird Module may continue to be used for cartridge testing. Facilities may mitigate new cybersecurity concerns within their own network environment.



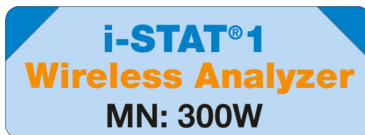
Reconfiguring wireless connectivity for the Laird module is not available with operating systems newer than Windows 7. For assistance with reconfiguration, contact your support representative.

The i-STAT 1 Wireless analyzer with the 2AAEX-SDMAC (Silex) Module will continue to receive new cybersecurity updates and can be configured for wireless connectivity with Windows 10. Contact your Abbott representative for upgrade options.

- **LAN Cable Filter (L/N: 06F23-63):** The LAN Cable filter is used with an i-STAT 1 Downloader or Downloader/Recharger when downloading an i-STAT 1 Wireless Analyzer with the Laird Module only. Please note that this product list number will be retired.

Currently, the i-STAT 1 Wireless analyzer with the YOPGS1500M (Gainspan) or the Silex module, do not use the LAN Cable Filter. Contact your Abbott representative for upgrade options.

- **i-STAT 1 Wireless analyzers with the Gainspan Module:** The Gainspan wireless module has reached end-of-life and no new cybersecurity updates will be available. The i-STAT 1 Wireless analyzer with the Gainspan Module may continue to be used for cartridge testing. Facilities may mitigate new cybersecurity concerns within their own network environment.



The i-STAT 1 Wireless analyzer with the Silex Module will continue to receive new cybersecurity updates and can be configured for wireless connectivity with Windows 10. Contact your Abbott representative for upgrade options.

i-STAT 1 Downloaders and Downloader/Rechargers:

- **i-STAT 1 Network and Serial Downloaders (L/N: 06F23-44, 06F23-43) and i-STAT 1 Network and Serial Downloader/Recharger (L/N: 06F23-46, 06F23-45):** The i-STAT 1 downloaders (DN-300, DS-300, DRN-300, and DRS-300), and their associated accessories have reached end of life and are no longer in inventory.

You may continue to use these products, access the product user documentation on the www.globalpointofcare.abbott website and receive assistance with troubleshooting. In the event any of these products require replacement, a DRC-300 Kit (L/N: 04P73-04) is available.

These products will reach end-of-support in November 2024. Customers may transition to the i-STAT 1 Downloader/Recharger (DRC-300) Kit (L/N: 04P73-04). Contact your Abbott representative for upgrade options.

i-STAT Martel Printer and i-STAT Dispensing Tips:

- **i-STAT Martel Printer (L/N: 06F23-91, 111300):** The i-STAT Martel Printer and its associated accessories have reached end of life. This product and its accessories are no longer available. Customers may still access the product user documentation on the www.globalpointofcare.abbott website and receive assistance with troubleshooting. These products will reach end-of-support November 2024. Customers may transition to the i-STAT 1 Printer Kit (L/N: 04P74-04).
- **i-STAT Dispensing Tips, QTY 500 (L/N: 06F24-30):** The list number (L/N: 06F24-30) for i-STAT Dispensing Tips, QTY 500 will be retired. i-STAT Dispensing tips will continue to be available in quantities of 100. Customers requiring larger quantities may order multiples of the i-STAT Dispensing Tip, QTY 100 (L/N: 06F24-20).

© 2023 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.