i-STAT 1 System Mandatory Software Update Release Notes April 2025

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 website: www.globalpointofcare.abbott.

REMINDER:

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

SOFTWARE VERSION

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

STANDARD SOFTWARE
JAM2259 & CLEW A50

Please note that the current software expires 18-JUNE-2025.

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 18-JUNE-2025, testing will be disabled and the analyzer will display "EXPIRED SOFTWARE – UPDATE REQUIRED – SEE MANUAL" (Quality Check Code 12).

The new software expires 10-DEC-2025.

VALUE ASSIGNMENT SHEETS (VAS and eVAS)

Value Assignment Sheets (VAS and eVAS) for the new CLEW A50 may be downloaded or printed from the Abbott 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 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.

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:
• a connected Serial *i-STAT 1 Downloader* (DS-300) or *i-STAT 1 Downloader/Recharger* (DRS-300) using a DB9 to DB9 cable with a USB-Serial adapter* **OR** • an *i-STAT 1 Downloader/Recharger Combination* (DRC-300) with USB Cable** **AND**	• a Network *i-STAT 1 Downloader* (DN-300) or *i-STAT 1 Downloader/Recharger* (DRN-300) **OR** • an *i-STAT 1 Downloader/Recharger Combination* (DRC-300) **AND**
• a downloaded Software File (CLEW/JAMS) from website www.globalpointofcare.abbott.	• access to Customization Workspace. **AND**
	• a downloaded Software File (CLEW/JAMS) from website www.globalpointofcare.abbott.
THEN	**THEN**
follow these instructions located at www.globalpointofcare.abbott:	**follow these instructions located at www.globalpointofcare.abbott:**
• *Instructions for Updating i-STAT 1 Analyzer Software Using www.globalpointofcare.abbott,* Art:731335	• *Network Options for Updating the i-STAT 1 Analyzer Using www.globalpointofcare.abbott,* Art:731336

* Follow the USB-Serial adapter manufacturer's instructions for installation. Abbott 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.

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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)

Microsoft Windows® 10 Notice

Many Abbott and partner products are compatible with and run on various operating systems and browsers. From time-to-time those systems come to the end of their useful life and are retired.

Microsoft has announced it will no longer support the Windows® 10 operating system with an end-of-life date of October 14, 2025. Please visit the Microsoft page for end-of-support info for calendar year 2025:

https://learn.microsoft.com/en-us/lifecycle/end-of-support/end-of-support-2025

Abbott recommends customers transition to a supported operating system for your Abbott i-STAT software component(s). Depending on your Abbott i-STAT product(s) there are alternate choices available for operating system.

Supported Abbott i-STAT products that run on Windows 10 include:

- i-STAT/DE versions: v2.8, v2.9, v2.10, v2.11, and v2.12
- Info HQ versions: Info HQ v3.1
- Wireless Configuration Software: AlinIQ NCi v2.1.0.1 & WCU v2.0
- JammLite v4.3

Please check user documentation specific to your software system at our website https://www.globalpointofcare.abbott/us/en/support.html

For assistance with transitioning any of the listed components contact your local i-STAT representative.

SYSTEM MANUAL & TECHNICAL BULLETIN UPDATES

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

i-STAT 1 System Manual Updates:

The Release Notes section on the back page of the Cover Sheet was updated to summarize the latest changes to the System Manual.

Section 1 (Introduction) was updated to include: information for Electromagnetic Compatibility; and list hs-TnI (Cardiac Troponin I) to Tests table

Section 3 (i-STAT Analyzer) was updated to include: Laser Notice No. 56 laser scanner specification; and the i-STAT 1 System Manufacturer's Declaration of Electromagnetic Compatibility table.

Section 4 (i-STAT Cartridge) was updated to include the addition of Cartridge Configurations and Sample Volume section.

Section 6 (i-STAT 1 Downloader/Recharger) was updated to include "max" for the Power Supply Specifications table for Input.

Section 9 (Procedure for Handling Cartridges) was updated to include images representative of different cartridge types.

Section 10 (Procedure for Cartridge Testing) was updated to include: reference to i-STAT/DE for reportable and reference range information; hs-TnI cartridge-specific cutoff information.

Section 11 (Troubleshooting the Analyzer) was updated to include Analyzer Coded Messages Technical Bulletin content.

Section 12 (Quality Control) and Section 13 (Calibration Verification) were updated to include the following statement: "Use caution to protect against cuts if scanning a barcode from an open glass control ampule."

Section 15 (Customization) was updated to include language regarding default settings and customization options, including the use of the analyzer keypad for customization.

Technical Bulletin Updates: The Support Services Technical Bulletin on the APOC website was updated with the most recent distributor support addresses and contact information available.