i-STAT 1 System Mandatory Software Update
Release Notes
April 2024

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.

UPDATES:

Note 1: As previously communicated in October 2023, the i-STAT 1 analyzer software is no longer being provided on CD-ROM and is only available in the Support section of the Abbott website www.globalpointofcare.abbott.

SOFTWARE VERSION

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

STANDARD SOFTWARE
JAM2157 & CLEW A48

Please note that the current software expires 19-JUNE-2024.

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 19-JUNE-2024, testing will be disabled and the analyzer will display "EXPIRED SOFTWARE – UPDATE REQUIRED – SEE MANUAL" (quality check code 12).

The new software expires 11-DECEMBER-2024.

VALUE ASSIGNMENT SHEETS (VAS and eVAS)

Value Assignment Sheets (VAS and eVAS) for the new CLEW A48 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.
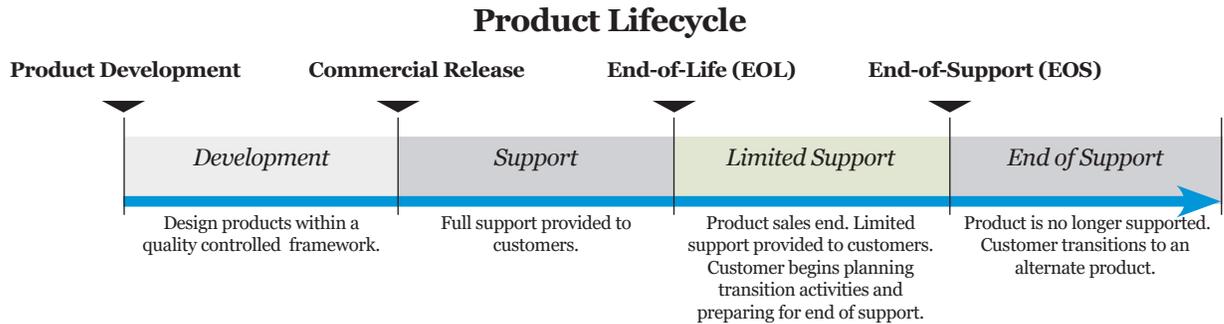
IF you have a Computer with:	IF you have i-STAT/DE with:
• a connected Serial *i-STAT 1 Downloader* (DS-300) or *i-STAT 1 Downloader/Recharger* (DRS-300) using a DB9 to DB9 cable with a USB-Serial adapter* **OR** • an *i-STAT 1 Downloader/Recharger Combination* (DRC-300) with USB Cable** **AND**	• a 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: • *Instructions for Updating i-STAT 1 Analyzer Software Using www.globalpointofcare.abbott,* Art:731335	**follow these instructions located at www.globalpointofcare.abbott:** • *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.

Art: 731668-01V   Rev. Date: 18-Mar-2024

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.

Product Lifecycle

Product Development	Commercial Release	End-of-Life (EOL)	End-of-Support (EOS)
Development	*Support*	*Limited Support*	*End of Support*
Design products within a quality controlled framework.	Full support provided to customers.	Product sales end. Limited support provided to customers. Customer begins planning transition activities and preparing for end of support.	Product is no longer supported. Customer transitions to an alternate product.

END-OF-SUPPORT REMINDER(S)

No products have reached end-of-life or end-of-support during this cycle.

i-STAT 1 SYSTEM MANUAL UPDATES

The i-STAT 1 System Manual Cover Sheet was updated with the following changes:

- The EC-REP information was removed
- Addition of release notes summarizing changes to the i-STAT 1 System Manual

The Table of Contents was updated to reflect current page numbering of each section.

Section 3 (i-STAT 1 Analyzer) and Section 15 (Customization) were both updated to include a new image which displays the updated contents of the Analyzer Status Page. A new Release parameter was added to the Status Page describing the current released version of application software installed in the analyzer.

- A new EMC Regulations section was also added directly after the Specifications table to indicate that the i-STAT 1 Analyzer is compliant with IEC 61326-1 and IEC 61326-2-6 requirements

Section 6 (i-STAT 1 Downloader/Recharger) was updated to include instructions for configuring the DRC-300 using Windows 11. Additionally, a row was added to the DRC-300 LED Indicator table to clarify the behavior of the LED lights when a spare battery is placed in the recharging compartment.

Section 11 (Troubleshooting the Analyzer) was updated to include Quality Check Code 69.

Section 12 (Quality Control) and Section 13 (Calibration Verification) were both updated to move the procedure for testing the quality control or calibration verification materials toward the beginning of each section.

TECHNICAL BULLETIN UPDATES

The Analyzer Coded Messages Technical Bulletin was updated to include Quality Check Code 69.