



i-STAT 1 System Mandatory Software Update Release Notes October 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.

UPDATES:

SOFTWARE VERSION

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

STANDARD SOFTWARE
JAMS260 & CLEW A51

Please note that the current software expires 10-DECEMBER-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 10-DECEMBER-2025, testing will be disabled and the analyzer will display “EXPIRED SOFTWARE – UPDATE REQUIRED – SEE MANUAL” (quality check code 12).

The new software expires 17-JUNE-2026.

OCTOBER 2025 SOFTWARE UPDATES AND ENHANCEMENTS

- The i-STAT 1 JAMS260 software has been updated to support the new blood gas Reportable Ranges for i-STAT CG8+, CG4+, EG7+ and EG6+ cartridges.

The analytes with new Reportable Ranges are pH and PO₂; once the JAMS260 software update is applied, the i-STAT will use the ‘Updated’ Reportable Ranges.

See table below for details:

Cartridges Impacted	Assay/Units	Parameter	Current	Updated
CG8+, CG4+, EG7+, EG6+	pH (pH units)	Reportable Range	6.500 to 8.200	6.500 to 7.800
	PO2 (mmHg)	Reportable Range	5 to 800	5 to 700

Note 1: These Reportable Range changes align with recent updates to the *i-STAT* G3+ cartridge.

Note 2: Please check and coordinate with your Data Management, LIS or EMR vendors in case corresponding reportable ranges changes are required in your data manager, LIS or EMR systems.

2. Operator ID Missing for i-STAT Internal Simulator Results
 - a. Fixed a condition where operator ID is sometimes missing from the result record for internal simulator results on the i-STAT1 analyzer. This condition existed even though the ID was entered prior to the test.
3. AlinIQ NCI, the network configuration utility for i-STAT and i-STAT Alinity has been qualified for use with Windows 11. The current released version is v2.1.0.1 and is available at the Abbott website for download at www.globalpointofcare.abbott.

VALUE ASSIGNMENT SHEETS (VAS and eVAS)

Value Assignment Sheets (VAS and eVAS) for the new CLEW A51 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>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* OR - an <i>i-STAT 1 Downloader/Recharger Combination</i> (DRC-300) with USB Cable** AND	- a Network <i>i-STAT 1 Downloader</i> (DN-300) or <i>i-STAT 1 Downloader/Recharger</i> (DRN-300) OR - an <i>i-STAT 1 Downloader/Recharger Combination</i> (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: <i>Instructions for Updating i-STAT 1 Analyzer Software Using www.globalpointofcare.abbott, Art:731335</i>	follow these instructions located at www.globalpointofcare.abbott: <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 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.

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.

October 2025 (Reminder)

In August Abbott received updated U.S. FDA 510(k) clearances for the following cartridges: *i-STAT CG4+* and *i-STAT CG8+*.

i-STAT CG4+ cartridge:

Currently, the *i-STAT CG4+* cartridge is **not FDA cleared for the measurement of lactate in capillary whole blood samples**. There are also adjustments to the Reportable Range for multiple analytes. Please note the following modifications contained within the new *i-STAT CG4+* cartridge 'Instructions for Use' as shown in the table below:

Assay/Units	Parameter	Current	Update
pH (pH units)	Reportable Range*	6.500 to 8.200	6.500 to 7.800
	Sample types	Arterial, venous, and capillary	No change
<i>PCO₂</i> (mmHg)	Reportable Range*	5.0 to 130.0	No change
	Sample types	Arterial, venous, and capillary	No change
PO2 (mmHg)	Reportable Range*	5 to 800	5 to 700
	Sample types	Arterial, venous, and capillary	No change
Lactate (mmol/L)	Reportable Range*	0.30 to 20.00	No change
	Sample types	Arterial, venous, and capillary	Arterial and venous

i-STAT CG8+ cartridge:

Currently the *i-STAT CG8+* cartridge is **not FDA cleared for the measurement of potassium and ionized calcium in capillary whole blood samples**. Please note the following modifications contained within the *i-STAT CG8+* cartridge 'Instructions for Use' documentation as shown in the table below:

Assay/Units	Parameter	Current	Update
pH (pH units)	Reportable Range*	6.500 to 8.200	6.500 to 7.800
	Sample types	Arterial, venous, and capillary	No change
<i>PCO₂</i> (mmHg)	Reportable Range*	5.0 to 130.0	No change
	Sample types	Arterial, venous, and capillary	No change
PO2 (mmHg)	Reportable Range*	5 to 800	5 to 700
	Sample types	Arterial, venous, and capillary	No change
Sodium (mmol/L)	Reportable Range*	100 to 180	No change
	Sample types	Arterial, venous, and capillary	No change
Potassium (mmol/L)	Reportable Range*	2.0 to 9.0	No change
	Sample types	Arterial, venous, and capillary	Arterial and venous
Ionized Calcium (mmol/L)	Reportable Range*	0.25 to 2.50	No change
	Sample types	Arterial, venous, and capillary	Arterial and venous
Hematocrit (% PCV)	Reportable Range*	15 to 75	No change
	Sample types	Arterial, venous, and capillary	No change
Glucose (mg/dL)	Reportable Range*	20 to 700	No change
	Sample types	Arterial, venous, and capillary	No change

*Results outside the updated Reportable Range have not been validated for accuracy

Additionally, the same range and sample type updates apply to the *i-STAT EG7+* and *EG6+* cartridges.

Abbott has not received reports of patient harm associated with the use of the *i-STAT CG4+* or *i-STAT CG8+* cartridges

RECOMMENDED ACTIONS

As this update applies to cartridges that you may already have on hand, please download, review and implement the updated cartridge Instructions for Use (IFU) from our website (www.globalpointofcare.abbott).

Capillary Whole Blood Use:

Discontinue use of:

- i-STAT CG4+* cartridges for lactate testing using capillary whole blood samples. Use arterial or venous samples or another method for testing capillary whole blood lactate instead.
- i-STAT CG8+*, *EG7+*, and *EG6+* cartridges for potassium and ionized calcium testing using capillary whole blood samples. Use arterial or venous samples or another method for capillary whole blood samples instead for potassium and ionized calcium.

Reportable Range Adjustments:

- pH: Updated range is 6.500 to 7.800
- PO₂: Updated range is 5 to 700 mmHg

The October 2025 and any subsequent software releases support the update of the *i-STAT 1* analyzer software to the latest approved Reportable Ranges for those customers not customizing their ranges in *i-STAT/DE*. *i-STAT/DE* users can customize their Reportable Ranges to match the updated ranges.

***i*-STAT Cartridge Menu Changes and Recommended Actions**

The *i*-STAT System is undergoing comprehensive modernization efforts. As a result, we are making changes to our cartridge menu to continue to meet the evolving needs of our customers for point-of-care testing.

On September 30, 2025, we will end shipment in the United States of the *i*-STAT cartridges listed in the below table. Please work with your internal teams as well as with your Abbott *i*-STAT representative to begin transitioning to alternative options (see below table). Please follow your facility policies and procedures for handling validation testing of alternative options, if required.

i-STAT Cartridge end of shipment in the US as of September 30, 2025		Recommended i-STAT Cartridge Replacement Available as of March 31, 2025	
Cartridge name	Cartridge list number	Cartridge name	Cartridge list number
<i>i</i> -STAT <i>cTnI</i> cartridge	03P90-25	<i>i</i> -STAT <i>hs-TnI</i> cartridge (NEW)	09P81-25 (NEW)
<i>i</i> -STAT <i>CK-MB</i> cartridge	03P92-25		
<i>i</i> -STAT <i>BNP</i> cartridge	03P93-25	No <i>i</i> -STAT cartridge replacement available. Please transition to another method.	N/A
<i>i</i> -STAT <i>Total β-hCG</i> cartridge	05P58-25	No <i>i</i> -STAT cartridge replacement available. Please transition to another method.	N/A

Note: all cartridges can be used until the expiration date printed on the packaging.

We understand this transition may be disruptive, so your ***i*-STAT representative** is available to discuss how we can best support the specific needs of your facility to help make this transition as seamless as possible.

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 make arrangements to 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.

i-STAT Connectivity & Configuration Software	Supported Versions	Windows 10 Support	Windows 11 Support
i-STAT/DE	v2.8 thru v2.12	Yes	v2.12 only
Info HQ	v1.2, v2.1, v3.0 and v3.1	Yes	v3.1 only
Wireless Configuration Software: AlinIQ NCi	v2.1.0.1	Yes	Yes
Wireless Configuration Software: WCU	v2.0	Yes	Yes
JammLite	v4.3	Yes	Yes

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**.

TECHNICAL BULLETIN UPDATES

i-STAT Technical Bulletin Updates:

- The 'Configuring Wireless Settings in an i-STAT 1 Wireless Analyzer' technical bulletin was updated to include compatibility information of Windows Configuration Utility (WCU) with Windows 11.
- The 'i-STAT/DE v2.12 - User Guide' was updated to include compatibility information of i-STAT/DE with Windows 11.

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