



# i-STAT ALINITY

## PRODUCT UPDATE

### NOVEMBER 2022 SOFTWARE RELEASE NOTES

#### MANDATORY SOFTWARE UPDATE

This is a mandatory software update. This document includes information regarding new OSi17 software for the i-STAT Alinity instrument and updates to i-STAT Alinity documentation.

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 OSi software -- delivered twice a year:

- re-establishes these standardized values and incorporates refinements to the internal quality monitoring system.
- allows the i-STAT Analyzer to recognize any newly launched cartridge types and to perform any newly launched features.

With regards to Quality Check Failure Code 90, some of the quality checks resulting in Quality Check Failure Code 90 are now only performed for the test channels that are applicable for the i-STAT cartridge being used. New Quality Check Failure Code 43 was added to Section 1.2 (i-STAT Alinity Instrument) of the System Operations Manual. Details in the i-STAT System Updates section.

#### CURRENT SOFTWARE

**The current software, OSi16, expires 18-Jan-2023.**

Fifteen days before the software expires, a message will be displayed on the instrument to alert the user of the pending expiration date. If this update is not performed by 8:00AM on 18-Jan-2023, the instrument will display an alert that software has expired, and that testing is disabled.

#### NEW SOFTWARE

**The new software, OSi17, expires 19-Jul-2023.**

Prior to performing the software update for OSi17, verify that your instrument has the current OSi16 software installed. If the instrument does not have OSi16 installed, see notes below.

#### NOTE(S):

- Instruments with OSi13, OSi14, OSi15 and OSi16 may install OSi17, without the need to install a previous version.
- Instruments with versions OSi12 and lower, please contact your local support specialist for return of instrument. Abbott Point of Care releases mandatory software updates for the i-STAT Alinity instrument every 6 months.



## DOWNLOAD SOFTWARE

i-STAT Alinity instrument software is available on the Global Point of Care website. The file is in a .apkg format, which is not zipped. The .apkg file is not required to be unzipped or extracted prior to use.

To obtain the file, access the i-STAT 1 and i-STAT Alinity SUPPORT page at [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott). Click on the link for i-STAT Alinity Resources Login and then i-STAT Alinity System Software. You will be required to log in with your user credentials to access system software.

## VALUE ASSIGNMENT SHEETS (VAS and eVAS)

Value Assignment Sheets (VAS and eVAS) for the new CLEW D45 may be downloaded or printed from the Abbott Point of Care website: [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott).

## INSTRUCTIONS FOR UPDATING INSTRUMENT SOFTWARE

The System Operations Manual provides detailed instructions for updating instrument software. To update the software, follow the instructions in section 1.13 Software Updates.

This section contains instructions for downloading software directly to the instrument via the Abbott Managed Server, as well as downloading software from i-STAT 1 and i-STAT Alinity SUPPORT page at [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott).

**Note:** If you use the automatic pass/fail customization for Control or Cal/Ver tests, you must download the new eVAS following software installation.

## i-STAT ALINITY SYSTEM UPDATES

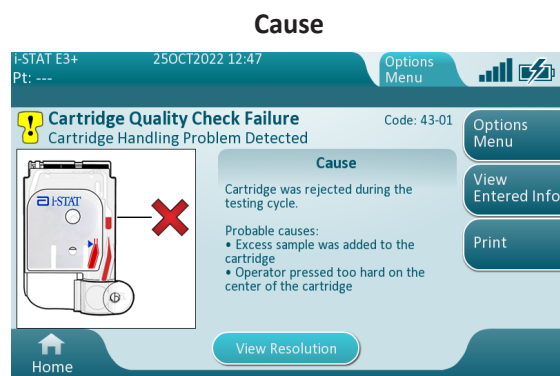
### i-STAT ALINITY INSTRUMENT SOFTWARE RELEASE NOTES

A summary of the changes made to the i-STAT Alinity instrument is listed below.

**1. Instrument Software:** Through Abbott Point of Care's continuous improvement process, updates have been made to our Quality Check Failure Codes.

- New Quality Check Failure Code 43 was added to Section 1.2 (i-STAT Alinity Instrument) of the System Operations Manual. Refer to the sample figures below to see Quality Check Failure Code 43 presentation, causes and resolutions.

Note: The cartridge type displayed will be dependent on the cartridge inserted.

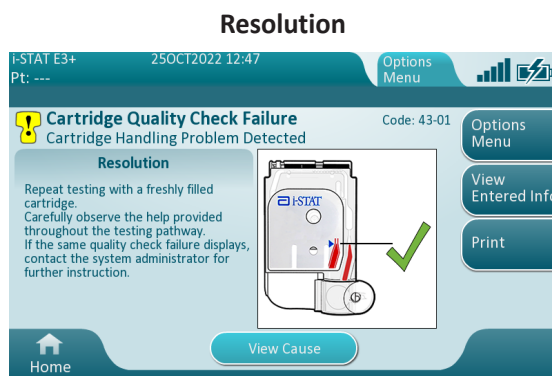


#### Cause:

Cartridge was rejected during the testing cycle.

Probable causes:

- Excess sample was added to the cartridge
- Operator pressed too hard on the center of the cartridge



#### Resolution:

Repeat testing with a freshly filled cartridge.

Carefully observe the help provided throughout the testing pathway.

If the same quality check failure displays, contact the system administrator for further instruction.

## i-STAT ALINITY SYSTEM DOCUMENTATION UPDATES

### i-STAT ALINITY SYSTEM OPERATIONS MANUAL (SOM) RELEASE NOTES

A summary of the changes made to the i-STAT Alinity SOM is listed below.

- 1. Section 1.2 (i-STAT Alinity Instrument):** i-STAT Alinity Intended Use statement is being updated to match the current i-STAT Alinity Quick Reference Guide.
- 2. Section 1.2 (i-STAT Alinity Instrument):** The Quality Check Failure Code table is being updated to match instrument software. Quality Check Failure Code 43 and Cause 20 are being added.
- 3. Section 3.1 (AlinIQ CWi):** The existing user login instructions are being updated to specify lockout and password reset instructions. Additionally, the URL for compatible web browsers is being updated to the current link.