

i-STAT 1 DISTRIBUTOR BULLETIN

i-STAT 1 Software Release Summary – November 2021

i-STAT 1 Analyzer: JAM2152, CLEW A43 i-STAT 300F Analyzer (for FUSO Japan only): JAM2152, CLEW A43 Interface 5 Software: Version 2.13.0 (No Change) i-STAT/DE Software: Version 2.10 (No Change)

A new release of the i-STAT software (names above) is now available on the Abbott Point of Care (APOC) website: <u>www.globalpointofcare.abbott</u>. Installation of this new software is mandatory for all i-STAT 1 handheld analyzers. The software packet must be in customer locations by 01-December-2021. The current software (CLEW A42) expires 15-December-2021.

Additionally, all i-STAT 1 analyzers currently in stock should be updated immediately with this software prior to shipping to customers.

This bulletin summarizes the relevant changes contained in this software release and provides a list of the software and documentation components of the release that must be downloaded from the APOC website in order to support this software release.

IMPORTANT INFORMATION

• The expiration date for the Novembver software, CLEW A43 is 22-June-2022.

i-STAT 1 handheld software may be downloaded directly from the Abbott Point of Care website: <u>www.globalpointofcare.abbott</u>.

Note: APOC will continue to provide distribution partners with analyzer software CDs to provide to customers who do not have internet access or cannot download executable files.

Reminder: Customers must have a user account at <u>www.globalpointofcare.abbott</u> to access software files.

Abbott Point of Care Inc. • 100 & 200 Abbott Park Road • Abbott Park, IL 60064 • USA

TECHNICAL BULLETINS

Technical Bulletins located within the i-STAT 1 System Manual have been updated for the following:

- Abbott Brand, document design, and website url update to www.globalpointofcare.abbott.
- With the exception of the following Technical Bulletins that were only updated for Abbott Brand and document design:
 - Instructions for Updating i-STAT 1 Handheld Software Using www.pointofcare.abbott
 - Instructions for Updating i-STAT 1 Handheld Software
 - Network Options for Updating the i-STAT 1 Handheld
 - Network Options for Updating the i-STAT 1 Handheld Using www.pointofcare.abbott

i-STAT 1 SYSTEM MANUAL

All sections of the i-STAT 1 System Manual have been updated for the following:

• Abbott Brand, document design, and website url update to www.globalpointofcare.abbott.

ADD/DELETE SHEETS

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

CENTRAL DATA STATION

As of 31-DEC-2020, Abbott Point of Care no longer supports Central Data Station. Former Central Data Station customers may still update their software using the JAMMLite Utility. For more details refer to the following technical bulletins:

- Instructions for Updating i-STAT 1 Handheld Software Using www.pointofcare.abbott
- Instructions for Updating i-STAT 1 Handheld Software (For CD-ROM customers)
- Network Options for Updating the i-STAT 1 Handheld (For CD-ROM customers)
- Network Options for Updating the i-STAT 1 Handheld Using www.pointofcare.abbott

i-STAT/DE

END-OF-LIFE NOTIFICATION

Abbott Point of Care will end support of i-STAT/DE versions less than 2.8.0.1 on 31-DEC-2022. i-STAT/DE versions 2.8.0.1, 2.9 and 2.10 will continue to be supported. For information on identifying the version of i-STAT/DE at your facility, see <u>IDENTIFYING VERSION OF i-STAT/DE</u> in this product update.

SOFTWARE UPDATES

Ensure that you are downloading the correct file for the version of i-STAT/DE at your facility by identifying the version and selecting the file based on the table below. For information on identifying the version of i-STAT/DE at your facility, see <u>IDENTIFYING VERSION OF i-STAT/DE</u> in this product update.

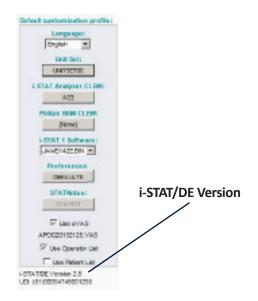
i-STAT/DE version < 2.5	Software Update File
2.0 ^ , 2.2 and 2.3	SUWXXXXX.EXE
i-STAT/DE Version ≥ 2.5	Software Update File
2.5, 2.6 [•] , 2.7, 2.8 , 2.8.0.1 [•] , 2.9, and 2.10	SUXXXXX.EXE

^ Indicates an i-STAT/DE version release that was a mandatory update.

IDENTIFYING VERSION OF i-STAT/DE

To identify the version of i-STAT/DE, access the i-STAT/DE customization workspace, locate the Default customization profile pane on the left hand side of the webpage. Below that pane will be the i-STAT/DE Version.

If you are unable to access your i-STAT/DE Customization Workspace, please contact your point-of-care program administrator for guidance.



DISTRIBUTOR ONLY: DOCUMENTATION AND INSTRUCTIONS FOR UPDATING CUSTOMERS

Abbott Point of Care recommends the preparation of Update Kits for distribution to your customers. These kits should contain a CD-ROM with the required files as listed below and paper copies of the appropriate documents listed under User Documentation below.

ANALYZER SOFTWARE COMPONENTS

The following archive file(s) must be downloaded from the APOC website.

i-STAT Analyzers – All Countries

Archive Title on the APOC Website: JAM2152, CLEW A43.

Archive description:

Name	Checksum*	Contents
SUY52A43.exe	e6f2e0fc94bfc754d467a9fe448a473a	Self extracting file that includes all files listed below
Files included:	Name	Description
	JAM2152A.BIN	i-STAT 1 Analyzer application
	A43.CLW	i-STAT Analyzers CLEW file
	Jammlite.exe	Windows download utility for use with all analyzers
	Copyclew.exe	DE installation Utility
	Update.cfg	Configuration file used by Jammit/Jammlite

* Note: the checksum value was generated using the MD5 application, and not the previous VERCHK application.

Archive Title on the APOC website: Transfer.bat for Distribution Disk.

Archive description:

Name	Checksum	Contents
Transfer.bat	1A615E	Batch file to copy from floppy hard drive

Note: Some of the software files may be self extracting zip files. The transfer.bat batch file automatically expands any existing zip files as it copies to C:\bins.

USER DOCUMENTATION

The following user documentation file(s) must be downloaded from the APOC website. Multiple languages are available. These documents are in Adobe Acrobat PDF format, and can be viewed and printed using the Adobe Acrobat application.

Product Updates

Title on APOC website:

i-STAT Software Update and Release Notes: November 2021 (art # 731668-XX Q)

- The Hungarian language document is at Rev. F
- The Polish, Czech, Norwegian, Romanian, and Croatian documents are at Rev. D

Technical Bulletins

Instructions for Updating the i-STAT 1 Handheld Using www.pointofcare.abbott (art # 731335-XX I)

- The Polish document is at Rev. H.
- The Czech, Norwegian, Romanian, and Croatian documents are at Rev. E.
- The Hungarian document is at Rev. F.

Network Options for Updating the i-STAT 1 Handheld Using www.pointofcare.abbott (art # 731336-XX I)

- The Polish, Czech, Norwegian, Romanian and Croatian documents are at Rev. E.
- The Hungarian document is at Rev. F.

Network Options for Updating the i-STAT 1 Handheld (art # 725768-XX I)

Instructions for Updating i-STAT 1 Handheld Software (art # 725708-XX I)

- The Polish document is at Rev. E.
- The Czech, Norwegian, Romanian and Croatian documents are at Rev. D.

Analyzer Coded Messages (art # 714260-XX T)

- The UK English and Turkish documents are at Rev. U.
- The Polish and Czech documents are at Rev. E.
- The Hungarian, Norwegian, Romanian and Croatian documents are at Rev. B.

New Ultralife 9-volt Lithium Battery for Use With the i-STAT System (art # 730271-XX B

Instructions for Restoring Analyzers that Produce *** for Hct and Quality Check Code 23 (art # 714962-XX E)

- The UK English and Turkish documents are at Rev. F.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

K2EDTA and K3EDTA Customization for Hematocrit on the i-STAT System (art # 716240-XX E)

- The German document is at Rev. G.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

ACT Test Result Options: PREWARMED and NON-PREWARMED Result Calibration Modes for the i-STAT 1 Analyzer (art # 715617-XX E)

• The Polish, Czech, Hungarian, Norwegian, Romanian and Croatian documents are at Rev. B.

Support Services (art # 716144-XX AL)

- The Polish, Czech, Romanian, and Croatian Documents are at Rev. D.
- The Hungarian document is at Rev. F.
- The Norwegian document is at Rev. H.

Value Assignment Sheets for Control Fluids

Please check the APOC website for new value assignment sheets for quality control and calibration verification solutions.

i-STAT 1 System Manual Sections

Cover Sheet (art # 714336-XX Q)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

Configuration Sheet (art # 714419-XX BD)

- The UK English document is at Rev. BE.
- The Polish, Czech, Norwegian, Romanian, and Croatian Documents are at Rev. E.
- The Hungarian document is at Rev. G.

Table of Contents (art # 714362-XX AD)

- The UK English document is at Rev. AE.
- The Polish, Czech, Norwegian, Romanian, and Croatian documents are at Rev. E.
- The Hungarian document is at Rev. G.

Section 1: Introduction (art # 714363-XX AA)

- The Polish, Czech, Norwegian, Romanian, and Croatian documents are at Rev. C.
- The Hungarian document is at Rev. E.

Section 2: i-STAT 1 Analyzer (art # 714364-XX U)

- The Polish, Czech, Hungarian, Romanian, and Croatian documents are at Rev. D.
- The Hungarian document is at Rev. E.

Section 3: i-STAT Cartridge (art # 714365-XX I)

- The Swedish document is at Rev. J.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

Section 4: PCx Glucose Test Strip (art # 714366-XX D)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

Section 5: Electronic Simulator (art # 714367-XX F)

- The UK English document is at Rev. G.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

Section 6: i-STAT 1 Downloader (art # 714368-XX L)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

Section 7: Portable Printer (art # 714369-XX L)

- The UK English document is at Rev. O.
- The French and Swedish documents are at Rev. M.
- The Greek and Turkish documents are at Rev. N.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. E.

Section 8: Data Management (art # 714370-XX G)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. D.

Section 9: Customization (are # 714371-XX J)

- The German, French, Italian, Portuguese, Greek, and Turkish documents are at Rev. I.
- The Polish, Czech, Norwegian, Romanian, and Croatian documents are at Rev. C.
- The Hungarian document is at Rev. D.

Section 10: Sample Collection (art # 714372-XX P)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. D

Section 11: Cartridge Handling (art # 714373-XX J)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. D.

Section 12: Cartridge Testing (art # 714374-XX N)

- The UK English and Portuguese documents are at Rev. O.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

Section 13: Glucose Strip Testing (art # 714375-XX G)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

Section 14: Quality Control (art # 714376-XX U)

- The UK English and Greek documents are at Rev. T.
- The Spanish document is at Rev. W.
- The Polish, Norwegian, Romanian, and Croatian documents are at Rev. C.
- The Czech and Hungarian documents are at Rev. D.

Section 15: Calibration Verification (art # 714377-XX S)

- The Spanish and Turkish documents are at Rev. T.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

Section 16: Proficiency or External Quality Control Testing (art # 714378-XX H)

- The Turkish document is at Rev. I.
- The Polish, Czech, Norwegian, Romanian, and Croatian documents are at Rev. B.
- The Hungarian document is at Rev. D.

Section 17: Routine Care of the Analyzer and Downloader (art # 714379-XX H)

- The UK English, Greek, and Turkish documents are at Rev. J.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. D.

Section 18: Updating the Software (art # 714380-XX J)

- The UK English document is at Rev. L.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

Section 19: Troubleshooting the Analyzer (art # 714381-XX J)

- The UK English, Greek, and Turkish documents are at Rev. L.
- The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

Section 20: Theory (art # 714382-XX E)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. B.

Introduction to Cartridge and Test Information (art # 714258-XX Q)

• The Polish, Czech, Hungarian, Norwegian, Romanian, and Croatian documents are at Rev. C.

US Military Support

The US Military will require the User Documentation to be in US English. In order to print documents for the US Military sites, please access the Support section of the APOC website.

Updates to System Manuals in Inventory

Updated System Manuals will be posted on the APOC website in the Support section. Please note that the Manuals appear in one large file. The documents appear consecutively just as they are arranged in the printed version of the System Manual. You can print the entire System Manual and replace the ones in inventory, or you may follow the Add/Delete sheets for the i-STAT 1 handheld posted on the web to update the Manuals currently in inventory.

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