STANDARD OPERATING PROCEDURE QMS/SOP/POCT/63/3

Title: Abbott i-STAT Operating Procedure for B-HCG Effective date: 31/08/2023

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Summary of Significant Changes at this Revision

- Amend the screen prompts in running an iQC.
- Change the picture in 6.1 as the cartridges are different now.

Purpose and Scope	**Items Required**
This document covers the use of the Abbott i-STAT handheld device for the measurement of B-HCG in patients during the early stages of pregnancy. Including the analysis of iQC, other quality checks, and maintenance. Further information can be found in the Abbott i-STAT 1 manual found on the intranet.	• i-STAT® β-hCG cartridges • i-STAT® β-hCG Level 1 Control • i-STAT® β-hCG Level 3 Control • Electronic simulator • Lithium heparin blood bottle & syringe • i-STAT® 1 hand held meter • EQA samples (once a month)
Definitions and Abbreviations B-HCG = Total Beta-Human Chorionic Gonadotropin iQC = internal quality control EQA = external quality assurance EPAC = early pregnancy assessment clinic CLEW = Version of standardization data installed in the analyser	**Grade / Qualifications** **Competencies Required** **Current Version of: FM/POCT/COMP/9**

Risk Assessment:
Current Version of: QMS/RA/POCT/15

Safety Precautions for This Procedure: Universal precautions should be used when handling any patient sample. PPE including gloves, eye protection & face masks (for known highly infectious samples), and an apron should be worn to avoid spillages of samples onto clothing and skin.

Access: Only trained user are authorised to use this device on completion of an assessed competency form (see above).

NOTE: It is against trust policy to share your personal log in details.

Contents

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- Andre Attrill (Abbott Regional Account Manager), andre.attrill@abbott.com

1 Clinical Relevance and Purpose

The Abbott i-Stat handheld POCT meter is to be used for the analysis of Beta-Human Chorionic Gonadotropin (HCG) in the early pregnancy assessment clinic (EPAC). EPAC cares for patients presenting with bleeding or pain during the first 14 weeks of their pregnancy, the HCG results will be used to aid the diagnosis of miscarriage and ectopic pregnancy.
The i-STAT HCG method is only suitable during the early stages of pregnancy as the upper detection limit is 2000 IU/L.

2 Related Documentation

- Quality control and maintenance form (FM/POCT/64/2)
- Abbott i-STAT user manual (EXT/POCT/16/1)
- I-STAT B-HCG cartridge kit insert (EXT/POCT/16/1)
- I-STAT user guide (EXT/POCT/16/1)
- Bulletin for software updates (EXT/POCT/16/1)
- Competency form (FM/POCT/COMP/9)
- Risk assessment (RA/POCT/15/1)
- Guideline for management of suspected ectopic pregnancy and pregnancy of unknown location (OBS-GYN-012)

3 Actions and Methods:

3.1 Principle and Method of the Procedure Used for the Examination

The i-STAT β-hCG test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for β-hCG are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the human chorionic gonadotropin molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The hCG within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate, releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product, which is proportional to the concentration of β-hCG within the sample.

3.2 Specimen Requirements and Means of Identification

3.2.1 Suitable Samples for Use With ß-hCG cartridges

- Heparinised venous whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin and filled to capacity.
- Non-heparinised venous whole blood or plasma samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

3.2.2 Unsuitable Samples for Use With ß-hCG cartridges

The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased ß-hCG readings.
Capillary tubes and direct skin punctures (e.g., fingerpricks) should not be used.

All samples must be identified with three points of patient identification in accordance with Positive Identification of Patients policy (Ref.: 255/2010)

3.3 Patient Preparation

Samples should be collected following trust venepuncture policy (ref: 782) and using the correct order of draw.

4 Consumables, Equipment, Calibrators and Quality Control and Required Environmental Conditions for use

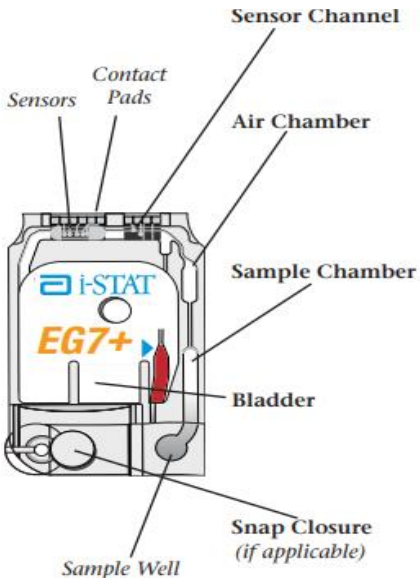
a) i-STAT® β-hCG cartridges
b) i-STAT® β-hCG Level 1 Control
c) i-STAT® β-hCG Level 3 Control
d) Electronic simulator
e) Lithium heparin blood bottle & syringe
f) i-STAT® 1 hand held meter

a) 

b&c) 
d) 
e) 
f) 

4.1.1 i-STAT® β-hCG cartridges

- When refrigerated at 2-8 °C, cartridges are stable until the expiration date.
- Cartridges may be stored at room temperature at 18-30 °C for the timeframe indicated on the cartridge box.
- Individual cartridges must be brought to room temperature for a minimum of five minutes before opening.
- An entire box of cartridges should stand at room temperature for one hour prior to use.
- All cartridges should be used immediately after opening the individual packaging.
- Used cartridges must be disposed into clinical waste bins.



NOTE: If the portion pack has been punctured, the cartridge should not be used

4.1.2 i-STAT® β-hCG Level 1 & Level 3 Control

- 6 Bottles (1 mL each) of Ready to use i-STAT control fluid prepared in human serum.
- Stable until the expiration date on the vial label when stored unopened at 2°C to 8°C
- Once opened, are stable for up to 30 days when tightly capped and stored at 2°C to 8°C

NOTE: These controls contain < 0.09% sodium azide as a preservative.

4.1.3 Target values and ranges for β-hCG Level 1 & Level 3 Control

Target values are printed on a Value Assignment Sheet (VAS) posted on the APOC website follow the link:
https://www.pointofcare.abbott/int/en/offerings/support/istat/value-assignment-sheets
Or from:
www.pointofcare.abbott select > **Support** (top menu bar) > select **i-STAT 1 VAS** (under Links to user resource accessible without login)

To find the right Value Assignment Sheet, you must have:

- CLEW revision (found within the handheld's Status Page)
- Control/Calibration Verification lot number found on the box (not the unique lot for each level located on the vials of the Calibration Verification kits)
- Cartridge type and lot number (found on cartridge pouch or cartridge box)

Follow the instruction on the page to locate the correct ranges for the current controls.

NOTE: NOTE: Always ensure that the control material lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software version in the handheld.

4.1.4 Electronic simulator

The external electronic simulator is a stable electronic device, which is inserted into the cartridge port (takes around 60sec). The simulator test should be performed daily or each day the meter is used, as it is a quality control check for the analyser's cartridge signal-reading function.

The internal electronic simulator will be automatically performed once the pre-set time has elapsed, and on insertion of a test cartridge, this will add 20 sec to the assay length.

NOTE: The Electronic Simulator test will fail if high humidity interferes with the measurements. Therefore it is not necessary to record humidity where the analysers are in use.

4.1.5 i-STAT® 1 hand held meter

The i-STAT meter should only be used under the following environmental conditions:

- Operating temperature is 16-30°C
- Transport temperature -10-46°C
- Relative humidity 90% (maximum) non-condensing
- Barometric pressure 300-850 mmHg

NOTE: Meter must be sat horizontally without movement during analysis for accurate results.

4.1.6 Calibration

Standardization is the process by which a manufacturer establishes "true" values for representative samples.

A multi-point calibration curve, the slope or sensitivity of which is defined by coefficients in the CLEW software, is derived for each sensor by this standardization process. These calibration curves are stable over many lots and only need to be adjusted if a change in a manufacturing process affects the curve or if the relationship between results on the i-STAT System and other major laboratory systems drifts.

For the convenience of users, CLEW updates are scheduled two times a year.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the analyser automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample's concentration from adjusted calibration curve.

5 Maintenance

5.1 Thermal Probe Check (every 6 months)

1. If the analyser and simulator have been stored separately in areas where the ambient temperature differs by more than 3 °C (5 °F), allow the simulator and analyser to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyser. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. Insert the simulator into the analyser.
3. When results are displayed, press the period key to view the difference between the thermal probes.
4. Interpretation of the thermal probe check value:
   Acceptable: a value from -0.1 to +0.1, inclusive.
   - Repeat the procedure if a FAIL message with a "t" Quality Check Code or a value less than -0.1 or greater than 0.1 is displayed.
   - Repeat the procedure if "--.--" is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyser and let it stand for 15 minutes before inserting all the way.
   - Contact your Technical Support representative if the repeat thermal check value is greater than 0.1 or less than -0.1 or if a Quality Check Code is displayed.

5.2 Software updates

To be performed every 6 months. For detailed instructions on this procedure, please refer to the i-STAT Technical Bulletin (appendix 1)

5.3 Procedure for the Analysis of a Quality Control

Both control solutions should be run on opening a new box of cartridges, the completion of this should be written on the box along with the date, and initials of user.

NOTE: Ensure controls, cartridges, and handhelds are at the same room temperature

1. Press ⏻ to turn on handheld.
2. Press MENU → 3 → 1 for Control Samples.
3. Follow handheld prompts.
4. Scan or entre your operator ID
5. Scan the barcode on the iQC bottle
6. Scan the lot number on the cartridge pouch:
   - Position barcode 3–9 inches (8–23 cm) from scanner window on the handheld.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The handheld will beep when it reads the barcode successfully.
7. Open the packaging and remove the cartridge
8. Immediately before use, gently mix the contents of the control vial (avoid foaming)
9. Open the vial and transfer a drop of fluid into the i-STAT Total β-hCG cartridge using the vial dropper tip. Tightly recap the control vial and store it at 2–8 ºC.
10. Seal the cartridge and immediately insert into the handheld port until it clicks into place.
11. Wait for the test to complete and review results

12. Evaluate the results with 1 = pass or 2 = fail
13. Confirm 1 = yes, 2 = no
14. Results must be recorded on the Quality Control and Maintenance Log.
15. Press 1 for test options and remove the cartridge

5.4 Procedure for the Analysis of an Electronic simulator tests

1. Press  to turn on handheld.
2. Press the  key
3. Press  to select Quality Test
4. Press  to select Simulator
5. Press  to scan the operator ID
6. Press 
7. Press  to scan the simulator
8. Press 
9. INSERT SIMULATOR is displayed
10. Remove the cover from the contact pads and insert into analyser (into cartridge port), ensure it is straight and avoid touching the contact pads.
11. Simulator Locked message displays on screen
12. A “PASS” or “FAIL” will display on screen when complete
13. Remove simulator and return cover onto the contact pads.
14. Record the pass or fail on the quality control maintenance log

NOTE: If a “FAIL” result is given repeat the test again and check common causes below.

5.4.1 Common causes for failed simulator test

The external Electronic Simulator test may occasionally fail even though it is in proper operating condition due to the extremely sensitive nature of the test.

- If the simulator has been dropped or damaged it may malfunction
- If the analyser has been moved from a cold to a humid environment, condensation can form on the internal connectors. Code “L” will be displayed, in this instance allow the analyser to sit for 30 minutes and repeat test.
- If the simulator has been inserted on an angle the test will fail

5.5 External Quality Assessment Schemes (EQA)

EQA involves running an unknown patient-like sample and comparing your results to peer results, in order to retrospectively monitor the accuracy of reporting.

A Sample will be provided by the POCT team on a monthly basis. This sample must be run immediately or as soon as possible upon receipt as if it were a patient using the ID provided.

Any trained user of the i-STAT can run this sample, and return the result form back to POCT (B38 first floor).
EQA is a requirement for all pathological tests, is expected that 100% of distributed samples are analysed and results returned within the time frame stated.

6 Procedure for the Analysis of a Patient Sample

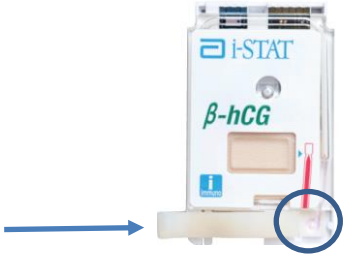
6.1 Patient & Cartridge Test Procedures

- DO NOT open cartridge pouch before scanning the barcode.

1. Press ⏻ to turn on handheld.
2. Press 2 i-STAT Cartridge.
3. Follow handheld prompts.
4. Scan the lot number on the cartridge pouch.
    - Position barcode 3-9 inches from scanner window on the handheld.
    - Press and hold SCAN to activate the scanner.
    - Align the red laser light so it covers entire barcode.
    - The handheld will beep when it reads the barcode successfully.
5. Continue normal procedures for preparing the sample.
6. Fill the sample well with whole blood so that the sample chamber is full:

Laser Radiation – Do not stare into beam. Class 2 laser product. Laser Diode 650 nm Maximum Output 1.0 mW.

7. Slide the seal over the sample well and ensure it snaps shut:



8. Push the sealed cartridge into the i-STAT port until it clicks into place. Wait for the test to complete.
9. Review results.

Note: For immunoassay testing (B-HCG), the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the Downloader/Recharger.

Cartridges must be disposed of into clinical waste. Syringes and needles and sample tubes bust be disposed into a hard plastic clinical waste burn bin.

6.2 Procedure for Reviewing and Recording of Results

6.2.1 Reviewing Results

- The 0 key can be used to backlight the display to view results in dim lighting. (The backlight turns off after 90 seconds or when the 0 key is pressed again.)
- Test results are displayed numerically and with bar graphs. Tick marks indicate the reference ranges on the bar graphs.
- Test results are displayed for 2 minutes or a customized time. To recall the last set of results to the screen, turn the handheld on and press 1 for Last Result.
- To review results from the same patient, when results are displayed, press 1 for Test Options and then 3 for History. Scroll through test records using the 1 and 2 keys.
- To review another patient's results, turn the handheld on and press the Menu key followed by:
    - 2 key for Data Review
    - Then the 1 key for patient.
    - Scan or enter the Patient's ID number.
    - Use the 1 and 2 keys to scroll through the test records.
    - Or, press the Menu key followed by the 7 key for List.
    - Select the test record(s) to be reviewed and press the Enter key.

6.2.2 Recording Results

The results must be recording into the patient notes to include:

- Time and date of analysis
- Name and ID of patient (if not already on notes)
- Test name (B-HCG) and the result
- The analyser this was produced on (I-STAT)
- The name of the person performing the analysis

The analyser holds 5000 results before overwriting the oldest, patient results must be kept for 30 years.

7 Reference Limits, Reportable intervals and Interpretation

7.1 Reference Limits

The reference range is <5.0 IU/L

7.2 Reportable Intervals

The reportable range is 5.0 – 2000.0 IU/L

< or > and < > depicts a result that is below or above the reportable range, a sample must be sent to the lab to obtain an accurate result if required.

7.3 Reporting and Interpretation

See: Guideline for management of suspected ectopic pregnancy and pregnancy of unknown location (OBS-GYN-012)

8 Potential Sources of Variation and Measurement Uncertainty of Measured Values

8.1 Measurement of Uncertainty (MoU)

This will be reviewed through audit after 12 months of iQC data can be collated (INTAUD/POCT/211).

8.2 Interferences

Interference studies were based on CLSI guideline EP7-A2.25. The following substances were found to have no significant effect (less than 10%) on the β-hCG method when added to a plasma pool containing approximately 40 IU/L of β-hCG at the concentrations indicated:

Compound	Test Level (µmol/L unless otherwise indicated)
Acetyl Salicylic Acid	3620
Acetaminophen	1660
Allopurinol	294
Ampicillin	152
Ascorbic Acid	342
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.53
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Ibuprofen	2425
Isosorbide dinitrate	636
Nicotine	6.2
Nifedipine	1156
Phenytoin	198
Propranolol	7.71
Salicylic acid	4340
Sodium Heparin	90 U/mL
Theophylline	222
Verapamil	4.4
Warfarin	65.2

8.3 Limitations

See the user manual (EXT/POCT/16) for detailed list of limitations

- This assay is capable of detecting whole molecule (intact) hCG as well as free β-hCG subunits. The i-STAT Total β-hCG assay is intended for use in the early detection of pregnancy only and should not be performed for any other purpose.
- Hook effect: no significant hook effect detected in samples up to 300,000 IU/L.
- β-hCG cannot be used alone to establish the diagnosis of ectopic pregnancy, the total β-hCG results should always be used and interpreted in the context of the overall clinical picture
- Specimens from post-menopausal women may elicit weak positive results due to low hCG levels unrelated to pregnancy.
- With a weak positive result, it is good laboratory practice to resample and retest after 48 hour
- Interfering substances such as heterophilic antibodies, non-specific proteins, or hCG-like substances, may falsely depress or falsely elevate results. In these cases results should be confirmed by an alternate hCG method.
- Partially clotted samples can result in elevated hCG results.
- Grossly hemolysed samples can lead to a decreased detection of hCG.
- Imprecision exceeding 10% (CV) has been observed for samples with hematocrit levels above 50% PCV.
- Motion of the handheld device during testing can increase the frequency of suppressed results

8.4 Performance characteristics

8.4.1 Plasma reproducibility at the Point-of-Care

The i-STAT Total β-hCG test is designed to have total imprecision ≤ 10% CV for concentrations above 14 IU/L, or a standard deviation (SD) of 1.4 IU/L for concentrations ≤ 14 IU/L in blood and plasma. A study using four levels of spiked plasma was performed over five days at three different sites. Five replicates of each level were tested on five analysers at each site. Within-day and within- site imprecision are represented below:

Target Concentration	n	Min	Max	Mean	Within-Day		Within-Site		Overall	
		IU/L	IU/L	IU/L	SD	%CV	SD	CV	SD	CV
5 IU/L	75	0.0	7.1	5.5	0.75	13.61	0.88	16.05	1.03	18.7
25 IU/L	75	21.9	27.2	24.3	1.26	5.16	1.26	5.16	1.26	5.18
Mid range	75	1038.5	1277.1	1155.7	49.76	4.31	50.77	4.39	53.08	4.59
High range	75	1636.1	2249.8	1874.5	104.95	5.60	104.95	5.60	111.11	5.93

This shows the greatest imprecision at concentrations around 5IU/L, the other concentrations are all below the (stated by Abbott) ≤ 10% CV.

In house comparison studies show a negative bias of i-STAT results compared to the laboratory (R^2 = 0.95).

8.5 Validation and Verification Report

Please see the validation and verification report Q-pulse reference: VAL/POCT/24

8.6 Metrological Traceability

The i-STAT System test for β-hCG measures hCG amount-of-substance concentration in plasma or the plasma fraction of whole blood (dimension IU/L) for in vitro diagnostic use. β-hCG values assigned to Abbott Point of Care's controls and calibration verification materials are traceable to Abbott Point of Care's working calibrators that are traceable to the World Health Organization's 5th International Standard (07/364), prepared from pooled plasma and hCG antigen obtained from 3rd party sources. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

8.7 Personnel Involved in Interpretation, Authorising, Reporting and Monitoring of Reports

All grades of staff can be trained to use the I-STAT (job role dependant) however, only staff who have completed training and have had their competency assessed are authorised to use the i-STAT. Results, if not obtained by requesting clinician, should be given immediately to the relevant clinician. Clinical members of staff who are involved in the patients care are authorised to interpret the results produced from the i-STAT.

It is the responsibility of the person analysing the sample to ensure the results are recoded in the patient's notes. If the person interpreting the result is different from the person analysing the sample then they are responsible for checking the result is in the patient notes and that any action taken is also recorded.

9 References

- Venepuncture Policy and Procedure (Ref.: 782)
- Positive Identification of Patients (Ref.: 755/2010)

Copy number	Location held
1	EPAC SOP folder
2	Intra net POCT page
3	Q-pulse

Appendix 1:

i-STAT

INSTRUCTIONS FOR UPDATING i-STAT 1 HANDHELD SOFTWARE

Overview

Why Do i-STAT Handhelds Need Software Updates?

The i-STAT 1 System is designed to eliminate operator influence on delivered results.

Due to the 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 CLEW software—delivered twice a year on a CD-ROM—re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the

i-STAT 1 Handheld to recognize any newly launched cartridge types and to perform any newly launched features.

JammLite Process Overview

Whether updating one, two, or many i-STAT 1 Handheld(s), the JammLite procedure must be used to update the first i-STAT 1 Handheld. This process is noted in the diagram below.

i-STAT is for *in vitro* diagnostic use.

Abbott

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

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Optional Steps

Once the first i-STAT 1 Handheld has been updated using the JammLite Utility, additional i-STAT 1 Handhelds may be updated the same way or by using the Handheld-to-Handheld method.

1. Update with JammLite Utility or 2. Update with the Handheld-to-Handheld Process

Choosing the Best i-STAT 1 Handheld Update Method

JammLite

Always update the first i-STAT 1 Handheld using the JammLite method. It's best to update all Handhelds via JammLite if they are readily available and near the PC you will use to run JammLite.

Handheld-to-Handheld

The Handheld-to-Handheld method is a good choice after the first Handheld has been updated via JammLite and other Handhelds that need updating are not near the PC that was used to run the JammLite Utility

i-STAT/DE

Users of i-STAT/DE who would like to update i-STAT 1 Handhelds via i-STAT/DE, please consult "Network Options for Updating the i-STAT 1 Handheld" (i-STAT Technical Bulletin 725768).

Instructions for Using This Technical Bulletin

Color-Coded Sections

This bulletin contains color-coded sections to easily identify the steps associated with the different methods for updating i-STAT 1 Handhelds.

Color-Coded, Numbered Steps

As stated above, there are several options for updating i-STAT 1 Handhelds. The color-coded, numbered steps help guide the user through a selected update process, as well as provide direction within the bulletin should the user encounter a technical issue, or need to repeat a step. For example, 2 indicates section 2 (Handheld-to-Handheld update method).

Tips for Troubleshooting

Troubleshooting tips are incorporated throughout the technical bulletin where needed. These tips are identified by the ⚠ icon, and appear on the right side of the page.

1. Update with JammLite Utility

Update with the

Follow these steps to update with the JammLite Utility

Gathering Equipment for JammLite

i-STAT 1 JammLite Utility

1.1 Before starting the process make sure all the required equipment is available:

- Computer with:
  - Windows 2000, Windows XP or Windows 7
  - A 9-pin serial port or USB port (if using a DRC-300)
  - A CD-ROM drive
- i-STAT System Equipment:
  - (1) Serial Downloader/ Recharger (DRS-300) or DRC-300
    or
  - (2) Serial Downloader (DS-300)
  - (3) Downloader power supply
  - (4) i-STAT 1 Handheld
  - (5) 9-Pin null modem serial cable supplied with the DS-300 or DRS-300 downloader
  - (6) USB cable supplied with the DRC-300
  - (7) The latest i-STAT Software and Documentation CD
  - (8) Electronic Simulator

When using a DS-300 or DRS-300, a computer with a traditional 9-pin serial port is required. If the computer does not have one, follow your internal technical support procedure (i.e., contact the IT Department or the individual in your office responsible for computer support). Indicate that the i-STAT 1 software update process requires:

- a 9-pin serial port
- a CD-ROM Drive

Need technical support?

Call your Support Services representative.

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1.2 Ensure your i-STAT 1 Handheld has enough battery power (7.5 volts or higher).

To do this:

- Press the **On/Off** (⏻) key
- Press the **MENU** key
- Press **1** for Analyzer Status
- Confirm the battery voltage

Bei Verwendung wiederaufladbarer Batterien das Handheld auf mindestens 7,5 Volt aufladen.

Wiederaufladbare Batterien

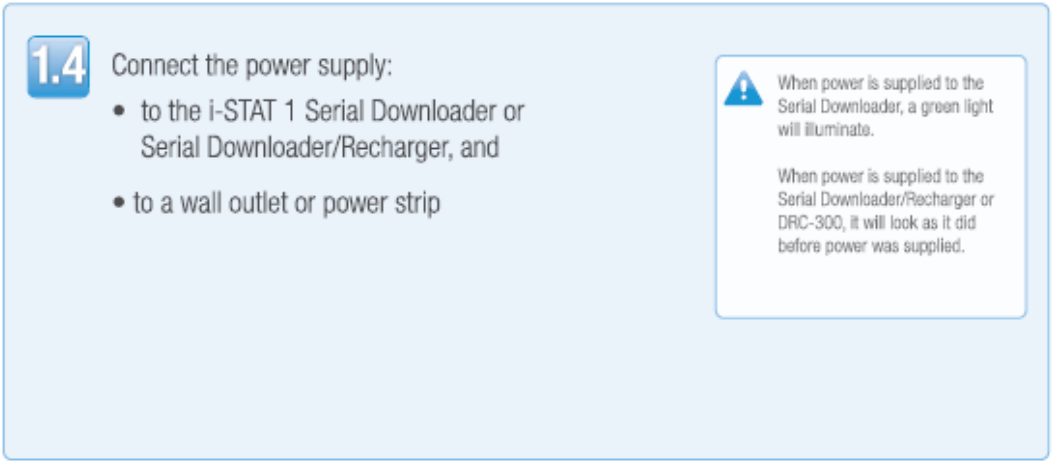
BBei Verwendung von Einwegbatterien diese durch neue ersetzen.

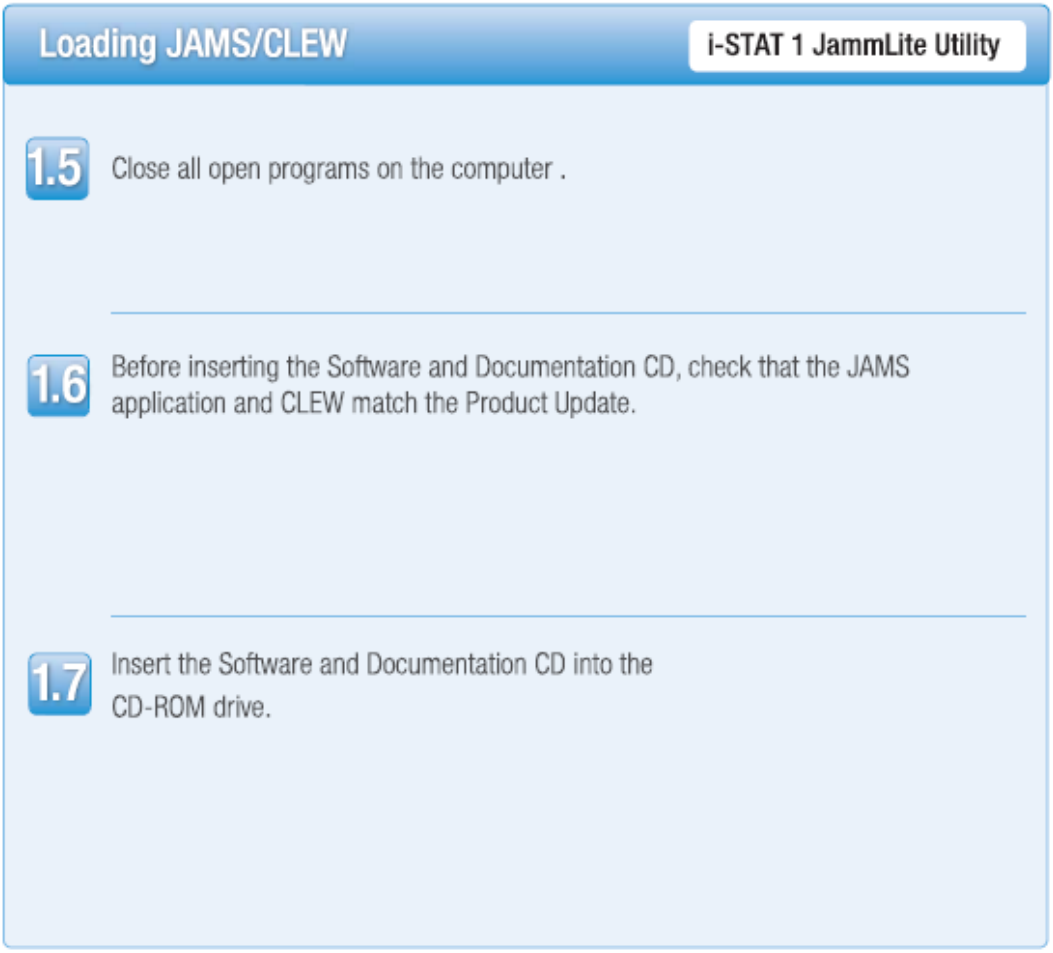
Einwegbatterien

Connecting/Setting Up Equipment

i-STAT 1 JammLite Utility

1.3





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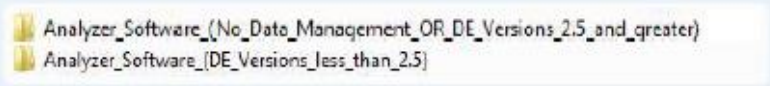
1.8 Wait 30 seconds and then close all windows that appear.

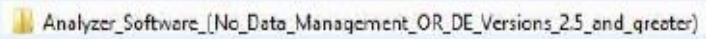
1.9 To open the Software and Documentation CD-ROM:

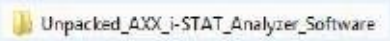
- Double click the following icon: 
- Double click **CD-ROM Drive** 

The following window will appear:



1.10 To open the JAMMLITE Utility:

Double click 

Double click 

Double click 

If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to complete step 1.10 of this document.

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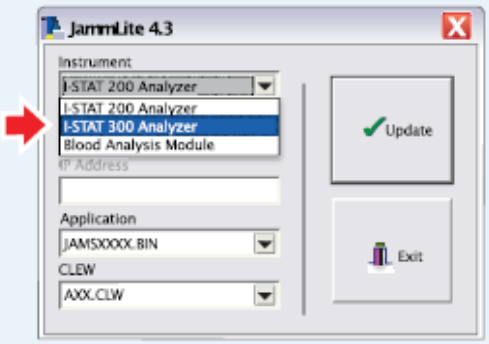
Updating Your i-STAT 1 Handheld

i-STAT 1 JammLite Utility

1.11 In the JammLite utility, select the **i-STAT 300 Analyzer** within the instrument dropdown menu..

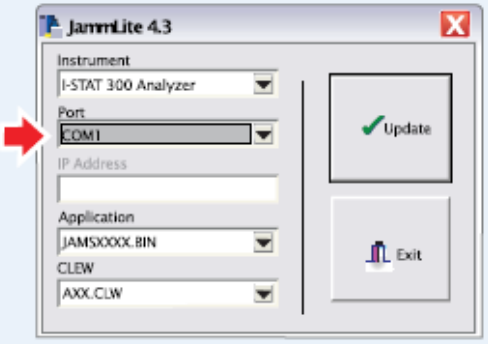


1.12 By default, the lowest numbered COM port will automatically be selected.

If the downloader is connected to a different COM port, change the selection to that COM port now.

If no ports are displayed, close all open programs including JammLite, and then re-launch JammLite.

If JammLite still has no available COM ports listed, call APOC Technical Support for assistance.



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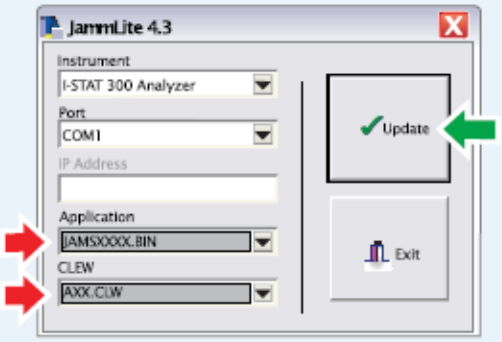
1.13 Check that the **Application** and **CLEW** listings match those in the Product Update.

Click the **Update** button.



Note: Application and CLEW numbers are for example only. The "numbers" have been replaced with X's in the example above and will change with each software update.

If an error occurs, check the serial connection between the downloader and the PC, as well as the power connection to the downloader.

If connected correctly, select a different COM port **(Do not select TCP/IP)** within the dropdown menu and click **Update.**

If errors persist after trying each of the COM ports listed in JammLite, verify the serial number of your downloader and call APOC Technical Support for assistance.

1.14 Follow the onscreen instructions.

*If using the Serial Downloader/Recharger, a **blue light** will illuminate when the Handheld is placed correctly within it.
If using the Serial Downloader, a **red light** will illuminate when the Handheld is placed correctly within it..

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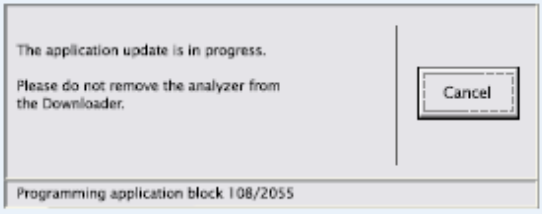
1.15 When the update is in progress, the following screen will appear:



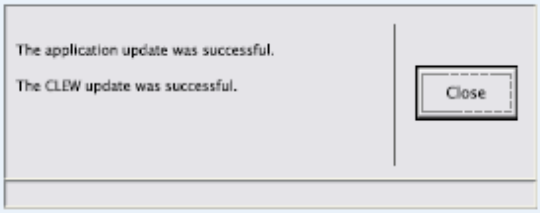
If you do not see the screen shown on the left—

—acknowledge the error message(s) and click **OK.**

Return to Step 1.13

The Receiving Handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the Handheld until the success screen is displayed.



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Verifying Software Update

i-STAT 1 JammLite Utility

1.16

If **PASS** is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, please contact your Support Services representative.

For additional information on running the electronic simulator, please see:

- Section 14 of the i-STAT 1 System Manual, or
- The Introduction and Start-up section of the i-STAT System Manual for Waived Tests

Congratulations. The process for updating the first i-STAT 1 Handheld is complete.

Review the options below for additional instructions.

If there are no additional Handhelds to update, the process is complete:

- Click the X button in the upper right corner of the software screen
- Close all other open boxes
- Confirm all messages

If there are additional Handhelds to update via JammLite:

- Click **Close**
- Repeat Steps **1.13** through **1.16**

If there are additional handhelds to update with the Handheld-to-Handheld process:

- Go to **2. Update with the Handheld-to-Handheld Process**

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Update with JammLite Utility

2. Update with the Handheld-to-Handheld Process

After updating the first i-STAT 1 Handheld, follow these steps to update additional Handhelds with the Handheld-to-Handheld Process

Gathering All Equipment

Handheld-to-Handheld

2.1 Before starting the process make sure all the required equipment is available:

- Recently updated i-STAT 1 Handheld (referred to in this section as the Sending Handheld) charged to 7.5 volts or higher*
- The Handheld unit to be updated (referred to in this section as the Receiving Handheld) charged to 7.5 volts or higher*
- Electronic Simulator

* For information on checking battery power, see step 1.2

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Connecting/Setting Up Equipment

Handheld-to-Handheld

2.2 Make sure the power is **off** on the Receiving Handheld

2.3 Place Sending and Receiving Handhelds on a flat surface with infrared (IR) windows aligned, approximately 1 foot apart.

2.4 Turn **on** the Sending Handheld and select **7-Utility.**

2.5 When prompted for a password, enter **ENT** and continue.

Note: Abbott Point of Care Inc. recommends changing the default password.

If the correct password was not entered, the Utility Menu will not appear. Check for data entry errors and retry.

If still unsuccessful, call APOC Technical Support and indicate:

- A Handheld-to-Handheld update has been attempted
- Password for Utility Menu is unknown

If that did not work, a password is needed.
Enter the password defined by your facility and press **ENT.**

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Updating your i-STAT 1 Handheld

Handheld-to-Handheld

2.6 In the Utility menu...

- Press **1-SEND SOFTWARE**
- Press **1-SEND**

Make sure the Receiving Handheld's power is **off.**

2.7 When the Sending Handheld displays **WAITING TO SEND**...

- Keep the infrared windows aligned
- Without lifting either Handheld off the flat surface move the Receiving Handheld towards the Sending Handheld until the Sending Handheld displays **SENDING.**

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2.8 When the [illegible] display **SENDING** along with a bar indicating that the software is being sent.

The Receiving Handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the Handhelds until the Sending Handheld goes back to the Utility menu, and displays **Last Send Successful** The update is now complete.

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Verifying Software Update

Handheld-to-Handheld

2.9

Run he Electronic Simulator in the newly updated Handheld.

When the simulator finishes, PASS will be displayed..

If **PASS** is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, please contact your Support Services representative.

For additional information on running the electronic simulator, please see:

- Section 14 of the i-STAT 1 System Manual, or
- The Introduction and Start-up section of the i-STAT System Manual for Waived Tests

Congratulations. The process for updating an additional i-STAT 1 Handheld is complete.

If there are other i-STAT 1 Handhelds to update, repeat steps 2.2 through 2.9

If there are no other Handhelds to update, the process is complete.