

## **CCAT iSTAT Use Clinical Practice Guideline**

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|--|----------|------------------------------|-------------|
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### **I. Background and Introductory Information**

- A. This guideline establishes expectations for maintenance, calibration and quality control of the iSTAT portable blood analyzer.
- B. Previous concerns about accuracy of the device may in part be related to improper storage of cartridges, calibration or other modifiable factors.
- C. Extreme environments may not allow strict compliance with these guidelines. CCATT personnel should make every effort to comply with all aspects of the storage and QC requirements for the iSTAT, even if perfect compliance is not possible due to the nature of the deployed environment.
  1. When deviation is necessary it should be noted on the 3899L.
  2. When significant deviation has occurred accurate interpretation of results may be impossible. Use of such results is at the provider's discretion.
- D. Abbott Point of Care offers customer support
  1. Online at [www.abbottpointofcare.com](http://www.abbottpointofcare.com)
  2. Military specific assistance and information is available – registration using a military email address is required
    - a. go to [www.abbottpointofcare.com](http://www.abbottpointofcare.com)
    - b. Choose customer support from horizontal menu at top of page. C
    - c. Choose Customer Information Center from vertical menu at left.
    - d. Choose US military at right of page
  3. Email [techsvc@apoc.abbott.com](mailto:techsvc@apoc.abbott.com)
  4. Phone 1-800-284-0702, Option 1

### **II. Training**

- A. All CCATT personnel will be trained in the use of the iSTAT device during the CCATT Initial Course.
- B. Sustainment training will occur at CSTARs Cincinnati during each deployment cycle.

### **III. Storage and maintenance of the iSTAT device**

- A. The iSTAT device, cartridges and accessories should be stored in the hard plastic case provided in the allowance standard.
- B. The device should be protected from extremes of temperature as much as possible.
- C. The device should be checked prior to each mission to determine the next scheduled maintenance date. Devices that are due for schedule maintenance should not be used.

### **IV. Storage of iSTAT cartridges**

- A. The main supply of cartridges should be stored at 2-8°C (35-46°F).
- B. If storage conditions are in doubt, controls should be run to verify that cartridges are performing properly.
- C. CG8+ cartridges in use may be stored at room temperature (18-30°C or 64-86°F) for usage for **up to two weeks**.
  1. When removed from the refrigerator place the expiration date on the cartridge package.
  2. This expiration date should be recorded on the 3899L.

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3. After removal from the refrigerator, every effort should be made to avoid exposure to extreme temperatures. This may require extraordinary efforts in some deployed settings.
  - D. Once cartridges have been brought to room temperature, they should not be returned to the refrigerator.
  - E. A cartridge should not be removed from its protective pouch until it is at room temperature.
    1. Condensation on a cold cartridge may prevent proper contact with the analyzer.
    2. Allow a single cartridge to stand for at least 5 minutes and a box of cartridges for 1 hour at room temperature before opening.
    3. Use cartridge immediately after removing it from its protective pouch. If the pouch has been punctured, the cartridge should not be used.
- V. Electronic Simulator
- A. Any device that fails an electronic simulator check (internal or external) should be removed from service and turned in for maintenance.
  - B. The iSTAT device runs a comprehensive check using an internal simulator each time a sample is run.
    1. Results will be suppressed if this check is not passed.
    2. No user intervention is required for this procedure.
  - C. External Electronic Simulator
    1. The external electronic simulator should be stored with the blue cap in place.
    2. The external electronic simulator check is accomplished by inserting the simulator into the cartridge port. The testing procedure takes approximately 60 seconds.
    3. The external electronic simulator should be run when indicated by the iSTAT device.
- VI. Liquid Controls
- A. Storage of control solutions
    1. Control solutions should be stored at 2 to 8 °C (35 to 46 °F).
    2. Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F).
  - B. **Liquid controls should be run each time a new lot of cartridges is opened.**
  - C. Running controls
    1. Step by step instructions are found in Appendix A.
    2. Verifying blood gas and chemistry measurements
      - a. iSTAT Calibration Verification Set levels 1, 3, and 5 should be run on the following cartridges: G, Crea, E3+, EC4+, 6+, EC8+, G3+, EG6+, EG7+, CG4+, and CG8+.
      - b. This procedure will verify the following measurements: Sodium, Potassium, Chloride, Ionized Calcium, Ph, PCO<sub>2</sub>, PO<sub>2</sub>, Glucose, Lactate, BUN/Urea, Creatinine.
      - c. **This procedure does not verify the hematocrit measurement.**
    3. Verifying hematocrit measurements requires RNA Medical® Hematocrit Calibration Verification Controls levels 1, 3, and 5 be run on the following cartridges: E3+, EC4+, 6+, EC8+, EG6+, EG7+, CG8+, and CHEM8+
    4. Consult manufacturers documentation if you plan to use cartridges not listed in this CPG (PT/INR, Lactate).
    5. Liquid controls do not need to be run if cartridges are obtained from a MTF lab that complies with this CPG.
  - D. Documentation
    1. Verification using liquid controls should be documented on a log or on the box containing the cartridges.

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2. The date controls were run on the cartridge lot used should be recorded on the 3899L.
- VII. Software Updates
- A. Software for the iSTAT is updated periodically.
    1. The iSTAT will not function with expired software.
    2. A warning will appear on the screen 15 days before the software expires.
  - B. The iSTAT can be updated using a desktop computer or another iSTAT with current software
    1. Updating using a desktop computer
      - a. This method may be problematic for deployed personnel due to regulations preventing attachment of devices to government computers.
      - b. If this method is chosen, the software can be downloaded from the internet.
        - (1) Navigate directly to site at <http://www.abbottpointofcare.com/Customer-Info-Center.aspx>
        - (2) Registration using a military email address is required.
    2. Update using another iSTAT device with current software
      - a. This method will likely be easier in most deployed settings using a device from another CCATT team or a MTF
      - b. Step by step instructions are in Appendix B
  - C. It is recommended that deployed personnel coordinate with a nearby MTF or contact their servicing Biomedical Maintenance Shop as needed for assistance with software updates.
- VIII. Practical advice to optimize use of the iSTAT
- A. Seek arrangements permitting you to obtain iSTAT cartridges from MTFs
    1. MTFs are in no way obligated to provide you with iSTAT cartridges. However, most are willing.
    2. It may also be possible to drop off your main store of cartridges at the MTF for temperature controlled storage and running controls when new boxes are opened.
    3. Obtaining cartridges from a MTF laboratory will eliminate the need to monitor storage temperature and run liquid controls.
  - B. Storage of cartridges in extreme conditions
    1. Ambient temperatures in many deployed environments far exceed the recommended room temperature range (18-30°C or 64-86°F).
    2. Even in these environments, creative and aggressive measures by the CCATT will decrease the degree to which these conditions are exceeded and improve iSTAT performance.
      - a. Consider hand carrying iSTAT cartridges rather than leaving them with rest of the gear set.
      - b. Always store the cartridges in a protective container, preferably the small pelican case the iSTAT is stored in.
      - c. Do not leave the iSTAT cartridges exposed to direct sunlight.
      - d. Maximize use of climate controlled environments (flight line vehicles, etc) to moderate temperature extremes.
  - C. Comparison of iSTAT results with MTF derived values
    1. When circumstances permit, teams are advised to perform one iSTAT test while MTF personnel simultaneously measure the same parameters.
    2. If the results are similar it adds some certainty to the accuracy of the iSTAT and cartridge lot currently in use.

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3. Discordant results suggest a problem with the device or cartridges and should prompt further investigation. Interpretation of results will be significantly impacted and the team should consider disregarding all results until the problem is identified and resolved.
4. There is no scientific basis for determining the direction and magnitude of difference between the iSTAT and MTF lab and then using that value as a “correction factor” to adjust results. There is no reason to believe that the difference in values will be in the same direction or of the same magnitude on subsequent measurements.

**IX. Summary of documentation requirements for iSTAT labs performed in flight**

- A. The next scheduled maintenance date for the iSTAT device should be recorded on the 3899L of each patient once per flight if labs are performed.
- B. The following information should be recorded each time labs are performed (writing “same as above” is acceptable if that is the case):
  1. Cartridge lot number
  2. Date cartridge was removed from refrigeration
  3. Date liquid controls were run on lot of cartridges being used **OR** MTF from which the cartridge was obtained if that is the case.

## **Appendix A Liquid Controls**

Prior to testing, the ampule to be used should be left at room temperature for four hours and the iSTAT device and cartridge for one hour.

| STEP | ACTION  |
|------|---|
| 1    | Access the i-STAT Cartridge Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.  |
| 2    | Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases.<br><br>To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. |
| 3    | Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.  |
| 4    | Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.  |
| 5    | Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results. Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample. |

After running controls, the target values should be determined by accessing the Value Assignment Sheets from the Abbott Point of Care website (<http://www.abbottpointofcare.com/Customer-Info-Center/Value-Assignment-Sheets.aspx>). You will need to know the CLEW version on your device and the lot # of the control solution you used. The values you obtained should fall within range reported on the Value Assignment Sheet. If it does not fall within the range, two additional cartridges should be run and the three results averaged should be compared to the Value Assignment Sheet range. If the averaged values are outside the range, there is a problem with your machine or the cartridges. The device should not be used until the problem is ascertained and resolved.

Correction of PO<sub>2</sub> value is required when running controls at locations more than 1000 feet above sea level. Use the barometric pressure reading from the iSTAT status screen and the following formulas:

For PO<sub>2</sub> values < 150 mmHg:

For every decrease of 15 mmHg in barometric pressure from 760 mmHg, add 1 mmHg to observed PO<sub>2</sub> value.

For PO<sub>2</sub> values > 150 mmHg:

For every decrease of 35 mmHg in barometric pressure from 760 mmHg, add 1 mmHg to observed PO<sub>2</sub> value.

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## **Appendix B**

### **Updating iSTAT CLEW Software Using Another iSTAT Device**

Step 1 – Be certain both iSTAT devices have at least 7.5 volts of battery power remaining.

Step 2 – Turn the power OFF on the receiving device. The power on the receiving device will remain off for the entire procedure.

Step 3 – Place both devices on a flat surface with the infrared windows aligned.

Step 4 – Turn on the sending device, press MENU, and select 7-Utility.

Step 5 – Press ENT when prompted for a password.

Step 6 – In the utility menu press 1-SEND SOFTWARE

Step 7 – Press 1-JAMS###/A##

Step 8 – When the sending device displays “WAITING TO SEND” start sliding the receiving device towards the sending device with the infrared windows aligned until the sending device displays “SENDING”.

Step 9 – Wait until the sending device returns to the utility menu and displays “LAST SEND SUCCESSFUL” before moving devices.

Step 10 – Run the external electronic simulator on the receiving device to verify successful software update.