

CRITICAL CARE AIR TRANSPORT CLINICAL PRACTICE GUIDELINE (CCATT CPG)



i-STAT Portable Blood Analyzer in Austere Locations

This CPG provides guidance for the management and use of the i-Stat portable blood analyzer in the aeromedical environment.

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MAJOR UPDATES

1. The frequency of performing an electronic simulator check for quality assurance.

GOAL

The goal of this CPG is to present the proper use and maintenance of use of the i-STAT portable blood analyzer, with a focus on the en-route care environment. This guideline outlines the expectations and instructions for maintenance, calibration, quality control, and use of the i-STAT portable blood analyzer. Updates include how to mitigate the negative impact of harsh environmental conditions found in deployment on the equipment and analyzer results. The series is developed by the Center for Sustainment of Trauma and Readiness Skills, University of Cincinnati Medical Center.

BACKGROUND

Point-of-care (POC) testing is defined as a pathology or laboratory test that is performed at the site of clinical interaction allowing immediate decision regarding treatment.¹ Because POC tests are performed in a non-laboratory setting, they are designed to be as simple as possible and produce reliable results when used by non-laboratory health-care professionals.² In this sense, POC testing is ideal for the En-Route Critical Care (ERCC) environment, however, austere ERCC conditions can affect the POC test results. One of most important environmental factors that medics must always be cognizant of are extremes in ambient temperature; exposure to extreme temperatures can render results inaccurate.

Critical Care Air Transport Teams (CCATTs) use the i-STAT (Abbott Point of Care, Princeton, NJ, USA) as their POC device (Figure 1).³ CCATT must therefore understand how to use the equipment, be able to troubleshoot and calibrate the analyzer, and also provide quality assurance with controls and simulators (the function of controls and simulators will be defined below). In addition, teams must be aware of the specific drugs and environmental conditions that alter test accuracy. Finally, teams are also responsible for protecting POC testing equipment from the elements.

The i-STAT analyzer can measure multiple different lab values: cardiac troponin I, electrolytes, blood gas, urea, creatinine, glucose, ionized calcium, and international normalized ratio (INR).

Test results from the i-STAT are generally available in 10 minutes or less. The results displayed on the screen depend on the type of cartridge inserted into the analyzer.

Figure 1. i-STAT Analyzer



The cartridges that are typically stocked for use by CCATT are the CHEM8+, CG8+, EG7+, and CG4+. Cartridges are each loaded with a sample of the patient’s blood and inserted into the bottom port of the analyzer for analysis.

The **CG8+ cartridge** (Figure 2) measures glucose, sodium, potassium, ionized calcium, hemoglobin, and hematocrit. The blue arrow just to the right of “CG8+” defines the fill mark when blood is loaded into the cartridge; this indicates the volume of blood necessary to perform the test.

The **EG7 cartridge** measures sodium, potassium, ionized calcium, hemoglobin, hematocrit, pH, PaCO₂, PaO₂, TCO₂, HCO₃, base excess, SO₂.

The **CHEM8+ cartridge** (Figure 3) measures creatinine, Blood Urea Nitrogen (BUN), glucose, ionized calcium, anion gap, TCO₂, chloride, potassium, and sodium. The fill mark is at the beginning of the blue segment.

The **CG4+ cartridge** measures lactate, pH, PaCO₂, PaO₂, TCO₂, HCO₃, base excess, SO₂.

The quality controls for the i-STAT system are simulators and controls. There are two types of simulators for the i-STAT: internal and external. Internal simulators are built into the analyzer and external simulators (Figure 4) must be inserted into the analyzer in the same port that receives the cartridge. Both types of simulators mimic the signals that a cartridge, loaded with blood, would send to the analyzer; simulators validate the analyzer. Controls are liquids that are injected into the cartridge (instead of blood); the cartridge is then inserted into the analyzer and run to validate the cartridge. CCATT members are tasked to perform these quality checks to ensure lab tests are accurate.

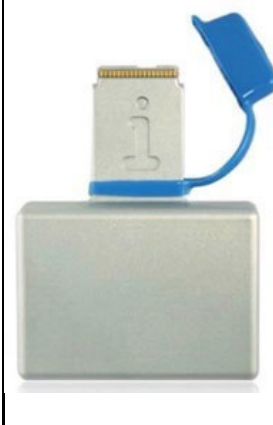
Figure 2. CG8+ cartridge.



Figure 3. CHEM8+ cartridge



Figure 4. External simulator



PROCEDURE FOR HANDLING NEW CARTRIDGE OR CONTROL SHIPMENTS

Cartridges must be kept refrigerated to maintain their integrity and reliability. Therefore, upon receipt, open the box marked “Refrigerate upon Arrival.” Next, identify the card with the temperature strip attached and read it. Once it is exposed to room temperature the reading will begin to change. Follow instructions on card and if the reading is found to be unacceptable, contact technical support.

Record the temperature reading on the “Receipt of New Cartridges” Log.

If the temperature strip reading is acceptable, perform a test of one cartridge from each box with the liquid control; this validates the remaining cartridges within each box. If you receive multiple boxes with the same cartridge lot number you only have to run the test once instead of running controls for each box. A similar procedure should be used for shipments of controls.

STORAGE: PROCEDURES FOR CARTRIDGES, CONTROLS, AND THE ANALYZER

Cartridges: The main supply of cartridges should be kept refrigerated at 2—8°C (35—46°F). In this state, they may be used until the date shown on the cartridge pack or box. Do not allow the cartridges to freeze. Cartridges may also be stored at room temperature (18-30°C or 64-86°F) for the time frame defined on the cartridge box. For example, CG8+ cartridges may be stored at room temperature for up to 2 weeks; then they must be discarded. Cartridges should not be returned to the refrigerator once they have been warmed to room temperature, and they should not be exposed to temperatures above 30°C (86°F). If a cartridge is removed from the refrigerator, then the labeled expiration date should be crossed out and the temperature expiration date should be written on the cartridge package.

Controls: Blood gas, electrolyte, and chemistry controls should be stored at 2—8°C (35—46°F). They may also be stored at room temperature (18 to 30 °C or 64 to 86 °F), but only for up to 5 days.

Analyzer: The i-STAT analyzer (and accessories) should be stored in the hard plastic case provided in the allowance standard. The device should be protected from extremes of temperature as much as possible. The optimal operating temperature range is 16 to 30 °C.

Electronic Simulator: Store at room temperature and protect contact pads from contamination by making sure the blue plastic cap (Figure 4) covers the contact pads when stored in its protective case after use.

DEPLOYMENT CONSIDERATIONS

One challenge for POC testing in the deployed setting is keeping the equipment within the proper temperature range.

- Cartridges used for a mission may be placed in the CCATT refrigerator bag to avoid temperature exposures above 30°C (86°F). Another option is to hand carry the i-STAT cartridges rather than leave them in the gear set. Do not leave the i-STAT cartridges exposed to direct sunlight and maximize use of climate-controlled environments (e.g., flight-line vehicles) to moderate temperature extremes.
- Optimal operating temperature for the i-STAT analyzer is 16—30 °C (61—86°F). If the device is either too hot or too cold at power-up, the following error message will be displayed on the screen: Temperature Out of Range. For a cold device, find a warm area on the aircraft or truck or place the analyzer in your flight suit to warm up. When the device is too hot, rest it on top of an ice pack and protect it from getting wet with a piece of plastic or a Chux pad. Typically only 5 minutes is needed to reduce the temperature to an acceptable level. If an aircraft is pre-

positioned with equipment to minimize response time for “wheels-up,” the i-STAT may become too hot and not function.

- If a cartridge is used beyond its temperature expiration date, or if a cartridge is used despite having been exposed to a temperature beyond 30°C (86°F), then annotate this on the 3899L (next to the lab result). It is left the provider’s discretion whether to use the results in clinical decisions.
- If you are seeing any of the following Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. If i-STAT unit locks up and are unable to insert CG cartridge into unit use ceramic conditioning cartridge to reset pins.



BLOOD SAMPLE COLLECTION: PROCEDURE FOR ARTERIAL AND VENOUS DRAWS

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrits, draw the patient’s blood as described below.

BLOOD DRAW

Completely fill a plain syringe, blood gas heparinized syringe (in the CCATT allowance standard), or a syringe with the minimum volume of heparin to prevent clotting (10 U/mL of blood). Mix a heparinized syringe by rolling it between the palms for at least 5 seconds in two directions, then invert the syringe repeatedly for at least 5 seconds. For best results, test the blood immediately. For samples measuring pH, PCO₂, PO₂, TCO₂, and ionized calcium, sample processing within 10 minutes of blood draw is acceptable; other analytes can be processed within 30 minutes of blood draw if a heparinized syringe was used. If a tourniquet is used for a venous stick, do not leave it on for more than 1 minute; do not draw blood proximal to an IV site.

CRITERIA FOR SPECIMEN REJECTION

1. There is evidence of specimen clotting.
2. Specimens were collected in vacuum tubes with anticoagulants other than lithium or sodium heparin.
3. Syringe for pH, PCO₂, PO₂, or TCO₂ has air bubbles in sample. An air bubble stuck only on the plunger will not affect the results.

PRECAUTIONS: AVOID THE FOLLOWING CIRCUMSTANCES

- Drawing a specimen from an arm with an IV.
- Stasis (tourniquet left on longer than 1 minute before venipuncture).
- Extra muscle activity (fist pumping).
- Hemolysis (alcohol left over puncture site or a traumatic draw).
- Time delays before filling cartridge.
- Exposing the sample to air when measuring pH, PCO₂, PO₂, or TCO₂.

CARTRIDGE PREPARATION FOR LOADING BLOOD SAMPLE

- Prior to using a cartridge, it must be removed from refrigerated storage and kept at room temperature in its protective pouch for at least 5 minutes.
- An entire box of cartridges must be kept at room temperature for 1 hour before a cartridge from the box can be used. Avoid condensation from forming on a cold cartridge as it may prevent proper contact with the analyzer.
- The process for loading the cartridge with blood is detailed in Appendix A.

QUALITY ASSURANCE

ELECTRONIC SIMULATORS

- The i-STAT analyzer has both an internal and external simulator to perform quality checks. Simulators mimic the signals that would be sent from a cartridge charged with blood to validate whether the analyzer is functioning properly.
- The analyzer runs a comprehensive check with the internal simulator each time a patient's blood sample is tested.
- The external simulator needs to be plugged into the analyzer where a cartridge is attached. **The external electronic simulator should be run when indicated by the i-STAT device or every 8 hours while in use. Additionally, it is recommended to run the external simulator prior to any mission and then again if the mission is over 8 hours.** The testing procedure takes approximately 120 seconds. Appendix B details how to run an external simulator.
- **Any analyzer that fails an electronic simulator check twice (internal or external) should be removed from service and turned in for maintenance.**

- The i-STAT analyzer is programmed to lock out if the internal or external simulator does not pass the quality control.

LIQUID CONTROLS

- Liquid controls, which are injected into cartridges, verify the cartridges are producing accurate results and should be used each time a new batch of cartridges is opened. Controls may also be ran if there is concern that a group of cartridges was placed in an environment outside of the storage guidelines – for example, in a place with an ambient temperature above 30°C (86°F). In particular, Level 1, 2, and 3 controls for blood gas/electrolyte/metabolite cartridges are formulated solutions that represent 3 clinically relevant levels of known pH and with known concentrations of sodium, potassium, chloride, ionized calcium, PCO₂, PO₂, TCO₂, glucose, lactate, BUN, and creatinine. Level 1 and 3 controls are typically stocked for deployed CCATs. **Note:** Hemoglobin is validated with another type of control (RNA Medical® Hematocrit Calibration Verification) that is not typically stocked for CCATs.
- Liquid controls do not need to be run if cartridges are obtained from a military treatment facility (MTF) lab that complies with this Clinical Practice Guideline (CPG). One should not assume, however, that the MTF is running controls with their cartridges.
- Consult the manufacturer’s documentation if you plan to use cartridges not listed in this CPG because you will need to obtain the proper controls and run them prior to use, as well as update the software through your local Biomedical Equipment shop.
- Appendix C describes how to run controls.

INTERNAL QUALITY CHECK

If stars (***) are displayed instead of a lab result, it means that a test failed the internal quality checks. All other reported results are accurate as long as the sample integrity is not in question. If this occurs, one can remix the tube of blood and repeat the test using a new cartridge. If the result fails to display again, draw a fresh blood sample and repeat the test. If the result is still not displayed, consider turning the device in for maintenance or call technical support.

MEDICATIONS THAT CAN AFFECT i-STAT RESULTS

- For patients administered propofol or thiopental sodium, i-STAT recommends the use of CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.
- Acetaminophen and creatine can increase creatinine measurements by 0.20—0.25 mg/dl.

DOCUMENTATION

- Document that liquid controls were used to verify a new box of cartridges on a log or on the box containing the cartridges.

- Document in the 3899L Patient Movement Record Enroute Critical Care form if a used cartridge was not stored or quality checked correctly: (1) if controls were not run for a new box of cartridges, and the cartridge was used, (2) if an expired cartridge was used, and (3) if a cartridge was used but was placed in an environment not consistent with proper storage (e.g., temperature above 30°C/86°F).

PRACTICAL ADVICE TO OPTIMIZE USE OF i-STAT IN THE DEPLOYED SETTING

- Seek arrangements permitting you to obtain extra i-STAT cartridges from MTFs if your supply chain is limited, however, they are in no way obligated to do so. If the deployed location does not have a refrigerator, it may also be possible to drop off your main store of cartridges at the MTF for temperature-controlled storage and the running of controls. Obtaining cartridges from an MTF laboratory will eliminate the need to monitor storage temperature. Some laboratories, however, do not use i-STAT, so they may only be able to store your controls and cartridges; you will still be responsible for ensuring that the liquid controls are completed.
- Consider comparing the i-STAT results with MTF derived values:
- When circumstances permit, teams are advised to perform one i-STAT test while MTF personnel simultaneously measure the same parameters on a patient.
- If the results are similar, it adds some certainty to the accuracy of the i-STAT and cartridge lot currently in use.
- Discordant results suggest a problem with the analyzer or cartridges and should prompt further investigation; the team should consider turning the device in for maintenance.
- **There is no scientific basis for determining the direction and magnitude of difference between the i-STAT 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 for subsequent measurements.

SOFTWARE UPDATES

- The sensors in the i-STAT cartridges are standardized against plasma methods used by major laboratory systems. The i-STAT is programmed with CLEW software, the coefficients of which are determined by comparing the i-STAT results to this standardization process. Due to possible changes in the manufacturing process, the CLEW software requires recalibration to avoid drift from the lab values produced by the major laboratory systems. This is why software updates are mandated twice a year.
- The i-STAT analyzer will not function with expired software. A warning will appear on the screen 15 days before the software expires.
- The i-STAT can be updated using a desktop computer or another i-STAT with current software (Appendix D).

- This method may be problematic for deployed personnel due to regulations preventing attachment of devices to government computers.
- If this method is approved by command, the software can be downloaded from the internet.
- Navigate directly to <http://www.abbottpointofcare.com/Customer-Info-Center.aspx>.
- Registration using a military email address will be required.
- The i-STAT can be updated using a second i-STAT with current software. This method may be easier in the deployed setting since it avoids the issue of having to attach a device to a government computer and does not require the internet. The second device may be obtained from another CCATT or an MTF. A step-by-step instruction set is presented in Appendix D.
- **It is recommended that deployed personnel coordinate with a nearby MTF or contact a servicing biomedical maintenance shop as needed for assistance with software updates.**

VISUAL OVERVIEW OF PROPERLY STORED EQUIPMENT



ABBOTT POINT OF CARE CUSTOMER SUPPORT

- Assistance from Abbott website.
 1. Go to <https://www.pointofcare.abbott/us/en/home>.
 2. Choose Support from the horizontal menu at the top of the page.
 3. You will need to create an account and/or log in.
- Email techsvc@apoc.abbott.com
- Call 1-800-284-0702.

FIXED (EXPECTED CLINICAL PROFICIENCY)

CCATT members are expected to be able to perform the following tasks:

1. Receive cartridge and control shipments.
2. Obtain blood specimens correctly and identify inadequate samples.
3. Perform quality controls for the i-STAT system.
4. Process blood samples.
5. Store the equipment correctly.
6. Mitigate environmental conditions (such as temperature) that can affect equipment and results.

REFERENCES

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2. Jacobs E, Vadasdi E, Sarkozi L, Colman N. Analytical evaluation of i-STAT Portable Clinical Analyzer and use by nonlaboratory health-care professionals. *Clinical Chemistry*. 1993 Jun 1;39(6):1069-74.
3. I-STAT System Manual 2016 Update, Abbott Point of Care Inc, Abbott Park, IL 60064.

APPENDIX A: PROCEDURE FOR PREPARING AND RUNNING AN i-STAT SAMPLE

Step 1: Verify the type of cartridge to use and check the expiration date. Ensure the cartridge is at room temperature.

Step 2: Power on the analyzer (bottom right button). Select option 2 to run a new lab test. You will be prompted to enter your user ID (use the last 4 digits of your SSN); hit ENTER. You will have to reenter your ID for confirmation. Then enter patient ID (last 4 of the patient's SSN, if available); hit enter. Repeat for confirmation.

Step 3: Scan the barcode on the cartridge packaging, (Figure A1); this defines for the analyzer which cartridge type is being run and it also checks the expiration date. Simply press and hold the SCAN button and point at the bar code on the cartridge packaging (Figure A1). The screen will then instruct you to insert a cartridge. You are ready to prepare the cartridge.

Step 4: Collect the blood sample. (Method is defined in *Blood Sample Collection: Procedure for Arterial and Venous Draw*).

Step 5: Tear open cartridge package and remove the cartridge, only touching edges (Figure A2). Touching the metal contacts on the top of the cartridge may affect results.

Step 6: Before injecting blood into the sample well, ensure there are no bubbles in the sample (these can affect CO₂ results).

Step 7: Fill cartridge to the appropriate fill line (Figure A3). The Chem8+ and CG4+ cartridges have fill lines that are at the beginning of the blue segment (Figure 3); CG7 and CG8+ cartridges have a blue arrow (Figure 2). Use the best flat surface on the aircraft for injection. The sample well should be about halfway full

Step 8: Seal the cartridge's sample well by rotating the well's cover and snapping it closed (Figure A4) **DO NOT press directly over the sample port**, as blood may be pressurized, potentially bursting/failing the cartridge (Figure A5). Apply pressure only at the edge of cap when sealing

Step 9: Insert the cartridge into the analyzer; results will display in 2–4 minutes. Toggle arrow buttons to view different pages of results.

Figure A1. Scanning cartridge bar code



Figure A2. Proper cartridge handling



Figure A3 Loading cartridge sample well with blood



Figure A4. Rotating cover



Figure A5. Sealing the cartridge



APPENDIX B: PROCEDURE FOR RUNNING THE EXTERNAL SIMULATOR

The external simulator (Figure 4) mimics the signals that would be sent from a cartridge to validate whether the analyzer is functioning properly. In particular, it simulates two levels of electrical signals that stress the analyzer's signal detection function both below and above measurement ranges. It provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current, and resistance from the cartridge. An analyzer will PASS or FAIL this test depending on whether or not it measures these signals within specified limits. ***The electronic simulator will fail if high relative humidity interferes with the measurements.***

If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3°C (5°F), allow the simulator and analyzer to stand in the same place for 30 minutes before inserting the simulator into the analyzer. ***Handle the simulator as little as possible to maintain its thermal uniformity and stability.***

Procedure for running the external simulator:

Step 1: Power on the analyzer (bottom right button).

Step 2: Ignore options 1 or 2 that appear on the screen and press the Menu button, then select Option 3 for Quality Test.

Step 3: A sub-menu appears; select Option 4 for Simulator.

Step 4: Scan the external simulator's barcode into the analyzer by pressing and holding the Scan button. Another option is to manually enter the number associated with the bar code.

Step 5: Insert the external simulator into the same port where cartridges are inserted with the "1" facing up (Figure 4); do not touch the contact pads. Cartridge Locked will be displayed, indicating that the simulator should NOT be removed. An attempt to forcibly remove the simulator during this cycle may damage the analyzer. It will take about 60 seconds for the test to run. PASS or FAIL will show on the screen.

- If PASS is displayed, remove the simulator ONLY after the *Cartridge Locked* message disappears from the screen.
- If FAIL is displayed, repeat the procedure with the same external simulator. If PASS displays after the second attempt, the analyzer may be used. If FAIL is displayed, repeat the procedure with a second analyzer; the analyzer may be used if PASS is displayed. If FAIL is displayed, repeat the procedure with the same, second simulator. The analyzer may be used if PASS is displayed. For a second FAIL display (using a second external simulator), the analyzer cannot be used and should be turned over to maintenance.

APPENDIX C: PROCEDURE FOR RUNNING CONTROLS

Level 1, 2, and 3 controls for blood gas/electrolyte/metabolite cartridges are formulated at three clinically relevant levels with known pH and with known concentrations of sodium, potassium, chloride, ionized calcium, PCO₂, PO₂, TCO₂, glucose, lactate, BUN/urea, and creatinine. Level 1 and 3 controls are typically stocked for deployed CCATTs.

Verifying hematocrit measurements, however, requires another type of control: the RNA Medical® Hematocrit Calibration Verification Controls. Levels 1, 3, and 5 should be run on the following cartridges: E3+, EC4+, 6+, EC8+, EG6+, EG7+, CG8+, and CHEM8+. This control is NOT typically stocked for CCATTs downrange.

Liquid controls used in a cartridge that measures oxygen concentration must stand at room temperature for a minimum of 4 hours before use; controls for other analytes only need to equilibrate at room temperature for 30 minutes. The analyzer should also stand at room temperature for 30 minutes.

Procedure for running a control:

Step 1: Put on gloves.

Step 2: Press the On button.

Step 3: Press the Menu key; then press 3 to select Quality Tests.

Step 4: Press 1 to select Control.

Step 5: You will be prompted to scan or manually enter the Operator ID and Control Number. It may be convenient to enter 1 as the operator ID for a level 1 control and 3 for a level 3 control; this may make it easier when comparing the results to the *Value Assignment Sheet*.

Step 6: Press Scan to scan the barcode cartridge lot number.

Step 7: Remove the cartridge from the package, taking care to handle it only along the edges, otherwise the results may be affected. Place the cartridge on a flat surface.

Step 8: Shake the control ampule (Figure C1) hard 15–20 times (for at least 10 seconds) and then tap the ampule to restore the liquid to the bottom of the ampule.

Step 9: Open the ampule by snapping off the tip. Protect fingers with gauze or use an ampule breaker.

Step 10: Immediately transfer control to syringe as follows: use a clean 3 mL syringe. Replace attached needle with a 19-gauge blunt tip needle, if available, for safety. Avoid drawing air bubbles into the syringe.

Step 11: Immediately expel 3 drops of control on a pad/gauze and then fill cartridge to the fill line and seal the cartridge (see Appendix A for details). Aqueous-based solutions such as controls do not

Figure C1. Level 1 and 3 ampules



have the buffering capabilities of whole blood; therefore, once opened, they must be immediately transferred to the cartridge (unlike with a patient's sample).

Step 12: Do not use the solution left in a syringe or ampule for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO₂, or PO₂; a new ampule must be used.

Step 13: Insert cartridge into the analyzer; do not remove until *Do Not Remove Cartridge – Cartridge Locked* message is gone.

Step 14: Control Evaluation. Compare the results to the *Value Assignment Sheet*. If any result is out of range, repeat the control testing with a fresh ampule and syringe. If any result is still out of range, do not use any of the cartridges from this lot. *Value Assignment Sheets* are obtained from the Abbott Point of Care website (<http://www.abbottpointofcare.com/Custom-Info-Center/Value-Assignment-Sheets.aspx>). You will need to know the CLEW version on your device and the lot number of the control solution you used.

Note: *Correction of PO₂ value is required when running controls at locations more than 1000 feet above sea level. Use the barometric pressure reading from the i-STAT status screen and the following formulas:*

- For PO₂ values < 150 mmHg: for every decrease of 15 mmHg in barometric pressure from 760 mmHg, add 1 mmHg to observed PO₂ value.
- For PO₂ values > 150 mmHg for every decrease of 35 mmHg in barometric pressure from 760 mmHg, add 1 mmHg to observed PO₂ value.

APPENDIX D: UPDATING I-STAT CLEW SOFTWARE USING I-STAT DEVICE

We recommend that biomedical maintenance perform this procedure, if possible.

The sensors in the i-STAT cartridges are standardized against plasma methods used by major laboratory systems. The i-STAT is programmed with CLEW software, the coefficients of which are determined by this standardization process. Due to possible changes in the manufacturing process, the CLEW software requires recalibration to avoid drift from major laboratory systems. This is why software updates are mandated to occur twice a year.

Step 1: Be certain both i-STAT 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 approximately 1 foot apart.

Step 4: Turn on the sending device, press Menu, and select option 7 for Utility.

Step 5: Press ENT when prompted for a password.

Step 6: In the utility menu press 1 for Send Software.

Step 7: Press 1 for JAMS###/A##.

Note: the numbers have been replaced with # in this example; they will change with each software update.

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*. Do not lift it off the flat surface.

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.