I-STAT 1 SYSTEM

Portable Clinical Analyzer for Measurement of Blood, Electrolytes, Gases, Ionized Calcium

PROCEDURE MANUAL

UCSF

PEDIATRIC NEONATAL EMERGENCY TRANSPORT SERVICE

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1.0 PURPOSE

To provide the Pediatric Neonatal Emergency Transport Service with the capability of performing blood gas and electrolyte analysis on a few drops of blood in any environment outside of a hospital laboratory.

2.0 PRINCIPLE

The i-STAT1 system is a battery powered portable analyzer that utilizes single-use disposable cartridges to analyze blood gases and electrolytes. When a cartridge is inserted into the analyzer, i-STAT1 controls all functions of testing including fluid movement, calibration, testing of patient sample and continuous quality monitoring. Results are displayed in 120 seconds. The i-STAT1 contains a microprocessor that is programmable and able to store user passwords, 6000 patient and control test records.

Each cartridge contains microfabricated sensors, calibrant solution, fluidics system, and a waste chamber. i-STAT runs a calibration on each cartridge before testing patient sample. No patient results are reported if calibration fails.

The Pediatric Transport Service utilizes the EG7+ to measure the following analytes at 37^{o} C: pH, pCO2, pO2, Sodium, Potassium, and ionized Calcium. I-STAT calculates and displays the following calculated values: BE_{ecf}, HCO3, TCO2, sO2 and pH, pCO2, and pO2 corrected to patient's temperature.

3.0 EQUIPMENT AND REAGENTS

3.1 i-STAT1 ANALYZER

Parts of the Analyzer

- Display Screen: Displays test and administrative menu, user entry prompts, and test results; use arrow keys to scroll between prompts and pages
- Keypad
    - Scan key: press when scanning user I.D.
    - ABC Key
    - ← → Arrow keys: use to scroll through alphabet, to clear data entry errors or to scroll up or down display
    - Numeric keypad
    - 0 key: press to backlight the display
    - Period key
    - Enter key: Press to accept data entry.
    - Menu key: Access to Test Menu and Administration Menu
    - ON/OFF Key: i-STAT1 is also activated whenever a cartridge is inserted
    - Print Key
- Infrared communication window is located at the top end of the analyzer.
- Barcode scanner is located at the top end of the analyzer.
- Battery compartment is located on the back of i-STAT1. i-STAT is powered by two 9-volt Lithium batteries. Battery status is displayed by pressing Menu, Administrative Menu, and 1-Analyzer Status. I-STAT conserves battery power by automatically shutting down after 2 minutes of inactivity.
- Cartridge port is located in the bottom end.

I-STAT is programmed to verify analyzer performance with an internal Electronic Simulator every 8 hours. The daily internal QC is triggered when i-STAT1 is activated. I-STAT1 will not lock the testing cartridge until it has passed the internal Electronic Simulator. Internal Electronic Simulator adds an additional 20 seconds to the testing process.

I-STAT1 operates in an ambient temperature of 18 to 30° C. The analyzer shuts downs and does not allow testing if the ambient temperature exceeds this range. Analyzer Status and data review functions are accessible at this time. Press Menu key, and "1-Analyzer Status" to display ambient temperature. Take corrective action by moving i-STAT1 to an ambient temperature of 18 to 30°C.

Three times a year or when necessary, I-STAT sends software upgrades with changes to the CLEW standard and Central Data System. Software on each analyzer must be upgraded before the current software expires. I-STAT shuts down and will not allow testing after the software expiration date.

3.2 CARTRIDGES

Cartridges are sealed in individual pouches and packaged 25 to a box. Cartridges must remain in its individual pouch until needed. Use the cartridge within 5 minutes of removal from its pouch.

Store the main supply of cartridges in the refrigerator at temperatures between 2-8° C until its expiration date. DO NOT ALLOW CARTRIDGES TO FREEZE. Freezing will cause higher than expected ionized Calcium test results.

Cartridges may also be stored at room temperatures up to 30° C or 86 ° F for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature. Mark the margins of individual pouches with the 14-day expiration date. Do not use if room temperature exceeds 30° C or beyond the expiration date.

New cartridges are shipped overnight at 2-8° C with a temperature monitor. The monitor contains 4 windows label A/1, B/2, C/3, and D/4 representing temperatures from 2 to 34° C. Accept shipment if only the "A/1" window is in color. Reject shipment if windows B, C, or D are colored. Notify i-STAT immediately if shipment is unacceptable.

Each shipment of cartridges must be tested with 3 levels of aqueous liquid controls before they can be used. Consult control package inserts for acceptable range.

Refrigerate each new shipment immediately.

3.3 I-STAT CONTROLS

3.31 External Electronic Simulator

The external Electronic Simulator verifies analyzer performance. It simulates two levels of electrical signals that stress the analyzer's signal detection function both below and across the measurement ranges.

Use the external Electronic Simulator when i-STAT fails the internal Electronic Simulator and if the analyzer is dropped or damaged.

Store the Electronic Simulator at room temperature. Protect the contact pads from contamination by replacing the plastic cap each time and store in its protective case.

Use the external Electronic Simulator to test i-STAT's thermal probes twice a year.

3.32 I-Stat Aqueous Controls

Store i-STAT levels 1, 2, and 3 controls in the refrigerator at 2-8° C. Each box contains one level of 10 ampules and is shipped on ice. Controls may be stored at room temperature up to 30° C for 5 days.

Package insert for controls can be obtained on the Abbott website (www.abbottpointofcare.com/istat). Acceptable ranges are listed for specific i-STAT Software Version, CLEW Standard, cartridge type and cartridge lot. Call i-STAT technical services for acceptance range if any of the above is not listed on the package insert.

Equilibrate controls at room temperature for 4 hours before use.

3.4 MARTEL PRINTER

Re-chargeable Lithium Battery supplies power to the printer. Turn off printer before recharging. Power is conserved after 2 minutes of inactivity.

Printer communicates with i-STAT1 via infrared light located next to the power switch. Align i-STAT infrared window with both infrared lights before printing. Printer uses thermal paper that fades with light exposure and is therefore not acceptable as a permanent chartable record.

I-STAT1 program must be customized to communicate with printer. See Customization Worksheet.

3.5 IR LINK

The IR Link is a docking station that allows i-STAT to communicate with other devices. An IR Link connect to the PC with the Central Data System allows i-STAT to communicate with the computer.

4.0 SPECIMEN REQUIREMENTS

4.1 MINIMUM VOLUME

The EG7+ cartridges require 0.1mL of blood. Draw 0.2 mL if using a 1 mL blood gas syringe. Total volume of blood gas capillary tube is 0.14 mL. Fill 80% of the capillary tube with blood sample.

4.2 ACCEPTABLE SPECIMENS

- Arterial samples collected in blood gas syringe with lithium or balance Heparin as anti-coagulant.
    1. Arterial samples collected by venipuncture.
    2. Arterial samples collected from an indwelling line requires withdrawing a discard syringe equivalent to three to six times the volume of the line, catheter and needle before drawing a sample that is representative of the patient.
- Arterial samples collected in blood gas syringe without anti-coagulant must be analyzed immediately.
- Capillary Samples collected in blood gas capillary tubes with lithium or balance Heparin as anti-coagulant. Follow Pediatric Neonatal Transport Service Nursing Procedure, “Skin Puncture for Blood Sampling and for Blood Gas Analysis in Neonates and Infants” for blood collection.
    1. Avoid drawing air into the capillary tube. Sample may not contain air bubbles.
    2. Avoid repetitive squeezing of the collection site.
    3. Test sample immediately.

4.3 CRITERIA FOR SAMPLE REJECTION

- Sample collected in a vacutainer tube
- Sample collected in anticoagulant other than lithium or balance Heparin
- Sample contains air bubbles or clots.
- Sample volume less than 0.1 mL.
- Sample collected in a blood gas syringe but left uncapped and not tested immediately
- Sample collected in capillary tube and not tested immediately.

5.0 DAILY MAINTENANCE

Follow procedure in PNETS i-STAT QA Binder.
Check Analyzer Status Daily

1. Press ON.
2. Press Menu
3. Select Analyzer Status
4. i-STAT displays the following:
    - Temperature
    - Barometer Pressure
    - Battery
    - Number of uses
    - Analyzer serial number
    - CLEW Std
    - Software Version

Battery check

1. Check battery status daily.
2. Press On/Off key.
3. Press Menu key.
4. Select 1 for Analyzer Status
5. Read and record Battery status on daily log.
6. If the battery status is $\leq$ 7, replace ***both*** batteries. Do not mix old and new batteries.
7. Press Menu to exit screen.
8. Document in Daily Maintenance Log.

Temperature

1. Read and record ambient and refrigerator temperature.

Examine infrared window. Clean i-STAT1 with damp gauze, moisten with 10% bleach if necessary. Do not use alcohol on display screen.

6.0 QC PROCEDURE

6.1 QC POLICY

I-STAT automatically verifies the performance of each analyzer every 8 hours with an internal Electronic Simulator. Use the External Electronic Simulator whenever the internal simulator fails, if the analyzer has been dropped or damaged, if ambient temperature exceeded 30^{o} C, if remedial action is warranted, and for biannual verification of analyzer Thermal Probe.

Once a week, test cartridges with Levels 1, 2, and 3 aqueous controls on one iSTAT to verify storage conditions. The iSTAT used for QC should be rotated weekly. Values that are outside the manufacturer's acceptance range must be repeated and corrective action documented.

Test each shipment of i-STAT cartridges with i-STAT Levels 1, 2, and 3 aqueous controls. Accept cartridge shipment if results are within the manufacturer's acceptance range

6.2 INTERNAL ELECTRONIC SIMULATOR

The internal Electronic Simulator is programmed to run every 8 hours. It automatically runs whenever i-STAT is activated. Results are stored as PASS or FAIL and may be viewed by selecting Database from the Menu.

1. Corrective action for FAIL
    - Repeat with external Electronic Simulator.
    - If external Electronic Simulator fails, call i-STAT Technical Services.
    - Document in Daily Maintenance Log and notify manager.
    - Take i-STAT1 out of service.

6.3 EXTERNAL ELECTRONIC SIMULATOR

1. i-STAT will power on when external Electronic Simulator is inserted.
2. i-STAT may also be powered on by pressing the ON/OFF key.
    a. Press Menu.
    b. Select 3-Quality Control
    c. Select 4-Electronic Simulator
    d. Follow prompts
3. Scan or enter user I.D.
4. Remove blue protective cap on Electronic Simulator.
5. Insert Simulator when prompted.
6. "Simulator Locked" is displayed. *DO NOT REMOVE* until "Locked" disappears.
7. i-STAT displays either PASS or FAIL.
8. Remove when prompted by analyzer.
9. Corrective action for FAIL external Electronic Simulator
    - Repeat external Electronic Simulator on same analyzer
    - Repeat on second i-STAT analyzer.
    - If the first analyzer again fails, take it out of service.
    - If both analyzers fail, Electronic Simulator pins may have been damaged.
    - Document in Daily Maintenance Log.
    - Notify manager.
    - Call i-STAT Technical Services at 1-800-366-8020 immediately.

6.4 AQUEOUS CONTROLS

6.41 Handling Aqueous Controls

1. Aqueous controls are stored in the refrigerator at 2 to 8^{o} C.
2. Controls may also be stored at room temperature up to 30^{o}C for 5 days.
3. Equilibrate controls at room temperature for a minimum of 4 hours before use.
4. Use a 1cc syringe and a 16-20 gauge needle to aspirate controls.
5. Aspirate control within 60 seconds after opening ampule.

6.4 i-STAT Menu

1. Press ON/OFF key to power i-STAT on.
2. Press Menu
3. Select Quality Control
4. Enter user I.D.
5. Follow prompts for entering control lot number and control level.

6.43 Testing Controls

1. Remove cartridge from its pouch. Do not touch contact pads.
2. Hold control between index finger and thumb and shake control vigorously from end to end for 10 seconds to equilibrate the solution and gas mixture. Avoid warming the ampule. Do not hold in your palm.
3. Gently tap to restore solution to the bottom of the ampule and to allow bubbles to rise to the top.
4. Cover ampule with a piece of gauze and snap open.
5. Immediately insert a syringe fitted with a 18-20 gauge needle into the bottom of the ampule.
6. Slowly aspirate approximately 1 mL of solution from the bottom of the vial. Do not aspirate any air bubbles.
7. Do not attempt to remove dead space from top of the column of solution. Remove the needle and expel one or two drops from the syringe before filling the cartridge.
8. Place syringe tip over sample well.
9. Dispense sample to the fill mark.

10. Close cover over the sample well until it snaps into place. Do not exert pressure over the sample well.
11. Insert cartridge into the i-STAT cartridge port when prompted.
12. Review displayed results.
13. Compare results to acceptance range. Document in QC Log.
14. Document controls on new cartridge shipment in New Cartridge Receipt Log.
15. Repeat procedure with Level 2 and Level 3 controls.

6.44 Corrective Action

1. Before repeating with a new ampule of control, review the following:
    - Ensure that the acceptance range on QC Log is for the appropriate cartridge lot.
    - Ensure that the CLEW software on the package insert is the same as the CLEW version on the analyzer.
    - Press Menu and select Analyzer Status to view i-STAT software version and CLEW Std.
    - Identify Cartridge lot number on control insert.
2. Call i-STAT Technical Services for acceptance range if the analyzer CLEW Standard and/or Cartridge lot number is not listed on the package insert.
3. Repeat control with a new ampule after equilibrating it at room temperature for 4 hours
4. Review control technique with i-STAT trainer and/or POCT coordinator. pO2 failure is usually due to poor technique.
5. If new shipment of cartridges fails to pass any level of aqueous control after repeat testing, sequester lot with a "Do Not Use" note. Document in Maintenance Log and notify i-STAT and manager immediately.

6.5 NEW SHIPMENT OF CARTRIDGES

6.51 Acceptance Criteria

- Temperature of cartridge shipping containing does not exceed 8^{o}C. Only window A/1 of Temperature Monitor is colored. Windows B/2, C/3, and D/3 are colorless. Document shipping temperature on Monitor card.
- Results of testing with all levels of i-STAT aqueous controls are within the manufacturer's acceptance range. Document results on New Cartridge Shipment Log.

6.52 Criteria for Rejection

- Windows B, C, or D of Temperature Monitor is blue. This is an indication that shipping container temperature has been compromised.
- Results of any level of i-STAT aqueous controls are outside of the manufacturer's acceptance range.
- Document results on New Cartridge Shipment Log and corrective actions taken.
- Quarantine lot of cartridges. Write "Do Not Use" on box.
- Notify unit manager and POCT coordinator.
- Notify i-STAT customer service as soon as possible.

7.0 PATIENT TESTING PROCEDURE

7.1 HANDLING THE CARTRIDGE

1. Cartridge must be at room temperature for a minimum of 5 minutes.
2. Remove cartridge from its pouch without touching the contact pads or exerting pressure over the center of cartridge.
3. Blood samples must be thoroughly mixed by rolling between the palms in 4 planes for 15 seconds.
4. Direct syringe tip or capillary tube containing the sample over the sample well.
5. Dispense sample until it reaches the fill mark. Sample must be dispensed without a break in one application.

6. Inspect and discard if air bubbles are present.
7. Close cover over the sample well until it snaps into place. Do not exert pressure over the sample well.

7.2 PROCEDURE USING THE CARTRIDGE INSERTION MODE

1. Insert cartridge into the i-STAT cartridge port.
2. Follow displayed prompts.
3. Enter user I.D. by pressing on scan key and scanning user barcode.
4. You may also use the ABC key and numeric keyboard to enter user I.D.
5. Press ENTER to accept.
6. i-STAT1 does not allow correction of an accepted entry. To modify a mistake, enter correction into data Field 3.
7. Do not remove cartridge when "Locked" is displayed.
8. Enter additional information.
    a. Field 1: enter sample type, source and patient temperature using codes provided.
    b. Field 2: Enter ventilation parameters using codes provided.
    c. Field 3: Additional information
9. Test results are displayed on several screens.
10. Use arrow key to scroll between screen pages.
11. Remove cartridge when "Locked" is no longer displayed.

7.2 PROCEDURE USING INFORMATION PRE-ENTRY MODE

1. Press ON/OFF key to turn i-STAT on.
2. Select 2-i-STAT Cartridge.
3. Enter operator I.D. by pressing the Scan key and scanning user barcode.
4. You may also use the ABC key and numeric keyboard to enter user I.D.
5. Enter patient I.D. using the ABC key.
6. Press ENTER to accept. i-STAT1 does not allow correction of an accepted patient I.D.
7. To modify a mistake, enter correction into patient data Field 3.
8. Insert filled cartridge.
9. Do not remove cartridge when "Locked" is displayed.
10. Enter additional parameters.
    a. Field 1: enter sample type, source and patient temperature using codes provided.
    b. Field 2: Enter ventilation parameters using codes provided.
    c. Field 3: Additional information
11. Test results are displayed on several screens.
12. Use arrow key to scroll between screen pages.
13. *Do Not Remove* cartridge when "*Locked*" is displayed. Remove after Locked disappears.

7.3 PRINTING RESULTS

1. Turn on printer.
2. Align printer's infrared window with that of i-STAT1.
3. Press print key on analyzer.
4. Do not move analyzer or printer until the printout is completed.
5. i-STAT prints pH, pCO2, and pO2 and electrolytes measured at 37^{o} C, gases corrected for patient's temperature entered in Field one, and calculated values.
6. Document results.

7.4 RECALLING RESULTS

1. i-STAT displays last results when it is powered on.
2. Select 1-for last results from Main Menu.
3. Press Menu key to view previous patient or control results.

8.0 REPORTING RESULTS

Results are displayed numerically with reporting units. Document test results in Patient Transport Record.

8.1 SUPPRESSED RESULTS

Three conditions in which i-STAT will not display results:

1. Results flagged with < or > are outside of the reportable range.
2. Results with <> flag indicates the results for this test is dependent on test flagged with either < or >.
3. *** Results are not reportable due to failed internal QC. Repeat test with a fresh sample and new cartridge.
4. Quality Check message is displayed if analyzer detects problems with sample, cartridge and/or analyzer.

8.2 REFERENCE RANGE MEASURED @37° C

Analyte	Age	Arterial	Venous (all ages)
pH		7.35 to 7.45	7.31 to 7.41
pCO2 (mmHg)	0-1 year	35 to 45	41 to 51
	>1 year	32 to 48	
pO2 (mmHg)	0-30 days	80 to 100	35 to 40
	> 30 days	83 to 108	
Na+ (mmol/L)		136 to 146	
K+ (mmol/L)	0- 6 months:	3.0- to 5.4	
	> 6 months	3.4 to 4.5	
iCA++ (mmol/L)	0- 6 months:	0.95 to1.50	
	> 6 months	1.15-1.29	
Calculated Parameters			
HCO3 (mmol/L)		22-27	
BE		-3 to +3	
TCO2		22-29	
O2 Sat		≥ 95-99	

8.3 PANIC VALUES, REPORTABLE RANGE AND I-STAT DISPLAY RANGE

Analyte	Panic Values	Reportable Range	i-STAT Display Range
pH, Arterial	<7.20 or >7.55	6.8 to 8.0	6.5 to 8.0
pH, Venous	<7.20		
pCO2, Arterial	<25 or >65 mmHg	10 to 79	5 to 130
pCO2, Venous	>75 mmHg		
pCO2, Venous	>75 mmHg		
Adult pO2	<40 mmHg	40 to 400	5 to 800
Neonatal Arterial pO2	<40 or >100 mmHg		
Na+	<125 or >155 mmol/L	100 to 180	100 to 180
K+	<3.0 to >6.0 mmol/L	2.0 to 8.0	2.0 to 9.0
iCA++	<0.80 or >1.55 mmol/L	0.6 to 1.6	0.3 to 2.5

9.0 PROCEDURE NOTES

9.1 I-STAT BATTERY

I-STAT requires two 9V disposable Lithium batteries. Do not mix old and new batteries. You must replace both. In an emergency, you may instead use two-9V alkaline batteries, which drains quickly.

- Low Battery

1. Battery status is displayed when you press Menu and Analyzer Status. Replace batteries when battery status is </= 7 volts.
2. i-STAT displays a low battery message if it is activated by pressing the ON key.

3. When i-STAT is activated with an inserted cartridge, it will ask you to remove the inserted cartridge before displaying the low battery message.
4. If the low battery message is display after insertion of new batteries, remove batteries from the holder and check alignment of contact points.

- Replacing Batteries

1. Battery door is located next to Infrared window.
2. Ensure that the i-STAT is on OFF.
3. Open the door by sliding it away from the analyzer.
4. Remove the battery holder keeping the contact points clean.
5. Remove each battery by pulling it down away from the holder.
6. Write the replacement date on the new i-STAT batteries.
7. Insert new batteries with the battery contacts in the down position.
8. Re-insert battery holder into the i-STAT ensuring that the holder contact pads are aligned with those in the analyzer.
9. Press down on the battery holder and slide the door back in.
10. i-STAT ***will not work without*** the door.
11. Document battery change on the Daily Maintenance Log.

9.2 ALPHA NUMERIC KEYS FOR DATA ENTRY

I-STAT defaults to the numeric keypad. Access the Alphabet by pressing on the ABC key. Search for desired alphabet by using either the left arrow or right arrow keys.

Using Alpha Keys

1. Press ABC key.
2. Press Left arrow key to start with the letter Z or the right arrow key to start with the letter A.
3. Press the arrow key until you see the desired letter.
4. Press ABC key to accept selected letter.
5. Press ABC key again to enter the next letter.
6. Use the left arrow key to correct an entry error.
7. Press ABC to return to numeric keyboard.
8. Press the ENTER key to accept entered I.D.
9. Do not press ENTER key until you have completed I.D. entry. *You cannot correct patient I.D. once it is accepted.*
10. If you make a mistake, enter correction into the patient data Field 3.

9.3 MARTEL PRINTER

1. i-STAT1 is programmed to recognize the printer. See Customization Worksheet.
2. Printer operates on re-chargeable Lithium Battery.
3. Power switch is located on the side.
4. Power light becomes green when it is turned on. Printer power is conserved after 2 minutes of inactivity and green light goes off. If the printer is in the conserved power mode, it can be activated by the print function on the i-STAT.
5. Status light indicates when the printer is out of power and the print process slows down. When the status light becomes orange, recharge on the Charger. Charger connector is located to the left of the power switch.
6. Turn off power on the printer before recharging. Printer *will not* recharge if the power is on.
7. Infrared window is located on the side of the printer next to the power switch. Align it with the infrared window on the i-STAT 1 before pressing the i-STAT print key.
8. Printer uses thermal paper.

9.4 RECALLING AND PRINTING RESULTS

I-STAT 1 stores 6000 patient and quality control test records.

1. Main Menu
   Press the ON key to view last result. Last result may also be viewed on the Main Menu by selecting 1-Last Result.
2. Administrative Menu
   Press Menu Key to view Administrative Menu
   Select 2-Data Review
   1-Patient: review patient history by I.D.
   2-Controls: liquid control data
   3-Proficiency
   4-Cal Ver
   5-Simulator
   6-All: displays results of all samples, record number displayed/total number of records, press 2 to view previous record
   7-List: List all test by time, date, and patient I.D. Select a record number to review or print an individual blood gas.

9.5 I-STAT THERMAL PROBE PROCEDURE

I-STAT analyzer contains a thermal control system that maintains testing temperature at 37^{o}C. A precise measurement of the temperature cannot be taken during the testing cycle. Use the Electronic Simulator to check the stability and accuracy of probes over the operational analyzer range biannually.

- Analyzer Procedure

1. Ambient temperature of i-STAT1 and Electronic Simulator is within 3^{o} C of each other.
2. Press Menu, select Quality Control, and Electronic Simulator.
3. Insert Simulator when prompted.
4. When PASS result is displayed, press the period key.
5. i-STAT displays the difference between thermal probes.
6. Acceptance Criteria: Thermal Difference between probes is within $\pm$ 0.1^{o} C.
7. Unacceptable results
   a. Difference between probes is greater than $\pm$ 0.1^{o} C.
   b. FAIL appended with either a “T”, difference exceeds 0.25 ^{o} C or “t “average difference exceeds $\pm$ 0.1^{o} C
   c. Value of “_._” indicates unstable temperature reading. Wait 15 minutes for i-STAT and External Simulator to warm to ambient temperature before repeating.

- Verification of Thermal Probe may also be viewed on Central Data Station report after downloading the analyzer.
  - Click on Data Viewer.
  - Select Record in Menu Task Bar
  - Select Extended Electronic Simulator Report
  - Review Probe Delta, external Simulator.
  - Results other than “_._” are considered in compliance.

9.6 ANALYZER SOFTWARE UPGRADE

i-STAT makes continuous manufacturing process improvements that necessitate re-establishing standardization values to maintain long-term consistency. by recalibrating the analyzer. This is accomplished by software upgrades that adjust the calibration on the analyzer. The manufacturer sends out software upgrades three times a year. Included in the packet are instructions and Technical Bulletins related to changes. Software on all i-STAT1 analyzers should be upgraded at the same time and before the current software expires.

- Upgrading Software Using The Central Data System
  1. Review iSTAT Technical Updates for changes. File updates.
  2. Follow procedure and install software in PC.
  3. Place i-STAT in IR Link.
  4. Transmit i-STAT test data to PC.
  5. Follow procedure for installing software.
  6. Repeat procedure for other analyzers.
  7. After software upgrade, test with Electronic Simulator.
  8. Document software upgrade on Software Log.
  9. Run an Electronic Simulator Test on each analyzer.
  10. Review aqueous control package insert usually included in the Technical Bulletin packet. Identify Jams Version, CLEW Std, Cartridge Type, and current Cartridge Lot number.
  11. If new control acceptance ranges are different, modify acceptance range on QC Log.
  12. If new version is not listed on aqueous control package insert, call i-STAT Technical Services for new control acceptance range.

- **Upgrading Software Using An Analyzer With Updated Software**

  Transmit all data from i-STAT1 being upgraded.
  On sending i-STAT1, press Menu.
  elect Utility from Administrative Menu.
  Enter password when prompted.
  Select 1-Send Software.
  Select 1-JAMS and CLEW or 2-CLEW Std. "Waiting to Send" is displayed.
  Ensure receiving i-STAT is OFF.
  Place both i-STATs one foot apart and align their infrared windows.
  Adjust position until the sending i-STAT displays "Sending" and a scrolling banner appears on the receiving i-STAT1.
  Do not move until the sending i-STAT1 display returns to the Send Software option with the message "Successful" or "Unsuccessful".
  Select Analyzer Status on the receiving i-STAT1 and verify new JAMS and CLEW Std.
  Test receiving i-STAT1 with external Electronic Simulator.
  Document in Software Upgrade Lot.

10.0 PRECAUTIONS

Cartridges are affected by freezing and should be stored at 2 to 8^{o} C. Freezing causes ionized calcium in the calibrant to precipitate resulting in falsely elevated values.

Sources of error can arise from improper collection and handling of blood sample. If sample is drawn from an arterial line, an adequate volume must be discarded before drawing a sample that is representative of the patient. If sample is not tested immediately, it must be well mixed just prior to testing.

Room air contamination may compromise samples, especially in samples with very low or high pO2 content. Air contamination may be avoided by expelling any air bubbles in the syringe immediately after drawing the sample. Samples collected in blood gas capillary tube with air bubbles will interfere with pO2 measurement and must be discarded.

Hemodilution associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies may cause clinically significant error on pH and electrolyte

results. These errors are associated with solutions that do not match the ionic characteristics of plasma.

11.0 REFERENCES

i-STAT System Manual, 01/25/2005

i-STAT Software Upgrade Technical Bulletins

UCSF Clinical Labs Laboratory Manual

12.0 APPENDIX

12.1 I-STAT 1 ANALYZER MENU

Main Menu
1-Last Result
2-i-STAT Cartridge

Press Menu for Administrative Menu

1-Analyzer Status
    Displays: Temperature, Barometric Pressure, Battery Status, Number of stored test records, Analyzer Serial #, CLEW Standard, and Software Version
2-Data Review
3-Quality Test
4-Customization allows operator to customize i-STAT1 program.
5-Set Clock requires key operator password.
6-Transmit Data
7-Utility requires key operator password.

Press Menu Key to return to Administrative Menu

12.2 I-STAT 1 CUSTOMIZATION MENU

Each analyzer may be individually customized key operator or through the Central Data System. Customization is password protected. However, operators may view settings by selecting 1-View which does not require Key Operator password.

1. Press Menu Key.
2. Select 4-Customization on Administrative Menu.
3. 4-Customization Menu
   1-View
   2-Customize
4. Select 1-View to review customization.
5. Select program to be reviewed.
6. Press menu to return to Administrative Menu.

Summary of i-STAT Customization
    1-Analyzer
        Date Format-mm/dd/yy
        Sound enabled
        Auto-transmit enabled
        Memory Full Allow Test
        Inactivity Timeout 120 seconds
        Uploader Schedule 744 hours Warn User
        Printing Protocol, disabled
        Clock Password enabled

2-I.D. Entry
- 1-Operator I.D.
  - Minimum Length 5 digits
  - Maximum Length 8 digits
  - Repeat I.D. disabled.
  - Manual entry No check digit
  - Codes: Enable all
- 2-Patient I.D.
  - Minimum Length 2 digits
  - Maximum Length 15 digits
  - Repeat I.D. disabled
  - I.D. Recall disabled
  - Manual entry No check digit
  - Codes: Enable all
- (Left arrow to return to Customization Menu)

3-Patient Tests
Cartridge information and Cartridge lot not required.
4-QC Tests
Ext Simulator disabled, Int Simulator 8 hours, Int Simulator Schedule Option, Lock out
5-Results