

DEPMEDS LABORATORY PROCEDURES
DEPARTMENT OF CLINICAL SUPPORT SERVICES
U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
FORT SAM HOUSTON, TEXAS 78234-6137

MCCS-HC

STANDARD OPERATING PROCEDURE

1 November 2002

i-STAT Clinical Analyzer

1. PRINCIPLE:

The i-STAT handheld Analyzer utilizes i-STAT cartridges for the in vitro quantification of various analytes in human blood, including: blood gases, pH, electrolytes, glucose, BUN, creatinine, hematocrit, lactate and activated clotting time. Analysis requires 2-3 drops (65 or 95 ul) of whole blood which the portable, battery powered Analyzer tests and displays quantitative results in approximately 2 minutes. The single use cartridge contains calibrating solution, a sample handling system and all the sensors for the completion of tests. The Analyzer automatically controls all steps in the testing cycle to including fluid movement within the cartridge, calibration, continuous quality monitoring, and thermal control (for tests where it is required). This eliminates many sources of error as well as time consuming and costly steps inherent in other methods.

Quality control is performed on the Analyzer by an electronic simulator, which checks the non-disposable components of the I-STAT system. Testing of actual control samples provides a final full check of the total analyzer system.

2. SPECIMEN:

- a. Use only fresh whole blood samples from skin (capillary), venous or arterial sites, either without anticoagulant or with balanced lithium or sodium heparin anticoagulant for later testing. Blood samples used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status.
- b. Test sample immediately after draw. Samples drawn without anticoagulant must be tested within 3 minutes and those with anticoagulant within 10 minutes. If testing is delayed, remix by rolling between fingers and discard the first drop of blood.

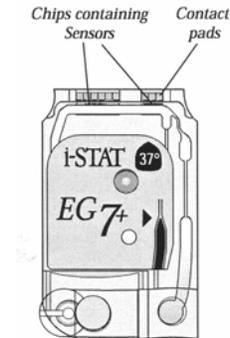
3. REAGEANTS AND MATERIALS:

- a. i-STAT Portable Handheld Analyzer
- b. Cartridges
- c. Portable printer



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- d. Electric Simulator
- e. Control Solution Levels 1,2, and 3
- f. Calibration Verification Set (5 Levels)
- g. Two 9 volt lithium batteries (analyzer)
- h. IR Interface Link
- i. Transfer pipettes
- j. Capillary tubes
- k. 1 cc syringes with needle no smaller than 20 gauge
- l. i-STAT printer cradle
- m. Four 1.5 volt alkaline AA batteries (printer)



4. SLIDE STORAGE AND PREPARATION:

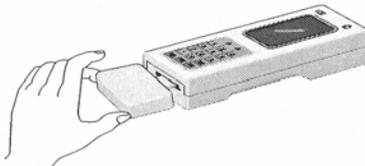
- a. Store cartridge between 2-8 °C (35-46 °F) until expiration.
- b. Cartridges may be stored at room temperature 18-30 °C (64-86 °F) for 14 days. Use calendar on cartridge box to annotate when the 14 day room temperature expiration occurs.
- c. All cartridges measuring PO₂ must remain at room temperature for 4 hours before use. Entire boxes should stand at room temperature for 1 hour.
- d. All other cartridges not measuring PO₂ may be used after 5 minutes at room temperature.
- e. The cartridge must be used immediately after removing it from the pouch.
- f. Cartridges containing tests which require thermal control are identified by the ^{37°} symbol on the box or cartridge.
- g. Reference fluid stored at 2-8 °C (46 °F) is stable until the expiration date. Warm fluid to room temperature for 30 minutes before use.

5. QUALITY CONTROL:

- a. Perform electronic simulator checks on each analyzer once per day and record test and results in QC Log.



- (1) The Electronic Simulator is inserted into the cartridge port of the analyzer to verify the electrical measurement.
- (2) Verify the performance by initializing a quality test at two- signal levels.
- (3) A PASS/FAIL message indicates whether the analyzer's measurements are within specification.
- (4) Electronic Simulator is not a substitute for not running controls or performing calibration checks.
- (5) If a FAIL message appears in the display window on the analyzer, repeat the test. If the instrument still fails, document the failure on the problem action log, contact the supervisor and use another instrument.



- b. Wet quality control is done by using three iSTAT control levels. Use all three controls with each cartridge type and one analyzer once per day of testing and record results in the QC Log.

- (1) Aqueous assayed control fluids used to verify the integrity of newly received cartridges.
- (2) i-STAT level 1,2, and 3 controls are formulated at three clinically relevant levels with known pH, and with known concentrations of Na^+ , K^+ , Cl^- , Ca^+ , CO_2 , O_2 , urea, Glu, and Crea.

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- (3) The aqueous control solution is contained in a 1.7 ml glass ampules.
- (4) Store control solution between 2-8 °C (35-46 °F) until expiration.
- (5) Control solution may be stored at room temperature 20-30 °C (68-86 °F) for 5 days.
- (6) Prolong storage temperature greater than 30 °C may cause changes in the values of some analytes.

NOTE: Do not use beyond the expiration day.

- (7) Prior to using cartridges that measure oxygen (G3+, EG6+ or EG7+), ampules should stand at room temperature for 4 hours before use.
- (9) When testing other cartridges not measuring oxygen (Glu, Crea, EC3+, EC4+, EC6+, 6+, or EC8+) ampules should stand at room temperature for 30 minutes before use.
- (10) For best result the cartridge, ampules and analyzer should be at the same temperature before use.
- (11) Use separate ampule for cartridges that contain sensors for ionized calcium, pH, PCO₂, PO₂, (G3+, EG7+, EG6+, EC6+, or EC8+)
- (12) If the above sensor are not present the content of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into the analyzer within 10 minutes of opening the ampule.

BIOHAZARD WARNING



- c. Control procedure:
- (1) Allow the ampules to reach to room temperature. Follow quality control steps 6-10 for each cartridge type outlined above.
 - (2) Immediately before use, agitate the ampule vigorously for 5-10 seconds to equilibrate the liquid and the gas phase.

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- (3) Agitate the ampule by holding the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
- (4) If necessary, tap the tip of the ampule to send the solution back into the bottom section of the ampule.
- (5) Immediately transfer the solution from the ampule to the test cartridge using a syringe, capillary tube or transfer pipette.
 - (a) When use a capillary tube to fill cartridge, always fill tube from bottom of ampule.
 - Avoid drawing the solution from the surface
 - Cover one end of the capillary tube with your index finger before insertion into the ampule.
 - Once the capillary tube is resting on the bottom of the ampule, remove your index finger from the tube allow capillary action to fill the tube.
 - (b) When use a syringe (use 1cc or 3cc sterile syringe with 20 gauge or larger needles are recommended).
 - Slow draw 1 ml of solution from the bottom of the ampule.
 - Discard syringe and ampule if bubble are continually being draw in the syringe barrow and tip of needle.
 - Expel one to two drops from the syringe before filling the cartridge.

NOTE: Do not use solution left in a syringe, ampule or capillary tube for addition testing of cartridges that contain sensors for ionized calcium, pH, PCO₂, or PO₂.

- (6) Immediately seal the cartridge and insert it into the analyzer.
- (7) Refer to i-STAT start up procedure for running samples.

NOTE: Do not expose the solution to room air since this will alter the test results.

- (8) Compare printed results to those listed on control chart for each analyte.

- (9) If results are out of the range, refer to Troubleshooting (Section 9) for corrective action.

6. INDIVIDUAL CARTRIDGE CALIBRATION:

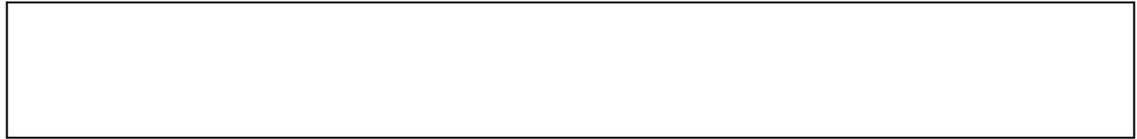
a. Calibration verification set:

- (1) A five-level aqueous calibration solution set is used to verify the calibration of i-STAT cartridges throughout the reportable ranges of Na⁺, K⁺, Cl⁻, Ca⁺, pH, PCO₂, PO₂, urea, Glu, and Crea.
- (2) The aqueous calibration verification solution is contained in a 1.7 ml glass ampule.
- (3) Store calibration verification solutions between 2-8 °C (35-46 °F) until expiration.
- (4) Calibration verification solution may be stored at room temperature 20-30 °C (68-86 °F) for 5 days.
- (5) Prolonged storage temperatures greater than 30 °C may cause changes in the values of some analytes.

NOTE: Do not use beyond the expiration date.

- (6) Prior to using cartridges that measure oxygen (G3+, EG6+ or EG7+), ampules should stand at room temperature for 4 hours.
- (7) When testing other cartridges not measuring oxygen (Glu, Crea, EC3+, EC4+, EC6+, 6+, or EC8+) ampules should stand at room temperature for 30 minutes before use.
- (8) For best results, the cartridges, ampules and analyzer should be at the same temperature before use.
- (9) Use separate ampules for cartridges that contain sensors for ionized calcium, pH, PCO₂, PO₂, (G3+, EG7+, EG6+, EC6+, or EC8+)
- (10) If the above sensors are not present the content of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into the analyzer within 10 minutes of opening the ampule.

BIOHAZARD WARNING



b. Calibration Procedures:

- (1) Allow the ampules to reach to room temperature. Follow calibration verification set steps 6-10 for each cartridge type outlined above.
- (2) Immediately before use, agitate the ampule vigorously for 5-10 seconds to equilibrate the liquid and the gas phase.
- (3) Holding the ampule at the tip and bottom with forefinger and thumb should minimize temperature increases in the solution.
- (4) If necessary, tap the tip of the ampule to send the solution back into the bottom section of the ampule.

NOTE: Protect fingers with gauze, tissue, or gloves, or use an ampule breaker to snap off the tip of the ampule at the neck.

- (5) Immediately transfer the solution from the ampule to the test cartridge using a syringe, capillary tube or transfer pipette.
 - (a) When using a capillary tube to fill the cartridge, always draw from the bottom of the ampule.
 - Avoid drawing the solution from the surface
 - Cover one end of the capillary tube with your index finger before insertion into the ampule.
 - Once the capillary tube is resting on the bottom of the ampule, remove your index finger from the tube to allow capillary action to fill the tube.
 - (b) When using a syringe, use 1cc sterile syringe with 20 or smaller gauge needle. (Needles with a gauge smaller than 20 will not fit into the cartridge filling well).
 - Slowly draw 1 ml of solution from the bottom of the ampule.

- Discard syringe and ampule if bubbles are continually being drawn into the syringe barrel and tip of needle.
- Expel one to two drops from the syringe before filling the cartridge.

NOTE: Do not use solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO₂, or PO₂.

- (6) Immediately seal the cartridge with the attached cover and insert it into the analyzer.
- (7) Refer to i-STAT start up procedures (section 7) for running samples.

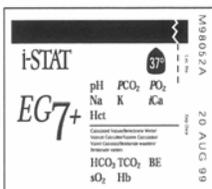
NOTE: Do not expose the solution to room air since this will alter the test results.

- (8) Compare printed results to those listed on the calibration verification set chart for each analyte and verification levels 1-5.
- (9) If results are out of the range, refer to Troubleshooting (Section 9) for corrective action.

7. START-UP PROCEDURE:

a. Prepare materials for use:

- (1) Allow the controls, calibrators, cartridges and analyzer to reach operating temperature. Ensure that the ambient temperature where the analyzer will be located is between 18-30 °C.
- (2) Insert Electronic Simulator is into the cartridge port of the analyzer to verify the electrical measurement.
- (3) Select a cartridge:
 - (a) Do not remove cartridge from its protective pouch until the pouch is at room temperature.
 - (b) Use all cartridges immediately after removing it from its protective pouch.

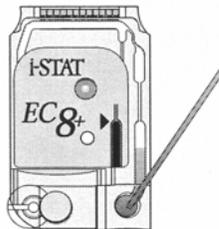


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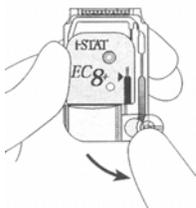
- (c) Do not contaminate the contact pads with finger-prints or talc from gloves as the analyzer may not be able to make proper contact with the cartridge.
- (d) Do not exert excessive pressure over the central area of the label as the calibrant pack underneath could burst prematurely.
- (e) Do not block the air vent as the sample will not be able to flow to the fill mark and the calibrant solution will not be able to flow over the sensors.
- (f) Do not use a cartridge on which blood or any other fluid spilled, as the analyzer connector may be contaminated.

(1) Fill the Sample Chamber.



- (a) Place the cartridge on a flat surface or hold it in horizontal position.
- (b) Do not hold cartridge between the fingers if using a syringe with needle to fill.
- (c) Direct the tip of the syringe, capillary tube or dispenser into the sample well.
- (d) Dispense sample slowly and steadily until it reaches the fill mark indicated on the cartridge label.
- (e) The cartridge is designed to fill correctly.

NOTE: If air bubbles are trapped in the sample chamber, discard the cartridge and fill another.

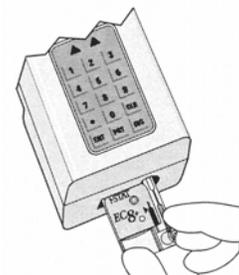


(2) Seal the Cartridge.

- (a) Fold the snap closure over the sample well.
- (b) Press the rounded end of the closure until it snaps into place.

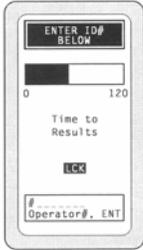
NOTE: Avoid exerting excessive pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark.

(3) Inserting Cartridge into the Analyzer.



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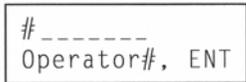
- (a) Orienting the cartridge with the contact pads facing up and toward the cartridge port.
- (b) Push the cartridge slowly and smoothly through the cartridge port until it will go no further.
- (c) When the cartridge is fully inserted, the sample well area will remain outside the port.
- (d) The analyzer will acknowledge proper insertion by displaying the **CONTACTING CARTRIDGE** message.
- (e) The display will change to **TIME** and **RESULTS** with the time bar counting down.



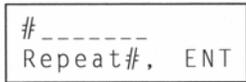
NOTE: When the LCK prompt is displayed indicating that the cartridge should not be removed. Do not attempt to remove cartridge from analyzer.

(4) Enter Operator Identification Numbers.

- (a) The operator prompt will appear in a box at the bottom of the screen with the first of seven blanks flashing with the word ENT.



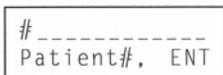
- (b) After entering the last digit press the **ENT** key. If an incorrect digit was added press the **CLR** key to erase.



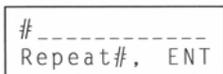
- (c) After the ENT key is pressed, the prompt “**Repeat #, ENT**” appear in the box.
- (d) Repeat the operator identification and press **ENT** key when finish.
- (e) The analyzer will compare the two entered operator numbers. If the entered numbers are not identical, the message “**ID DID NOT MATCH START AGAIN**”. Repeat step 1-4.

(8) Enter Patient Identification Numbers

- (a) After the operator has been identified the analyzer will ask for patient identification number.

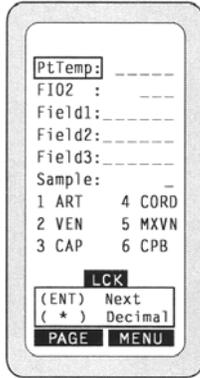


- (b) The patient prompt will appear in a box at the bottom of the screen with the first of twelve blanks flashing with the word ENT.



- (c) Use the same procedure described for inputting the operator identification number.

(9) Enter blood gas and patient information



- (a) After the patient identification number is enter, the PAGE key is activated allowing access to an additional data entry screen.
- (b) If results are already displayed, press the **PAGE** key twice to access the data entry screen.
- (c) The cursor will be flashing at the first input area..
- (d) Use the numbered key to input information and press the ENT key to advance to the next input area.

NOTE: Invalid numbers will be ignored, and incorrect inputs an be corrected using the CLR key as a backspace.

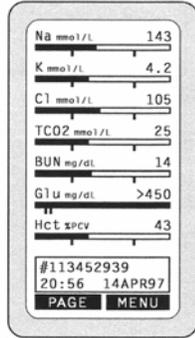
- (e) Patient temperature.
- Enter Patient temperature in either degrees Fahrenheit or Centigrade. Use the * key to enter a decimal point.
 - The analyzer will interpret number between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees Centigrade.
- (f) Enter FIO₂ value
- FIO₂ represents the number of liters or a percentage of the oxygen the patient is receiving.
 - Use the * key to enter a decimal point.

NOTE: INPUT PATIENT TEMPERATURE A FIO₂ IS ONLY POSSIBLE WHEN USING CARTRIDGE CONTAINING PH, PCO₂, AND PO₂ SEMSORS.

- (g) Field 1, 2, & 3
- Used to enter other blood gas parameters such as PEEP.
- (h) Sample type

(c) Record results on lab slip. Results are reported in mmol/L. No further calculation is necessary unless the specimen has been diluted

(d) Flags



- Flags are displayed when the analyzer detects an out of range result or an uncharacteristic sensor signal, the condition is indicated by a flag.

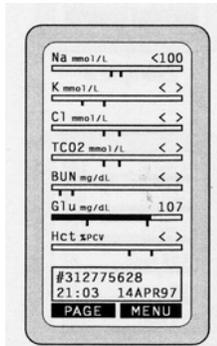
- When the follow flags occur, the sample must be tested by another type of analyzer in order to obtain results.

- The” >” (greater than sign) indicates that the results falls above displayed concentration or above the linearity of the analyzer.

- The” <” (less than sign) indicates that the results falls below displayed concentration or below the linearity of the analyzer.

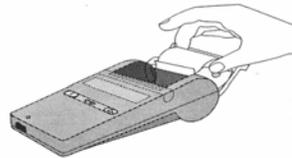
- The “<>” indicates that the calculations for the test are dependent upon another test which has been flagged either “<” or “>”.

- The “<>” flag will also be displayed for TCO₂, pH, PCO₂, HCO₃, anion gap, base excess and, sO₂ if the TCO₂ result is outside the reportable range



8. PRINTER:

a. Turn printer on.



- (1) Place the analyzer in the printer cradle.
- (2) If the printer indicator light is not on, turn the printer on by switching the **ON/OFF** switch located on top of the printer to the **ON (I)** position.
- (3) If the indicator light is not lit but the **ON/OFF** switch is in the on position, reactivate the printer by pressing the paper advance switch.

b. Print Display results

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- (1) Print displayed results by pressing the **PRT** key.
- (2) The most recent test record can be printed only if a patient identification number has been entered or actively bypassed.
- (3) To recall a stored test record to the displayed screen, press the **MENU** soft key.



- (a) Select **Stored Results** by pressing the “**2**” key.
- (b) From the **Stored Results** menu, select Display a Result by pressing the “**1**” key
- (c) Select the record to be displayed by pressing the key (“**1**” to “**5**”) on the page (1 to 10) corresponding to the test record.

c. Print Stored results

- (1) Press the **MENU** soft key and select **Stored Results** by pressing the “**2**” key.
- (2) From the **Stored Results** menu, select **Print Results** by pressing the “**2**” key
- (3) Use the soft keys to page up or down through the ten pages of stored test records.
- (4) Press the “**1 to 5**” keys to select the desired records on each page.
 - (a) When a key is pressed, the number selected will appear with a dark background with white numbers.
 - (b) To deselect a record, re-press the same number keying in the number will return to the light background with dark numbers.
 - (c) When all the test records desired are selected, press the **PRT** key.
 - (d) The message “**PRINTING**” will be displayed while the records are transmitted to the printer.
 - (e) A record will take from 40 to 70 seconds depending on the number of tests in the record.

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- d. Abort printing: To stop printing before all test records are printed, press the * key.

9. TROUBLESHOOTING

a. CLEW

- (1) If this error message appears, then a new CLEW must be downloaded into the Analyzer.
- (2) A new disk and software will be sent with new values for assignment of current quality control and calibration verification solutions included in the software.
- (3) If you have not received a disk with the latest version of CLEW or do not have the ability to access Technical support via the Internet, use of the analyzer will not be possible.

b. Out of Range results

- (1) All specimens must be repeated for duplication. If values are still out of assay range, the sample should be analyzed on another instrument.

10. APPENDIX

a. Sample Cartridges

- (1) i-STAT EC8+
- (2) i-STAT 6+
- (3) i-STAT EC6+
- (4) i-STAT EC4+
- (5) i-STAT E3
- (6) i-STAT G
- (7) i-STAT Crea
- (8) i-STAT EG 7+
- (9) i-STAT EG 6+
- (10) i-STAT G 3+



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11. REFERENCES

I-STAT™ TECHNICAL BULLETIN, Lit. # 151662 REV.1
11/20/00 i-STAT Corporation

I-STAT Corporation 1-800-366-8020
Technical Information

Reviewed 1 NOV 02
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NCOIC, DEPMEDS