i-STAT SYSTEM

	DATE	NAME
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ADOPTED BY:	1/10/10	MAS
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Replaces: 1/11/11, MAS, updated reference range

PRINCIPLE:

The i-Stat System performs point of care blood analysis using a single disposable cartridge which contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. The measurements of the different assays are electrochemical, using the microfabricated sensors housed in each cartridge to measure analyte concentrations directly in a single whole blood sample. The analyzer used is the handheld i-Stat Portable Clinical Analyzer. When a cartridge is filled with blood and inserted into the i-Stat Analyzer for analysis, it automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. A dedicated desktop computer, called the i-Stat Central Data Station, provides the primary information management capabilities for the i-Stat System. An Infrared Interface Link (IR Links) for handheld analyzers allows for transmission of patient records from several analyzers to the Central Data Station. Data can be stored, organized, edited and is transferred to the St. Cloud Hospital Laboratory Information System.

The FDA has granted waived status November 13, 2008 for the E3+ cartridge. ***Waived status is applicable only when testing venous samples collected in evacuated tubes with sodium or lithium heparin (green top tubes) with the E3+ cartridge and the i-Stat 1 Analyzer.*** If the manufacturer's instructions are not followed for any test categorization, the test defaults to high complexity.

SPECIFIC TEST METHODOLOGY:

1. Potassium:
   These parameters are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

SPECIMEN :

VOLUME REQUIRED: 95 ul of whole blood volume

CRITERIA FOR SPECIMEN REJECTION:

1. Evidence of clotting
2. Specimens collected in a syringe or tube with anticoagulant other than lithium or sodium heparin
3. Other fluid types such as urine, CSF, or pleural fluid

AVOID THE FOLLOWING CIRCUMSTANCES:

1. Collecting a specimen from an arm with an I.V.
2. Stasis (tourniquet left on longer than one minute before venipuncture)
3. Extra muscle activity (fist pumping)
4. Hemolysis (alcohol left over puncture site, or a traumatic draw)
5. Icing before filling cartridge.
6. Time delays before filling cartridge

(REFER TO THE i-STAT SYSTEM MANUAL FOR FURTHER INFORMATION)

SUPPLIES AND REAGENTS:

E3+: K+ only

CARTRIDGE STORAGE:
The main supply of cartridges will be stored refrigerated at 2-8C. Cartridges stored at 2-8C (35-46F) are stable until the printed outdate on the box. Cartridges may be stored at room temperature 18-30C (64-86F) for 14 days. *This time frame (date at room temperature and resulting outdate) must be documented on the box by each department doing testing*. Cartridges should never be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30C or 86F. Do not freeze cartridges.

CALIBRATION:

Calibration is automatically performed as part of the test cycle on each cartridge. Cartridges are self-calibrating. Operator intervention is not necessary.

Every cartridge includes a sealed foil pack, which contains a calibrant solution with a known concentration of each analyte. During the first part of the testing cycle, the calibrant solution is automatically forced out of the foil pack and over the sensors. The signals produced by the sensors in response to the calibrant solution are stored. Once this sequence is completed, the analyzer automatically moves the sample over the sensors. By comparing the sensors' response to the sample with that of the calibrant, the concentration of each analyte in the sample is calculated. A message and quality check code will be displayed if calibration fails. If a failure occurs, take a new cartridge and try to perform testing again. If the failure reoccurs, refer to the i-Stat System Manual for troubleshooting purposes.

Quality System Instructions for Waived testing:

1. Perform daily Quality control with the external Electronic Simulator
2. Read and record temperature strip with Each New Shipment of Cartridges
3. Test two levels of Liquid Controls with each new shipment of cartridges
4. Test two levels of Liquid Controls weekly
5. Ensure Proper cartridge storage - daily room temp and refrigerated temperatures
6. Perform Thermal probe checks every 6 mos – performed by the POCT specialist
7. Update software every 6 mos – performed by the POCT specialist

QUALITY CONTROL:

CONTROLS: i-Stat Controls are ordered from Abbott

Level 1 Aqueous control
Level 3 Aqueous control

Store i-Stat controls at 2-8C (35-46F). Controls may be stored at room temperature 18-30C (64-86F) for 5 days. Do not use after the expiration date on the box and ampules.

External Electronic Simulator

Store at room temperature and protect contact pads from contamination by placing the Electronic Simulator in its protective case.

ANALYZER VERIFICIATON:

The electronic simulator is a quality control device for the analyzer. Every 8 hrs the i-Stat analyzer automatically performs a check using an internal electronic simulator. The i-Stat has a QC lockout mode, meaning patient testing can not be performed if the electronic simulator test has not been done for 8 hours. It will automatically initiate the check before patient testing is to be performed, adding about 15-20 seconds to the testing cycle. While the analyzer performs internal electronic checks and calibration during each testing cycle, the electronic simulator test provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current, and resistance from the cartridge. The simulator produces signals at TWO LEVELS to check both the accuracy and sensitivity of the electrical measurement circuitry and the electrical isolation between individual measurement channels. These specific signals which are generated, stress the measurement capabilities of the analyzer well beyond any signals generated during cartridge analysis. When the analyzer is within specification limits, PASS will appear at the conclusion of the testing cycle. If the analyzer is not within specifications, FAIL will display with one or more letters, which are an aid in troubleshooting the problem. (Refer to the I-Stat System Manual for more detailed information).

DAILY QUALITY CONTROL PROCEDURES:

INTERNAL ELECTRONIC SIMULATOR

Verify that the internal electronic simulator results in a “PASS” message. This will automatically be performed every 8 hrs. This “PASS” message will appear in the analyzer’s stored results and is transmitted to the Central Data Station enabling the laboratory staff to monitor the performance of each i-Stat analyzer.

1. If the internal electronic simulator ‘FAILS”, repeat using the external electronic simulator. If a “PASS” message is displayed, it is acceptable to use the analyzer.

2. If a “FAIL” is displayed after using the External electronic simulator, proceed as follows:
    a. DO NOT analyze patient samples with the analyzer
    b. Transmit the result to the Central Data Station.
    c. Deliver the faulty analyzer to the laboratory i-Stat System Coordinator.
    d. Send any patient samples to the laboratory for analysis, or analyze on a i-Stat analyzer that has successfully passed the electronic simulator test.

EXTERNAL ELECTRONIC SIMULATOR

This will be performed by the testing personal at the testing sites each day of patient testing.

To perform the external electronic simulator please follows the step outlined below.

- Turn on the I-stat
- Press MENU button
- Press #3 for Quality Tests
- Press #4 for Simulator

- Enter or Scan your Operator ID (repeat)
- Enter or Scan the Simulator ID #
- Insert the Simulator

PASS / FAIL will be displayed after 60 seconds
Remove the simulator

DAILY VERIFICATION OF CARTRIDGE STORAGE CONDITIONS:

1. Refrigerated Cartridges:
    a. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Discard any outdated cartridges.
    b. Verify that the refrigerator did not exceed the limits of 2-8C (35-46F). If the temperature is outside the range of 2-8C (35-46F), quarantine the cartridges in the storage refrigerator. Notify the i-Stat system coordinator immediately. DO NOT USE the cartridges from the out-of-range refrigerator.

2. Room Temperature Cartridges:
    a. Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than **14 days**, but need to be out of the refrigerator for more than **5 minutes** for testing.
    b. If the measured room temperature has exceeded 30C (86F) for any period of time, quarantine the cartridges. Notify the I-Stat system coordinator immediately. DO NOT USE the cartridges.

WEEKLY VERIFICATION OF CARTRIDGE CONDITIONS:

1. E3+ cartridge will have 2 levels of Aqueous QC.

SIX MONTH ACCREDITATION REQUIREMENTS:

COMPARISON: (LABORATORY)
Twice per year the laboratory must evaluate the results obtained with the various instruments and methodologies used within the laboratory compared to the results obtained by the i-Stat analyzer.

PERIODIC PROCEDURES (LABORATORY):

Record on the i-STAT QC Log: *INCOMING QC*

1. New shipment of cartridges received:
    a. i-Stat cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit. Fill out the record of receipt. To be acceptable, window 3 and 4 must be white
    b. If either or both the “C” or “D” windows are pink, quarantine the suspect cartons. Notify the i-Stat system coordinator immediately. Do not use the cartridges from the suspect cartons. Record the information in the i-Stat QC logbook.

2. With each new shipment, the laboratory will verify the cartridge integrity. This is accomplished by assaying two levels of the i-Stat controls. The results obtained must be within the stated expected values published in the package insert. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed. Transmit the results to the Central Data Station.

a. Cartridges must be warmed to room temperature for a minimum of 5 minutes before use. (For best results, analyzers, control ampules, and cartridges should be at the same temperature).
b. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the vial..
c. When using a capillary tube, fill from the bottom of the vial. Avoid drawing solution from the surface.
d. Immediately transfer the solution to the cartridge. It is important not to expose the solution to room air since this will alter the results.
e. Results must be within the stated expected values published in the package insert. If the results are not within the expected range, quarantine the cartridges. DO NOT USE FOR PATIENT TESTING. Notify i-Stat Company of the problem for replacement cartridges.

PERSONNEL COMPETENCY ASSESSEMENT

1. Internal proficiency will be checked on each i-Stat operator initially (during training) and then six months later. Thereafter, competency will be verified on a yearly basis. Each staff member will be required to demonstrate competency by performing >80% on a written i-STAT competency assessment test. Employees of Centracare will be doing an online module under the education system.

2. These results will be documented and retained by the point-of-care charge person for accreditation purposes.

3. Competency of the staff performing testing on the i-Stat is also monitored by the laboratory chemistry staff reviewing the test data that is transmitted to the central data station. Reoccurring errors such as patient identification input errors and cartridge testing errors will be available for review and may require the point-of-care charge person to initiate a retraining session.

PROCEDURE:

CARTRIDGE PREPARATION:
All cartridges are required to be at room temperature for ***5 minutes*** before use.

PROCEDURE FOR MONITORING CARTRIDGE STORAGE AND TEMPERATURES IN DECENTRALIZED AREAS :

Use the i-Stat QC Log: *EXPIRATION DATE AND STORAGE CONDITIONS* to record daily the following data:

1. Date box with date put into use at room temperature.
2. Mark the outdate of 14 days on the box based on the date placed at room temperature.
3. Do not use after the labeled expiration date.
4. *Monitor and record daily the temperature* of the refrigerator used to store cartridge supply.
5. *Monitor and record daily the room temperature* where the i-STAT cartridges are stored.

PROCEDURE FOR PATIENT TESTING: (While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling or rejection by the analyzer)

1. Medicare rules require that all laboratory testing be performed only if written authorization is received from the physician or other health care personnel authorized to order laboratory tests. Please ensure that there is a written request for each component of the i-Stat cartridge that is to be performed. Orderable components of the i-Stat cartridge are potassium only. IF no written order request is on the medical record, please stop and obtain the order before proceeding.

2. Press ON/OFF button

3. Press #2 for I-stat cartridge

4. Enter/scan hospital ID number when the analyzer prompts you to enter "operator" number, and then press the ENT (enter) key. Repeat this process for verification.

5. Enter/scan patient medical record number when prompted, the press the ENT key. Repeat this number for verification.

6. Remove the cartridge from its pouch. *Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge. Do not contaminate the contact pads with finger prints or talc from gloves* as the i-Stat analyzer may not be able to make proper contact with the cartridge.

7. Place the cartridge and i-STAT analyzer on a flat surface. For patients in isolation, place the cartridge and i-STAT analyzer on a barrier also, such as a paper towel. Direct the syringe tip containing the blood, which was collected as described previously, into the sample well. Dispense the sample slowly and steadily until it reaches the blue fill mark indicated on the cartridge label. Leave some blood in the well. 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 to the sensors.

8. If the sample well fills but the rest of the chamber does not, ensure that the air vent is not blocked. Tilt the cartridge slowly so that gravity aids the flow. When the sample starts to flow into the chamber, return the cartridge to a horizontal position. If the sample is considerably short of fill mark, the analyzer will detect the condition and display SAMPLE POSITIONED SHORT OF FILL MARK.

9. If the sample is overfilled, the analyzer will detect this condition and display SAMPLE POSITION BEYOND FILL MARK. If air bubbles are trapped in the sample chamber, discard the cartridge and fill another. This condition would be detected as INSUFFICIENT SAMPLE.

10 Seal the cartridge by folding the snap closure over the sample well. Press the rounded end of the snap closure until it snaps. Avoid exerting excessive pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark. The analyzer will detect this condition and display SAMPLE POSITIONED BEYOND THE FILL MARK. Closing the cartridge before the sample chamber has filled will stop the flow of the sample. The analyzer will detect this condition and display SAMPLE POSITIONED SHORT OF FILL MARK. Failure to close the cartridge before inserting it into the analyzer will prevent sample movement and can cause the sample to flow backward and out of the sample well. The analyzer will detect this condition and display UNABLE TO POSITION SAMPLE. Be careful not to touch the sensors or contact pads or the center of the cartridge. Handle on side edges only.

11 Orienting the cartridge with the contact pads facing up and toward the cartridge port, push the cartridge slowly and smoothly through the cartridge port until it will go no further. When the cartridge is fully inserted, the sample well area will remain outside the port. The analyzer will acknowledge proper insertion by displaying the CONTACTING CARTRIDGE message. The display will change to TIME TO RESULTS with the time bar counting down. The LCK (lock) prompt is displayed indicating that the cartridge should not be removed. ***Never attempt to remove a cartridge while the LCK (lock) message is displayed.*** (Damage to the I-Stat analyzer will result if an attempt is made to remove the cartridge when the LCK message is showing).

12. From the screen choose which tests you want to assay from the cartridge. If the entire cartridge panel is to be selected, choose "0" for all. If you want to select specific test parameters, and do not need all the tests, choose which parameters you want by entering only the corresponding number of the tests you wish to assay.

13. After the patient identification number and the test selection are entered, the PAGE key is activated allowing access of an additional data entry screen. (If results are already displayed, press the PAGE key twice to access the data entry screen). The cursor will be flashing at the first input area. Use the numbered keys to input information and press the ENT key to advance to the next input area (or to return to the first area from the last input area). Incorrect entries can be corrected using the CLR key as a backspace.

    Patient temperature can be entered as Centigrade or Fahrenheit. Use the * key for a decimal point. The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees Centigrade.

    FIO2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving. The analyzer will accept a range of 0 to 100. Use the * key to enter a decimal point.

    Choose the number corresponding to the type of sample used when prompted at the Sample Type Field. (***This field is required in order to advance to the next page***)

14. View results on the analyzer's display. The analyzer will display test results once the cartridge has been unlocked and the LCK prompt disappears. Results of the last test results can be recalled by pressing the display key.

15. The i-Stat analyzer electronically attaches its serial number, the test date, and test time to the results.

16. Remove the cartridge after the LCK (lock) message disappears. Grasp the cartridge by the sides of the sample well and pull straight out. Discard the used cartridge in a container designated for biohazardous waste. Once the cartridge is removed, even if results are still display, the analyzer is ready for a new cartridge.

TRANSMITTING TEST RESULTS:

1. Place analyzer in Downloader. The analyzer will automatically turn itself on.

2. Do not move analyzer until Communication in Progress message disappears

3. Do not store the analyzer in the Downloader. Remove the analyzer after download process is complete.

CALCULATIONS ERROR CODES:

The i-Stat analyzer contains a microprocessor that performs all the calculations required for reporting results.

SUPPRESSED RESULTS:
There are three conditions under which the I-Stat system will not display results.

1. Results outside the System's reportable ranges are flagged with a "<" or ">", indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges listed later in this procedure). Repeat analysis once and if the error reoccurs, send the specimen to the laboratory in accordance with the Laboratory's Procedure Manual for analysis.

2. Results, which are unreportable, based on internal QC rejection criteria are flagged with "***". Stars will appear in place of concentration if the signals from that particular sensor are uncharacteristic. Uncharacteristic signals can be caused by a compromised sensor or by an interfering substance in the sample. Calculated results that depend on the value from a measured test will show as stars if the measured test shows as stars. When results are flagged with '***", reanalyze the sample once. If the results are still flagged with stars, contact the lab and send the specimen to the lab in accordance with the laboratory's procedure manual. Also verify that the cartridges have been properly stored. If this error code is reoccurring, contact the i-Stat program coordinator to run control solution with that supply of cartridges. (If the controls are starred, use of this supply of cartridges may need to be discontinued).

3. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, sensors, mechanical or electrical functions of the analyzer. Repeat with another cartridge. If the problem reoccurs, record the action code displayed with the message that identifies the problem. Refer to the i-Stat Systems Manual for corrective action, and/or to the i-Stat Systems Coordinator.

REPORTING RESULTS:

It is very important test results are downloaded to the IR link as soon as possible after testing.

By downloading through the IR link, the central data station and the laboratory information system will enable the test to be ordered, billed, and resulted in the same format as other laboratory results. If the operator does not transmit the results, this process will not occur.

SEE THE "PROCEDURE" SECTION FOR INFORMATION REGARDING TRANSMITTING RESULTS FROM THE i-STAT TO THE IR LINK.

REFERENCE RANGE:
Potassium: 3.5 - 5.1 mmol/L

REPORTABLE RANGE:
Potassium: 2.0 - 9.0 mmol/L

(For additional information on the performance characteristics of specific assays, refer to the test information section in the i-Stat System Manual).

CRITICAL VALUES:
Any abnormal result may be reassayed at the discretion of the i-Stat operator. Alarm values must be confirmed by reassaying the specimen, unless the patient's previous results correlate with this critical value. The following parameters are considered to be ALARM values and must be called to the attention of physician or the nurse in charge.

Potassium ≤ 3.0 or ≥ 6.0 mmol/L

MONITORING REPORTING VIA THE CENTRAL DATA STATION (LABORATORY):

Laboratory will monitor the results downloaded from the i-Stat into the central data station periodically per shift. The technologist will review the individual test results, monitor patient medical records to avoid a duplicate Sunquest order when the test is repeated, and investigate instances where the test results were not transmitted from the central data station into the laboratory's Sunquest computer.

The technologist will record on a log sheet next to the central data station the time and date of review, along with an explanation of any corrective action that was taken. In the central data station the technologist will also edit the patient report, under the comment section, to indicate any action taken regarding that set of test results.

In situations of < or > values, star out errors, or other instances where an unsuccessful result was obtained, the procedure of repeating the testing once and, if the same situation occurs, sending the sample to the laboratory is followed, the technologist will then initiate a credit for the i-Stat results.

In addition to the test results, the Point of care Specialist will monitor error codes generated by the i-Stat operators, review the data for quality assurance, to monitor for trends based on both the I-Stat serial number or operator code number. This will ensure that the analyzer is operating properly and that the individuals doing the testing are assaying the test cartridges in a competent manner.

COMPUTER DOWNTIME:

The i-Stat analyzer will hold 1000's of test results. If the computer is down for a short time, hold the information in the i-Stat analyzer and download it once the computer is operable.

LIMITATIONS:

TROUBLESHOOTING:
Refer to the i-Stat System manual for troubleshooting analyzer error codes. The i-Stat system coordinator can be a resource person to help solve the problem. If you are unable to solve the problem, the i-Stat hotline number for troubleshooting is 1-800-366-8020.

BATTERY REPLACEMENT:

Two 9-volt **lithium** batteries power the i-Stat analyzer. The low battery indicator (a flashing battery symbol) will appear when the battery voltage drops to 7.4. At this point there is sufficient power to test approximately 50 more cartridges before a DEAD BATTERIES message is displayed (less time if coag testing is being performed).

1. Wait until any testing in progress is completed before replacing the batteries or results will be lost. Stored results will not be lost when replacing the batteries.
2. Place the analyzer upside down and slide the battery compartment door off.
3. Remove the old batteries. Orient the + and - poles of the new batteries with the + and – labels in the battery compartment, and slide the new batteries into place.
4. Reinstall the battery compartment door back into place.

SPECIFIC PERFORMANCE CHARACTERISTICS:
Refer to the i-Stat System manual for specific test information regarding clinical significance, performance characteristics, interfering substances, precision, linearity etc., for each assay.

REFERENCES:

i-Stat Corporation, i-Stat System Manual, Publication Code 714336-00C, Revision date 3/29/04

i-Stat Corporation, i-Stat Implementation Guide, Publication Code 151570, Revision May 15, 1998

Franklin, Dr. G., Neonatologist, St. Cloud Hospital, May, 1999.