Abbott

i-STAT 1
System Manual

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IVD

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INTRODUCTION 1

This Manual

This manual describes the i-STAT 1 Analyzer and the Data Manager software. Related sections are grouped behind tabs.

Note: Not all products are available in all regions.

Intended Use

The i-STAT 1 Analyzer is intended for use in the *in vitro* quantification of various analytes in whole blood or plasma in point of care or clinical laboratory settings. Analyzers and cartridges should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT System is for *in vitro* diagnostics use. Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

FDA Test Categorization

With the i-STAT 1 System, the FDA has categorized the tests included on the i-STAT G (L/N 03P83-25) and Crea (L/N 03P84-25) cartridges as waived when testing is performed using venous whole blood samples collected in lithium heparin evacuated tubes. Other venous whole blood samples, capillary and/or arterial samples tested using these same cartridges on the i-STAT 1 System are categorized by the FDA as moderate complexity.

For waived testing, laboratories are required to follow the manufacturer's requirements for the testing. They may elect to perform additional quality control testing (such as the QC required for a moderate complexity test) but this does not change the FDA categorization of the test as waived or release the laboratory's responsibility to follow the manufacturer's instructions for it as a waived test.

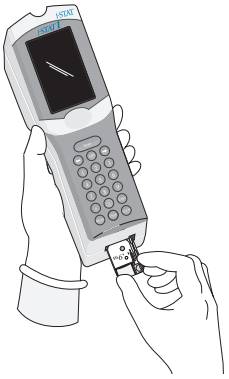
Other testing performed with the i-STAT 1 System (other than the testing performed using the aforementioned cartridges) is FDA categorized as "moderate complexity".

Overview of the i-STAT System

The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable handheld analyzer, a cartridge with the required tests, and 2-3 drops of blood will allow the caregiver to view quantitative test results for blood gas, chemistry and coagulation tests in approximately two minutes.

Portable printers and infrared communication devices allow all patient information obtained at the bedside to be printed on demand and transmitted to centralized information systems for record keeping and billing.

The Data Manager provides system management tools including real-time monitoring of testing and operator competency.



Components

The i-STAT System consists of:

- ✧ i-STAT Cartridges
- ✧ i-STAT 1 Analyzer
- ✧ Portable Printer
- ✧ Quality Assurance Materials
  - Electronic Simulator
  - Control Solutions
  - Calibration Verification Set (for cartridges)
- ✧ Data Management System
  - i-STAT 1 Downloader
  - i-STAT 1 Downloader/Recharger
  - Data Manager
- ✧ LIS/HIS Interface Software

Selection of Components

The selection of system components is dependent on factors unique to each facility such as:

- ✧ Types of tests to be performed
- ✧ Number of testing sites
- ✧ Number of tests per site
- ✧ System administration requirements

Summary of the Procedure

The cartridge test cycle is initiated by selecting i-STAT Cartridge from the Test menu or Quality Tests from the Administration menu. To perform cartridge testing, the operator fills a cartridge with sample, seals the cartridge with its snap or slide closure, and inserts the cartridge into the analyzer. The unit-use cartridge contains all applicable components to perform one or more tests including: calibrating solution, sample handling system, sensors and reagents. The analyzer automatically controls all steps in the testing cycle, which may include: fluid movement, reagent mixing, calibration and thermal control. Quality checks are performed continuously throughout the test cycle. Operator and patient IDs and patient chart information can be entered. When the test cycle is completed, results are displayed and the test record is stored.

Data Management

Test records can be transmitted to the Data Manager where they can be printed and/or transmitted to the Laboratory Information System or Hospital Information System. An optional portable printer enables the operator to print results at the point of care.

Interfacing

The Data Manager can be interfaced to a Laboratory Information System (LIS) or Hospital Information System (HIS) to automate billing and patient record keeping.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Theory section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

Electromagnetic Compatibility (EMC)

This equipment is designed for use in a professional healthcare facility environment.

It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended. The electromagnetic environment should be evaluated prior to operation of the device.

Operating the i-STAT 1 System outside of the specified ranges may interfere with system operation. Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

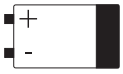
Do not allow devices such as portable phones and transceivers close to the i-STAT 1 System as it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference. In the case of a loss of analyzer functionality or performance, refer to Section 11 *Troubleshooting the Analyzer.* Wireless specifications for the i-STAT 1 Wireless analyzer (Model 300W) are found in the *Technical Bulletin for the i-STAT 1 Analyzer*, located in the support area of the APOC website, www.globalpointofcare.abbott.

Symbols

Symbols can be helpful in reducing the necessity for translating important information into multiple languages, particularly where space is limited. The following symbols may be found on components of the i-STAT System.

Symbol	Definition
	Attention: See instructions for use.
	Caution: Risk of electrical shock.
	Laser radiation hazard symbol.
	Biological Risks.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Upper limit of temperature. The upper limit for storage is adjacent to the upper arm.
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used. An expiration date expressed as YYYY-MM means the product cannot be used past the last day of the month specified.
LOT	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
REF	Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.
SN	Serial number. The serial number will appear adjacent to this symbol.
MN or #	Model number. The model number will appear adjacent to this symbol.
	Date of manufacture.
	Manufacturer.
IVD	*In vitro* diagnostic medical device.
Rx ONLY	For prescription use only.

Symbol	Definition
EC REP	Authorized Representative for Regulatory Affairs in the European Community.
	Importer in the European Community.
CE	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) with respect to safety, health, environment and consumer protection.
	Contains sufficient for < n > tests.
	Direct Current (DC).
	Alternating Current (AC).
	Class II Construction.
	Consult instructions for use or see System Manual for instructions.
CONTROL	Control.
	Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010-1: 3rd Ed.; Am. 1 CAN/CSA C22.2 No. 61010-1-12 3rd Ed. (R2017) +U1;U2
	i/immuno: Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.
	Battery: i-STAT 1 Analyzer low battery icon (flashes on lower left side of display screen).
	Note concerning batteries: The following information is applicable to EEA (European Economic Area) countries: The directive 2006/66/EC requires separate collection of spent batteries. You are requested to dispose those batteries referred to on page 2-3 in accordance with local regulations. This product also contains a separate internal lithium battery that is not intended to be replaced by the user. See page 2-4 under "Additional Power" for more information.
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
BODYYYY-MM-DD	Born On Date: the label BODYYYY-MM-DD defines year, month and day of manufacture.
	Do not reuse.

Symbol	Definition
	This symbol is used for compliance with the China RoHS regulation (s). It indicates in years the Environmentally Friendly Use Period (EFUP) for the labeled electronic medical device product.
<< >>	As the Martel Printer is incapable of printing the ↑ or ↓ symbols, this symbol appears on the Martel printout next to results which are outside the action range limits.
	14 days room temperature storage at 18-30 °C
	2 months room temperature storage at 18-30 °C
	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.
	The near-patient testing symbol illustrates that a device can only be used in a near-patient setting by a health care worker, professional or trainee.

Symbol	The following symbols are used on the i-STAT 1 keypad.
SCAN	Key used to scan information into the analyzer.
ABC	Key used to enter letters.
	Key used to enter information.
MENU	Key used to access the analyzer's menu.
	Key used to print a test record.
	Key used to turn the analyzer off and on.

Acronym	The following acronyms are listed in the i-STAT 1 System Manual
CTI	Cartridge and Test Information
IFU	Instructions for Use

Symbol	The following symbols are used on i-STAT Value Assignment Sheets
$\bar{X}$	Mean
R	Range

Symbol	TEST
Na	Sodium
K	Potassium
Cl	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
pH	pH
***P*CO$_2$**	Partial pressure of carbon dioxide
***P*O$_2$**	Partial pressure of oxygen
iCa	Ionized Calcium
BUN/UREA	Urea nitrogen/Urea
Hct	Hematocrit
ACTc Celite ACT	Activated Clotting Time with Celite® activator
ACTk Kaolin ACT	Activated Clotting Time with Kaolin activator
PT	Prothrombin Time
INR	International Normalized Ratio
Hb	Hemoglobin
TCO$_2$	Total carbon dioxide concentration
HCO$_3$	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extra cellular fluid)
AnGap	Anion Gap
sO$_2$	Oxygen saturation
cTnI	Cardiac Troponin I
hs-TnI	Cardiac Troponin I
CK-MB	Creatine Kinase MB Isoenzyme
BNP	B-type Natriuretic Peptide
Total ß-hCG	Total Beta-Human Chorionic Gonadotropin

Warranty

Abbott Point of Care Inc. warrants this medical product (excluding disposable or consumable supplies) against defects in materials and workmanship for one year from the date of shipment. If Abbott Point of Care Inc. receives notice of such defects during the warranty period, Abbott Point of Care Inc. shall, at its option, either repair or replace products which prove to be defective. With respect to software or firmware, if Abbott Point of Care Inc. receives notice of defects in these products during the warranty period, Abbott Point of Care Inc. shall repair or replace software media and firmware which does not execute their programming instructions due to such defects. Abbott Point of Care Inc. does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free. If Abbott Point of Care Inc. is unable, within a reasonable time, to repair or replace any product to a condition as warranted, Buyer shall be entitled to a refund of the purchase price upon return of the product to Abbott Point of Care Inc.

Note: Warranty rights may vary from state to state, province to province and country to country.

Limitations of Warranty

The foregoing warranty shall not apply to defects resulting from:

1. Improper or inadequate maintenance by Buyer or an unauthorized person,
2. Using accessories and/or consumables that are not approved by Abbott Point of Care Inc.,
3. Buyer-supplied software or interfacing,
4. Unauthorized repairs, modifications, misuse, or damage caused by disposable batteries, or rechargeable batteries not supplied by Abbott Point of Care Inc.
5. Operating outside of the environmental specifications of the product, or
6. Improper site preparation or maintenance.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED. ABBOTT SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

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THEORY 2

ANALYZER FUNCTIONS

Introduction

The i-STAT 1 analyzer is a microprocessor-controlled electromechanical instrument designed to:

- identify the cartridge type.
- control the flow of fluids within the cartridges.
- mix sample and reagent (where applicable).
- apply electrical signals to certain types of sensors within the cartridges.
- control the temperature of the cartridge at 37°C (where applicable).
- measure electrical signals generated by the sensors (cartridge and test strip).
- measure the barometric pressure of the surrounding environment (where applicable).
- calculate concentrations of analytes using the generated electrical signals.
- display the results in numerical values and on bar graphs (where applicable).
- communicate the results to a printer and computer.
- sense and communicate operational errors.
- maintain an internal clock/calendar.
- store all test records, Electronic Simulator results and Quality Check Codes and messages.

Microprocessor System

The microprocessor control system manages all functions of the analyzer. It accesses three types of memory storage devices. A “FLASH” EEPROM module stores the software program in the analyzer. The RAM, which is backed up by an internal lithium battery, is used for temporary storage of sensor signals measured during operation and for storage of test records. Another EEPROM stores factory calibration information, the instrument serial number and cumulative count of uses. Neither of the EEPROMs relies on the lithium battery for maintaining information.

Sensor Interface

Electrical signals from the cartridge sensors are conducted from the contact pads on the cartridge, through the internal connector in the analyzer, to the sensor interface circuit board. Electrical signals from the test strip sensor are conducted from the contact bars to a sensor interface circuit board. These circuits amplify the signals from the sensors so that they can be further processed by the main electronic circuit board. Four signals are relayed to the main electronic circuit board from the cartridge sensor interface circuit board:

- A multiplexed potentiometric signal line
- A multiplexed amperometric signal line
- An AC fluid conductivity signal
- A digital identification code to identify the type of cartridge being inserted into the analyzer

Mechanical System

A single DC gearmotor drives mechanical system components:

- An electrical interconnecting system which brings the analyzer's electrical internal connector into contact with the contact pads on the cartridge
- A calibrant delivery system
- A sample delivery system
- A thermal control interconnectivity system which brings the analyzer's thermal controller into contact with heater elements on the back of cartridges. In addition, a latching mechanism locks the cartridge into place upon insertion.

Analog-to-Digital Conversion

An analog-to-digital converter converts all analog signals into digital form so that the microprocessor can perform mathematical calculations on the signals. An analog signal multiplexer makes it possible for the microprocessor to measure eight different types of analog signals:

- The potentiometric signals from the sensor interface circuit
- The amperometric signals from the cartridge and test strip sensor interface circuits
- A DC conductivity signal
- The battery voltage
- A thermistor signal representing the internal temperature of the analyzer
- A motor feedback signal used to control the speed of the mechanical motion
- Cartridge temperature signals used to control the cartridge temperature to 37°C
- A pressure transducer signal representing the barometric pressure of the environment

Analog Control Signals

The analyzer creates and applies two types of signals to the sensors: a digital-to-analog converter generates a voltage which is applied to amperometric sensors, and the AC conductivity circuit generates an AC excitation signal which is applied to the conductivity sensors. The digital-to-analog converter also provides voltages to the motor driver circuit.

Operator Interface

The microprocessor control system coordinates the reading of information input by the user, the writing of information onto the display, and the communication of results. The microprocessor control system, also, communicates with a clock/calendar circuit allowing the operator to set and read the time and date. The clock/calendar circuit is backed up by a lithium battery.

ELECTROCHEMICAL MEASUREMENTS

Method

Measurements are performed on undiluted specimens. Undiluted methods are also called direct methods, while methods requiring dilution of the sample are called indirect methods.

Indirect methods measure the total molar concentration of analyte per unit volume of plasma. Direct methods measure the total molar activity of analyte (apparent or free ion activity) per unit volume of plasma water. It is understood that the direct method result is the clinically significant result for electrolytes. When there is disagreement between the methods, such as when the patient has abnormal total protein or lipid levels, it is due to interference on the indirect method.

At normal levels of protein and lipids the systematic offset between methods is often corrected for in commercial direct measuring instruments so that the normal ranges for all instruments are in agreement. Sensor outputs have been set so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

Sensors

The general term “sensor” is used to refer to the three types of electrodes incorporated into the cartridges:

- Potentiometric
- Amperometric
- Conductometric

Sensors are thin film electrodes microfabricated onto silicon chips. Sensing functionality is imparted to each electrode by a number of chemically sensitive films coated over the active region of the electrodes.

Potentiometric Sensors

Potentiometry is the measurement of the difference in potential that exists between an indicator electrode and a reference electrode. Ion-selective electrodes (ISE) are examples of potentiometric sensors. The indicator electrode is designed to be sensitive to a particular ion in a solution. In cases where other ions are sensed by the system, selectivity coefficients can be used to correct for this interference. An enzyme can be added to an ISE to produce ions from analytes of interest that are not themselves ions.

The Nernst Equation

The Nernst equation relates the measured potential to the activity of the ion being measured.

$$E = E^\circ + RT/nF \ln a$$

Where E is the potential, E° is a constant dependent on the electrode/sensor system, R is the gas constant, T is the absolute temperature, F is Faraday’s constant, (n) is the valance (positive or negative charge) for the ion being measured, and (a) is the activity of that ion.

The Nernst equation can be rewritten as:

$$E = E^\circ + S \log a$$

Where S replaces the constant term which defines the slope of the sensor. The slope is the change in millivolts per tenfold change in the activity of the analyte. For a positively-charged monovalent ion, the theoretical slope would be 59.1 mV at 25°C.

Activity Versus Concentration

Ion-selective electrodes measure activity rather than concentration. Activity (a) is related to concentration (c) through the activity coefficient (γ): $a = \gamma c$.

While ion activities, which reflect free rather than total ion concentrations, are the physiologically relevant quantity, activity values are converted to conventional concentration units so that values obtained by direct ISE measurements can be compared to values obtained from methods that measure total ion concentrations. The latter includes the indirect methods, which have activity coefficients close to unity or one, and flame photometric, atomic absorption and titration methods.

Amperometric Sensors

In amperometric measurements, a potential is applied to the measuring electrode while current generated by the resulting oxidation or reduction reactions in the test system is measured. The current generated is directly proportional to the concentration of the analyte. An enzyme can be added to a layer on or near an amperometric sensor to produce electroactive species from analytes of interest that cannot themselves be oxidized or reduced.

Conductometric Sensors

In a conductometric measurement, an alternating current is applied between two electrodes in contact with the test solution and the resulting voltage difference is measured. The conductivity of the solution is proportional to the magnitude of the voltage difference. In aqueous solutions, conductivity is dependent upon the concentration of electrolytes; an increase in the electrolyte concentration causes an increase in conductivity.

DETERMINATION OF TEST RESULTS

Determination of Analyte Concentration

Potentiometric and amperometric sensors are used for the determination of analyte concentration. For both sensors, the concentration of the analyte can be calculated using:

1) the known value of the analyte concentration in the calibrant solution,
2) the measured voltage (potentiometric) or current (amperometric) signal generated by the analyte in the calibrant, and
3) the measured signal generated by the analyte in the test solution.

For potentiometric sensors, the analyte activity in the sample is calculated from the Nernst equation according to:

$$E_{sample} - E_{calibrant} = S \log (a_{sample}/a_{calibrant}).$$

Complex solutions such as blood deviate slightly from Nernstian behavior due to interfering ions and matrix effects that result in junction potentials. By including selectivity coefficients in the Nernst equation (Nikolsky equation), these effects can be minimized. By characterizing the reference electrode in different solutions, effects of matrix on the reference junction potential can also be minimized.

It is known that direct methods read up to 7% higher than indirect methods in measuring the concentration of electrolytes. This is because there is an excluded volume occupied by plasma protein and lipids that is not considered in indirect measurements. Typically, however, the elevation of results is less than the full 7% because some of the analyte is bound to protein and other ions, and is not assayed by direct methods. For each analyte this discrepancy is characterized, and the result of the direct measurement is adjusted so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

DETERMINATION OF CELL CONCENTRATION

Hematocrit

In whole blood, plasma conducts electricity while the cellular constituents, red and white blood cells and platelets, do not. For a sample of a given electrolyte concentration, as the number of cells per unit volume of plasma increases, the conductivity of the sample decreases. The total cell concentration in whole blood can, therefore, be determined from:

1) the known electrolyte concentration of the calibrant,
2) the measured electrolyte concentration of the sample,
3) the measured conductivity of the calibrant and
4) the measured conductivity of the sample.

These measured quantities are determined using a combination of potentiometric and conductometric sensors.

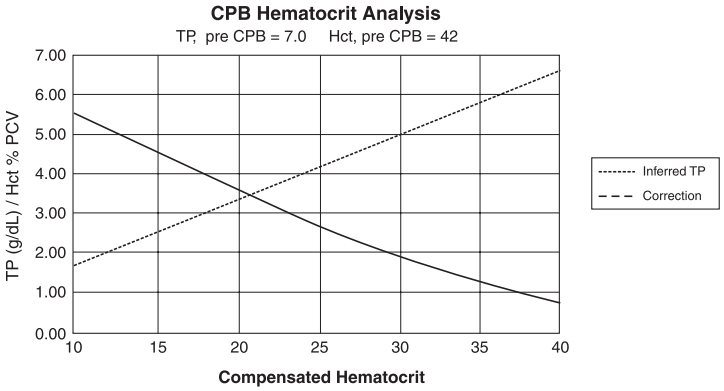
Direct measurement of hematocrit by the conductometric technique gives a result related to the non-conducting excluded volume fraction of the sample fluid. Red blood cell volume is the predominant component of the non-conducting volume, but proteins, lipids, and white blood cells also contribute. Elevated hematocrit readings are expected at abnormally elevated levels of these components. Decreased hematocrit readings are expected at abnormally low levels of protein, such as found in hemodiluted samples taken from patients on cardiopulmonary bypass.

Osmotic imbalance causes a discrepancy between direct (conductometric, spun) and indirect (Coulter) measurements because of variation in the mean cell volume.

Cardiopulmonary Bypass (CPB)

Each time a cartridge containing a hematocrit sensor is used, the operator has the option of selecting, in addition to the sample type, the CPB compensation algorithm for samples with abnormally low protein levels. The CPB option is specifically intended for use when samples are collected from patients on cardiopulmonary bypass. However, the facility may validate its use for other patient populations known to have protein levels significantly lower than the normal adult population.

The CPB algorithm infers the total protein level by assuming the pump priming solution dilutes the hematocrit and total protein equally. Modeling the pre-pump hematocrit as 43 %PCV and the pre-pump total protein as 7.0 g/dL, the following graph indicates the inferred total protein and resultant correction.



For example:

- uncompensated Hct = 21 %PCV
- 21 %PCV = 0.50 of 42 %
- inferred total protein = 7.0g/dL x 0.50 = 3.5 g/dL
- 21 %PCV + 3 g/dL = 24 %PCV (CPB)

Limitations of the CPB Algorithm

The CPB algorithm is based upon a series of inferences:

- The algorithm models initial pre-pump values for total protein and hematocrit. Although actual initial values may be different than those used in the algorithm, typical deviations rarely affect the accuracy of the correction by more than 0.5 %PCV. More often than not, the actual values are consistent with a “pre-dilution” of the modeled values.
- The algorithm assumes that the pump priming solution has no added albumin or other colloid. The algorithm will tend to overcorrect if solutions with added colloids are utilized, though the size of the over-correction will seldom be more than 1 %PCV.
- Other therapies which affect the ratio of total colloids to hemaotcrit (administration of colloids, packed red blood cells, etc.) will affect the interference.

When to discontinue use of the CPB algorithm will depend on when the patient's total protein level reaches the pre-pump level.

It is recommended that each practice verify the hematocrit determination for cardiopulmonary bypass procedures so that the impact of these limitations upon a particular practice’s protocol is understood.

DETERMINATION OF COAGULATION ENDPOINTS

ACT and PT/INR

In coagulation tests, the result that is reported is the time required for the process of coagulation to occur. To determine this time, there must be a detectable change in a sample parameter correlated to progression of the process. In traditional coagulation tests, endpoint detection typically relies on monitoring increases in either blood viscosity or plasma turbidity that occurs as thrombin converts fibrinogen to clotable fibrin. In an electrogenic test an electroactive marker that can be detected at either an amperometric or potentiometric sensor is used to indicate the endpoint. The marker is generated when a substrate that has been added to the test sample is acted upon by thrombin. As the coagulation reaction proceeds, the marker concentration increases, increasing the signal at the sensing electrode. The time required for generation of the marker correlates to the time required for conversion of fibrinogen. The coagulation endpoint can, therefore, be determined by monitoring the marker concentration. Unlike traditional coagulation tests, electrogenic tests will not be prolonged in samples with abnormally low (less than 100 mg/dL) fibrinogen levels.

QUALITY CONTROL AND THE i-STAT SYSTEM

Overview

Quality control, as a component of an overall quality assurance program, consists of tests and procedures for monitoring and evaluating the analytical performance of a measurement system to assure the reliability of patient test results.

As new technologies evolve, quality control regimens must match the requirements of the particular analytical system. Abbott Point of Care recognizes the importance of effective quality control for its analytical medical devices, and has developed a program that is tailored to the unique characteristics of the i-STAT System.

The i STAT System performs blood analysis when a unit-use cartridge filled with a patient’s sample is inserted into a handheld analyzer.

The measurement methodologies are electrochemical, using microfabricated sensors housed in each cartridge to measure analyte concentrations directly in a single whole blood sample (i.e., neither dilution nor reagent mixing steps are required).

i-STAT’s microfabrication production processes are inherently capable of creating sensors with highly reproducible characteristics. For the measurement of blood gases, electrolytes and chemistries, this means that the i-STAT System requires only a one-point calibration, using a calibrant solution packaged in the cartridge, to meet the demanding requirements for clinical accuracy. As described in the Quality Control section of the i-STAT System Manual, the calibrant solution is also used to verify the integrity of the sensors as a key component of the quality system.

Two characteristics of the i-STAT System, which distinguish it from traditional laboratory equipment, have significant impact upon the design of the quality control regimen: its intended user and the unit-use cartridge technology.

As the system is intended to be used by individuals not trained in laboratory science, the onus is upon the system’s design to ensure that the quality of results is not dependent upon either user technique, skilled maintenance and calibration procedures, or the accompanying quality control regimens which ensure these procedures have been properly performed.

The use of unit-use cartridges frees the i-STAT System from these skilled maintenance and calibration procedures. It also allows for the design of a quality control system which automatically monitors those aspects of the measurement process which are the most likely to impact quality, including the characteristics of the individual sensors and the operator's actions.

i-STAT's quality control regimen has four aspects, resting on the foundation of a system design which reduces the opportunity for the type of error which traditional quality control regimens are designed to detect:

1) A series of automated, on-line quality measurements that monitor the sensors, fluidics and instrumentation each time a test is performed.

2) A series of automated, on-line procedural checks monitors the user each time a test is performed.

3) Liquid materials are used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question.

4) Traditional quality control measurements verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way which stresses the performance characteristics of the instrumentation.

Similarities to Traditional Laboratory Quality Control Regimen

Although the more significant aspects of i-STAT's quality control regimen are the quality checks automatically performed with each unit-use cartridge, many principles of the quality control regimen are similar to traditional regimens.

Laboratory quality control methods are statistical. They assess the quality of the measurement process by intermittently inserting pseudosamples (controls) into the stream of samples being tested.

The approach implicitly assumes that the elements of the measuring system persist from run to run so that the repeatability and accuracy of the measurement of patient samples can be predicted by the repeatability and accuracy of pseudosamples.

The i STAT system uses an analogous approach to monitor the part of the testing process which persists from run to run – the handheld analyzer.

An Electronic Simulator, which mimics the electrical characteristics of the signals produced by the sensors, is inserted into the handheld analyzer on a daily basis. The Simulator produces signals consistent with both very low and very high concentrations of each of the analytes. The handheld analyzer causes the Simulator to change the signals via a control signal.

The software in the handheld analyzer measures these signals as it would measure signals from a cartridge. The software checks the measurements against predetermined thresholds and indicates their acceptability to the user via a PASS/FAIL message.

All analyzers that pass the Electronic Simulator test are equivalent. Therefore, any representative number of analyzers that pass the simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, proficiency testing, and method comparison studies.

An important aspect of the Simulator is that it mimics the sensitive nature of the sensor's signals to ensure that the adjacent input channels within the handheld analyzer maintain the required degree of electrical isolation from each other to prevent "crosstalk" (see US Patent #51246661 for details). This cannot be achieved by the traditional internal self-consistency checks characteristic of modern microprocessor-controlled instrumentation.

Comparison of this regimen to laboratory quality control procedures can seem confusing because it does not employ liquid control solutions. However, the principle is the same in that the traditional intermittent quality control measurements are applied to the persistent part of the system. In the case of the i-STAT System, only the instrumentation is persistent so only this portion is tested with an external challenge.

Further, use of an electronic quality control device has distinct quality advantages:

1) Non-laboratory-trained individuals do not need to interpret control results because the analyzer software, expecting certain simulator signals, automates the interpretation. In comparison, many quality control regimens using liquid controls at the point of care are ineffective because an out-of-control result is easy to ignore.

2) Injecting signals into the handheld analyzer allows very tight control limits to be set. Control limits using liquid controls at the point of care are generally very wide to allow for sensor-to-sensor variation.

The i-STAT Unit-Use Cartridge as an Element of Design Robustness for Point-of-Care Testing

The most important quality measure in the i-STAT System is that it is designed to reliably deliver quality results in the hands of individuals not trained in laboratory science. It addresses those aspects of the design in traditional laboratory-based equipment and other point-of-care devices which detract from robustness in the hands of these individuals.

1) In the interest of making batch processing efficient, laboratory devices make extensive use of components which are exposed to each test sample (sensors, tubing, etc.). These devices must be continuously recalibrated as successive samples interact with these elements. Quality control regimens are designed to detect incorrect or required calibrations.

   All elements which are exposed to the test sample are unit-use in the i-STAT System. Many of the out-of-control conditions which a laboratory quality control regimen is designed to catch simply do not exist.

   Furthermore, the use of unit-use devices is directly related to the design of i STAT's quality approach. Each test begins with fresh sensors and a fresh calibrant fluid, if applicable. The response of the sensors' signals to the fresh calibrant fluid, if applicable, is well characterized from a large database of tests run in i STAT's manufacturing facility. If the sensor signal is uncharacteristic due to mismanufacture, mishandling or misstorage, the handheld analyzer software will suppress the result (displays "***").

2) Many point-of-care devices require the non laboratory-trained user to interact directly with the sensing elements (paper strip technologies for example). Many Point-of-Care Coordinators rely heavily on the daily quality control regimen not only as a means for monitoring system performance, but more significantly, as a means for monitoring user proficiency.

The analyzer controls all fluid motions in the i-STAT System. The calibrant, if applicable, and sample are brought to the sensors under instrument control so that the user does not directly impact on the quality of the analytical process and therefore cannot impinge on the quality of the results.

Further, the analyzer uses a fluid sensor to electronically verify the proper flow of fluids within the cartridge on every run. This can easily be demonstrated by attempting to fool the system by:

- putting in too much sample
- putting in too little sample
- rerunning the same cartridge
- introducing an air segment into the fluid segment, etc. The analyzer will flag these conditions and not deliver a result.

3) The design of some unit-use point-of-care devices can allow an entire batch of unit-use devices to be affected by a single event, for example, by leaving a tube of paper strips open and exposed to a high humidity environment.

   With the i-STAT System, each unitized device is sealed in a separate foil pouch and has its own individual history. The only external factor, which can create a shared history among cartridges, is temperature. This is controlled by appropriately monitoring the storage environment.

The Foundation of i-STAT's Quality Control Regimen – On-Line Tests

The fundamental backbone of i-STAT's quality regimen is the series of automatic checks performed each time a cartridge is run.

The tables below list the key elements and operations of the i-STAT System that are verified **each time** a cartridge is used.

For completeness, those operations which are qualified by the Electronic Simulator are also listed.

Unit-Use Cartridge

Verification	When Verified
Microfabricated Electrochemical Sensor Elements	
• verify sensors are present	Every cartridge use
• verify sensor characteristics are consistent with expectations of a properly manufactured and maintained device (by testing calibration fluid), if applicable	Every cartridge use
Calibration Fluid (if applicable)	
• verify fluid is present	Every cartridge use
• verify fluid is delivered free of bubbles	Every cartridge use
• verify fluid has proper concentration	Every cartridge use
Fluidic System	
• verify sample holding chamber is sealed	Every cartridge use
• verify fluid flowpaths are intact (no part of the analyzer comes into direct contact with fluid)	Every cartridge use
• verify waste chamber is not occluded	Every cartridge use
Elements that interact with the handheld analyzer	
• verify electrical contact pads (that allow access to sensor signals) are unoccluded	Every cartridge use
• verify internal element of cartridge that allows the handheld analyzer to control the release of calibration fluid, if applicable, over the sensors is functioning properly.	Every cartridge use
• verify internal element of cartridge that allows the analyzer to control the replacement of calibration fluid, if applicable, with sample is functioning properly	Every cartridge use

Handheld Analyzer

Verification	When Verified
Motorized Mechanical System	
• verify electrical contact is made with sensors on cartridge	Every cartridge use
• verify ability to properly move calibration fluid, if applicable	Every cartridge use
• verify ability to properly move sample	Every cartridge use
Electrical Measurement System	
• verify voltage measuring system for potentiometric sensors	Electronic Simulator
• verify current measuring system for amperometric sensors	Electronic Simulator
• verify resistance measuring system for conductometric sensors	Electronic Simulator

Verification	When Verified
Other	
• verify internal self-consistency of electronic systems	Every cartridge use
• verify fluid flow using the conductivity sensor	Every cartridge use
• verify function of transducers used for measuring barometric pressure	Every cartridge use
• verify function of the thermistors used to control chip temperature	Electronic Simulator

Operator Sample Handling/Cartridge

Verification	When Verified
Verify the cartridge inserted has not been previously used	Every cartridge use
Verify the calibrant pack, if applicable, has not prematurely ruptured	Every cartridge use
Verify the electronic contact pads are dry and uncontaminated	Every cartridge use
Verify the proper amount of sample was placed into the sample chamber	Every cartridge use
Verify the sample was properly positioned within the sample chamber	Every cartridge use
Verify the sample is free of included bubbles	Every cartridge use
Verify the sample is not clotted	Every cartridge use
Verify the sample chamber is properly sealed with the closure	Every cartridge use

Validating the Performance of the i-STAT System

Until recently, regulations and laboratory accreditation standards specified the use of traditional quality control regimens, including the daily use of liquid “control” materials.

As new technologies such as the i-STAT System have become available, the community has recognized the limitations of relying upon traditional regimens, prompting various regulatory and accreditation organizations to modify their standards accordingly.

Many of the newly drafted regulations and accreditation standards recognize the danger of denoting specific methods of achieving an effective quality control regimen. Additionally, specific methods cannot anticipate future technological changes, so many of the regulatory and accreditation organizations are changing their standards to place the responsibility of establishing and validating the quality system a laboratory employs on the laboratory director.

Quality control regimens should be established using information from the manufacturer and scientific literature.

It is important to validate the performance of the i-STAT System and the recommended quality control regimen to develop personal confidence in our approach to the challenges of putting a diagnostic device in the hands of individuals untrained in laboratory science.

Some of the regulatory and accreditation organizations recommend the daily use of liquid “control” materials for the first month of use, slowly stepping back the frequency as a database of performance information increases confidence levels. The number of lots of materials examined should also be considered when determining a validation protocol.

QUALITY CONTROL AND THE i-STAT COAGULATION TESTS

Operating Principles of the Coagulation Cartridge–Overview

The i-STAT coagulation cartridges measure the time required for complete activation of the coagulation cascade once initiated by the activator. Coagulation instruments determine this time by sensing a characteristic change in a measured property of the sample. In the i-STAT System the measured property is the concentration of an electroactive marker . The time to clot is indicated by a relative increase in the concentration as measured by an amperometric sensor.

i-STAT dries the activator and a precursor of the electrochemical marker (a substrate to the thrombin enzyme produced by the coagulation cascade) onto the wall of the reaction chamber during the manufacturing process. At the beginning of the test the system agitates the blood back and forth across the chamber wall to mix these reagents into the blood sample.

Quality System for Coagulation Cartridge

The critical performance feature of the coagulation cartridge centers on the repeatability of the reagent mixing process. The accuracy to which the reagent is mixed into the blood sample directly impacts the accuracy of the result.

The system quantitatively confirms the accuracy of the mixing step by monitoring the key parameters of mix uniformity, magnitude and timing. These quality tests are performed on each coagulation cartridge.

i-STAT’s microfabrication production processes are inherently capable of creating sensors with highly reproducible characteristics. For the measurement of blood gases, electrolytes and chemistries, this means that the i-STAT System requires only a one-point calibration, using a calibrant solution packaged in the cartridge, to meet the demanding requirements for clinical accuracy. As described in the Quality Control section of the i-STAT System Manual, the calibrant solution is also used to verify the integrity of the sensors as a key component of the quality system.

For the measurement of ACT and PT, the required accuracy for the amperometric sensor to detect the relative increase in concentration of the electroactive marker is more modest. A calibrant solution is required neither for a one-point calibration nor to verify the wetup characteristics of the sensor. Instead, the magnitude and rate of change of current is assessed quantitatively throughout the test in order to verify the quality of the mix, and the integrity of both the sensor and the reagent coating.

Regulatory Aspects of the Quality System for Coagulation

Alternatives to traditional quality systems have been developed that are suitable for ensuring the performance of unit-use in-vitro diagnostic systems. These alternative systems rely upon a variety of internal self-tests and electronic/optical checks. As unit-use devices have become more widespread in clinical practice, regulations and guidance documents have adapted to recognize the effectiveness of these alternative quality systems, albeit with some variation. For example, some state regulations require that the alternative quality system include an on-board "wet" control. The i-STAT Quality System for the coagulation test is able to address this requirement even though the cartridge does not contain an on-board wet calibration fluid. The quantitative confirmation that the activator and the marker are accurately mixed into the blood sample is a "wet" test that acts as a control of the most critical aspect of the coagulation test.

Electronic Quality Control

i-STAT's electronic simulator (both the internal and external versions) check the amperometric and conductivity circuitry used in the coagulation tests at multiple levels. The instrument checks the accuracy of the measurement of elapsed time each time a test is run by comparing the clock rates from two independent clocking circuits. The instrument also runs a battery of general instrument checks during each test.

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i-STAT 1 ANALYZER 3

INTRODUCTION

The i-STAT 1 Analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of specific analytes in whole blood.

For information on the analytes that can be measured using i-STAT Cartridges, refer to the Cartridge and Test Information (CTI) sheets or Instructions for Use (IFU), located at www.globalpointofcare.abbott.

BEFORE YOU USE THE ANALYZER

Install Batteries

See the Care of the Analyzer section in this manual for the procedure to install the disposable batteries. If a rechargeable battery is to be used, the disposable batteries can be used while the rechargeable battery pack is charged in the Downloader/Recharger. Charge rechargeable batteries fully before use. See the i-STAT 1 Downloader section for this procedure. When using a rechargeable battery, store the disposable battery carrier for possible future use.

Check Date and Time

Press the On/Off key and check that the date and time at the top of the display are correct. To change the date and time, see Administration Menu in this section.

Check Software

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have standard CLEW and application software. If a different CLEW and/or application software is in use in your facility, it must be installed in new, repaired or replaced analyzers before they are put into use. Check the Analyzer Status page for the installed CLEW and application software. For steps to verify the software, see *Procedures for Customization using the Analyzer Keypad* in Section 15 of this manual. See under "Standardization and Calibration" in section 4 of this manual for an explanation of CLEW.

Customization

Analyzers can be customized for many site-specific testing requirements. See Section 15 in this manual for a list of customizable parameters and their default values. To change the customization profile via the analyzer keypad see "Customization" under "Administration" in this section of the manual. To change the customization profile via i-STAT/DE, see the "i-STAT/DE User Guide" located at www.globalpointofcare.abbott.

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have the factory default settings in the customization profile, as indicated by the DEFAULT0 on the Analyzer Status page. If analyzers in your facility do not use the default customization profile, the appropriate customization profile should be installed before a new, repaired or replaced analyzer is put into use.

Perform Quality Check

Use the Electronic Simulator to verify the cartridge-reading performance of new or repaired analyzers.

DESCRIPTION

Specifications



DIMENSIONS	Width 7.68 cm (3.035 in.) Length 23.48 cm (9.245 in.) Depth 7.24 cm (2.85 in.)
WEIGHT	With rechargeable battery 650 grams (22.9 oz.) With disposable battery 635 grams (22.4 oz.)
POWER	Two 9-volt lithium batteries, or rechargeable battery.
CALIBRATION	Factory: electronic, mechanical, thermal, pressure
MEMORY/CLOCK BACKUP POWER	Lithium Battery
DISPLAY	Dot matrix supertwist liquid crystal
COMMUNICATION LINK	Infrared light-emitting diode (LED)
OPERATING TEMPERATURE	16-30°C (61-86°F) for i-STAT cartridge testing
TRANSPORT TEMPERATURE	-10-46°C (14-115°F)
RELATIVE HUMIDITY	10-90% non-condensing
BAROMETRIC PRESSURE	300-850 mmHg
LASER SCANNER	Complies with U.S. 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019 EN 60825-1:2014 IEC 60825-1:2014

EMC Standards

The i-STAT 1 System is compliant with:
IEC 61326-1: Electrical Equipment for measurement, control and laboratory use - EMC requirements - Part1: General requirements.
IEC 61326-2-6: Electrical Equipment for measurement, control and laboratory use -EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment.

Software

All analyzer functions are controlled by application software that can be updated as additional tests and features are developed. Coefficients used to maintain the accuracy of cartridge results over time are programmed into the analyzer via CLEW software updates every six months. See under “Standardization and Calibration” in Section 4 of this manual for an explanation of CLEW.

Power

There are two power options for the analyzer: disposable and rechargeable. The analyzer is shipped with a battery carrier for use with two disposable Ultralife 9-Volt lithium batteries (APOC List Number: 06F21-26). Ultralife 9-Volt lithium batteries are manufactured by Ultralife Battery and Energy Products and sold by Abbott Point of Care for use with the i-STAT 1 Analyzer. Only i-STAT rechargeable batteries (APOC List Number: 06F23-55) may be used.

Note: The Ultralife 9-volt lithium battery (APOC List Number: 06F21-26) has a safety feature that provides protection preventing the i-STAT 1 Analyzer from overheating due to component failure within the analyzer circuitry.

Battery Compartment

The battery compartment is located at the display end of the analyzer next to the laser barcode scanner window. The procedure for changing disposable and rechargeable batteries can be found in the Routine Care of the Analyzer and Downloader section of this manual.

Disposable Batteries

The analyzer requires two 9-volt lithium batteries. The lifetime for a set of batteries is mainly dependent on the mix of cartridges in use. Cartridges that require thermal control consume more energy because of heating. Coagulation and immunoassay cartridges consume more energy because of the longer test cycle. A minimum of 400 thermally controlled cartridge uses, about 100 coagulation cartridges, or 50 immunoassay cartridges can be expected before replacement is necessary. Backlighting, if used continuously, may reduce battery life up to 50%. Extensive laser scanning will affect battery life slightly.

The lithium batteries should be removed from the analyzer when long periods, such as six months, of no use are anticipated.

Rechargeable Battery

The analyzer can be powered by a nickel-metal-hydride rechargeable battery. The battery capacity for one full charge is 30% (minimum) of the capacity of one set of disposable lithium batteries (see above). If the analyzer is not in use, batteries will lose approximately 10-30% of their charge over 30 days if not recharged.

Store rechargeable batteries in a cool dry place when not in use.

The battery recharges when the analyzer is placed in a Downloader/Recharger. The battery pack can be removed from the analyzer and placed in the separate recharging compartment on the Downloader/Recharger. Full recharge from a discharged state takes approximately 40 hours. The analyzer will display “Low Battery” when battery recharge is needed.

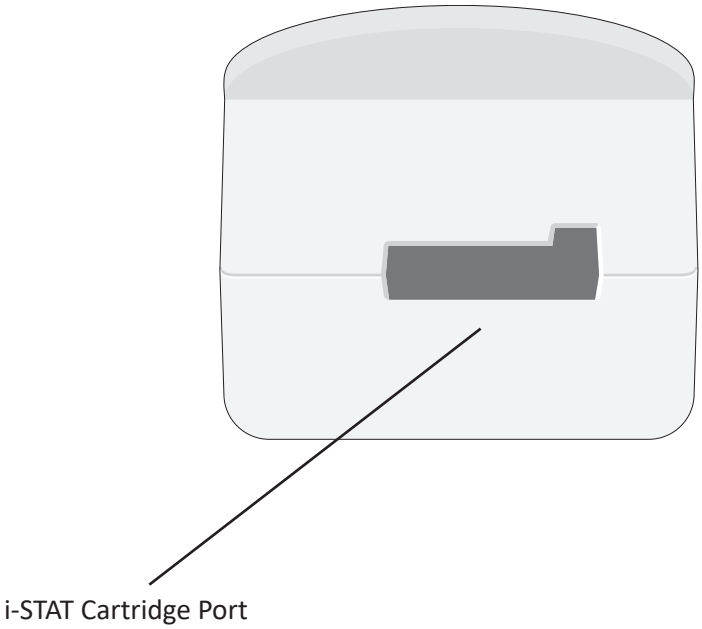
Caution: Do not short circuit, incinerate or mutilate the rechargeable batteries.

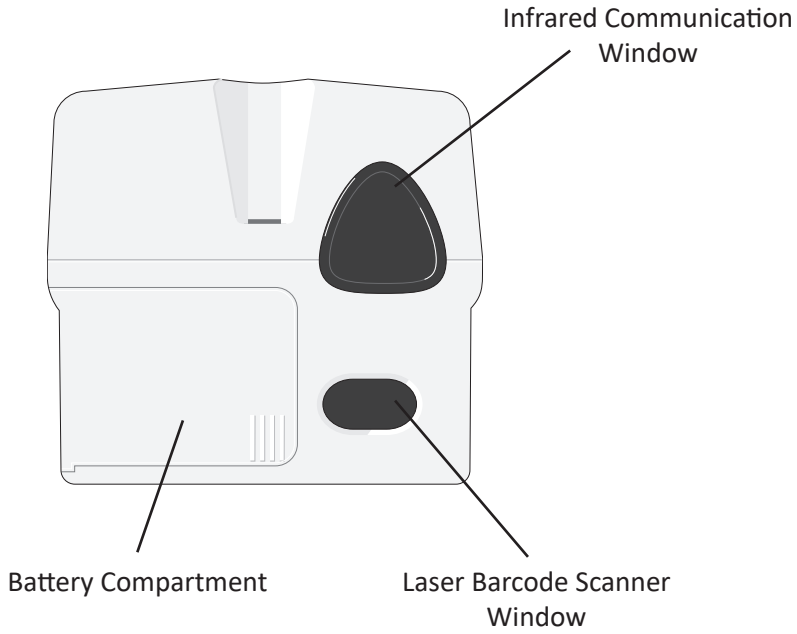
Low Battery Warning

The analyzer will display “Low Battery” when the On/Off key is pressed. Additionally, a flashing battery icon will display on the results screens, as well as the Test Menu and Administration Menu screens when battery replacement is needed. Data is not lost when batteries are fully discharged.

Additional Power A lithium battery inside the analyzer maintains the clock/calendar and customization profile. This battery should last seven years.

Cartridge Port Cartridges and the Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer.





Infrared Communication Window

The Infrared Communication Window provides the analyzer with two-way communication to i-STAT/DE via a Downloader, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.

Thermal Control

The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and fluids that come into contact with the sensors to 37°C. This subsystem is activated automatically when a cartridge containing tests which require thermal control at 37°C is inserted into the analyzer.

Barometric Pressure Sensor

The analyzer contains a solid-state barometric pressure sensor, which determines the ambient atmospheric pressure used for the $\boldsymbol{P}O_2$ sensor calibration.

Cartridge Test Cycle

An operator starts a cartridge test cycle either by selecting i-STAT Cartridge from the Test Menu or Quality Tests from the Administration Menu.

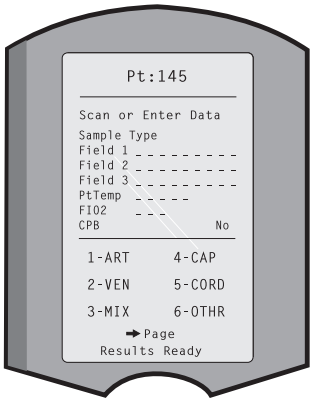
The analyzer:

- makes electrical contact with the cartridge
- identifies the cartridge type
- releases calibration fluid to the sensors (when applicable)
- mixes sample and reagent (when applicable)
- measures barometric pressure
- heats the sensors to 37°C (when required by the test)
- measures electrical signals generated by the sensors and calibration fluid (when applicable)
- displaces the calibrant solution with sample (when applicable)
- measures electrical signals generated by the sensors and sample
- accepts the operator and patient IDs scanned or entered by the operator
- accepts chart page information
- calculates and displays results
- stores results

Data Entry

Data that can be scanned into the analyzer or entered via the keypad include:

- Operator ID
- Patient ID, Proficiency ID, or Simulator ID
- Cartridge Lot Number
- Control Lot Number
- Cal Ver Kit Lot Number
- Comment codes for patient and control results
- Chart Page
  - Sample Type
  - Patient Temperature - The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees centigrade. When a patient temperature is entered, blood gas results will be displayed at both 37°C and the patient's temperature.
  - FIO2
  - Free Fields: three fields, up to 9 characters each



See the Customization section in this manual for barcode formats recognized by the analyzer.

Storage of Results

The analyzer automatically stores up to 1,000 test records. A test record consists of:

- a set of results
- the date and time the test was performed
- the cartridge type
- all information entered by barcode scanner or keypad including:
  - Operator and Patient IDs
  - Lot numbers for controls and cartridges
  - Chart page data
  - Serial number of the Electronic Simulator
- the serial number of the analyzer
- the number of times the analyzer has been used
- the software and CLEW versions installed in the analyzer
- the name of the analyzer's customization profile

Quality Check Codes, which may appear during the test cycle indicating a problem with the sample, calibration, sensors, mechanical or electrical functions of the analyzer, are also stored.

The Analyzer Status option under the Administration Menu lists the number of stored records as "Total" and "Unsent" records. Test records are stored as "Unsent" until the analyzer uploads data to i-STAT/DE at which time the records are marked as sent. The analyzer can be customized to display a Memory Full prompt or to disable testing until data is transmitted to i-STAT/DE. Otherwise, the oldest data is overwritten when the memory becomes full. Stored test records can be reviewed through the Data Review option on the Administration Menu screen described later in this section.

LCD Display and Backlight

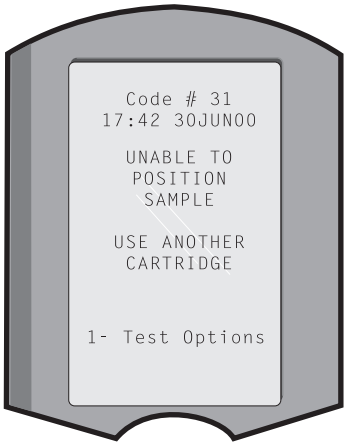
Test results, operator prompts and other messages are displayed on the analyzer's LCD Screen. The backlight for the display is turned on and off by pressing the 0 key for one second. The backlight will automatically turn off after ninety seconds and when the analyzer powers down or is turned off. The backlight cannot be turned on while data entry screens are displayed.

Audible Indicator

The analyzer will beep to indicate:

- whenever a key is pressed.
- a successful barcode entry.
- results are ready.
- a Quality Check Message is displayed.

The analyzer can be customized to disable beeping when a key is pressed or results or messages are displayed.



Time Out

The analyzer automatically turns off after a certain period of inactivity.

- **Results displayed:** Results are displayed for 2 minutes before the analyzer turns off provided that a mandatory Comment Code prompt is not displayed. This Inactivity Time Out default time can be increased using Customization.

  If a mandatory Comment Code prompt is displayed, the analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater. In the case of a missed required Comment Code, results will be stored and "_ _ _" will be entered as the Comment Code.

- **Prompting for mandatory data when results are ready for display:** The analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater, if there is no response to a mandatory data prompt. A mandatory data prompt is a prompt for information that must be entered before pending results are displayed.

  In the case of a missed mandatory data prompt, results will not be stored and the test record will state "Test Cancelled by Operator."

- **Waiting for insertion of cartridge:** After the prompt "Insert Cartridge" is displayed, the analyzer will wait 15 minutes for the operator to insert a cartridge unless the analyzer is in the Proficiency path, in which case the analyzer will wait 5 minutes. If a cartridge is not inserted, the analyzer will turn off. This timeout cannot be customized.

- **Other:** The analyzer will turn off after 2 minutes of inactivity (no keys pressed) in all other circumstances.

Keypad

There are 19 keys located directly below the display. When using the keypad to enter information, the number of dashes in the data entry line will indicate how many characters can be entered on the line. The dash where the next entry will be placed will flash.

Key	Function
SCAN	Activates the barcode scanner. Information that can be entered into the analyzer via the scanner includes: operator ID, patient ID, control and cartridge lot number, patient chart data and comment codes.
← →	Used to move the cursor on the Set Clock screen and to move up and down the alphabet when the ABC key is pressed. The → (right arrow) key is used as a page key to move from one screen to the next. When Patient ID Recall is enabled, the → key will recall the last patient ID when the analyzer is prompting for Patient ID. The ← (left arrow) key is used to backspace and clear keypad entries, and to move backward through the screens within a menu.
ABC	Used to enter alpha characters on data entry screens. When the ABC key is pressed the letter A is entered. The arrow keys are used to move up and down the alphabet. To enter a second letter, press the ABC key once to move to the next position and again to enter an A. To enter a number after a letter, press a numbered key. To erase a letter, press the ABC key to move to the next position, then use the ← key to backspace and clear the letter.
0 – 9	Used to enter digits on data entry screens and to select menu options and stored records.
•	Enters a decimal point or a comma separator according to the analyzer's Customization Profile.
	Used to turn the screen backlight on and off.
Enter 	Used to respond to a prompt to complete an action, such as entering an operator or patient ID via the keypad.
MENU	Used to return to the previous menu and switch between the Test and Administration Menus.
Print 	Used to print either directly to the portable printer or to the portable printer attached to a Downloader.
On/Off 	Turns the analyzer on or off. When the analyzer is on, the On/Off key must be pressed for a second to turn the analyzer off. This key is inactive when a test is in progress and when the analyzer is prompting for mandatory data.

i-STAT 1 Menu Tree

There are two main menus: The Test Menu and the Administration Menu.

Test Menu

1- Last Result

2- i-STAT Cartridge

Administration Menu		
1. Analyzer Status	Temp Pressure Battery Uses Serial CLEW Release Version Custom Stored Records Total Unsent	
2- Data Review	1-Patient 2-Control 3-Proficiency 4-Cal Ver 5- Simulator 6- All 7- List	
3-Quality Tests	1-Control 2- Proficiency 3- Cal Ver 4- Simulator	
4- Customization	1-View	1- Analyzer 2- ID Entry 3- Patient Tests 4- QC Tests 5- Results
	2-Change	1- Analyzer 2- ID Entry 3- Patient Tests 4- QC Tests 5- Results 6- Password 7- Restore Factory Settings
5- Set Clock		
6- Transmit Data	1- Most Recent 2- This Month 3- Last Month 4- All 5- Unsent	
7-Utility	1- Send Software 2- Clear Memory 3- Receive Software	

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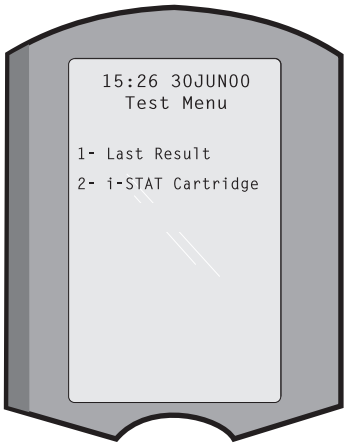
TEST MENU

The Test Menu is displayed when the analyzer is turned on using the On/Off key.



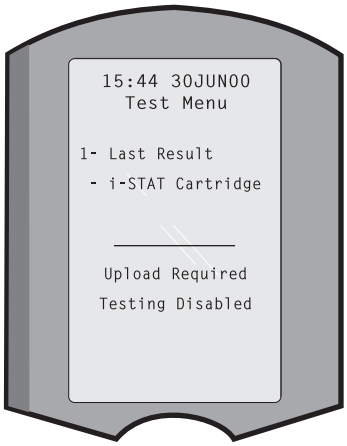
The options are:

1 - Last Result

2 - i-STAT Cartridge

Option 2 is used for testing patient samples.

Note: If the handheld is customized to disable testing under certain conditions, the disabled option will be listed without its number so that it cannot be selected.



ADMINISTRATION MENU

Overview

The Administration Menu is accessed by pressing the Menu key from the Test Menu screen. The options are:

1 - Analyzer Status

2 - Data Review

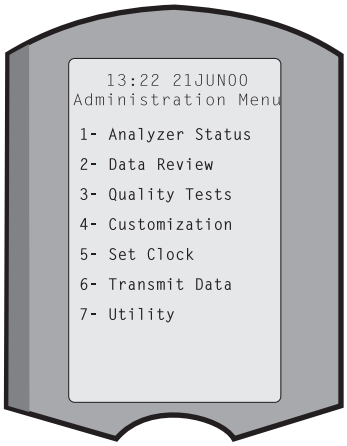
3 - Quality Tests

4 - Customization

5 - Set Clock

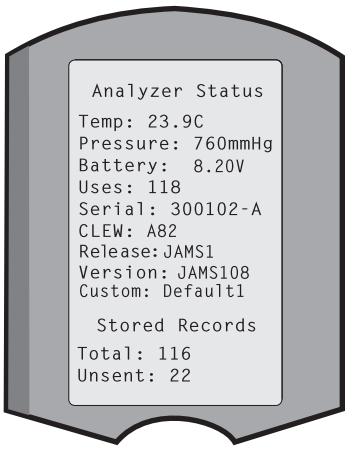
6 - Transmit Data

7 - Utility



Analyzer Status

The Analyzer Status screen contains information about the condition or "status" of the analyzer. Fresh readings are made whenever this option is selected.



Temp Room temperature.

Pressure Barometric pressure.

Battery Battery voltage.

Uses Total number of cartridge and simulator test cycles, whether or not results reported.

Serial Serial number of the analyzer.

CLEW Version of standardization data installed in the analyzer.

Release The current release version of application software installed in the analyzer.

Version The full version of application software installed in the analyzer.

Custom Customization profile name.

Stored Records Total: The number of test records in the analyzer's memory. The maximum storage capacity is 1,000 test records, which include records with results and Quality Check Codes for patients and controls both liquid and electronic.

Unsent: The number of test records that have not been transmitted to i-STAT/DE.

Data Review

The Data Review function allows the operator to review stored results by the categories listed below. The number of test records stored is indicated at the bottom center of the screen as x/y where x is the record on the screen and y is the total number of stored records in the selected category. The 1 and 2 keys are used to scroll through the stored records as indicated on the bottom right and left of the screen. The most recent test record is always in the first position. The right arrow key is used to page through the screens of the displayed record.



1 - Patient The records for a patient are recalled by scanning or entering via the keypad the Patient ID. If no Patient ID is entered, all patient tests are recalled.

2 - Control

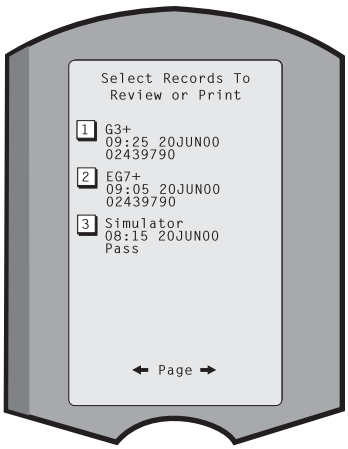
3 - Proficiency

4 - Cal Ver

5 - Simulator All external and internal Electronic Simulator records.

6 - All All test records in the analyzer's memory.

7 - List Records are listed with Cartridge type, date and time of test, patient ID, control lot, proficiency ID, or Cal Ver lot and test level as applicable. Any number of test records can be selected for viewing or printing using the number keys. Pressing the number key corresponding to a record selects a record; pressing the number key a second time deselects the record.



To view one or more records, select the records and press the Enter key. To print records, select the records and press the Print key.

Quality Tests

Non patient tests can be initiated from the Quality Tests menu. Options are:

1 - Control

2 - Proficiency (external quality control)

3 - Cal Ver (Calibration Verification for cartridges)

4 - Simulator (cartridge-reading function only)



When testing is initiated from one of these options, the handheld prompts the operator to scan or enter the Operator ID; the Control Lot Number, Proficiency ID, Cal Ver Kit Lot Number, or Simulator ID as applicable; and the Cartridge Lot Number.

When the Quality Tests option is used, results can be reviewed according to the corresponding options under the Data Review option.

Customization

Analyzers can be customized for site-specific testing characteristics and requirements. A complete list of customizable parameters and their default values can be found in the Customization section. An analyzer can be customized via the keypad or via i-STAT/DE. Items that cannot be customized via the analyzer's keypad are operator lists, test strip lists, reference and action ranges, sample types and order of items on the Chart page.

i-STAT/DE's Customization function can be used to create one customization profile for all analyzers or different profiles for different locations. When the Customization function is enabled, the profiles are transmitted to the analyzers when they are placed in a Downloader.

Caution: If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB: Automatically Adjust" or "CPB: Do Not Adjust" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional affect of pump fluid during cardiopulmonary bypass surgery. If an analyzer customized for the CVOR as "CPB: Automatically Adjust" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If an analyzer customized as "CPB: Do Not Adjust" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

It is recommended that only one method, i-STAT/DE or the keypad, be used to customize all analyzers within a site. If both methods are in use, and the Customization function is not disabled in i-STAT/DE, any changes made to the profile of an analyzer via the keypad will be overwritten the next time the analyzer is placed in the downloader.

The customization profile of an analyzer is identified in the Customization option under the Administration Menu on the analyzer. DEFAULT0 indicates that the analyzer has factory settings. When an analyzer has been customized via i-STAT/DE, the name assigned to the profile by i-STAT/DE is listed. If the default or i-STAT/DE profile is changed on the analyzer, the profile is listed as 00000000.

Viewing the Customization Profile

Select **4- Customization** from the Administration Menu, select **1- View** then select from the Customization Menu:

1 - Analyzer

2 - ID Entry

3 - Patient Tests

4 - QC Tests

5 - Results

Select a category to review. Use the ← and → keys to scroll through the preferences for each category and use the ← key to return to the Customization menu.

The Customization review option on the analyzer does not display the certified operator list. This item can be viewed in i-STAT/DE.

Note:

- Outside the USA, the following changes should be considered: language, unit set, date format and decimal separator.

1 - Analyzer

First page
Date Format
Sound
Auto-transmit
Memory Full
Batch Mode Timeout

Second page
Inactivity Timeout
Upload Schedule
Clock Password
Sync Clock
Patient Record Limit Access

Third page
Wireless (only available with the i-STAT wireless analyzer)

2 - ID Entry

1 – Operator ID

First page
Minimum Length
Maximum Length
Repeat ID
Manual Entry
Code I2of5

Second page
Code 128
EAN-8, EAN-13
Codabar
Code 93
Code 39

Third page
Code 39 Check Digit
Truncate First
Truncate Last
Operator List
Not Certified Action
Not In List Action

Fourth page
Warn User
Print ID

2 – Patient ID

First page
Minimum Length
Maximum Length
Repeat ID
ID Recall
Manual Entry

Second page
Code I2of5
Code 128
EAN-8, EAN-13
Codabar
Code 93

Third page
Code 39
Code 39 Check Digit
Truncate First
Truncate Last
Patient List
Not in List Action

Fourth page
Lockout Override
Confirmation Method
Print ID

3 - Patient Tests

First page
Cartridge Auto-chart
Cartridge Information
Cartridge Barcode
Cartridge Lot Number
Comment Code In Range

Second page
Comment Code Out of Range
Cart Sample Type
Result Output
Downloader Lockout
STATNotes

4 - QC Tests
1 – Simulator
Ext Simulator
Int Simulator
Int Simulator Schedule Option

2 – Cartridge QC
First page
Pass/Fail Method
Comment Code In Range
Comment Code Out of Range
Result Format
APOC fluid Lot Scan Only
Second page
eVAS Name

5 - Results
1 – ACT/Ref Ranges
2 – Display Ranges
3 – Units
4 – Options
First page
Decimal Separator
Test Selection
Hematocrit
Base Excess
ACT-C

Second page
ACT-K
Print Ref. Ranges

Changing the Profile

To customize via the handheld keypad, select **4- Customization** from the Administration Menu, then select **2- Change**. If the handheld has already been customized with a password, enter the password. If not, press the Enter key. (It is recommended that the Change function be password protected). Then make selections from the Customization menu. To change a setting, select the item by pressing the number key corresponding to the item, then select the setting. Use the → key to view all items. After all items have been set, turn the handheld off to save and activate the settings.

Note:

- Outside the USA, the following changes should be considered: language, unit set, date format and decimal separator.

1 - Analyzer
First page
Language
Date Format
Sound
Auto-transmit
Memory Full

Second page
Batch Mode Timeout
Inactivity Timeout
Upload Schedule
Clock Password
Sync Clock

Third page
Wireless (available with the i-STAT 1 wireless)

2 - ID Entry

1 – Operator ID

First page
Minimum Length
Maximum Length
Repeat ID
Manual Entry
Code I2of5

Second page
Code 128
EAN-8, EAN-13
Codabar
Code 93
Code 39

Third page
Code 39, Check Digit
Truncate First
Truncate Last
Print ID

2 – Patient ID

First page
Minimum Length
Maximum Length
Repeat ID
ID Recall
Manual Entry

Second page
Code I2of5
Code 128
EAN-8, EAN-13
Codabar
Code 93

Third page
Code 39
Code 39 Check Digit
Truncate First
Truncate Last

3 - Patient Tests

First page
Cartridge Auto-chart
Cartridge Information (functionality preset by analyzer firmware)
Cartridge Barcode (functionality preset by analyzer firmware)
Cartridge Lot Number (functionality preset by analyzer firmware)
Comment Code, In Range

Second page
Comment Code, Out of Range
Cart Sample Type
Result Output
Downloader Lockout

4 - QC Tests

1 – Simulator

Ext Simulator
Int Simulator
Int Simulator Schedule Option

2 – Cartridge QC
- Pass/Fail Method
- Comment Code In Range
- Comment Code Out of Range
- Result Format
- APOC Fluid Lot Scan Only

5 - Results

1 – Units and Ranges

2 – Options

- First page
- Decimal Separator
- Test Selection
- Hematocrit
- Base Excess
- ACT-C
- Second page
- ACT-K
- Print Ref. Ranges

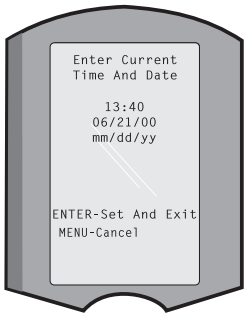
6 - Password

7 - Restore Factory Settings

Note: For additional procedures related to customization using the analyzer keypad, refer to *Procedures for Customization using the Analyzer Keypad* in Section 15 of this manual.

Set Clock

If the analyzer is customized with a password, the Set Clock function will be password protected. If a password has not been assigned, pressing the Enter key will display the time and date screen. Use the arrow keys to move the cursor to the digit to be changed. Use a number key to change the digit. Press Enter to accept the changes or Menu to cancel the changes. An invalid entry, such as 13 for a month, will not be accepted.



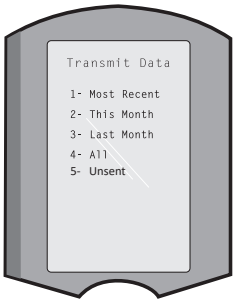
The format of the date on this screen can be customized using the i-STAT/DE customization function, as mm/dd/yy or dd/mm/yy. The analyzer recognizes years in which February has 29 days.

The analyzer can be customized using i-STAT/DE to synchronize or update the real time clock to the i-STAT/DE's clock at the time of each download. This option eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Saving Time. Otherwise, the clock must be manually changed for Daylight Savings Time changes.

Transmit Data

Unsent test records are automatically transmitted to i-STAT/DE when an analyzer is placed in a Downloader/Downloader/Recharger. In some cases it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:

1 – Most Recent
2 – This Month
3 – Last Month
4 – All
5 – Unsent



Most Recent is the result from the last cartridge tested.

The analyzer can be customized using i-STAT/DE to apply a date range limit to the Transmit All functions.

Auto-transmit is temporarily disabled when the Transmit Data option is selected to allow the user to control transmission of data.

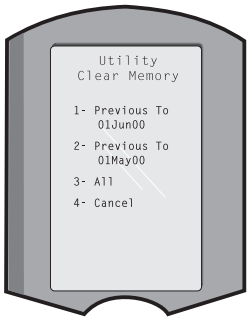
Utility

The Utility menu can be password protected using the Customization function on the analyzer or in i-STAT/DE.

1 – Send Software: Allows the analyzer to transmit software to another analyzer. See the Software Update section of this manual.

2 – Clear Memory: Erases results from the analyzer's memory. Options are:

- 1 – Previous to 01MMMYY (where MMMYY is current month and year, such as 01JUN00)
- 2 – Previous to 01mmmyy (where mmmyy is previous month and year, such as 01May00)
- 3 – All
- 4 – Cancel



3 – Receive Software: Allows users to remotely request a JAMS and CLEW update for the analyzer from i-STAT/DE. See section 17 (Updating Software) for full details.

LASER BARCODE SCANNER

Laser Barcode Scanner

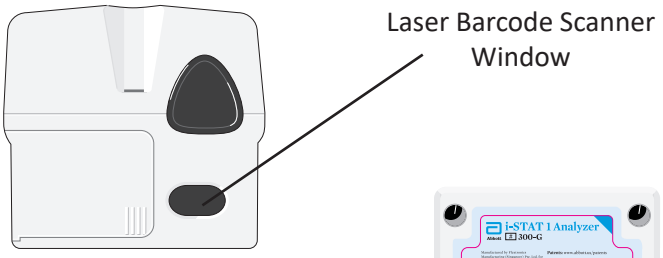
The barcode scanner is used to scan barcode information into the analyzer. Parameters that can be entered into the analyzer via the scanner include: operator and patient IDs, control and cartridge lot numbers, comment codes and patient chart data. The laser beam emerges from the recessed window on the front of the analyzer adjacent to the battery compartment. The laser beam automatically turns off after 3-4 seconds or after the barcode is successfully scanned.

Laser Specifications

The barcode scan engine is manufactured by Motorola Inc. or Opticon Inc. The scan engine contains a laser diode that emits laser radiation at a frequency of 650 nm. The scan engine outputs power (i.e., the power output of the engine if removed from this product) up to 1.9 mW in scanning mode. The scanner in this product only operates when the Scan key is pressed. The scan engine is intended to be used in a Class 2 device.

Warning Labels

Warning labels are shown below. The warning labels are located on the back or under-side of the analyzer, as shown. The location of the laser window from where the analyzer emits the laser beam is also shown below.





Caution

Do not open the analyzer. The analyzer may only be opened by factory authorized service personnel. **Class 2 laser radiation when open; DO NOT stare into the laser aperture or the laser beam, or point the laser beam at other persons.**

Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

Class 2 laser scanners use a low power, visible light diode. As with any bright light source, such as the sun, the user should avoid staring directly into the laser beam. Momentary exposure to a Class 2 laser is not known to be harmful.

Barcode Label Quality

To ensure that printed barcode labels are reliably read by i-STAT handhelds, the best available printing methods and settings should be used. However, as specified in the *Health Industry Bar Code (HIBC) Provider Applications Standard* (ANSI/HIBC 1.3-2010), the quality of printed labels should meet the minimum grade level of 1.5.

Ambient Lighting from LED Light Sources

The analyzer's barcode scanning functionality may experience interference when scanning barcodes under ambient light from an LED light source. This interference results in the analyzer being unable to scan a barcode at all (no beep acknowledgement). When scanning barcodes under ambient light from an LED light source, it is recommended that the barcode be shielded from the ambient light when attempting to scan the barcode.

Procedure

Before scanning, check to see what information is required by the displayed prompt. Hold the analyzer 3-9 inches (8 – 23 cm) from the barcode to be scanned. An angle of about 10 degrees from perpendicular is best. Hold the analyzer and place the object to be scanned on a flat surface or, place the analyzer on a flat surface and hold the object in front of the analyzer. Avoid accidentally scanning other nearby items. Avoid pointing the beam into anyone's eyes.

STEP	ACTION
1	Press and hold down the Scan key to start the barcode scanner. The analyzer emits a visible red beam.
2	Position the analyzer and barcode so the beam forms a red line that spans the entire barcode. Increasing distance between the barcode and analyzer lengthens the red line. The analyzer does not need to touch the barcode.
3	When the analyzer accepts the barcode, it will beep in acknowledgement and automatically turn off the beam. The beam will also turn off after 3-4 seconds.
4	View the data that was scanned by the analyzer and verify that it is correct.
5	Release the Scan key.
Note:	If the Scan key is released as soon as the beep is heard, the next prompt will be displayed and the information scanned will not be able to be viewed.

I-STAT 1 SYSTEM – MANUFACTURER'S DECLARATION OF ELECTROMAGNETIC COMPATIBILITY (EMC)

i-STAT 1 System – Manufacturer's Declaration of Electromagnetic Compatibility (EMC) i-STAT 1 analyzer (Model # 300-G or 300W) with Electronic Simulator i-STAT 1 Downloader/Recharger (Model # DRC-300) i-STAT 1 Printer (Model # PR-300)				
Phenomenon *(Port)*	**EMC Basic Standard**	**Test Levels IEC 61326-2-6**	**Test Levels IEC 60601-1-2**	**Compliance**
Electrostatic discharge *(Enclosure)*	IEC 61000-4-2	+/-2kV and +/-4kV contact discharge +/-2kV, +/-4kV, and +/-8kV air discharge	+/-8kV contact +/-2kV, +/-4kV, +/-8kV +/-15kV air	Complies to both standards
Radiated RF susceptibility *(Enclosure)*	IEC 61000-4-3	3V/m (80MHz to 1Ghz) 3V/m (1.4GHz to 2Ghz) 1V/m (2GHz to 2.7Ghz)	3V/m (80MHz - 2.7GHz) 80% AM at 1kHz	Complies to both standards
Power frequency magnetic field susceptibility *(Enclosure)*	IEC 61000-4-8	3 A/m (50Hz, 60Hz)	30 A/m (50Hz, 60Hz)	Complies to both standards
Proximity field from RF wireless communications equipment *(Enclosure)*	IEC 61000-4-3	Not specified.	IEC 60601-1-2 Sec. 8.10 Table 9	Complies to 60601-1-2
Voltage dip *(AC power including protective earth)*	IEC 61000-4-11	0% during 1 cycle 40% during 5/6 cycles 70% during 25/30 cycles	0% during 1 cycle 0% during 0.5 cycle (0°,45°,90°,135°,180°,225°, 270°,315°)	Complies to both standards
Short interruptions *(AC power including protective earth)*	IEC 61000-4-11	Less than 5% 250/300 cycles	0% 250/300 cycles	Complies to both standards
Burst transients *(AC power including protective earth)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	+/-2kV (100kHz)	Complies to both standards

i-STAT 1 System – Manufacturer's Declaration of Electromagnetic Compatibility (EMC) i-STAT 1 analyzer (Model # 300-G or 300W) with Electronic Simulator i-STAT 1 Downloader/Recharger (Model # DRC-300) i-STAT 1 Printer (Model # PR-300)				
Phenomenon *(Port)*	**EMC Basic Standard**	**Test Levels IEC 61326-2-6**	**Test Levels IEC 60601-1-2**	**Compliance**
Surges *(AC power including protective earth)*	IEC 61000-4-5	1kV (line to line) 2kV (line to earth)	+/-0.5kV (line to line, line to earth) +/-1kV (line to line, line to earth) +/-2kV (line to earth)	Complies to both standards
Conducted RF *(AC power including protective earth)*	IEC 61000-4-6	3V (150kHz - 80MHz)	3V (0.15Mhz - 80MHz) 6V in ISM bands (0.15Mhz - 80MHz) 80% AM at 1kHz	Complies to both standards
Burst transients *(DC power including protective earth)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	+/-2kV (100kHz)	Complies to both standards
Surges *(DC power including protective earth)*	IEC 61000-4-5	1kV (line to line) 2kV (line to earth)	+/-0.5kV (line to line, line to earth) +/-1kV (line to line, line to earth) +/-2kV (line to earth)	Complies to both standards
Conducted RF susceptibility *(DC power including protective earth)*	IEC 61000-4-6	3V (150kHz - 80MHz)	3V (0.15MHz - 80MHz) 6V in ISM bands (0.15MHz - 80Mhz) 80% AM at 1kHz	Complies to both standards
Burst transients *(I/O Signal/Controls)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	+/-1kV (100kHz)	Complies to both standards
Surges *(I/O Signal/Controls)*	IEC 61000-4-5	None	+/-2kV (line to earth)	Complies to 60601-1-2
Conducted RF susceptibility *(I/O Signal/Controls)*	IEC 61000-4-6	3V (150kHz - 80MHz)	3V (0.15MHz - 80MHz) 6V in ISM bands (0.15MHz - 80MHz) 80% AM at 1kHz	Complies to both standards
Electrostatic discharge *(I/O Signal/Controls)*	IEC 61000-4-2	None	+/- 8kV contact +/-2kV, +/- 4kV, +/- 8kV air	Complies to 60601-1-2

i-STAT 1 System – Manufacturer's Declaration of Electromagnetic Compatibility (EMC) i-STAT 1 analyzer (Model # 300-G or 300W) with Electronic Simulator i-STAT 1 Downloader/Recharger (Model # DRC-300) i-STAT 1 Printer (Model # PR-300)				
Phenomenon *(Port)*	**EMC Basic Standard**	**Test Levels IEC 61326-2-6**	**Test Levels IEC 60601-1-2**	**Compliance**
Burst transients *(I/O Signal/Controls connected to mains)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	None	Complies to 61326-2-6
Conducted RF susceptibility *(I/O Signal/Controls connected to mains)*	IEC 61000-4-6	3V (150kHz - 80MHz)	None	Complies to 61326-2-6
Proximity magnetic fields 9kHz-14.56Mhz *(Enclosure)*	IEC 60601-1-2 section 8.11	N/A	30KHz, CW, 8A/m 134.5KHz, Pulse, 65A/m 13.56MHz, Pulse, 7.5A/m	Complies to 60601-1-2
IEC CISPR Group 1 Radio frequency emission *(Enclosure)*	IEC CISPR 11 2010-05	Radiated emissions (30-1000MHz)	N/A	Complies with CISPR 11 2010-05
IEC CISPR Group 1 Radio frequency emission *(AC/DC power adaptor)*	IEC CISPR 11 2010-06	Conducted emissions (150KHz - 30MHz)	N/A	Complies with CISPR 11 2010-05
FCC: 47 CFR Part 15 subpart B Class A unintentional radiators *(AC/DC power adaptor)*	FCC: 47 CFR Part 15 subpart B Class A	Conducted emissions (150KHz - 30MHz)	N/A	Complies with FCC: 47 CFR Part 15 Class A
FCC: 47 CFR Part 15 subpart B Class A unintentional radiators *(AC/DC power adaptor)*	FCC: 47 CFR Part 15 subpart B Class A	Radiated emissions (41-2378MHz)	N/A	Complies with FCC: 47 CFR Part 15 Class A

Additional Immunity Testing to 5G FR1 and FR2 Radio Frequencies			
Phenomenon *(Port)*	**Test Purpose**	**Test Levels**	**Compliance**
Proximity field from 5G RF wireless communications equipment *(Enclosure)*	Ad hoc testing for 5G immunity	FR1, 617MHz-7100MHz, 3m, 34V/m	Complies to manufacturer's test plan.
Proximity field from 5G RF wireless communications equipment *(Enclosure)*	Ad hoc testing for 5G immunity	FR2, 24.5-40 GHz, 0.1m, 34V/m	Complies to manufacturer's test plan.

PROMPTS AND MESSAGES

Prompts

Either before or during the testing cycle, the analyzer will display prompts that require an operator action or keypad entry, such as "Enter Operator ID." Prompts are described in the manual when used. Some prompts require input before results are displayed. Prompts for the following information are mandatory:

- Operator ID
- Patient ID
- Lot Numbers for Quality Tests
- Cartridge Lot Number

Startup Messages

When the On/Off key is pressed the analyzer may display one or more startup messages. A startup warning message indicates an action that should be taken in the near future to maintain the analyzer in working condition. If the analyzer is customized to disable testing under certain conditions, a startup lockout message indicates the action that must be taken before testing is re-enabled.

Quality Check Messages

If the analyzer detects a problem during power on, a Quality Check message will be displayed indicating the action that must be taken before testing can begin.

A Quality Check message will also be displayed and testing halted if the analyzer detects a problem during the test cycle.

Startup messages and Quality Check messages are described in the Troubleshooting section of this manual. “Upload Required, Testing Disabled” is an example of a startup lockout message, “Battery Low ” is an example of a startup warning message, and “Unable to Position Sample” is an example of a quality check failure during the testing cycle.

Note: The “Cartridge Locked” or “Simulator Locked” prompt is always displayed when a cartridge or Electronic Simulator is inserted into the analyzer. Any attempt to remove a cartridge or Electronic Simulator before this prompt is removed from the screen may cause damage to the analyzer.

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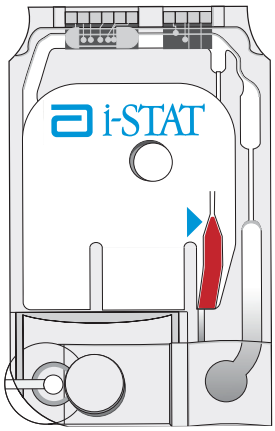
Contents

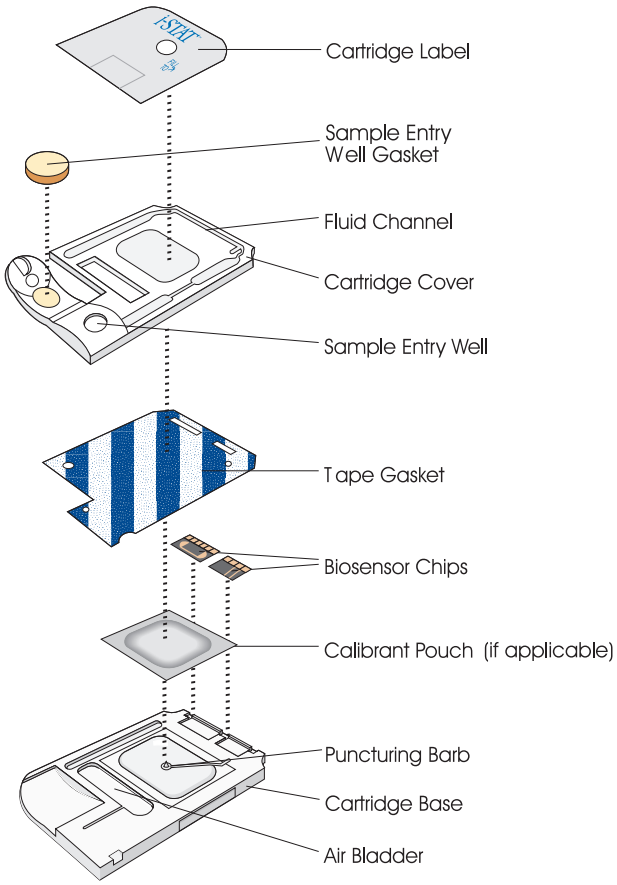


The unit-use disposable cartridge contains many of the subassemblies typically found in complex laboratory systems. Microfabricated thin film electrodes or sensors are assembled in unit-use cartridges containing:

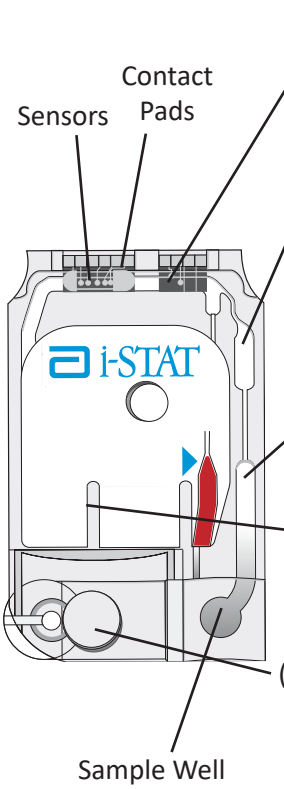
- calibrant solution in cartridges with sensors for blood gases, electrolytes, chemistries and hematocrit
- analysis solution in immunoassay cartridges
- reagents in cartridges with sensors for coagulation
- sample handling system
- waste chamber
- an array of miniaturized sensors
- conductive pads to make electrical contact with the analyzer
- heating elements for thermal control at 37 °C

For specific cartridge details, see the Cartridge and Test Information Sheets or Instructions for Use located at www.globalpointofcare.abbott.

The following diagram shows how a typical blood gas/chemistry cartridge is constructed.



Sample Handling System



Part	Function
Sensor Channel	The sensor channel directs the sample from the sample chamber to the sensors. An extension of this channel becomes a waste chamber to receive the calibrant solution, if applicable, as it is displaced by the sample.
Air Chamber	An air chamber is located in blood gas/electrolyte/chemistry/hematocrit cartridges between the sample chamber and sensor channel. This creates an air segment between the calibrant solution, if applicable, and the sample to prevent the two from mixing. The size of the air segment is monitored by the analyzer.
Sample Chamber	The sample chamber includes the sample well and the channel leading from the well up to the fill mark. When filled, the sample chamber contains sufficient sample for testing. Sample volume and placement are monitored by the analyzer.
Bladder	The bladder (concealed by the label) is connected to the sample well. The analyzer presses on the bladder to displace calibrant solution, if applicable, from the sensors to move the sample from the sample chamber to the sensors or to mix sample and reagents.
Snap Closure	The snap closure creates an airtight seal necessary for proper fluid movement within the cartridge. The closure also ensures that calibrant, if applicable, and sample remain contained within the cartridge during the testing cycle and subsequent disposal. Immunoassay cartridges, such as cTnI, use a plastic slide enclosure clip.
Air Vent	An air vent on the underside of the cartridge, beyond the fluid front, allows the calibrant and the sample to flow forward, but not out of the cartridge.
Waste Chamber	A waste chamber (beneath the cartridge label) holds calibrant fluid after it has been used.

Sensors

The sensors are electrodes microfabricated on silicon chips. Electrodes have chemically sensitive coatings such as ion-selective membranes and enzyme layers. In cartridges that perform coagulation tests, reagents, such as clot activators, are coated on the plastic above the sensors. Each sensor is connected to a contact pad by a signal line. The sensors respond to the calibrant solution, if applicable, and the sample by producing measurable signals related to analyte concentration. The performance characteristics for each sensor are described in the Cartridge and Test Information section. The section on theory describes the measurement principles.

Contact Pads

The contact pads conduct the signals generated by the sensors to the analyzer. In order to function properly, care must be exercised not to contaminate the contact pads during cartridge handling.

Heating Elements

All i-STAT cartridges require thermal control at 37 °C, and include heating elements on the underside of the sensor chips which are contacted and heated by the handheld's thermal probes.

Standardization and Calibration

Standardization is the process by which a manufacturer establishes “true” values for representative samples. The sensors in the i-STAT cartridges are standardized against plasma methods used by major laboratory systems or, for blood gases, against tonometry. A multi-point calibration curve, the slope or sensitivity of which is defined by coefficients in the CLEW software, is derived for each sensor by this standardization process. These calibration curves are stable over many lots and only need to be adjusted if a change in a manufacturing process affects the curve or if the relationship between results on the i-STAT System and other major laboratory systems drifts. For the convenience of users, CLEW updates are scheduled two times a year.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors’ responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the analyzer automatically moves the sample over the sensors and the signals produced by the sensors’ responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample’s concentration from adjusted calibration curve.

Packaging

Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage.

Labeling on the carton, box and pouch/portion pack identify:

- the panel name.
- the tests included in the panel.
- the lot number.
- the expiration date of the cartridge.

If the pouch/portion pack has been punctured, the cartridge should not be used.

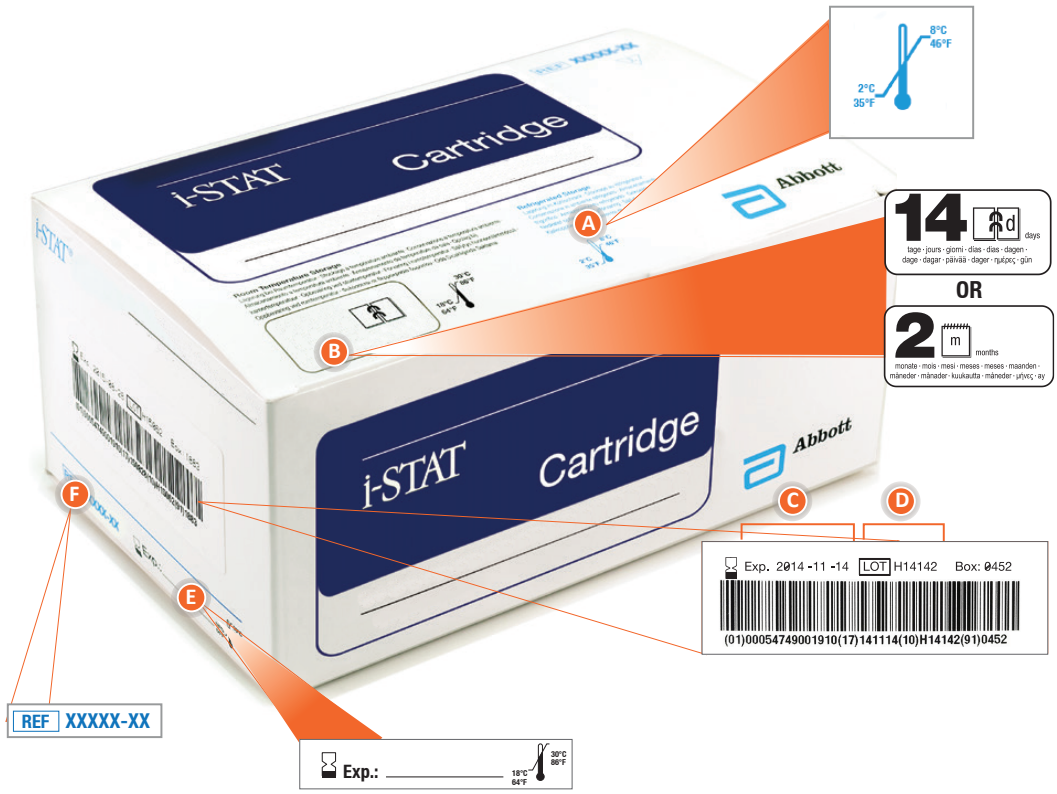
Storage Conditions

The main supply of cartridges should be stored at 2-8°C (35-46°F). Cartridges must be at room temperature before removing them from their pouches. Allow 5 minutes for an individual cartridge and one hour for a box of cartridges to come to room temperature. Cartridges in use may be stored at room temperature (18-30°C or 64-86°F) for the time frame indicated on the cartridge box. The cartridge box and pouch contain a line used to indicate the room temperature expiration date.

Disposal

Although the sample is contained in the cartridge, cartridges should be disposed of as biohazardous waste, according to local, state, and national regulatory guidelines.

Cartridge Box

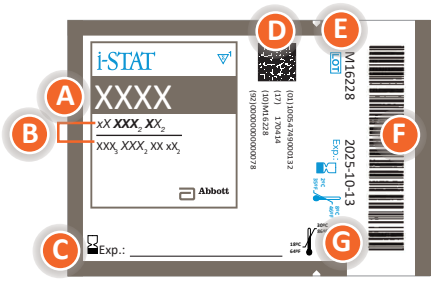


Anatomy of a box:

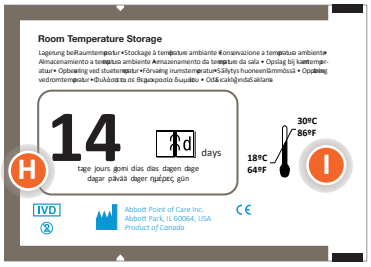
- **A** **Refrigerated storage temperature indicator:** 2-8°C (35-46°F)
- **B** **Indicates shelf life when stored at room temperature**
- **C** **Refrigerated storage expiration date**
- **D** **Cartridge LOT number**
- **E** **Location to record room temperature expiration date**
- **F** **Cartridge List Number**

Cartridge Pouch

Pouch Front

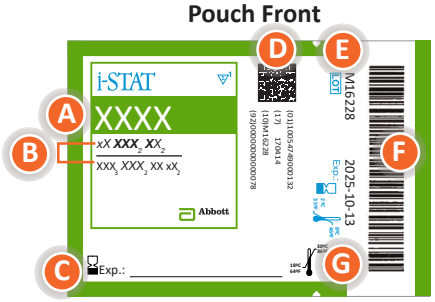


Pouch Back

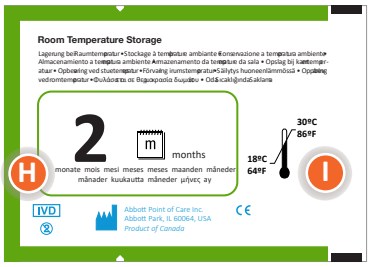


OR

Pouch Front



Pouch Back



Anatomy of a pouch:

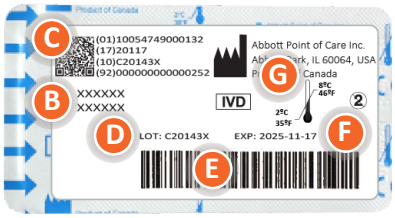
- **A** Cartridge name
- **B** Analytes – measured and calculated, if applicable
- **C** Location to record room temperature expiration date
- **D** 2D barcode for manufacturing quality control; not scannable
- **E** Cartridge LOT number
- **F** Cartridge pouch barcode
- **G** Refrigerated storage expiration date
- **H** Indicates shelf life when stored at room temperature
- **I** Room temperature storage range

Cartridge Portion Pack

Portion Pack Front

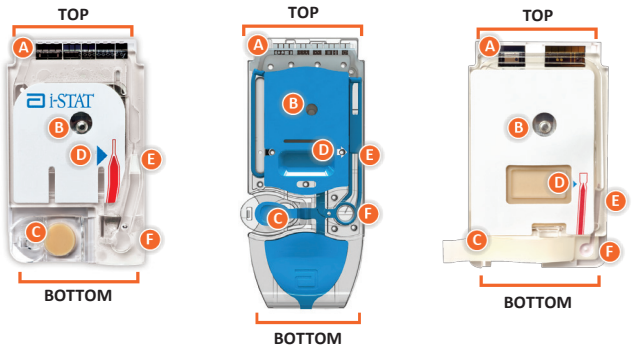


Portion Pack Back



Anatomy of a portion pack:

- **A** Cartridge name
- **B** Analytes – measured and calculated, if applicable
- **C** 2D barcode for manufacturing quality control; not scannable
- **D** Cartridge LOT number
- **E** Cartridge portion pack barcode
- **F** Refrigerated storage expiration date
- **G** Refrigerated temperature storage range



Anatomy of a cartridge

- **A** CONTACT PADS & SENSORS (do not touch)
- **B** CALIBRANT PACK OR ANALYSIS FLUID, if applicable (do not touch)
- **C** CARTRIDGE CLOSURE
- **D** FILL TO MARK
- **E** SAMPLE CHAMBER
- **F** SAMPLE WELL

i-STAT Cartridge Configurations

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT 1 Analyzer* for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

Note: Cartridge-specific Instructions for Use (IFU) and individual analyte CTI Sheets are available for download and printing from the Support page of the Abbott Point of Care website: www.globalpointofcare.abbott.

Analysis Time:

- Cartridges that test for ACT: to detection of end point - up to 1000 sec (16.7 min)
- Cartridges that test for PT and INR: to detection of end point – up to 300 sec (5 min)
- hs-TnI* cartridge: 15 min
- cTnI, *ß*-hCG and BNP cartridges: 600 sec (10 min)
- CK-MB cartridge: 300 sec (5 min)
- Other cartridges: typically 130 to 200 sec

* The i-STAT cTnI, CK-MB, Total ß-hCG, BNP and hs-TnI are immunoassay cartridges that require the use of an i-STAT 1 analyzer bearing the 

symbol.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, APOC recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT *CHEM8+* (95 µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO_2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT *G* (65 µL)
Glucose (Glu)

i-STAT *Crea* (65 µL)
Creatinine (Crea)

i-STAT *EG7+* (95 µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
$\boldsymbol{P}CO_2$
$\boldsymbol{P}O_2$
TCO_2*
HCO_3*
BE*
$\boldsymbol{s}O_2$*
Hemoglobin* (Hb)

i-STAT *EG6+* (95 µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
$\boldsymbol{P}CO_2$
$\boldsymbol{P}O_2$
TCO_2*
HCO_3*
BE*
$\boldsymbol{s}O_2$*
Hemoglobin* (Hb)

i-STAT *CG4+* (95 µL)
pH
$\boldsymbol{P}CO_2$
$\boldsymbol{P}O_2$
Lactate
TCO_2*
HCO_3*
BE*
$\boldsymbol{s}O_2$*

i-STAT *CG8+* (95 µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
$\boldsymbol{P}CO_2$
$\boldsymbol{P}O_2$
TCO_2*
HCO_3*
BE*
$\boldsymbol{s}O_2$*
Hemoglobin* (Hb)

i-STAT *Celite ACT* (40 µL)
Celite ACT

i-STAT *Kaolin ACT* (40 µL)
Kaolin ACT

i-STAT *Total ß-hCG* (17 µL)
Total Beta-Human Chorionic Gonadotropin

i-STAT *PT/INR* (20 µL)
Prothrombin Time

i-STAT *cTnI* (17 µL)
Troponin I

i-STAT *CK-MB* (17 µL)
Creatine Kinase MB

i-STAT *BNP* (17 µL)
B-type Natriuretic Peptide

i-STAT *PT^{plus}* (20 µL)
Prothrombin Time

i-STAT *hs-TnI* (22 µL)
Troponin I

**Calculated*

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

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CARTRIDGE AND TEST INFORMATION

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT 1 Analyzer* for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

Note: Cartridge-specific Instructions for Use (IFU) and individual analyte CTI Sheets are available for download and printing from the Support page of the Abbott Point of Care website: www.globalpointofcare.abbott.

CARTRIDGE SPECIFICATIONS

Shelf Life:

Refrigerated at 2 to 8 °C (35 to 46 °F) until expiration date.

Refer to the cartridge box for room temperature storage requirements.

Preparation for Use:

Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Sample Type:

Fresh whole blood from arterial, venous, or skin punctures.

(Note: Skin puncture for direct application is only recommended for the PT/INR cartridge.)

cTnI and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw.

ß-hCG cartridges require the use of heparinized whole blood or plasma samples.

BNP cartridges require the use of EDTA whole blood or plasma samples.

Sample Volume:

17 µL, 20 µL, 40 µL, 65 µL, or 95 µL depending on cartridge type.

Test Timing:

Immediately after collection

- Samples for the measurement of ACT, PT/INR and Lactate

Within 3 minutes after collection

- Samples collected in capillary tubes with balanced heparin anticoagulant
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant

Within 10 minutes after collection

- Samples collected with anticoagulant for the measurement of pH, ***P***CO_2, ***P***O_2, TCO_2 and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection

- Samples collected with anticoagulant for the measure of sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, ß-hCG and BNP. Remix thoroughly before testing.

* The cTnI, CK-MB, ß-hCG and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the 

symbol.

Analysis Time:

- ACT cartridge: to detection of end point - up to 1000 sec (16.7 min)
- PT/INR cartridge: to detection of end point – up to 300 sec (5 min)
- cTnI, *ß*-hCG and BNP cartridges: 600 sec (10 min)
- CK-MB cartridge: 300 sec (5 min)
- Other cartridges: typically 130 to 200 sec

Cartridges	Collection Options			
	Syringes	**Evacuated Tubes**	**Capillary Tubes**	**Directly from Skin Puncture**
ACT Celite and ACT Kaolin Cartridges	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Not recommended
PT/INR Cartridge	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Recommended
CK-MB and cTnI Cartridges	• With sodium or lithium heparin anticoagulant (syringe must be filled to labeled capacity) • Without anticoagulant if tested within one minute of patient draw	• With sodium or lithium heparin anticoagulant (tubes must be filled to capacity) • Without anticoagulant if tested within one minute of patient draw	• Not recommended	• Not recommended
Total ß-hCG Cartridge	• With sodium or lithium anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic	• With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Not recommended	• Not recommended
BNP Cartridge	• With EDTA anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic	• With EDTA anticoagulant (tubes must be filled to capacity) • Tubes must be plastic	• Not recommended	• Not recommended

Note: For information regarding cartridges not listed in the Collection Options table, please refer to the Instructions for Use (IFU) documents found on the APOC website at: https://www.pointofcare.abbott/us/en/offerings/support/i-stat/cartridge-test-information-sheets.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, APOC recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

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ELECTRONIC SIMULATOR 5

Overview

The Electronic Simulator, external and internal, is a quality control device for the analyzer's cartridge signal-reading function. It simulates two levels of electrical signals that stress the analyzer's cartridge signal detection function both below and above measurement ranges.

While the analyzer performs internal electronic checks and calibration during each test 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. An analyzer will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the analyzer software.

The schedule for the Electronic Simulator can be customized to meet local, state, or national accreditation requirements. A reminder message for the operator to run the external simulator can be set by the number of hours or tests on the i-STAT 1 Analyzer. The schedule for the automatic internal Electronic Simulator can be set by the number of hours or tests on the i-STAT 1 Analyzer. For details and lockout options, see the Customization section of this manual.

Note: All analyzers that pass the Electronic Simulator test are equivalent. Therefore, any representative number of analyzers that pass the Simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, proficiency testing, and method comparison studies.

Relative Humidity

The Electronic Simulator test will fail if high humidity interferes with the measurements. Therefore it is not necessary to record humidity where the analyzers are in use.

Internal Simulator

When the specified time has elapsed since the last Electronic Simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted before the sample is tested, adding about 20 seconds to the testing cycle.

External Simulator

The external Electronic Simulator is a stable electronic device, which is inserted into the cartridge port. The test cycle for the external Electronic Simulator is about 60 seconds. (The test cycle for the internal simulator is shorter because it shares the initial part of the test cycle with the cartridge.)

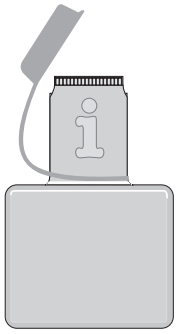
Operating Characteristics

Operating Characteristics	
Dimensions	Height 1.9 cm Width 7.0 cm Length 9.0 cm
Weight	85 g
Operating Temperature	Same as Analyzer being tested
Operating Ambient Humidity	10-90% RH non-condensing (as shipped)
Storage Temperature	-20-50˚C (-4-122˚F)

Even when the internal Electronic Simulator is enabled, an external Electronic Simulator is needed:

- to validate an internal simulator failure.
- to reset the internal simulator schedule if a simulator test might interrupt testing, such as in a CVOR.

  Note: CVOR = Cardiovascular Operating Room
- for on-demand testing at any time.
- to perform the thermal probe check.



The external Electronic Simulator should be stored in the box in which it is shipped and the blue cap should be replaced after each use to protect the contact pads.

Stored Result

The results of the Simulator test are stored as a distinct record in the analyzer and can be transmitted to the Data Manager.

Use

Use of the Electronic Simulator is described further in the Quality Control section of this manual.

Cleaning the Simulator

Before cleaning, cover the connector area with the blue rubber boot. This will minimize the possibility of any cleaning fluid getting into the simulator housing, thus contaminating the internal circuitry.

Clean the simulator with any of the cleaning agents approved for the analyzer and listed under the heading **Cleaning the Analyzer and Downloader** in Section 16 of this manual.

Rinse the simulator using another gauze pad moistened with water and dry. DO NOT IMMERSE THE SIMULATOR IN ANY FLUID, AT ANY TIME.

If the connector itself is contaminated, the user should contact their Support Representative and arrange to have the simulator returned.

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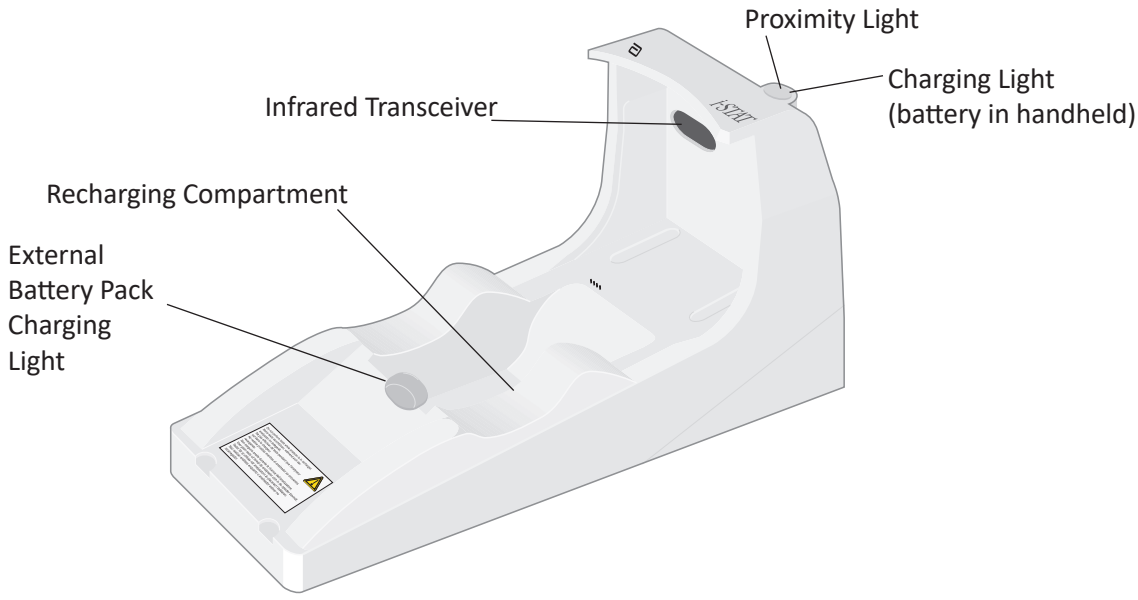
i-STAT 1 DOWNLOADER/RECHARGER 6

OVERVIEW

This document contains the instructions for using the i-STAT 1 Downloader/Recharger (Model Number DRC-300), which is used to:

- transmit i-STAT 1 handheld test records via infrared signals using USB or network cabling to i-STAT/DE software.
- transmit data from i-STAT/DE to the i-STAT 1 handheld, via infrared signals.
- recharge the rechargeable battery installed in the i-STAT 1 handheld or a rechargeable battery installed in the recharging compartment of the DRC-300.



If you have questions regarding the information in this document, please contact your Support Services representative.

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IDENTIFICATION OF THE i-STAT 1 DOWNLOADER/RECHARGER

Previously, there were two separate versions of the i-STAT 1 Downloader/Recharger, one with serial connection capabilities to the Data Manager (DRS-300) and one with network connection capabilities to the Data Manager (DRN-300). To distinguish the DRC-300 from the previous DRS-300 and DRN-300 downloader/recharger versions, look at the Model Number (MN) label on the underside of the downloader/recharger. The i-STAT downloader/recharger will have an MN DRC-300 (Figure 1).



Figure 1

SPECIFICATIONS OF THE DRC-300

Specifications	
Size	4.12 in (10.4 cm) Wide 9.60 in (24.4 cm) Long 5.00 in (12.7 cm) High
Weight	1.2 lb. (0.55 kg)
Power	AC-DC power adapter Input 12Vdc
Operating Temperature	15 to 40 °C 59 to 104 °F
Storage Temperature	-20 to 50 °C -4 to 122 °F
Pollution Degree (Allowable ambient pollution level)	2
Installation Category (Allowable overvoltage specification)	2
Communication to Data Manager	USB, or Network
Communication Link to and from Handheld	Infrared Transceiver
<u>Indicator LEDs</u> Power Proximity Charge	 N/A Blue Red/Green
Configuration	By host computer

Note: This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements.

POWER SUPPLY SPECIFICATIONS

Specifications	
Input	100 – 240V 50 – 60Hz 1.1A max
Output	12 Vdc 3A max

DRC-300 INDICATOR LEDs

Handheld Battery LED (near top of the DRC-300)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging

Spare Battery (near middle of DRC-300)	
Off	No Rechargeable Battery
Green	Trickle Charging
Blink Green Then Off	Charging

POWER REQUIREMENTS

The DRC-300 requires one power outlet. The DRC-300 must be used with the AC power supply adapter supplied with the DRC-300. Using the Y-Splitter cable, the DRC-300 power supply can be used to supply power to the i-STAT Printer (Model Number PR-300), which reduces the number of power outlets required in the downloading and printing area.

CAUTIONS

- The DRC-300 is not intended for use in the patient environment (i.e., within 1.5 meters of the physical location of the patient).
- Users should not connect the DRC-300 to a medical electrical system.
- Do not place metal objects on or near the exposed gold charging contacts.
- Be sure to install all cables and power supplies so they do not post a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as a disconnect device for the DRC-300; therefore the socket outlet must be easily accessible and installed (or located) near the DRC-300.
- Use only the AC power supply provided with the DRC-300 to power the DRC-300.
- Only APOC provided printers may be connected to the DRC-300 printer port.
- A network cable and USB cable may NOT be connected to the DRC-300 at the same time.
- If using rechargeable batteries to power the handheld, use only rechargeable batteries and recharging equipment supplied by your APOC distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients.
- A falling handheld may cause injury. Always place the handheld and peripherals on a stable surface or in a location where it will not cause injury if dropped.
- Security Consideration: Disable TFTP (Trivial File Transfer Protocol) to prevent malicious downloads to the DRC and enhance security.

RUNNING CARTRIDGES IN A HANDHELD DOCKED IN THE DRC-300

All i-STAT cartridges may be run in handhelds that are docked in the DRC-300.

DRC-300 EFFECT ON AMBIENT OPERATING TEMPERATURE RANGE

The operating temperature for an i-STAT 1 handheld is 16 °C to 30 °C. The DRC-300 and Rechargeable Battery may raise the temperature of the i-STAT 1 handheld 2 °C to 3 °C relative to the ambient temperature if:

- The handheld is frequently lifted and replaced into the DRC-300
- Multiple cartridges are run in the handheld while it is in the DRC-300.

TRANSMITTING DATA FROM THE DRC-300 TO i-STAT/DE

1. Place handheld in the DRC-300 cradle. If properly aligned, the blue proximity light will turn on and a “Waiting to Send” message will be displayed on the handheld until communication is established with the i-STAT/DE software.
2. Once the handheld establishes communication with the i-STAT/DE software, a “Communication in Progress” message will then appear on the handheld display and the arrows will circle until the transmission is complete.





Note: Do not move handheld until the “Communication in Progress” message disappears.

TRANSMITTED INFORMATION

The following information is transmitted from the i-STAT 1 handheld with each test record:

- Date and time the test was performed.
- Operator and Patient ID or Quality Test fluid lot number.
- All information entered by the operator, e.g., lot numbers, sample types, and comment codes.
- Result(s).
- Serial number of the handheld.
- Uses count on the handheld.
- Application software full version in the handheld.
- CLEW standardization software in the handheld.

CHARGING BATTERIES BEFORE USE

Place a new rechargeable battery in the recharging compartment on the DRC-300 for forty hours. The battery will then be 100% charged and ready for use. A handheld with disposable batteries may be placed on the DRC-300 to download data until the rechargeable battery is ready.

RECHARGEABLE BATTERY LIFE

A fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge of the battery by either:

- Keeping the rechargeable battery in a handheld that is periodically placed on the DRC-300, or
- Storing the rechargeable battery separately in the external charging bay of the DRC-300.

CHARGING A RECHARGEABLE BATTERY WHILE INSTALLED IN THE HANDHELD

Placing a handheld containing the rechargeable battery in the DRC-300 will automatically initiate charging of the rechargeable battery. The indicator light on top of the DRC-300 will be:

- green (trickle charge),
- red (fast charge), or
- blinking red (fast charge pending).

Note: No damage will be caused if a handheld with disposable batteries installed is placed in the DRC-300.

CHARGING A RECHARGEABLE BATTERY IN THE EXTERNAL RECHARGE COMPARTMENT

Placing a rechargeable battery into the external recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

1. The battery pack has two labels: one for orientation in the handheld and one for orientation in the DRC-300. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2. To remove the battery after it is charged, back the pack out of the compartment.

CONFIGURING THE i-STAT 1 DRC FOR NETWORK OPERATION

This section includes procedures to configure the i-STAT 1 DRC-300 to transmit data between the i-STAT 1 handheld and the Data Manager PC running the i-STAT/DE software.

Successful programming of the i-STAT 1 DRC-300 for network operation, requires the completion of all the following steps in sequence.

Note 1: Example screenshots were captured with Windows® XP and are for example purposes only. The appearance of your screens may differ.

Note 2: To perform the following steps, it may be necessary to log into the Windows PC with **Administrator rights**.

Note 3: If the MAC address of the DRC-300 is required, it will be displayed on the Current Settings screen, shown below at Step 10 or the mac address information may be displayed as part of the serial number label.

Note 4: The Windows Operation System workflow instructions in this section are for guidance only. Instructions may differ based on specific operation system subtypes.



Increasing Number of Simultaneous Connections

It may be necessary to increase the number of simultaneous connections allowed by your data manager to 256, in order to maintain data transmissions to the i-STAT/DE software after installing a DRC-300 on your facility's network. This action does not apply when using a DRC-300 for USB serial communication. The following instructions will increase the number of simultaneous connections allowed by i-STAT/DE.

i-STAT/DE Customers

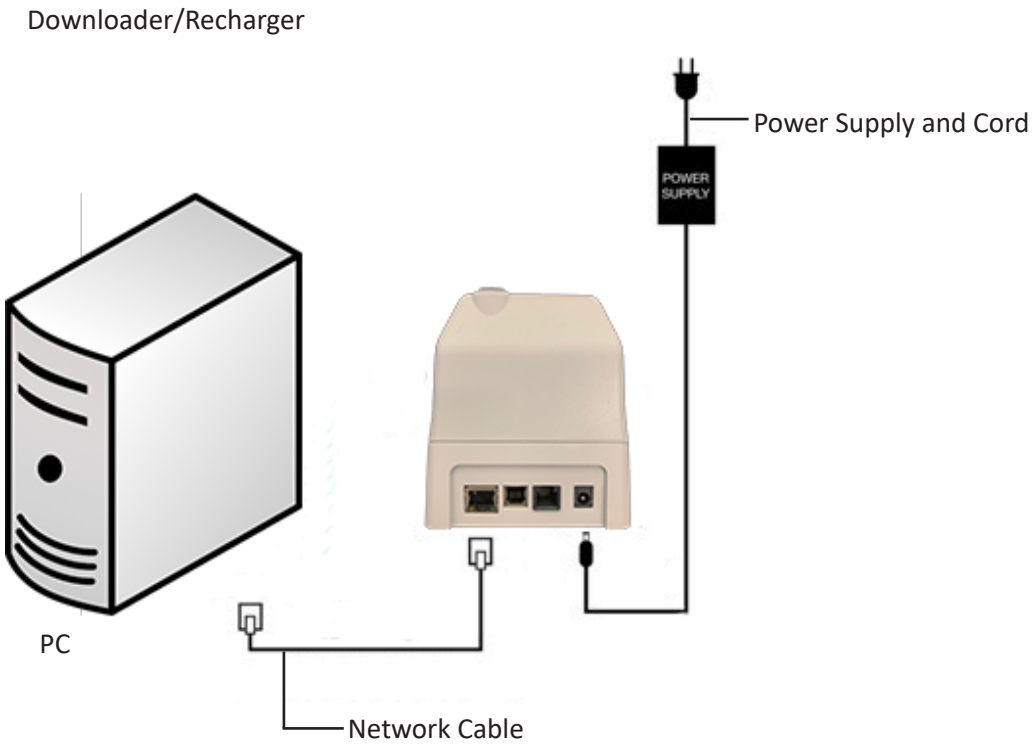
i-STAT/DE is used with Info HQ, RALS or a third-party Data Manager.
For more information on the i-STAT/DE software, refer to the *i-STAT/DE User Guide* located at www.globalpointofcare.abbott. Before beginning, consult with your IT department as Steps 1 thru 6 may require their support.

1. Identify the DE Server name. Use this information in step 2.
2. Using Microsoft Edge or Google Chrome, type http://< ServerName> / istatdesystem, where **<ServerName>** is the DE Server name identified in step 1, into the address line and then press **ENTER**
3. At the i-STAT/DE System–Main/Status page, select **View/Set Configuration.**
4. At the "**Maximum simultaneous connections**" selection box, increase the number of connections to **<256>**.
5. Click **OK**.
6. Reboot the i-STAT DE Server. i-STAT DE will then start with 256 connections.
7. You may now continue uploading as normal.

Procedure for Configuring the DRC-300

1. Preparation: For each DRC-300 to be configured, determine the
   - IP Address (on the same network as the Data Manager PC).
   - Gateway Address.
   - Subnet Mask.
   - IP Address of Data Manager.
2. **Do NOT connect the DRC-300 to a PC.** Depending on the Domain policies, network connectivity may be needed to access network TCP/IP settings.

Note 2.1: Use a standard network cable. A crossover cable is not required.



3. **Change the PC Network Configuration to detect the DRC-300.**

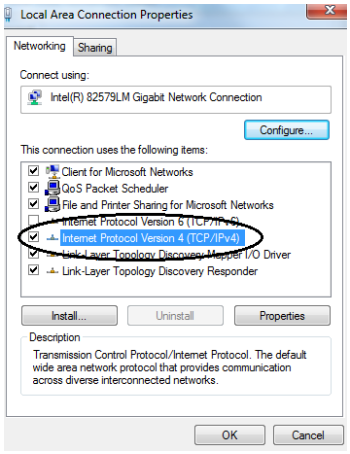
   Windows 10: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Change Adapter Options**.

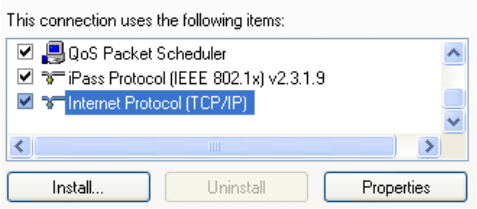
   Windows 11: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Advanced Network Settings** → **More Network Adapter Options.**

4. Right click on **"Ethernet"** and select **Properties**.

5. In ethernet properties, verify that only ONE Internet Protocol (TCP/IP) version is checked. If multiple versions are checked, uncheck all until there is only ONE checked. Select that TCP/IP, then click **Properties.**

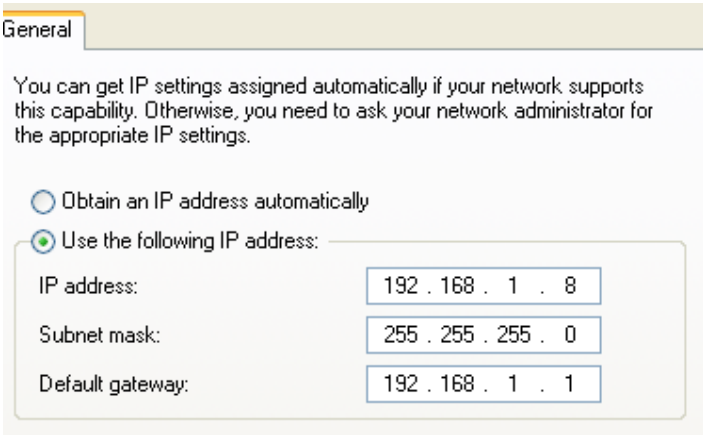
6. Record all Internet Protocol (TCP/IP) Properties for later use.





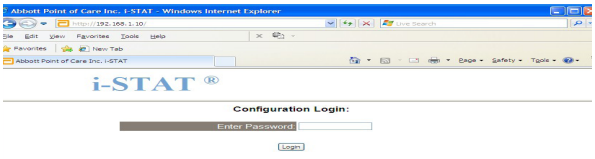
7. Select the **"Use the following IP Address"** radio button and input the following information:

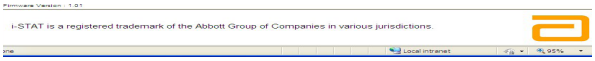
   - IP Address: 192.168.1.8
   - Subnet Mask: 255.255.255.0
   - Default Gateway: 192.168.1.1



8. Unplug network cable from the wall and plug it into the back of the DRC-300 and apply power to the DRC-300.

9. Using Microsoft Edge or Google Chrome or another browser, navigate to http://192.168.1.10. The Abbott Point of Care Inc. i-STAT login screen should appear.





Note 9.1: Internet connectivity is not required. Do not plug the computer into the facility's network.

Note 9.2: If the webpage does not appear, check the following:

1. Check to make sure the network cable is connected
2. Check to make sure that power has been applied to the DRC-300.
3. Check the proxy settings to make certain they are disabled.
4. Type "Internet Options" in the Windows search bar → **Connections** tab → LAN Settings**.**
5. Under **Proxy server**, deselect the **Use a proxy server for your LAN** check box, if selected.
6. Reset the DRC-300.

Note: 9.3: If the webpage does not appear, the password to the DRC-300 has been forgotten, or the DRC-300 IP address settings are unknown, it is possible to *temporarily** reset all DRC-300 settings back to factory default.

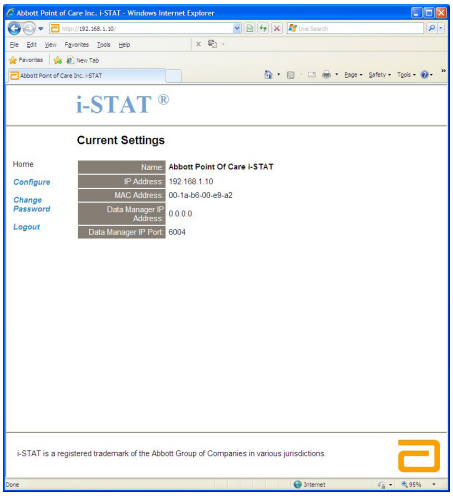
1. Connect the network cable between the PC and the DRC-300, if not already connected. Press and hold the factory reset button (shown below) on the underside of the DRC-300 while applying power, until the green light below the network connector on the back of the DRC-300 illuminates.



2. Once the DRC-300 has been reset, go to Step 9 of this section.

*The DRC-300 will stay at the factory default settings until power to the DRC-300 is disconnected, or until configuration is complete.

10. At the Configuration Login screen, enter your password and click **Login.** If a separate password has not been assigned, the default password is **"i-STAT"** and is case sensitive. Following a successful login, the home page will appear.



Note 10.1: Abbott Point of Care recommends changing the default password.

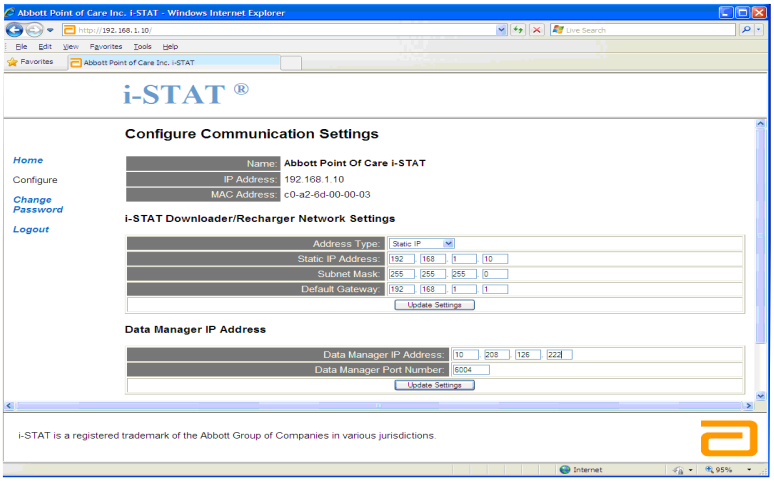
Note 10.2: The session will terminate after 15 minutes of inactivity, after which the user must re-enter their password.

Note 10.3: To change the configuration password, perform the following steps:

- Under “Current Settings”, click **Change Password.**
- Enter the existing password and the new password twice identically. Passwords must be 6 to 14 characters in length and contain only the letters a to z, A to Z, digits 0 to 9 and the characters ‘-‘ (hyphen) and ‘_’ (underscore).
- Click **Change Password.**

Note 10.4: If the new password is forgotten later, it can be temporarily reset to the factory default (i-STAT) by resetting the DRC-300 as described in Note 9.2. **However, please note that this will also reset the Downloader’s Internal settings.**

11. Under “Current Settings”, click **Configure.** The Configure Communication Settings page will appear.



12. Determine the following site-specific information for this DRC-300:
    - IP Address of the DRC-300.
    - Subnet Mask.
    - Default Gateway Address.
    - IP Address of the Data Manager.
    - Data Manager Port Number (Default is 6004).

Note 12.1: You must configure the “Data Manager IP Address” first, followed by the “i-STAT Downloader/Recharger Network Settings” to maintain connection to the DRC-300 and complete configuration.

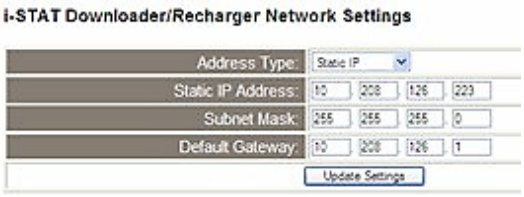
13. Scroll down to the “Data Manager IP Address” section, enter the Data Manager IP Address for this DRC-300 and the Data Manager Port Number (default is 6004), and click **Update Settings.**



Note 13.1: The “Data Manager IP Address” is the IP address of the PC where the i-STAT/DE software is installed.

14. Once back to the “Current Settings” screen, click **Configure.**

15. Scroll to the “i-STAT Downloader/Recharger Network Settings” section, and select the address type for assigning the IP Address of the DRC-300 being configured:



16. To configure for a **static IP address**, follow the instructions in **16A.** To configure for **DCHP**, follow **16B**.

Note 16.1: Static IP addresses are required when using handheld customization by Download Locations.

16A. If you want to configure the DRC-300 with a **static IP Address**, select **“Static IP”** from the **Address Type** drop down menu, and enter the assigned IP Address, Subnet Mask, and Default Gateway for the DRC-300 and click **Update Settings.**

16B. If you want to use the **DHCP** server, select **“DHCP”** from the **Address Type** drop down menu and click **Update Settings.**

After completion, the following screen will be displayed.



17. If additional DRC-300s require configuration, connect the next DRC-300 to the PC and apply power to the DRC-300 and repeat steps 9 through 16. Otherwise, proceed to step 18 to restore the PC's network configuration.

18. **Disconnect the Ethernet cable from the DRC-300 and connect to the network.**

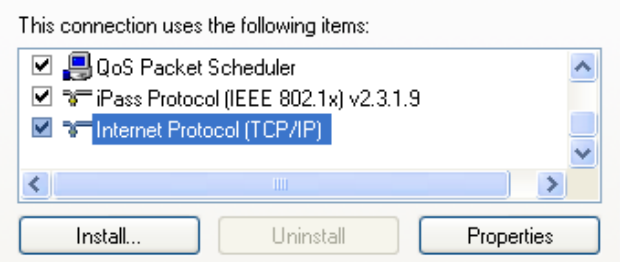
    Windows 10: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Change Adapter Options**.

    Windows 11: On the PC, click **Start Icon** → **Settings** → **Network and Internet** → **Advanced Network Settings** → **More Network Adapter Options.**

19. Right click on **"Ethernet"** and select **"Properties"**.

20. Select the **"Internet Protocol (TCP/IP)"** connection and click the **"Properties"** button.

21. Restore Internet Protocol (TCP/IP) properties in the **General** tab to the network settings recorded in Step 6.



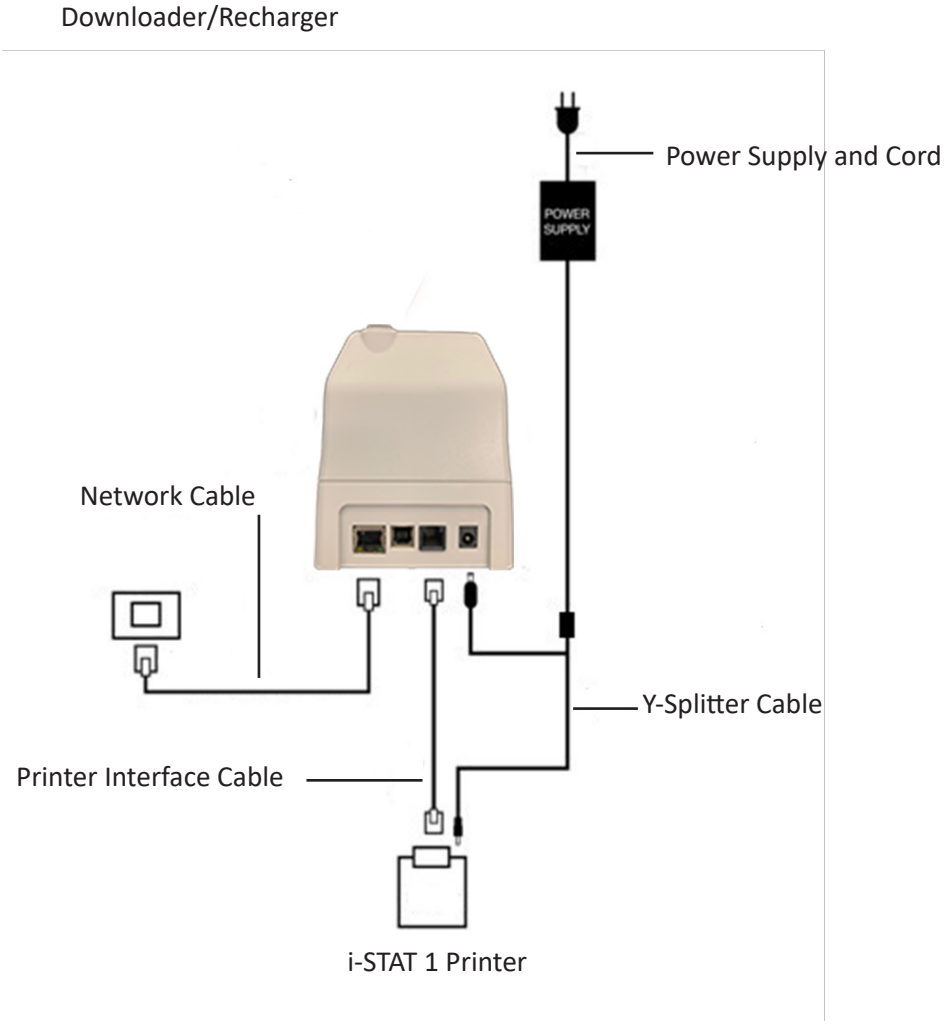
22. Check the additional internet protocol(s) previously unchecked in Step 5.

23. To connect the configured DRC-300 for transmission to the Data Manager, follow the instructions in the **Wiring the Downloader/Recharger** sections below.

CONNECTING AND WIRING THE DRC-300 FOR NETWORK COMMUNICATION

The following diagram shows how to connect the portable printer to the DRC-300 and the DRC-300 to the network for communication to the Data Manager. The parts are:

- Network Cable.
- Printer Interface Cable.
- Power Supply and Cord.
- Y-Splitter Cable (Optional).
- LAN Cable Filter (Abbott L/N 06F23-63) - For use only with the i-STAT 1 Wireless Analyzer containing Wireless Module FCC ID: P1405W (Firmware: 6.5.X.X/X.X)



Note: Once the DRC-300 has been configured and connected to the facility's network, you can view the DRC-300's configuration page by using Microsoft Edge or Google Chrome and navigating to the DRC-300's configured IP Address using any computer on the same node of the network.

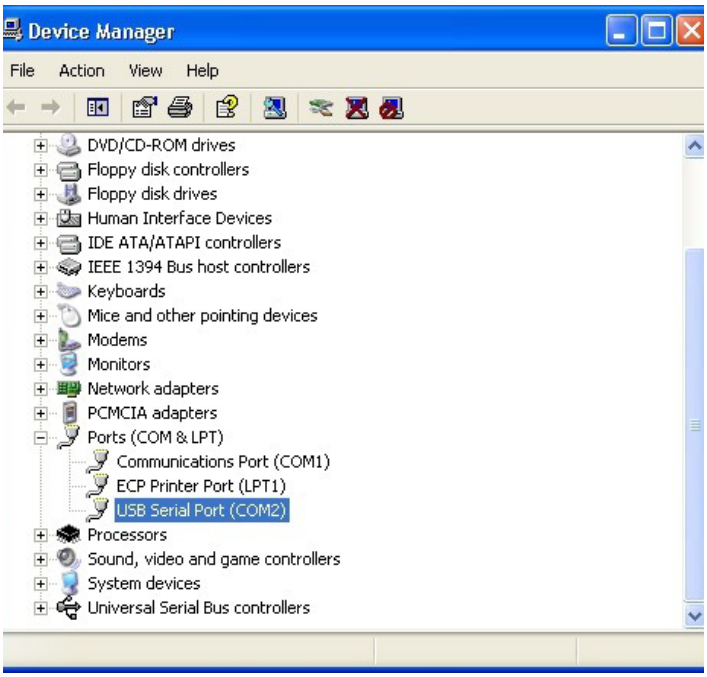
CONFIGURING THE i-STAT 1 DRC-300 FOR USB SERIAL OPERATION

To install the USB drivers for the DRC-300 for use with JammLite applications, it is necessary to be logged into a Windows PC with **Administrator rights**. Windows 10 and Windows 11 automatically installs drivers for devices that are connected to the PC.

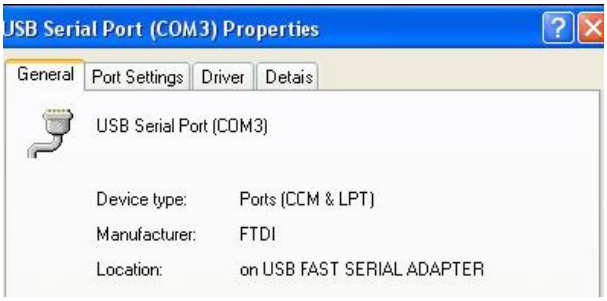
Note: i-STAT/DE does not support direct serial connection.

The following instructions require a PC connected to the Internet as well as Administrative rights to receive and install Windows Updates.

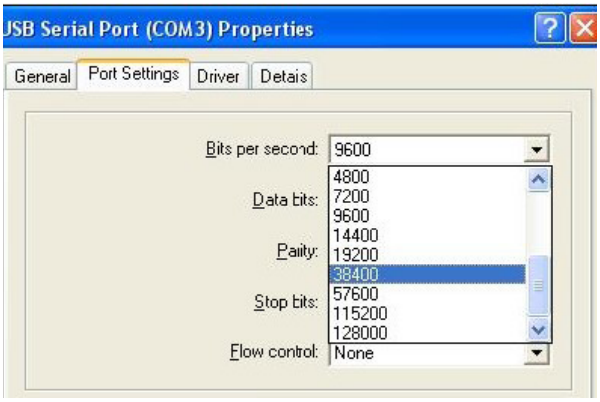
1. Apply power to the DRC-300. Connect the USB cable from the DRC-300 to the PC.
2. Wait while the "USB Serial Converter" driver (FT232R USB UART) installs. This may take a few minutes.
3. If the DRC-300 USB driver installs successfully, you may see a **"Device is Ready"** message appear on the PC Taskbar.
4. Click on the Windows Start icon, type in **"Device Manager"**, then select **"Device Manager"** to show a list of devices. Expand "Ports (COM & LPT)" to list all the COM Ports (as shown below). The newly installed DRC-300 port is named "USB Serial Port".



5. Right click on the **"USB Serial Port"** device entry and select **Properties.** A "USB Serial Port Properties" dialog box will open. Select the **Port Settings** tab.



6. Using the drop-down menu, set the **“Bits per second”** to 38400. Other dropdown menus should remain as the default.



7. Click the **“Advanced”** button. Using the drop-down menu, change the port number to the lowest available number. Determine availability by viewing the existing COM Ports in Device Manager. Click **OK** twice.



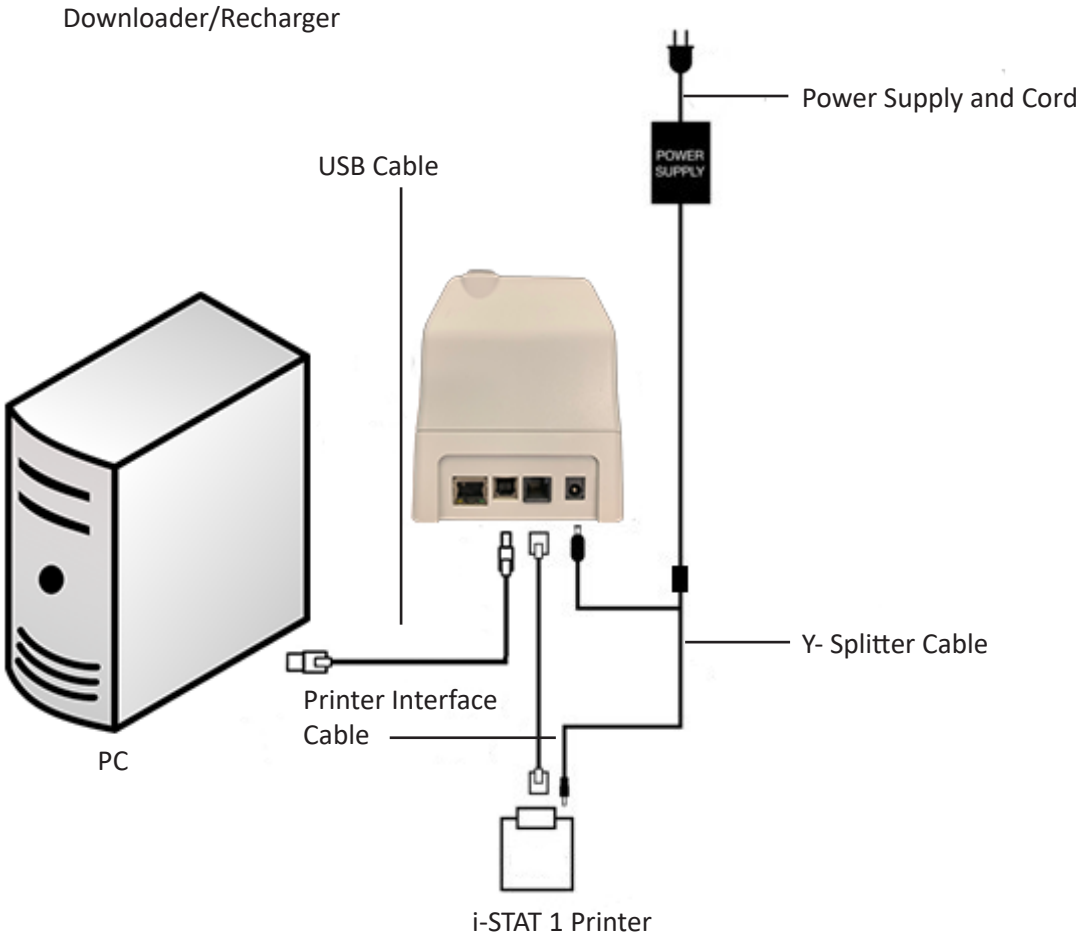
8. Close all **Control Panel** windows.

CONNECTING AND WIRING THE DRC-300 FOR USB SERIAL COMMUNICATION

Note: For successful data transmission to occur, the USB cable should first be connected between the DRC-300 and the PC prior to installing or opening the JammLite applications.

The following diagram shows how to connect the DRC-300 to the computer, where the JammLite application is installed via USB connection and how to connect the portable printer to the DRC-300 for communication. The parts are:

- USB Cable.
- Printer Interface Cable.
- Power Supply and Cord.
- Y-Splitter Cable (Optional).



CONFIGURING THE RALS RRC FOR USB SERIAL TO NETWORK COMMUNICATION

For USB Serial to network communication, i-STAT/DE customers may utilize the RALS Remote Connect (RRC) software on a PC with the DRC-300. For more information visit, https://www.rals.com/.

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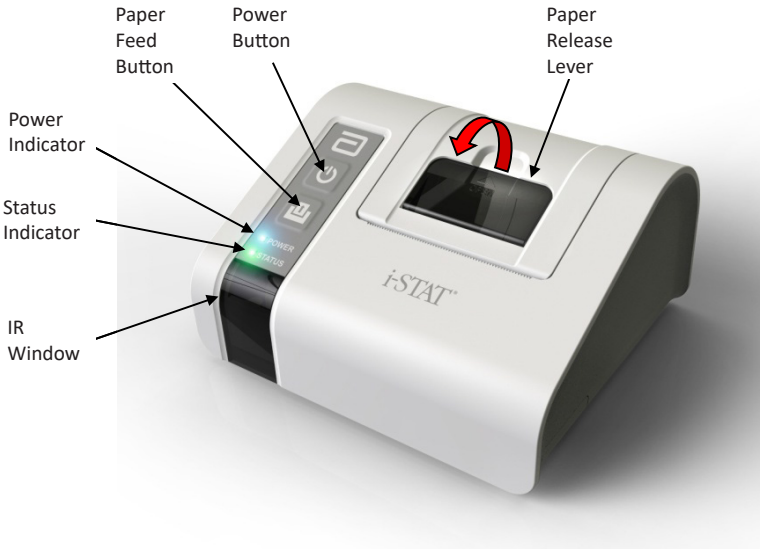
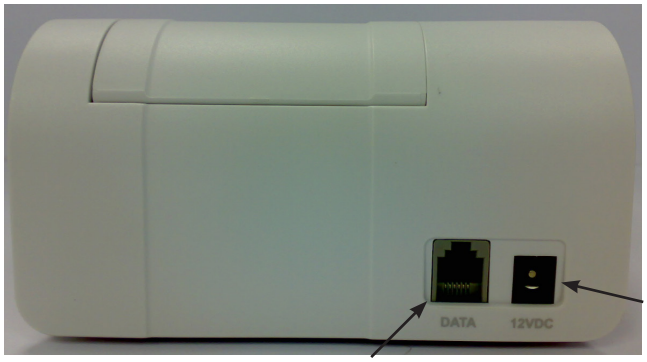
PORTABLE PRINTER 7

OVERVIEW

This section describes the instructions for using the new i-STAT Printer, which is used to print results from all models of the i-STAT 1 Analyzer (handheld).

Note: This printer cannot be used with the i-STAT Portable Clinical Analyzer (PCA).





SPECIFICATIONS

Dimensions	Height: 72.5 mm Width: 136 mm Depth: 120 mm
Weight	500 g (Approx.)
Power	1. 4.8V NiMH rechargeable battery pack 2. Power adaptor for AC outlet
Communication Link	1. Infra-red 2. RJ11
Paper	5.7 cm thermal
Buttons	1. On/Off 2. Paper Feed
LED Indicators	POWER: Green/Orange/Red STATUS: Green/Orange/Red
Printing Method	Thermal line printing
Printing Speed	Battery: Up to 10 lines per second AC Adaptor: Up to 2.5 lines per second
Temperature	Operating: 15 °C to 40 °C Storage: -20 °C to 50 °C
Printer Power Requirements	The printer is rated at: • 12Vdc • 1.5A max • 18W
External Power Supply Unit (PSU)	The external PSU is rated at: • 100-240Vac • 50-60Hz
Fuses	There are no operator replaceable fuses with the i-STAT Printer.

Note: This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements.

i-STAT PRINTER KIT COMPONENTS AND ACCESSORIES

The following individual components are included in the i-STAT Printer kit:

1. i-STAT Printer
2. AC adapter
3. Power Cord
4. Rechargeable Battery
5. One roll of printer paper (not shown below)



ORDERABLE COMPONENTS

The following individual i-STAT Printer kit items can be ordered separately from Abbott Customer Service for replacement or supplemental inventory purposes.

ORDERABLE ITEM	ABBOTT LIST NUMBER
i-STAT Printer	04P74-01
i-STAT Combo Power Supply	04P74-02
Rechargeable Battery for the i-STAT Printer	04P74-03
Portable Printer Paper (6 rolls per box)	06F17-11
i-STAT Printer Kit	04P74-04

i-STAT PRINTER PAPER

Printer paper may be ordered along with other supplies for the i-STAT System

The STATUS indicator will illuminate to indicate the print status:

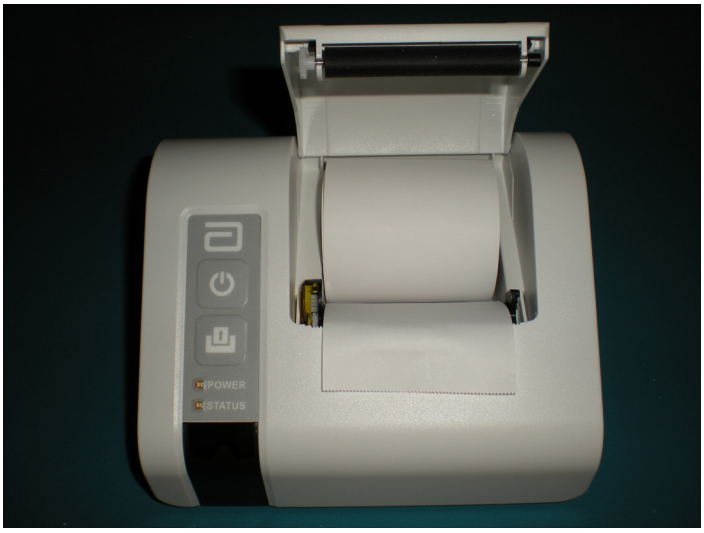
Ready:	**Green** ●
Out of Paper:	**Orange** ●
Error:	**Red** ●

Paper for the i-STAT Printer can be installed or replaced as follows:

1. Open the paper compartment lid by pulling the release lever as shown in the printer illustration on page 1 and remove any remaining paper.

2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.

3. Sit the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.



4. Close the lid until it snaps into place.

Note 1: Should the paper become creased or misaligned, simply reload the paper as described above ensuring that the paper has a clean, straight edge.

Note 2: When removing a printout from the printer, pull the printout toward the front of the printer and tear from one side to the other across the serrated edge.

i-STAT PRINTER POWER

There are three options for powering the i-STAT Printer:

- Using the AC adapter and power cord only,
- Using the Rechargeable Battery only, and
- Using the Rechargeable Battery with the AC adapter and power cord.

The i-STAT Printer can be turned on and off by pressing the POWER button. When the printer is on, the POWER indicator will be illuminated:

Power OK:	Green ●
Battery Low:	Orange ●
Battery Empty:	Red ●

If the printer is inactive for >60 seconds, it will automatically enter the power-saving mode. When in the power-saving mode, the POWER indicator will change from a solid color light to pulsed illumination.

The printer's rechargeable battery needs to be recharged when the POWER indicator turns orange. If the battery becomes exhausted, the POWER indicator will turn red and printing will be disabled.

The printer's battery can be recharged using the supplied AC power adapter. The socket for the AC power adapter is located on the rear of the printer. Note: Charging only occurs when the printer is switched off or is in the power-saving mode. A full charge takes approximately 3 hours.

Symptoms Indicating that the Rechargeable Battery Requires Replacement:

1. A steady Orange or Red POWER indicator light on the printer, even after charging it for the recommended 3 hours.
2. Loss of battery capacity, indicated by a shorter interval between charges.

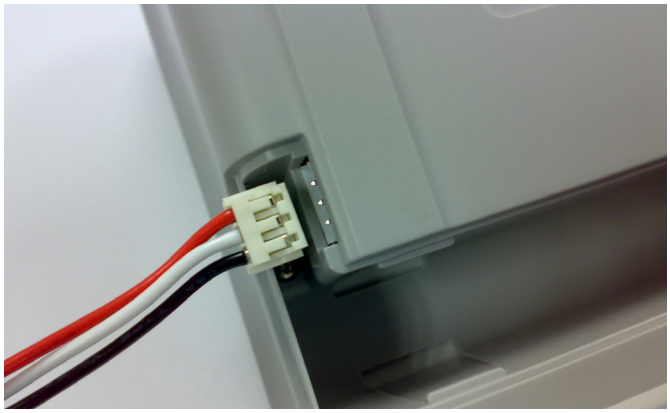
Installing or Replacing the Rechargeable Battery in the i-STAT Printer:

1. Disconnect the printer from the AC adapter.
2. Turn the i-STAT Printer upside down and place it on a flat surface. Remove the battery door by sliding it off while pressing on the grooved section. Set the door aside.



3. If replacing an existing rechargeable battery in the printer, disconnect the existing battery by gently pulling up on the red/white/black wires until the connector releases from the three metal pins. Once the battery is disconnected, remove it completely from the battery compartment.
4. Remove the new rechargeable battery from its packaging. With the thumb and index finger of one hand, grasp the connector at the end of the red/white/black battery wires.

5. Assure proper connector alignment as shown.



6. Slide the connector onto the three metal connector pins.



7. Once the wires are connected, place the battery portion of the pack into the rectangular compartment. Make sure the wires are not under the battery or projecting out of the opening. The correct positioning is shown below.



8. Slide the battery door back onto the compartment until it closes and locks into place.

9. Turn the printer over, plug it back into the AC power adapter, and charge the new battery in the printer for a minimum of 3 hours before use.

Note: If the rechargeable battery is removed or becomes exhausted, it is still possible to print at reduced speed using the AC power adapter.

Powering the i-STAT Printer Using the AC Adapter and Power Cord:

1. Connect the power cord to the AC adapter as shown.



2. Plug the round connector from the AC adapter into the 12VDC port on the back of the i-STAT Printer.

3. Plug the power cord into a wall outlet.

PRINTING DIRECTLY FROM THE i-STAT 1 HANDHELD

1. Ensure that the printer is turned on and that the POWER indicator is green.

2. Align the handheld's IR communication window with the printer's IR LED window. Generally, the printer must be within 1 to 5 inches (2.5 to 12.7 cm) of and not too close to the handheld.

3. Display the results to be printed on the handheld.

4. Press the PRT key on the handheld. Do not move handheld or printer until printing is complete.

5. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

PRINTING VIA A DOWNLOADER/RECHARGER

1. Place i-STAT 1 handheld in a Downloader/Recharger that is connected to the i-STAT Printer.
2. Display the results to be printed on the handheld.
3. Press the 

key on the handheld. Do not move handheld or printer until printing is complete.
4. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

PRINTING MANY RESULTS

1. Turn the i-STAT 1 handheld on.
2. Press the Menu key to bring up the Administration Menu.
3. Press **2 – Data Review.**
4. Press **7 – List**.
5. Scroll through the results using the ← and → keys.
6. Press the number key for the test record(s) to be printed. (Press the numbered key again to deselect a record.)
7. Align i-STAT 1 handheld and i-STAT Printer IR window or place in the Downloader/Recharger attached to the i-STAT printer. Press the 

key.
8. Do not move handheld or printer until printing is complete.
9. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

PRINTOUT CONTENTS

Name of Test	i-STAT catridge type
Sample ID	Patient ID or quality test type and lot number of solution tested
Results	Results are printed with units as well as flags, reference ranges, and comment codes, if applicable.
At Patient Temperature	If the patient's temperature was entered on the Chart Page, a second set of results is displayed for blood gases at the patient's temperature.
Sample Type	Sample type selected from Chart Page when sample is patient or proficiency test
Free Fields	Information entered into the Free Fields on the Chart Page when sample is patient or proficiency test
Time and Date	Time and Date when test was performed
Operator ID	Operator ID
Lot Number	Lot number of cartridge
Serial Number	Serial number of the handheld
Version	Handheld application software
CLEW	Standardization software

PRINTER CAUTIONS

- Use only a Rechargeable Battery pack purchased from Abbott Point of Care (List Number 04P74-03). Rechargeable battery packs not recommended by or purchased from Abbott Point of Care may be susceptible to overheating and could lead to a potential fire or burn hazard.
- Use only power adaptor and power supply (List Number 04P74-02) provided with the i-STAT Printer kit.
- Do not operate the printer without paper.
- Do not allow the power supply to become a trip hazard.
- Do not disturb the handheld or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and handheld or replace the handheld in the Downloader to resume printing. Note: if significant time has elapsed, some results may be missing from the printout. Reprint the results.

- If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the handheld. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the handheld data, the printer requires service and the printed results must not be used.
- Skin irritation, including caustic burns/injury, may occur following exposure to a leaking battery. Always wear gloves when handling a leaking battery, and do not permit a leaking battery to contact skin. Should skin exposure to a leaking battery occur, follow the first aid measures outlined in the MSDS Sheet for the Novacell nickel metal hydride battery.
- Fluorescent light sources can cause interference with communications sent to the i-STAT 1 Printer. When light from a fluorescent source of sufficient proximity or brightness has a direct path into the IR (Infrared Radiation) window of the i-STAT 1 Printer, the printer may fail to respond when records are sent for printing over a serial (wired) connection to a Downloader/Recharger.

PRINTER TROUBLESHOOTING

PRINTER SYMPTOM	RECOMMMENDED ACTION(S)
Printer is not printing. The POWER indicator light is green/orange and the STATUS indicator light is green.	• Check that the results are displayed on the handheld, or that results have been selected from List under Data Review. • If printing directly from the handheld, check that the distance between the analyzer and printer is not too short or too long. • Perform printer self test to ensure that printer is functioning. Turn the printer off. While pressing the Paper Feed button, press down on the Power button until the printout begins, and then let go of both buttons. Ensure that the resulting printout is clear and complete.
Printer is not printing over a wired connection to a Downloader/Recharger. The POWER indicator light is green/orange and the STATUS indicator light is green.	<u>If the printer is in close proximity to a fluorescent light:</u> • Reposition the printer or shield the IR window to prevent direct line-of-sight between the fluorescent light and the IR window. • Relocate the printer or fluorescent lamp to a greater distance from each other. • Turn off fluorescent lights within close proximity of the i-STAT 1 Printer when printing records via a serial connection. • Print directly from the handheld via an IR connection.
Printer is feeding paper, but nothing is printed.	Check that the paper is feeding from under the roll.

PRINTER SYMPTOM	RECOMMMENDED ACTION(S)
Printer is not printing and POWER indicator is red.	Battery needs to be recharged.
Printer POWER indicator does not illuminate when printer is turned on.	Battery needs to be recharged.
Printer is not printing and STATUS indicator is orange.	Printer is out of paper.
Printer is not printing and STATUS indicator is red.	Print head temperature is out of range. Printing will be inhibited until print head temperature returns to normal level.

CLEANING THE i-STAT PRINTER

Clean the external casing of the i-STAT 1 printer with any of the following:

- A gauze pad moistened with:
  - – Isopropyl alcohol (IPA) or
  - – 10% bleach solution
- A PDI® Super Sani-Cloth®

DO NOT IMMERSE THE PRINTER IN ANY FLUID, AT ANY TIME.

i-STAT PRINTER STORAGE AND BATTERY CHECK

Printer Storage Instructions

When the Printer is not in use for an extended period:

- Keep the AC adapter connected to wall outlet and Printer, if possible.
- If AC power is unavailable, disconnect the i-STAT Printer Rechargeable Battery from the Printer. Failure to remove the battery may result in the inability for the battery to be charged following storage.

Battery Check

If the battery does not appear to accept charge during regular use, follow the instructions below to determine if the i-STAT Printer Rechargeable Battery is capable of charging:

1. Plug AC adapter into Printer and wall outlet and install i-STAT Printer Rechargeable Battery into the i-STAT Printer.
2. Make sure the Printer is turned off. Perform a self test on the i-STAT Printer by pressing the Paper Feed button then the Power button and holding both down until printing starts.
3. If the battery can be charged, the last line of the self test print out will state “Charging Enabled”. If the battery cannot be charged, the last line will state “Charging Disabled”.

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BLOOD COLLECTION 8

Overview

The sample used to fill an i-STAT test cartridge must be collected and handled properly to ensure that the results represent the patient's current status. Blood collection should be performed according to the facility's policies and procedures.

Best practices for blood collection techniques are provided in this section, along with requirements for i-STAT Test cartridges. These practices may help prevent potential sources of error for test results.

For test cartridge information, see the Cartridge and Test Information (CTI) sheets and cartridge Instructions For Use (IFU) located in the support area of the APOC website, www.globalpointofcare.abbott.

VENIPUNCTURE - BEST PRACTICES

Overview

Venipunctures are typically performed for:

- acid-base balance
- electrolyte studies
- metabolic studies
- coagulation studies
- hematologic studies

Observe the following precautions: Use Universal precautions for blood collection and follow your facility's policies or procedures.

Blood Flow

Collection technique resulting in good blood flow must be used. Inadequate blood flow may produce erroneous results.

I.V. Line

Avoid drawing from an arm with an I.V. line. I.V. solutions will dilute the sample and may interfere with the tests.

Tourniquet

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid.

If a tourniquet is applied for more than one minute while looking for a vein, release and reapply after two to three minutes. Allow the tourniquet to remain in place until all blood is withdrawn.

Muscle Activity

Avoid extra muscle activity, such as clenching and unclenching the fist.

Hemolysis

Avoid hemolysis (bursting of red cells) by

- allowing residual alcohol to dry over the puncture site
- discarding a sample from a traumatic draw.

VENIPUNCTURE BEST PRACTICES (continued)

Tube and Syringe Order

Collect blood collection tubes in the prescribed sequence to avoid interference due to carry-over of additive from one tube to the next:

- No additive
- Citrate
  Note: If a citrate tube is drawn, draw a 5 mL plain discard tube before drawing the heparin tube.
- Heparin
- EDTA - Na_2, K_3 or K_2
- Oxalate, fluoride, iodoacetate

Note: CLSI guidelines recommend that the sample for coagulation testing be the second or third tube drawn when using a blood collection system (use a discard tube if this is the only sample being drawn) or be taken from the second syringe if a double syringe technique is used for drawing blood.

Fill Requirements for Tubes and Syringes

Fill blood collection tubes with and without anticoagulant and syringes with anticoagulant to capacity.

- Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios and may affect other results.
- Under filling blood collection tubes and/or syringes may effect test results.
- Partial-draw blood collection tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL), with or without anticoagulant, are not recommended.

Mixing Tubes and Syringes

Gently mix anticoagulated blood collection tubes and syringes immediately to avoid clotting.

- Invert a blood collection tube at least 10 times.
- Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe.

Exposure to Air

Avoid exposing the sample to air.

Time to Test

For the most accurate results, test samples immediately after collection.

Sample on Ice

Using a cold sample may produce erroneous results.

ARTERIAL PUNCTURE - BEST PRACTICES

Overview

Arterial punctures are performed to access blood gas status. Use Universal precautions for blood collection and follow your facility's policies or procedures.

PCO_2, ***P***O_2, and pH values change with changes in ventilatory support at a rate dependent on underlying conditions. Sample should be drawn after these changes have stabilized.

Blood Flow

Collection technique resulting in good blood flow must be used. Inadequate blood flow may produce erroneous results.

Tubes

Blood collection tubes are not recommended for blood gas analysis.

Syringe Order

Note: CLSI guidelines recommend the sample for coagulation testing be taken from the second syringe if a double syringe technique is used for drawing blood.

Syringes and Anticoagulant

A plain syringe can be used if the sample can be tested immediately.

If the sample cannot be filled and tested immediately, the sample should be collected in a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium (such syringes contain balanced or low-level heparin).

Tubes and Syringes with anticoagulant

- Samples for coagulation testing cannot be collected into blood collection tubes or syringes that contain anticoagulants, activators, or separators.

Plastic Tubes and Syringes

- Blood collection tubes and syringes for coagulation testing should be plastic.

Glass Tubes and Syringes

- Samples collected into glass tubes or syringes cannot be used for coagulation testing.
- If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.

Plastic Syringes

- Syringes for coagulation testing should be plastic.

Glass Syringes

- Samples collected into syringes cannot be used for coagulation testing.

Fill Requirements for Syringes

Fill syringes to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting.

- If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.
- Under filling syringes will cause higher heparin-to-blood ratios and may affect results.
- Under filling syringes with liquid heparin will also dilute the sample causing results to be affected.

ARTERIAL PUNCTURE - BEST PRACTICES (continued)

Mixing Syringes

Mix anticoagulated syringes by rolling between the palms for at least 5 seconds, each in two different directions. Then invert the syringe repeatedly for at least 5 seconds.

Note: Discard the first two drops of blood before filling the test cartridge.

Exposure to Air

Avoid exposing the sample to air and maintain anaerobic conditions.

Time to Test

For the most accurate results, test samples immediately after draw.

Sample on Ice

Fill the test cartridge before icing the sample for transport. Using a cold sample may produce erroneous results.

SKIN PUNCTURE BEST PRACTICES

Use Universal precautions for blood collection and follow your facility's policies or procedures. **Note**: Capillary samples are not intended for use with all tests available on i-STAT Test cartridge configurations, see the Sample requirement for i-STAT test cartridges in this section.

Blood Flow

- Use a lancet that provides free-flowing blood. Inadequate blood flow may produce erroneous results.
- Blood flow can be stimulated by warming the puncture site. Follow the facility’s policy and procedure for warming (arterializing) skin puncture area.

Hemolysis

- Avoid hemolysis (bursting of red cells) due to vigorous massaging or “milking.”
- Avoid hemolysis by allowing residual alcohol to dry over the puncture site.

Tissue Fluid

Excess tissue fluid may produce erroneous results. Follow proper collection technique and refer to the test cartridge CTI sheet or IFU for test specific requirements.

Anticoagulant

Use balanced heparin tubes.

- Most heparinized capillary tubes are not suitable for electrolyte measurements, especially ionized calcium, due to the high concentration of heparin (50 U/mL or more).

Time to Test

Test samples collected in capillary tubes immediately to avoid clotting (especially in neonates whose blood may clot more quickly).

Warming Area

Blood flow can be stimulated by warming the puncture site. Follow the facility’s policy and procedure for warming (arterializing) an infant’s heel or other skin puncture area.

SAMPLE TRANSFER DEVICES

Dispensers

A dispenser can be used to avoid the use of needles when transferring a blood sample from a blood collection tube.

- Do not use dispensers that would introduce air into the sample.

Capillary Tube

A capillary tube may be used to transfer a sample to a cartridge.

Syringe

A 1cc syringe (such as a tuberculin) and needle (no smaller than 20 gauge) can be used to withdraw a sample from a blood collection tube.

- Take care not to draw air with the sample.

BLOOD COLLECTION FOR i-STAT TEST CARTRDIGE

The sample used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status. Samples should be collected according to the facility's policies and procedures.

See the Cartridge and Test Information sheets and the cartridge Instructions For Use on the APOC website for further information.

i-STAT BLUE CG4+ CARTRIDGE ONLY

- ***P*CO$_2$, *P*O$_2$, and pH values change with changes in ventilatory support at a rate dependent on underlying conditions. Sample should be drawn after these changes have stabilized.**
- **Arterial:** whole blood collected in balanced heparin or lithium heparin syringes. If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.
- **Venous:** whole blood collected in balanced heparin or lithium heparin syringes or; whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity. Blood collection tubes contain approximately 15 U/mL when filled to capacity. If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.
    - Do not leave tourniquet on for more than 2 minutes.
    - Do not draw above an I.V. I.V. solutions will dilute the sample and may interfere with the tests.
- **Capillary:** Not recommended. This cartridge has not been evaluated with capillary samples.
- **Indwelling Line:** If blood must be drawn from and indwelling line for blood gas or chemistry testing, back flush the line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.
- **Tourniquet:** Allow the tourniquet to remain in place until all blood is withdrawn to prevent changes in pH results.
    - Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid.
- **Muscle Activity:** Avoid extra muscle activity, such as clenching and unclenching the fist which may increase potassium results.

i-STAT BLUE CG4+ CARTRIDGE ONLY (continued)

- **Fill Requirements:** Fill blood collection tubes with and without anticoagulant and syringes with anticoagulant to capacity.
  - Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios which will decrease ionized calcium results and may affect other results.
  - Under filling blood collection tubes and/or syringes may effect test results. Blood collection tubes with and without anticoagulant may also cause decreased PCO_2, HCO_3 and TCO_2 results.
  - Partial-draw blood collection tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL), with or without anticoagulant, are not recommended for blood gas or CHEM8+ cartridge analysis because of the potential for decreased PCO_2, HCO_3 and TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.
- **Exposure to Air:**
  - When testing venous samples for ionized calcium, pH, PCO_2 and TCO_2, test immediately if the sample is drawn into a blood collection tube.
  - Expel any air bubbles immediately if the sample is drawn into a syringe or leave an air bubble next to the plunger and do not allow it to move through the sample.
- **Mixing and Test Timing (time from collection to cartridge fill):**
  - Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds.
  - Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
  - Test for lactate immediately. Samples for pH, PCO_2, PO_2, TCO_2 should be tested within 10 minutes.
- **Samples on Ice:** Fill the test cartridge before icing the sample for transport. Icing will affect oxygen levels in samples collected in plastic syringes.
- **Dispenser:** When, pH, or PCO_2 are being measured, do not use dispensers that would introduce air into the sample.

OTHER CHEMISTRY AND BLOOD GAS CARTRIDGES (INCLUDING CHEM8+) CAN USE:

- **PCO_2, PO_2, and pH values change with changes in ventilatory support at a rate dependent on underlying conditions. Sample should be drawn after these changes have stabilized.**
- **Arterial:** Plain syringe, heparinized syringe labeled for analytes to be tested and filled to capacity, or syringe with minimum volume of heparin to prevent clotting (10 U/mL of blood).
  - For ionized calcium, use balanced heparin syringes.
  - Avoid drawing air into syringes for blood gas and ionized calcium tests.
  - If not tested immediately, remix and discard 2 drops of blood before filling cartridge.
  - Do not use iced samples.
- **Venous:** Plain syringe, heparinized syringe (for ionized calcium, use balanced heparin syringes) or; whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity.
  - Do not leave tourniquet on for more than 2 minutes.
  - Do not draw above an I.V. I.V. solutions will dilute the sample and may interfere with the tests.

OTHER CHEMISTRY AND BLOOD GAS CARTRIDGES (INCLUDING CHEM8+) CAN USE (continued):

- **Capillary (except CHEM8+):**
  - The process of capillary collection may change PO_2, PCO_2, and the calculated sO_2. Arterial specimens are preferred for blood gas analysis.
  - Most heparinized capillary tubes are not suitable for electrolyte measurements, especially ionized calcium, due to the high concentration of heparin (50 U/mL or more).
    - The Lithium heparin capillary tubes may be used for testing all analytes except ionized calcium.
    - For all analytes, including ionized calcium, use a balanced heparin capillary tube.
  - Allow alcohol to dry over puncture site before collecting sample.
  - Do not "milk" finger or heel while collecting sample. To increase blood flow, massage a finger gently from about three inches from the tip to the fleshy portion of the tip.
  - Wipe away the first drop of blood as it may contain excess tissue fluid, which can increase potassium results, and decrease the other test results.
  - Skin puncture for direct application without the use of a transfer device, is only recommended for i-STAT PT/INR and PT^{plus} cartridges.
- **Tourniquet:** Allow the tourniquet to remain in place until all blood is withdrawn to prevent changes in ionized calcium and pH results.
  - Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid.
- **Muscle Activity:** Avoid extra muscle activity, such as clenching and unclenching the fist which may increase potassium results.
- **Anticoagulants:**
  - Sample should be collected in a blood collection tube with lithium heparin or a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium (such syringes contain balanced or low-level heparin). If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.
  - Samples collected in EDTA anticoagulant may be used only with the i-STAT Glucose cartridges. It may be convenient to collect a single EDTA tube when testing for glucose and glycated hemoglobin (HbA1c) simultaneously. **EDTA may not be used with any cartridge type other than the Glucose or BNP cartridges.** EDTA will cause a clinically significant error in sodium, potassium, chloride and hematocrit results and may affect other chemistry tests. Do not use an EDTA sample with a cartridge that includes glucose as part of a panel. Even if only the glucose result is to be used, all results are stored in the analyzer's memory and, since results can be printed and transmitted to a Central Data Station, they can become part of the patient's permanent record.
- **Indwelling Line:**
  - If blood must be drawn from and indwelling line for blood gas, electrolyte or chemistry testing, back flush the line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.

OTHER CHEMISTRY AND BLOOD GAS CARTRIDGES (INCLUDING CHEM8+) CAN USE (continued):

- **Fill Requirements:** Fill blood collection tubes with and without anticoagulant and syringes with anticoagulant to capacity.
  - Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios which will decrease ionized calcium results and may affect other results.
  - Under filling blood collection tubes and/or syringes may effect test results. Blood collection tubes with and without anticoagulant may also cause decreased PCO_2, HCO_3 and TCO_2 results.
  - Partial-draw blood collection tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL), with or without anticoagulant, are not recommended for blood gas or CHEM8+ cartridge analysis because of the potential for decreased PCO_2, HCO_3 and TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.
- **Exposure to Air:**
  - When testing venous samples for ionized calcium, pH, PCO_2 and TCO_2, test immediately if the sample is drawn into a blood collection tube.
  - Expel any air bubbles immediately if the sample is drawn into a syringe or leave an air bubble next to the plunger and do not allow it to move through the sample.
- **Mixing and Test Timing (time from collection to cartridge fill):**
  - Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds.
    - Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
  - Test for lactate immediately. Samples for pH, PCO_2, PO_2, TCO_2 and ionized calcium should be tested within 10 minutes. Test other analytes within 30 minutes.
  - Test samples collected in capillary tubes immediately to avoid clotting.
- **Hemolysis:** Causes an increase in potassium results and a decrease in calcium results.
- **Samples on Ice:** Fill the test cartridge before icing the sample for transport. Icing will increase the potassium and will affect oxygen levels in samples collected in plastic syringes.
- **Dispenser:** Do not use dispensers that would introduce air into the sample, when ionized calcium, pH, or PCO_2 are being measured.

COAGULATION CARTRIDGES: CELITE ACT AND KAOLIN ACT

- The ACT test may be performed using venous or arterial samples.
- Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators. Samples for coagulation testing cannot be collected into syringes that contain anticoagulants or activators.
- Test Timing (time from collection to cartridge fill):
  - Test sample immediately upon draw.
- For venipuncture, some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing samples for coagulation testing.
- If a second measurement is needed, draw a fresh sample.
- For indwelling line testing for ACT:
  a. Fluid drip through the line must be discontinued.
  b. If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.
  c. Withdraw the sample into a fresh plastic syringe with no anticoagulant and test immediately.
- For extracorporeal line testing for ACT:
  a. Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
  b. Withdraw the sample into a fresh plastic syringe with no anticoagulant and test immediately.

COAGULATION CARTRIDGES: PT/INR AND PT^{plus}

- PT and INR tests may be performed using capillary or venous samples.
- i-STAT PT/INR and PT^{plus} cartridges should be filled directly from the puncture site by allowing blood to flow from the site into the cartridge - no transfer device should be used.
- Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators. Samples for coagulation testing cannot be collected into syringes that contain anticoagulants or activators.
- Test Timing (time from collection to cartridge fill):
  - Test sample immediately upon draw.
- For venipuncture, some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing samples for coagulation testing.
- If a second measurement is needed, draw a fresh sample.

IMMUNOASSAY CARTRIDGES FOR CTNI AND CK-MB TESTS

- **cTnI or CK-MB cartridges require the use of either:**
  a. Heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin and filled to capacity, or;
  b. Non-heparinized whole blood or plasma samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.
- **Anticoagulants:**
  - The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB test results.
- **Capillary:**
  - Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the cTnI or CK-MB, cartridges.
- **Fill Requirements:** Fill evacuated tubes or syringes to capacity. Under filling will cause higher heparin-to-blood ratios, which may affect results.
- **Mixing and Test Timing (time from collection to cartridge fill):**
  - Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds.
  - Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
  - For the most accurate results, test samples immediately after drawing. If testing is not immediate, re-mix the sample prior to filling the cartridge.
  - Test blood collected in heparinized evacuated tubes within 30 minutes.
  - Test blood collected in non-heparinized evacuated tubes or syringes within one minute.
- **Hemolysis:** For cTnI and CK-MB cartridges, gross hemolysis can also cause a decreased alkaline phosphatase activity and an increased proteolytic activity, resulting in decreased detection of cTnI or CK-MB.

IMMUNOASSAY CARTRIDGE FOR HS-TNI TEST

- The hs-TnI cartridge requires the use of:
  a. Heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium heparin and filled to capacity, or;
  b. Non-heparinized whole blood samples tested within three minutes of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.
- **Anticoagulants:**
  - The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased hs-TnI test results.
- **Capillary:**
  - Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the hs-TnI cartridges.
- **Fill Requirements:** Fill evacuated tubes or syringes to capacity. Under filling will cause higher heparin-to-blood ratios, which may affect results.
- **Mixing and Test Timing (time from collection to cartridge fill):**
  - Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds.
    - Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
  - For the most accurate results, test samples immediately after drawing. If testing is not immediate, re-mix the sample prior to filling the cartridge.
  - Test blood collected in heparinized evacuated tubes within 4 hours of collection.
  - Test blood collected in non-heparinized evacuated tubes or syringes within three minutes.
- **Hemolysis:** For hs-TnI cartridges, gross hemolysis can also cause a decreased alkaline phosphatase activity and an increased proteolytic activity, resulting in decreased detection of hs-TnI.

IMMUNOASSAY CARTRIDGE FOR BNP

- BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA and filled to capacity.
    - The use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes.
- **Anticoagulants:**
    - The use of whole blood or plasma samples containing other anticoagulants such as oxalate and citrate is not recommended.
    - Samples collected in EDTA anticoagulant may be used only with the i-STAT BNP cartridge. EDTA may not be used with any cartridge type other than the Glucose or BNP cartridges. EDTA will cause a clinically significant error in sodium, potassium, chloride and hematocrit results and may affect other chemistry tests.
- **Capillary:**
    - Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the BNP cartridge.
- **Fill Requirements:** Fill evacuated tubes or syringes to capacity. Under filling will cause higher heparin-to-blood ratios, which may affect results.
- **Mixing and Test Timing (time from collection to cartridge fill):**
    - Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds.
        - Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
    - For the most accurate results, test samples immediately after drawing. If testing is not immediate, re-mix the sample prior to filling the cartridge.
    - Test blood collected in heparinized evacuated tubes within 30 minutes.
    - Test blood collected in non-heparinized evacuated tubes or syringes within one minute.
- **Hemolysis:** For BNP cartridges, gross hemolysis can also cause a decreased alkaline phosphatase activity and an increased proteolytic activity, resulting in decreased detection of BNP.

IMMUNOASSAY CARTRIDGE FOR ß-HCG

- Total ß-hCG cartridges require the use of heparinized whole blood or plasma samples collected in plastic syringes or evacuated tubes containing lithium or sodium heparin and filled to capacity.
- **Anticoagulants:**
  - The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased Total ß-hCG readings.
- **Capillary:**
  - Capillary tubes and direct skin punctures (e.g., fingersticks) should not be used with the ß-hCG cartridge.
- **Fill Requirements:** Fill evacuated tubes or syringes to capacity. Under filling will cause higher heparin-to-blood ratios, which may affect results.
- **Mixing and Test Timing (time from collection to cartridge fill):**
  - Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds, then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds.
    - Blood in the tip of the syringe may have been exposed to air and may not be homogeneous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.
  - For the most accurate results, test samples immediately after drawing. If testing is not immediate re-mix the sample prior to filling the cartridge.
  - Test blood collected in heparinized evacuated tubes within 30 minutes.
  - Test blood collected in non-heparinized evacuated tubes or syringes within one minute.

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HANDLING AND FILLING CARTRIDGES 9

PREPARING TO USE THE i-STAT CARTRIDGE

Select the appropriate cartridge for the test or tests required.

RECEIVING i-STAT CARTRIDGE SHIPMENT

- Immediately check temperature strip enclosed with each shipment of i-STAT Cartridges. Follow the instructions on the card.
- Verify the integrity of cartridges, included in every shipment, upon receipt. See the QUALITY CONTROL section of this user guide for additional details.

HANDLING THE i-STAT CARTRIDGE

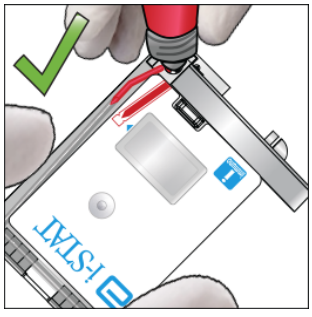
While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling and Quality Check failures.

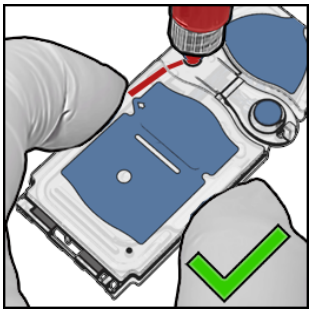
- A cartridge should not be removed from its protective pouch or portion pack.
- For best results, the cartridge and analyzer should be at the temperature of the room where they are to be used. Condensation on a cold cartridge may prevent proper contact with the analyzer.
- Equilibrate a single cartridge for 5 minutes or a box of cartridges for 1 hour at room temperature (18 - 30 °C or 64 - 86 °F) before opening pouch or portion pack.
- Use a cartridge immediately after removing it from its protective pouch or portion pack — prolonged exposure may cause a cartridge to fail a Quality Check.
- If the pouch or portion pack has been punctured, the cartridge should not be used.
- Once cartridges have been brought to room temperature, they should not be returned to the refrigerator.

CAUTIONS FOR HANDLING THE i-STAT CARTRIDGE

- Avoid touching the contact pads, as this may cause contamination and prevent the analyzer from making proper contact with the cartridge.
- Avoid touching the sensors on the top.
- Do not apply pressure to the central area of the cartridge.
- Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.
- To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled.
- Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.



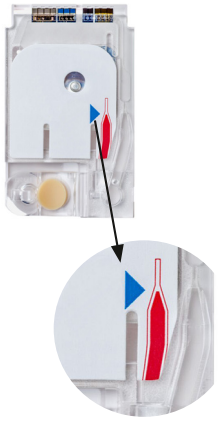




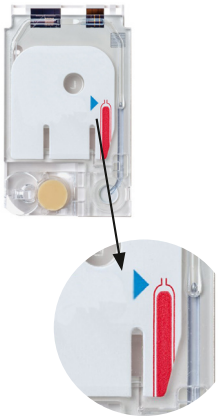
PROCEDURE FOR HANDLING, FILLING AND SEALING TEST CARTRIDGES

STEP	ACTION
1	Place the cartridge on a flat surface. Note the location of the sample well and fill mark indicator, as identified in the images below.

Cartridges with tests for Chemistries/Electrolytes, Blood Gases and Hematocrit



Cartridges with tests for PT, INR and ACT



Cartridges with immunoassay tests for cTnI, CKMB, BNP, β-hCG and hs-TnI



i-STAT (blue) CG4+ and CHEM8+ cartridges



2 **Mix the sample thoroughly.**

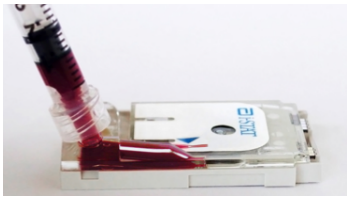
a. Invert a blood collection tube at least 10 times.

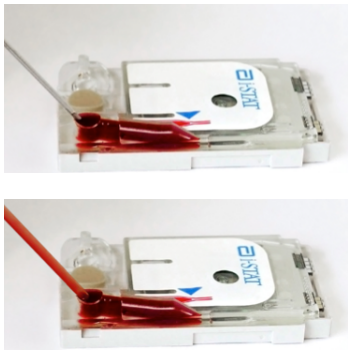
b. Roll a syringe repeatedly between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe

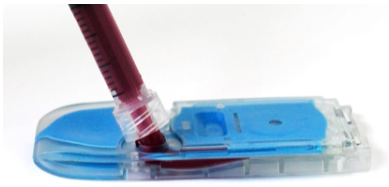
c. Expel a few drops of sample from the transfer device before filling the cartridge

3 Direct the tip of the transfer device (syringe, capillary tube, pipette, or dispensing tip)* into the sample well/inlet port, as shown below.

Note: Not directing the transfer device into the sample well could result in a sample not filling the cartridge or pooling on the sample well/inlet port





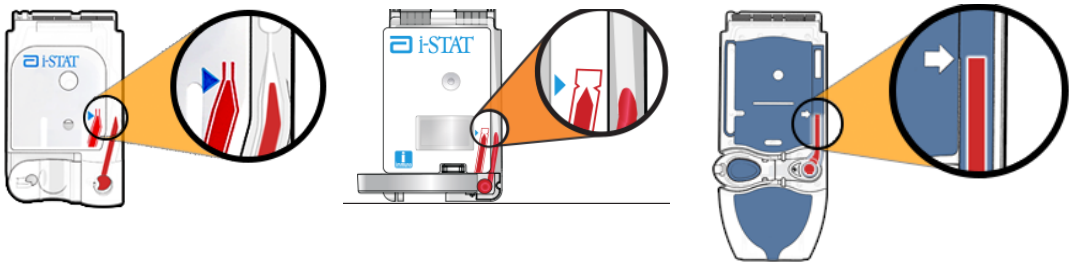


*For a complete list of recommended transfer devices, refer to the Blood Collection section of this manual.

PROCEDURE FOR HANDLING, FILLING AND SEALING TEST CARTRIDGES (continued)

STEP	ACTION
4	Dispense a small amount of sample, ensuring it travels toward the fill mark before applying additional sample. Avoid creating a bubble on the sample well. a. Continue dispensing until the sample reaches the fill mark indicated on the cartridge b. Ensure that there is sample in the inlet port, as well as the sample chamber

These images display a properly filled cartridge.
In the images, the sample fills the sample chamber to the fill mark indicator.

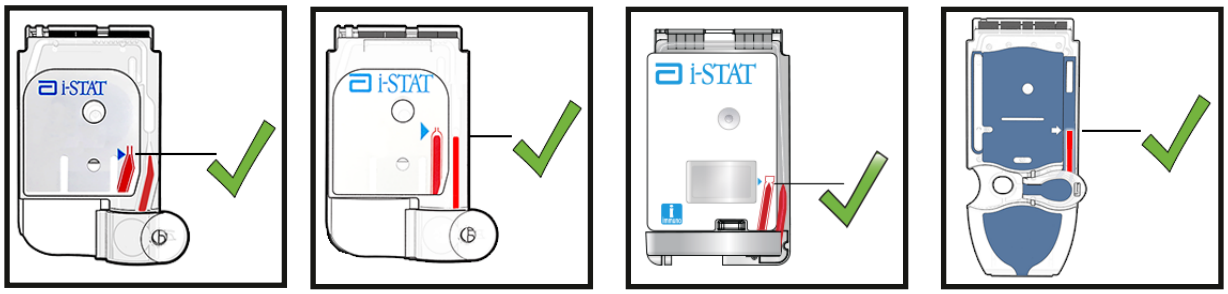


NOTE(s):

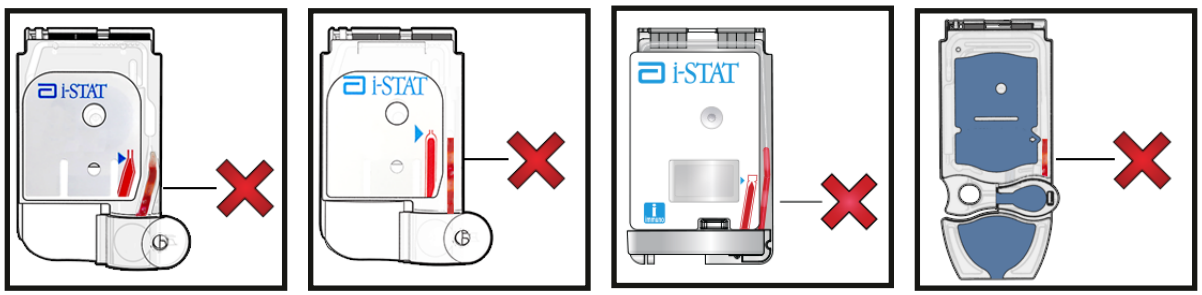
- No bubble appears in the sample pathway. To prevent a quality check failure, ensure that there are no bubbles introduced into the sample.



- To prevent a quality check failure:
  - ensure that the sample is filled to the fill mark.



  - ensure that there are no bubbles introduced into the sample.

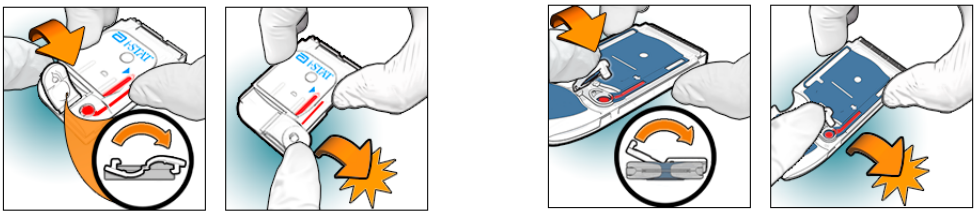


PROCEDURE FOR HANDLING, FILLING AND SEALING TEST CARTRIDGES (continued)

STEP	ACTION
5	**Fold the snap closure over the sample well:**

a. Keeping your thumb or finger on the outside edge of the closure clasp, press the rounded end of the closure until it snaps into place

b. Ensure that the cartridge is completely closed before inserting it into the device



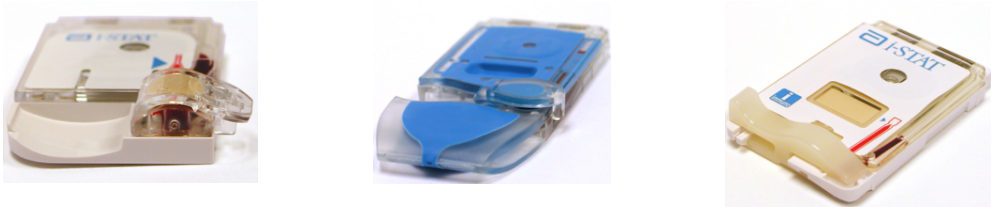
To close the immunoassay cartridge with the plastic closure clip:

a. First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet.

b. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well.



IMPORTANT NOTE: Properly filled and closed cartridges can be inserted into the analyzer.



PROCEDURE FOR HANDLING, FILLING AND SEALING TEST CARTRIDGES (continued)

Examples of Overfilled Cartridges

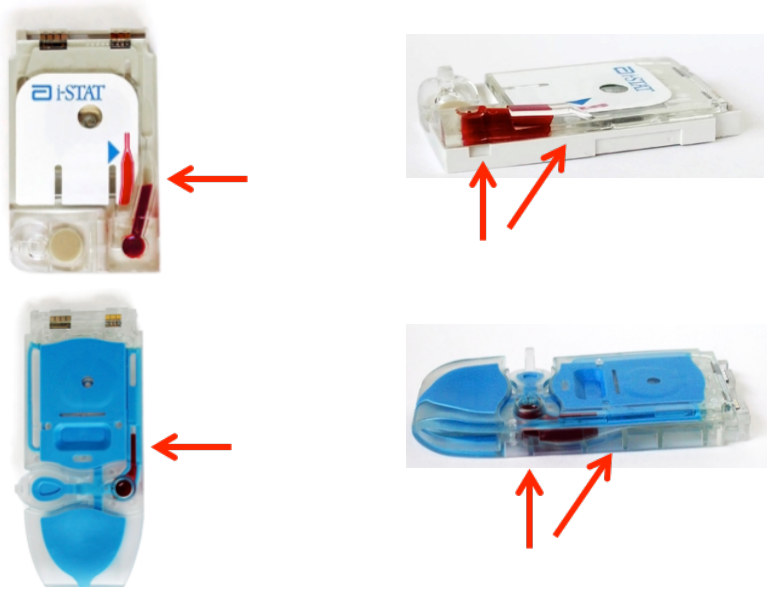
In the images below, the sample exceeds the fill mark indicator (Overfilled). In the image (below left) for the white snap closure cartridge, there is a bubble in the sample well. Every effort should be made to fill cartridges properly before inserting into the analyzer's cartridge port.



Examples of Under-filled Cartridges

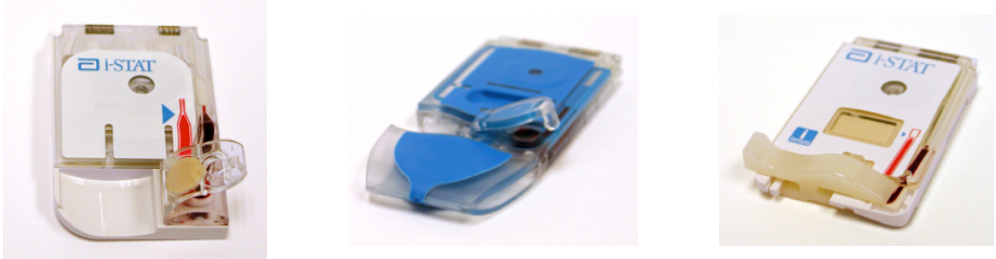
These images display under-filled cartridges. In the images below, the sample well is insufficiently filled, and the sample does not reach the fill mark indicator.

In the images below, the sample well is sufficiently filled, but the sample does not reach the fill mark indicator. Every effort should be made to fill cartridges properly before inserting into the analyzer's cartridge port.



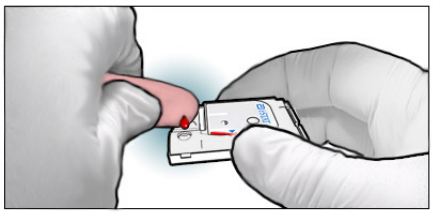
Examples of Improperly Closed Cartridges

These images display improperly closed cartridges. Although they were properly filled, they must be closed sufficiently before they may be inserted into analyzer's cartridge port.



PROCEDURE FOR HANDLING, FILLING AND SEALING CARTRIDGES WITH PT, INR TESTS USING DIRECT FINGERSTICK SAMPLING

STEP	ACTION
1	Remove test cartridge for PT and INR from foil pouch and place the cartridge on a flat surface.
2	Prepare lancet device and set aside until needed.
3	Clean and prepare the finger to be sampled using a 70% aqueous solution of isopropanol (70% v/v). Allow the finger to dry thoroughly before sampling. When disinfecting fingerstick skin puncture sites, swabs or solutions containing substances other than isopropanol (e.g. Chlorhexidine Gluconate) are not recommended. Refer to the “Limitations" section in the PT/INR Cartridge and Test Information Sheet OR i-STAT PT^{plus} Instructions for User for more information.
4	Prick the bottom side of the fingertip with the lancet device.
5	Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure (“milking”) as it may cause hemolysis or tissue fluid contamination of the specimen.*
6	Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.



7	Apply sample until it reaches the fill mark indicated on the cartridge.
8	Fold the sample closure over the sample well.
9	Press the rounded end of the closure until it snaps into place. Slightly lift finger or thumb and ensure that the cartridge is closed before completely removing finger or thumb from the closure.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridges to the finger for easier application. Do ensure that the instrument remains on a flat, vibration-free surface for testing.

INSERTING AND REMOVING THE CARTRIDGE FROM THE ANALYZER

STEP	ACTION



Inserting Cartridge into Analyzer

1 Align the cartridge with the contact pads facing up and toward the analyzer's cartridge port.

2 Push the cartridge slowly and smoothly into the analyzer's cartridge port until it clicks into place.

Removing Cartridge from Analyzer

3 Do not attempt to remove the cartridge while the message “Cartridge Locked” remains on the screen.

4 When results are displayed, pull the cartridge straight out of the analyzer.

5. Dispose of the cartridge in a container for biohazards, following local, state, and national regulatory guidelines.

INCORRECT PROCEDURE

Overview

The cartridge is designed to fill and seal correctly. However, the conditions described below may occur, especially during the training period. If the condition is not detected by the operator, the analyzer will detect the condition, halt the test cycle and display a cause message followed by the action message "USE ANOTHER CARTRIDGE."

Condition	Operator Action	Analyzer Display
Sample beyond fill mark.	If the sample flows only slightly beyond the fill mark, the cartridge can still be used. If the sample is close to or enters the air segment chamber, use another cartridge.	SAMPLE POSITIONED BEYOND FILL MARK
Sample not up to fill mark.	If the sample well fills but the sample does not reach the fill mark, ensure that the air vent (small hole on the underside of the cartridge) is not blocked. Tilt the cartridge slightly so that gravity aids the flow. When the sample starts to flow into the chamber, return the cartridge to the horizontal position. If the sample is considerably short of fill mark, the analyzer will detect the condition and halt the test cycle.	SAMPLE POSITIONED SHORT OF FILL MARK
Sample well empty.	If the sample reaches the fill mark, but the sample well is left completely empty, there may be insufficient sample for the test.	INSUFFICIENT SAMPLE
Air bubbles in sample.	If air bubbles are trapped in the sample chamber, discard the cartridge and fill another.	INSUFFICIENT SAMPLE
Sample well overfilled.	If the sample well is so full that sample is seen above the sample well after the sample chamber is filled, do not wipe or absorb the excess with a gauze or tissue but draw the excess back into the syringe or a capillary tube. If the sample spreads over the outside of the sample well, an airtight seal may not form when the cartridge is closed. In this case the analyzer may not be able to move or position the sample over the sensors.	UNABLE TO POSITION SAMPLE
Sample clotted.	If the sample clots in the sample well the analyzer will not be able to move or position the sample over the sensors.	UNABLE TO POSITION SAMPLE
Cartridge contaminated.	If sample spills onto the cartridge or if the cartridge has collected debris, discard the cartridge. Inserting a contaminated cartridge into the analyzer will cause debris to build up on the pins that contact the cartridge pads which will cause a cartridge or analyzer Quality Check code.	CARTRIDGE ERROR or ANALYZER ERROR
Sample pushed beyond fill mark.	Avoid applying excess pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark.	SAMPLE POSITIONED BEYOND FILL MARK
Cartridge sealed before sample reaches fill mark.	Closing the cartridge before the sample chamber has filled will stop the flow of the sample to the fill mark.	SAMPLE POSITIONED SHORT OF FILL MARK
Cartridge not sealed before inserted into analyzer.	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.	UNABLE TO POSITION SAMPLE.

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PROCEDURE FOR CARTRIDGE TESTING 10

Caution

The following cautions should be taken to prevent damage to the analyzer and to ensure the safety of the operator and the integrity of results.

- Ensure cartridges and analyzers are at room temperature.
- Scan the cartridge barcode before opening cartridge pouch or portion pack.
- Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent eye damage.
- Use a cartridge immediately after removing it from its protective pouch or portion pack. Prolonged exposure may cause a cartridge to fail a Quality Check.
- Do not attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the analyzer. The message "Cartridge Locked" will remain on the screen until the analyzer unlocks the cartridge.
- Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-borne pathogens.
- A falling analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.
- The analyzer may be rendered inoperative by damage due to mishandling, such as dropping, by exhausting the batteries or by other causes. Clinical settings that demand fail-safe testing should reduce this risk by having a backup analyzer or test source available.
- The analyzer and its peripherals are not listed by any authority with respect to suitability for use in oxygen enriched atmospheres.
- Proper procedure must be used to ensure correct manual entry of patient ID, operator ID, sample type and other data that may affect the clinician's interpretation of results.
- To protect from nosocomial infections, decontaminate analyzers periodically and whenever blood is spilled or transferred to an analyzer. See the "Cleaning the Analyzer and Downloader" section of this manual.
- The analyzer should not be used in environmental conditions that exceed the operating temperature and humidity specifications. An analyzer that has been exposed to extreme environmental conditions must be allowed to come to equilibrium with the operating environment prior to use. Note: the analyzer will display the message "Temperature Out of Range" until it has reached its operating temperature.

PROCEDURE FOR PATIENT TEST

1. Press ⏻ to turn on the analyzer.
2. Press 2 for i-STAT cartridge.
3. Follow the analyzer prompts.
4. Scan the lot number on the cartridge pouch or portion pack.



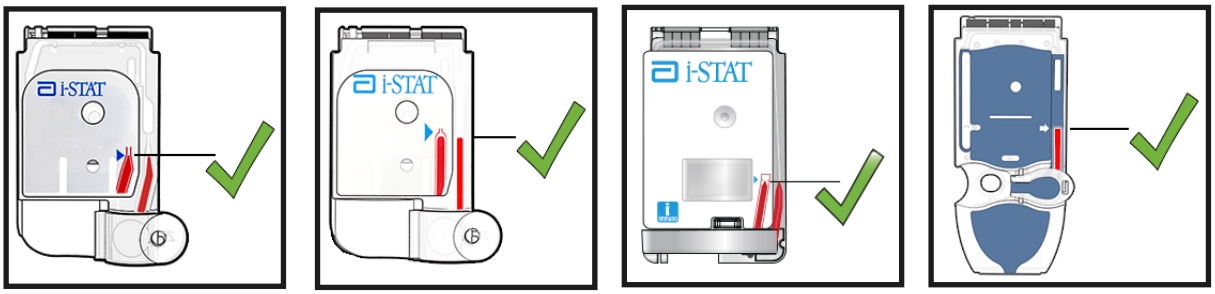


   - Position barcode 3-9 inches from scanner window on the analyzer.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The analyzer will beep when it reads the barcode successfully.



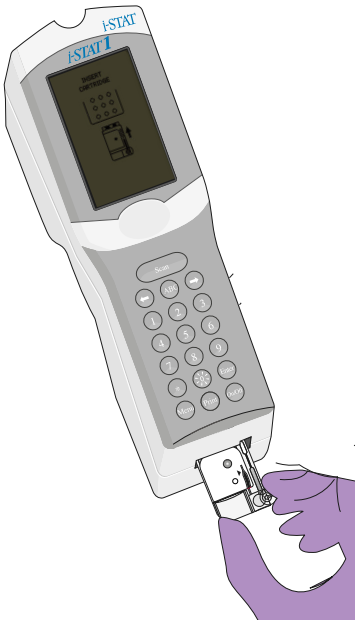
Laser Radiation – Do not stare into beam. Class 2 laser product.
Laser Diode 650 nm Maximum Output 1.0 mW.

5. Continue normal procedures for preparing the sample, and filling and sealing the cartridge.



6. Push the sealed cartridge into the analyzer's cartridge port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT, INR, Hct, cTnI, CK-MB, BNP, ß-hCG, and hs-TnI testing, the analyzer must remain on a level surface with the display facing up during testing.
   A level surface includes running the analyzer in the downloader/recharger.



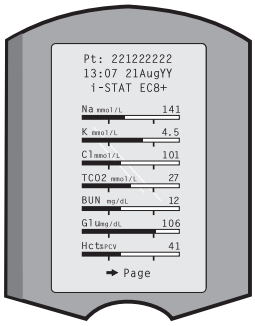
7. Review results.

INTERPRETATION OF DISPLAYED RESULTS

Results Display

Test results are displayed with numerical concentration values in the units selected for the Customization profile. For patient test results, bar graphs depicting the values in relation to reference ranges are also displayed. Reference ranges are marked on the bars by tic marks. When all test values are within their reference ranges, the tic marks will be centrally aligned. The bar graphs can be used as a visual cue for distinguishing between “normal” and “abnormal” results. Blood gas, coagulation, and immunoassay results are not displayed with bar graphs and reference ranges.

If a value exceeds the reference range, the bar graph may be rescaled to show the reference range and value in relation to the measurement range.

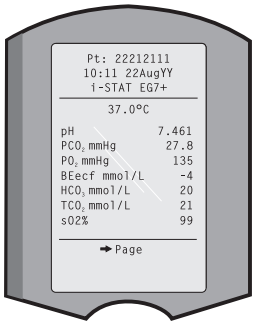


Reportable Ranges

The reportable range (sometimes referred to as the linear range) is the concentration range over which test results are valid. Reportable ranges programmed into the analyzer are listed in the Cartridge and Test Information (CTI) Sheets/Instructions for Use (IFU) on the APOC website at www.globalpointofcare.abbott. Reportable ranges may be customized into the analyzer using the Customization features available with optional i-STAT/DE software.

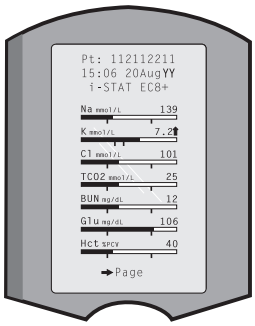
Reference Ranges

Reference ranges (sometimes referred to as normal ranges) in the default Customization profile are derived from the literature and are listed in the Cartridge and Test Information (CTI) Sheets/Instructions for Use (IFU) on the APOC website at www.globalpointofcare.abbott as well as in the Customization option on the analyzer. Variables such as sex, age, heritage and other demographic factors of a population may cause a shift in these ranges. Therefore, it is usually recommended that each facility determine its own reference ranges. Reference ranges may be customized into the analyzer using the Customization features available with optional i-STAT/DE software.



Action Ranges

Action ranges (sometimes referred to as critical values) indicate results that require immediate attention. When a test result falls outside the action range it is flagged as either above the high action range ↑ or below the low action range ↓. Action ranges may be customized into the analyzer using the Customization features available with optional i-STAT/DE software.



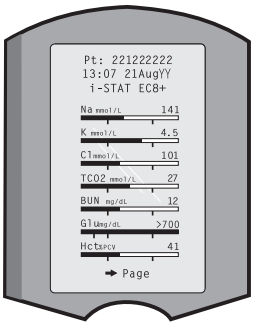
ACT Cartridges

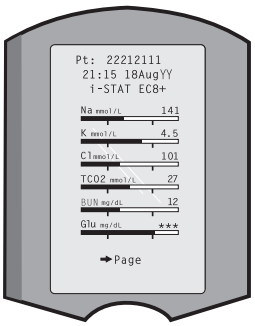
When testing a Celite ACT or Kaolin ACT cartridge, an option to cancel the test will appear on the analyzer screen. The cancel test option will only appear after all the data entry has been completed. If the operator chooses to cancel the test, the result will display as "0".

Flags

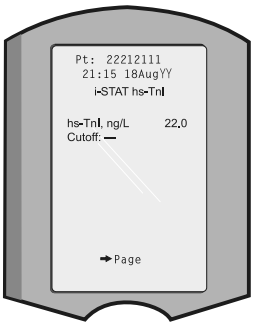
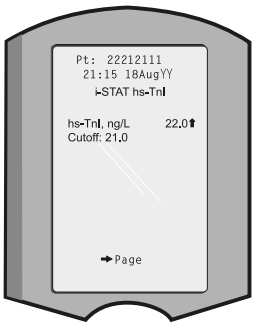
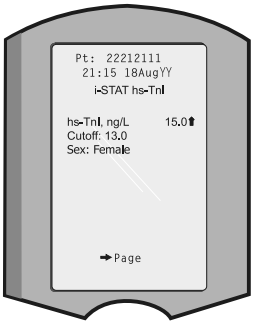
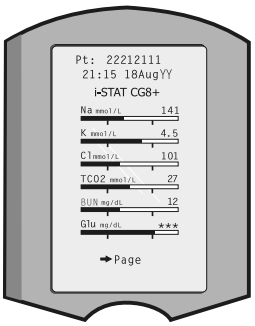
When the analyzer detects an out-of-range result or an uncharacteristic sensor signal, the condition is indicated by a flag. See table below for flags and symbols used with results.

Note: The reportable range flags do not apply when testing is performed under Quality Tests Option **3 – Cal Ver**. Action flags do not apply to Option **1 – Control** or Option **3 – Cal Ver**.





Display	Action	Analyzer Response / Comments
>	*The result falls above the reportable range of the test.*	*If an ACT result is displayed as >1000, the result should be reported as "greater than 1000 seconds."*
<	*The result falls below the low end of the reportable range of the test.*	*If a pH result is displayed as <6.5, the result should be reported as "less than 6.5."*
< >	*This result is dependent on another test that has been flagged.* *The <> flag will also be displayed for TCO_2, pH, **P**CO_2, HCO_3, anion gap, base excess, and sO_2 if the TCO_2 is <1 or >80 mmol/L. Because the values outside this range are essentially non-physiological, the TCO_2 range check is used as an additional quality check on the validity of the underlying pH and **P**CO2 results.*	*If a sodium result is displayed as >180, the calculations for potassium, chloride, BUN/Urea and hematocrit, which depend upon the sodium measurement, will be flagged < >.*
↑	*The result is above the high action range.*	*If the action ranges for potassium are 3.2 and 5.5, a result of 6.0 will be displayed as 6.0 ↑.*
↓	*The result is below the low action range.*	*If the action ranges for potassium are 3.2 and 5.5, result of 3.0 will be displayed as 3.0 ↓.*

Display	Action	Analyzer Response / Comments
 Cutoff: ---	*Displayed with hs-TnI test result. By default the analyzer will display a cutoff as ---.*	*When customized using optional i-STAT/DE software, an up arrow will display based on the customized cutoff.* *Refer to the i-STAT hs-TnI Instructions for Use for more information on reference ranges and sex-specific cutoffs. Follow your facility's policies and procedures for interpreting hs-TnI test results.* *Refer to the i-STAT/DE User Guide for information on customizing reference ranges with the optional i-STAT/DE software.*
 ↑, Cutoff: XX	*Displayed with hs-TnI test result above the specified cutoff.* *Analyzer has been customized with optional i-STAT/DE software for non-sex specific reference range cutoff.*	
 ↑, Cutoff: XX Sex: XXX	*Displayed with hs-TnI test result above the specified sex specific cutoff.* *Analyzer has been customized with optional i-STAT/DE software for sex specific reference range cutoff.*	
 ***	*The signals from a particular sensor are uncharacteristic. Uncharacteristic signals can be caused by a compromised sensor, mishandling and/or improper filling the cartridge or by an interferent in the sample.* *This flag also appears for any test dependent on another test which is flagged with stars.*	*Draw a fresh sample, ensure that the cartridge is handled correctly and filled to the fill mark and repeat test.* *If starouts reappear, use another method.*

TROUBLESHOOTING

Warning Message

If testing is disabled due to a warning message, the condition must be corrected and the analyzer must be turned off and back on again before testing is enabled.

Message and Quality Check Code

See Troubleshooting section.

*** Instead of Results

Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Since the sensor check is part of the i-STAT quality system, an occassional result will be flagged due to a bad sensor. Other causes of this flag are improperly stored cartridges or an interfering substance in the patients sample, either extrinsic, such as the wrong anticoagulant, or intrinsic such as medication. Also, aged samples may contain products of metabolism that can interfere with the tests.

- If the specimen's integrity is not in question, the results that are not suppressed should be reported in the usual manner.
- Check the supply of cartridges in use with a control solution.
- If the control is in range, draw a fresh sample from the patient and retest.
    - If the stars appear in place of results again, test the sample using another method.
    - Refer to the Cartridge and Test Information (CTI) Sheets/Instructions for Use (IFU) on the APOC website at www.globalpointofcare.abbott for a list of interfering substances.
- If the control is out-of-range or if stars are displayed in place of results, there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and contact your support representative. (Refer to Support Services information in the Technical Bulletin section.)

Unexpected Results

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions.

- If the controls are in range, there may be an interfering substance in the sample.
    - Check the Cartridge and Test Information (CTI) Sheets/Instructions for Use (IFU) for the test in question.
    - Test by another method to verify the result.
- If the controls are out of range there may be a problem with the cartridge lot number.
    - Use another lot number or repeat the test using another method, and contact your support representative. (Refer to Support Services information in the Technical Bulletin section.)

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TROUBLESHOOTING THE ANALYZER 11

Overview

When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem and the next step to be taken will be displayed.

The Code number may be helpful to a technical support representative if a problem cannot be resolved. If a problem cannot be resolved by the procedures described in this section, refer to Support Services information in the Troubleshooting section.

Note: Troubleshooting for results and quality tests are covered in those sections of this manual.

Caution

DO NOT OPEN THE ANALYZER, or any other i-STAT product, or perform any unauthorized procedures. Opening any i-STAT product, including analyzer, Electronic Simulator, printer or communication device, in attempt to repair it or resolve a problem may cause erroneous results.

If the troubleshooting procedures found in this manual or requested by an i-STAT support specialist do not resolve the problem, the product must be returned to i-STAT for repair.

Information Needed

Have the following pertinent information available for review with the representative:

- Description of problem
- When problem first occurred and what has been done so far to resolve the problem
- Serial number of component(s)
- Lot number of cartridge
- Lot number of i-STAT liquid quality controls or calibration verification materials
- Displayed message and code number
- Frequency of problem
- Software version
- Environmental conditions
- Result of last Electronic Simulator test
- Battery voltage from Analyzer Status page

STARTUP MESSAGES

Overview

Whenever the analyzer is turned on using the On/Off key, the analyzer performs self-checks.

- If a condition that should be corrected in the near future, but that will not affect results is detected, a warning is displayed. The operator presses the 1 key to continue with testing.
- If the analyzer has been customized to disable testing under any of these conditions, the condition must be corrected and the analyzer turned off and back on before testing will be enabled.

Message on Display	Explanation	How to Respond
Electronic Simulator Test Required	Analyzer customized to alert the operator that a scheduled simulator test is due.	Insert the external Electronic Simulator at the earliest convenient time.
Stored Memory Low	Memory space for 50 unsent test records available before the “Stored Memory Full” message is displayed.	Place the analyzer in a Downloader.
Stored Memory Full	The analyzer is customized to alert the operator that the memory for unsent records is full. If the operator does not transmit the test records to the Point-of-Care Central Workstation, the analyzer will either block further testing or will overwrite oldest records depending on how the analyzer is customized.	Place the analyzer in a Downloader.
Upload Required	The analyzer is customized to alert the operator that a scheduled transmission of test records to the Central Data Station is due.	Place the analyzer in a Downloader.
Battery Low	Battery voltage has dropped to 7.4 volts. There is sufficient power to test a few more cartridges, the number depending mainly on the types of cartridges in use. Under this condition, a flashing battery icon will also appear on the result page, the Test Menu screen, and the Administration Menu screen.	Change the disposable lithium batteries or recharge the rechargeable battery.
Software Expires DDMMMYY	Message appears 15 days before the software expires.	Update the analyzer before the expiration date.

TEST CYCLE MESSAGES AND QUALITY CHECK CODES

Overview

If a problem is detected during a testing cycle, the cycle will be stopped and a message will identify the problem and indicate the next step to be taken. If the problem causes testing to be disabled, the problem must be corrected and the analyzer must be turned off and back on before testing will be enabled.

Environmental Conditions

The following messages usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the the offending condition is corrected.

Message on Display	Cause	Action
Date Invalid, Check Clock	The analyzer will not allow a date that precedes or exceeds the six months lifetime of the CLEW software.	Press **Menu** once to go to the Test Menu and then again to go to the Administration Menu. Press 5 to go to the Set Clock screen and correct the date.
Dead Batteries, Replace Batteries	There is insufficient battery power to complete a test cycle.	Change the disposable lithium batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status Page	The analyzer makes a temperature measurement before initiating a test cycle.	Check the temperature reading on the Analyzer Status screen (under the Administration Menu). If below the operating range, move to a warmer area. If above the operating range, move to a cooler area. Allow time for the analyzer to equilibrate to the new temperature. Check the Analyzer Status screen periodically.
Expired Software, Update Required	The software has become corrupt or has expired. The Product Update for each software update includes the expiration date.	Verify that the date in the analyzer is correct. Change the software if expired. Update the software again if not expired. If the message is displayed again, refer to Support Services information at the end of this section.
Analyzer Interrupted, Use Another Cartridge	The analyzer detected that the last cartridge run was not completed. This can happen if battery voltage is low, or if batteries were removed or making poor contact while a cartridge was still in the analyzer.	Check that the battery pack is inserted properly. Turn the analyzer on and check for the Low Battery message; replace or recharge if needed.

Error in Cartridge or Fluid Movement

The following conditions usually indicate an error condition relating in some way to the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Message on Display	Cause	Action
Cartridge Error Use Another Cartridge	These codes can all be caused by a variety of reasons including sample-related problems, users, cartridges or analyzers. Errors are most likely • a sample-related problem (an interferent), • an aberrant cartridge, or • a user-induced situation such as touching cartridge contacts, pressing on center of cartridge or • bubbles in the sample (“frothy” samples).	Repeat the test with another cartridge. If the same code repeats more than twice on a single sample, use another method. If the same code repeats more than twice on multiple samples, there may be an analyzer problem. Try another analyzer if available.
Cartridge Preburst Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • cartridges may have been frozen. • calibrant pack, if applicable, may have been burst by operator exerting too much pressure on the center of the cartridge.	Try another cartridge. Make sure that the cartridges were not frozen.
Unable to Position Sample Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to: • not closing the snap closure on the cartridge. • a clot in the sample preventing movement of the sample. • an aberrant cartridge.	Use another cartridge.
Sample Positioned Short of Fill Mark Use Another Cartridge	The cartridge was under-filled.	The sample must reach the fill mark. Try another cartridge.
Sample Positioned Beyond Fill Mark Use Another Cartridge	The cartridge was overfilled.	The sample was past the fill mark. Try another cartridge.

Error in Cartridge or Fluid Movement (continued)

Message on Display	Cause	Action
Insufficient Sample Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample.	Try another cartridge.
Cartridge Not Inserted Properly Reinsert Cartridge	The code indicates the cartridge or external Electronic Simulator may not be pushed in all the way.	Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Refer to Support Services.
Test Cancelled by Operator	No response to mandatory prompt before analyzer time out.	No action required. Training may be required if a particular operator has a high rate of cancelled tests.

Electrical or Mechanical Failures

The following conditions are related to electronic or mechanical failures in the analyzer.

Message on Display	Cause	Action
Analyzer Error Use Electronic Simulator	The analyzer usually recovers from these errors when the Electronic Simulator is run. This error can occur if the cartridge or Electronic Simulator was “angled” when inserted. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?).	Push cartridge or Simulator straight through the cartridge port. Try another Simulator. • If the analyzer passes the Electronic Simulator check, continue to use it. • If the analyzer fails the Electronic simulator check or if the Quality Check Code is recurrent, the analyzer may need repair.
Analyzer Error See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover.	Use an external Electronic Simulator twice and use a cartridge with sample or control solution. • If an error condition occurs, refer to Support Services. • If not, continue to use the analyzer.

Electrical or Mechanical Failures (continued)

Message on Display	Cause	Action
Cartridge Type Not Recognized Use Another Cartridge	This error could be due to: • The analyzer could not identify the cartridge or simulator • Insertion of an Electronic Simulator when performing a cartridge test • Insertion of a cartridge when performing an Electronic Simulator test	Insert the correct cartridge or simulator for the test. • If the message continues to occur after inserting the correct cartridge or simulator, contact i-STAT Technical Services or your Support Services Representative, as the analyzer may need repair.
Internal Simulator Failure	This error can occur if poor contact is made between the handheld pins and the contact pads of the cartridge.	**Lockout Enabled:** Immediately rerun the cartridge in the same handheld. If the simulator test fails again, rerun the cartridge is another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator. **Lockout Not Enabled:** Immediately rerun the cartridge in another handheld. Note: the cartridge should not be run if there is more than a three minute delay from the time it was filled. Verify the failed handheld using an external electronic simulator.

No Display

Symptom	Possible Cause	Action
The display screen remains blank, either after a cartridge has been properly inserted or after the On/Off key has been pressed.	Batteries dead. Keypad not responding. Internal Start switch broken.	Change or recharge batteries. • If this does not fix the problem, reinstall the current software in the analyzer. • If the problem persists, the analyzer should be returned for repair. If using the analyzer recharging function of the i-STAT 1 Downloader/Recharger, ensure that the Downloader/Recharger is working as intended. If experiencing an issue, contact your support representative and use disposable batteries for continued use of the analyzer.

"Cartridge Locked" Not Removed

Symptom	Possible Cause	Action
Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the "Cartridge Locked" message will remain on the screen.	• Dead batteries. • Mechanical problem.	Wait until the analyzer turns off or turn the analyzer off. Then turn the analyzer on. If it can reset, it will release the cartridge and remove the "Cartridge Locked" message. • If the cartridge is not released, change or recharge the battery and turn the analyzer on. • If the "Cartridge Locked" message does not disappear, do not attempt to remove the cartridge and refer to Support Services.

Alert Messages

Message on Display	Possible Cause	Action
Invalid Cart. **See Admin.**	Analyte action or reference range limit, customized using i-STAT/DE software, is outside the analyte measurement range for the cartridge being tested.	Ensure that the action and reference range limits for analyte(s) are customized to values within the analyzer measurement range for the cartridge(s) being tested. Refer to the *Customizing Reference and Action Ranges* section in the i-STAT/DE User Guide.
	Barcode scanned from a cartridge that is not supported.	Scan the barcode from a supported cartridge that contains the analytes needed to perform testing.
Lot Expired	Cartridge lot being tested is expired.	Check the expiration date and repeat the test using a non-expired cartridge lot.

ANALYZER CODED MESSAGES

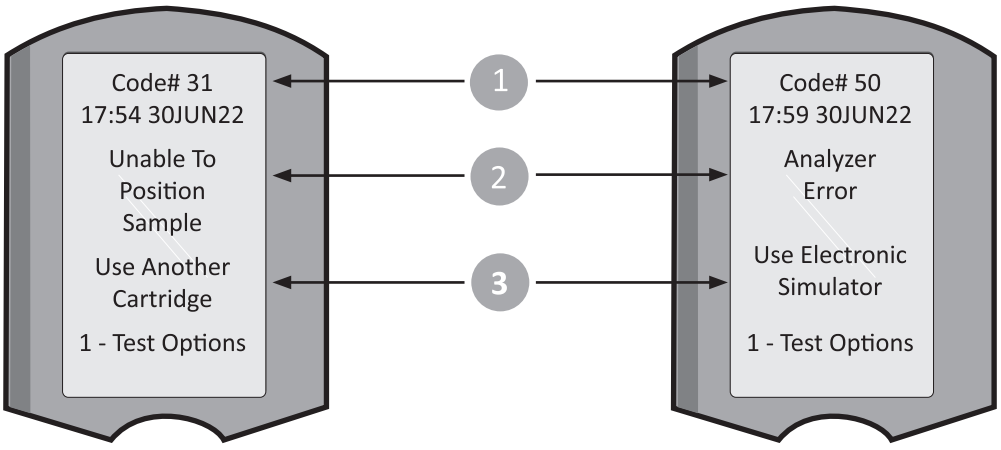
Overview

From the time it powers up until the time it powers down, the i-STAT Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause", an "action" message, and a code.

1 **The Cause Code:**
This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Services or your local support organization for further assistance.
The codes are stored in the analyzer's memory along with other test records and can be transmitted to a data management system with optional i-STAT/DE software and configuration for network connectivity. When using an optional data management and network connectivity configuration, the code list can be viewed and printed.

2 **The Cause Message:**
This message describes the likely cause of the failed quality check.
For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".

3 **The Action Message:**
This message indicates the appropriate action.
For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.



Codes 1-15 and 95

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away

- after the next cartridge or Electronic Simulator is inserted,
- or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 Analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
4, 8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
11	**Date Invalid** / Check Clock on Status Page	Check the date on the real time clock. If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Expired Software Update Required /** See Manual	The standardization software (CLEW) has expired. Download a valid CLEW. The date on the real-time clock in the analyzer exceeds the expiration date of the CLEW. Check the date on the real-time clock and adjust as necessary.

Codes 1-15 and 95 (continued)

Code Number	Cause/Action Message on Display	Explanation
12	**Expired Software Update Required /** See Manual	Check the date on the real-time clock and adjust as necessary. The standardization software (CLEW) has expired. Download a valid CLEW. The date on the real-time clock in the analyzer exceeds the expiration date of the CLEW.
13	**Invalid CLEW Update Required /** See Manual	The standardization software (CLEW) is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. When using optional i-STAT/DE software, if this code occurs after a software upgrade and the customization application is enabled, change the CLEW version in the Customization Profile to the latest version and retransmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. When using optional i-STAT/DE software, if this code occurs retransmit the profile to the analyzer. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
15	**Barcode Does Not Match Cartridge Type**	Cartridge identified via barcode does not match inserted cartridge. The user should run another cartridge, being careful to scan the barcode from the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

Codes Associated with the Cartridge or Fluid Movement within a Cartridge

The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related.

- In most cases, a new cartridge must be used.
- If a condition persists, especially if isolated to one analyzer, there may an analyzer problem.

Code Number	Cause/Action Message on Display	Explanation
17-19	**No Clot Detected** / See Manual	During the coagulation test cycle, no clot was detected. Run another cartridge. If the code reappears, run the sample on an alternate methodology.
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization.

Codes Associated with the Cartridge or Fluid Movement within a Cartridge (continued)

Code Number	Cause/Action Message on Display	Explanation
26	**Cartridge Error** / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27-29, 32, 33, 40, 41, 45, 87	**Cartridge Error** / Use Another Cartridge	These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. 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. The specific conditioning procedure is described at the end of this section. The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.
42, 43	**Cartridge Error** / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a: • pre-burst calibrant pack, • dirty cartridge contact pads, or • a dirty connector in the analyzer.
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: • poor metalization of the chips, • dirt on the metalization, or • bent or broken thermal probes in the analyzer.

Codes Associated with the Cartridge or Fluid Movement within a Cartridge (continued)

Code Number	Cause/Action Message on Display	Explanation
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • mishandling of cartridges (putting pressure in the center of the cartridge), • poor storage conditions of cartridges (frozen), or • rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due: • to a clot in the sample (especially in neonates), • to not closing the snap closure on the cartridge, or • to an aberrant cartridge.
35, 36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample** / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due • to a clot in the sample (especially in neonates), • to not closing the snap closure on the cartridge, or • to an aberrant cartridge.

Codes Associated with the Cartridge or Fluid Movement within a Cartridge (continued)

Code Number	Cause/Action Message on Display	Explanation
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
23, 49	**Poor Contact Detected** / See Manual	Code 23 may be caused by poor contact between the analyzer contact pins and the cartridge sensor contact pads. Code 49 may be caused by poor contact between the analyzer contact pins and the cartridge identification chip contact pads. These quality check codes can sometimes be corrected by conditioning the analyzer contact pins using the ceramic conditioning cartridge. The conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. • Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. • If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. • This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. • Note: If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 126 and 128 are sometimes related to electrical connection as well. • If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement. The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. • Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. • If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. • Try fresh batteries. • If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.

The following conditions are related to electronic or mechanical failures in the analyzer. (continued)

Code Number	Cause/Action Message on Display	Explanation
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. • Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. • If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Services or your local support organization for further assistance.
69	**Cartridge Type Not Recognized** / Use Another Cartridge	This condition may be due to: • Analyzer could not identify the cartridge or simulator • Insertion of an Electronic Simulator when performing a cartridge test • Insertion of a cartridge when performing an Electronic Simulator test Insert the correct cartridge or simulator for the test. • If the message continues to occur after inserting the correct cartridge or simulator, contact i-STAT Technical Services or your Support Services Representative, as the analyzer may need repair.

The following conditions are related to electronic or mechanical failures in the analyzer. (continued)

Code Number	Cause/Action Message on Display	Explanation
53, 55-57, 63, 65-68, 72-74, 82, 83-85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover. **Codes 82 and 92** typically indicate a problem with the pressure transducers in the analyzer. • If these codes persist, contact i-STAT Technical Services or your local support organization for further assistance. **Codes 83 and 84** indicate an underlying hardware failure in the i-STAT 1 Wireless Analyzer. • If these codes persist, contact i-STAT Technical Support or your local support organization for further assistance. **Code 55:** The rate of quality check code 55 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. • To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature. **Code 56** occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. • If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned. **Code 86** can occur when an i-STAT Analyzer is stored in an i-STAT Downloader/Recharger without adequate ventilation. This problem can usually be resolved by moving the Downloader/Recharger to an open location which is free of obstructions and external heat sources such as heater vents or other electronic equipment. • If this code persists, or if code 86 occurs with the i-STAT 1 Analyzer without a Downloader/Recharger, contact i-STAT Technical Services or your local support organization for further assistance. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. • If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. • If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact i-STAT Technical Services or your local support organization for further assistance.

Codes in the range of 119 to 138 and 142 to 151 indicate a failure during an immuno or barcoded pouch cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used.

Code Number	Cause/Action Message on Display	Explanation
119	**Cartridge Error** / Use Another Cartridge	The analyzer detected a high sample resistance. This could be due to the sample having a high hematocrit. Try another cartridge.
120-122, 124, 125, 133, 144, 148	**Cartridge Error /** Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. However, this code can also be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. • This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. • **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 50 and 128 are sometimes related to electrical connection as well. • If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.
127	**Cartridge Error /** Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.

Codes in the range of 119 to 138 and 142 to 151 indicate a failure during an immuno or barcoded pouch cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used. (continued)

Code Number	Cause/Action Message on Display	Explanation
128, 131, 132, 134, 135-138	**Cartridge Error /** Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. **Discard** (always) 1 drop from delivery device to clear unseen bubbles. 2. **Hang** single drop slightly larger than round target well. 3. **Touch** 1 drop (only) to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of fill mark. 5. **Close** cartridge. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge for insertion. • Original thumbwell design: grasp the closure between your thumb and first finger. There is a recess for your thumb on the closure. • Large thumbwell cartridge: grasp the thumbwell between your thumb and first finger. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129	**Cartridge Error /** Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
142, 143	**Cartridge Error /** Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. If these codes persist, sample interferences should be considered. Try another cartridge.
130	**Cartridge Error /** Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.

Codes in the range of 119 to 138 and 142 to 151 indicate a failure during an immuno or barcoded pouch cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used. (continued)

Code Number	Cause/Action Message on Display	Explanation
145	**Cartridge Error /** Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • **failure to close the cartridge completely.** Ensure that the closure is fully engaged before inserting the cartridge into the analyzer. • **underfilled cartridge.** Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the fill mark and then close the cartridge. • **cartridge leak.**
146	**Cartridge Error /** Use Another Cartridge	Overfilled cartridge. Repeat the test.
147	**Analyzer Error /** See Manual	In order to run an immunoassay cartridge, the i-STAT 1 Analyzer must bear the immuno symbol:
149 - 151	**Cartridge Error** / Use Another Cartridge	The analyzer detected an atypical data stream from the cartridge. Try another cartridge. **For BNP**, if code 150 is encountered when running a whole blood sample, it is recommended that the sample be centrifuged and the test be repeated with the resulting plasma.



A code in the range 165–175 indicates a failure during a coagulation cartridge cycle. In all cases, the cartridge is spent and another cartridge should be used.

Code Number	Cause/Action Message on Display	Explanation
165	**Cartridge Error /** Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • user is attempting to run a used cartridge or • user did not allow the cartridge to equilibrate to room temperature before opening the cartridge pouch. (Individual cartridges should equilibrate for 5 minutes at room temperature or a box of cartridges for 1 hour before opening the cartridge pouch.)
166	**Cartridge Error /** Use Another Cartridge	The sample arrived at the sensors too late. This may indicate that the cartridge was underfilled or that there was a bubble in the sample. Try another cartridge.
167	**Cartridge Error /** Use Another Cartridge	The sample arrived at the sensors too early. This may indicate that the cartridge was overfilled. Try another cartridge.
170	**Cartridge Error /** Use Another Cartridge	A resistance value detected during the testing cycle was too high. Try another cartridge.
171-175	**Cartridge Error /** Use Another Cartridge	The analyzer detected a bubble on or near the sensors. Try another cartridge.

The following conditions are related to the Electronic Simulator

Code	Explanation	How to Respond
Numerical Code	See under Analyzer Coded Messages.	See under Analyzer Coded Messages.
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Contact i-STAT Technical Services or your local support organization for further assistance.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Contact i-STAT Technical Services or your local support organization for further assistance.
R, r	Resistance reading on conductometric channel out of limits.	Contact i-STAT Technical Services or your local support organization for further assistance.
t	Thermal probe failure.	Contact i-STAT Technical Services or your local support organization for further assistance.
B	Potentiometric channel out of limits.	Contact i-STAT Technical Services or your local support organization for further assistance.

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact i-STAT Technical Services or your local support organization for further assistance.

PROCEDURE FOR USING AN i-STAT CERAMIC CONDITIONING CARTRIDGE (CCC) FOR ANALYZER PIN CONDITIONING

Step Number	Explanation
1. Run an external Electronic Simulator.	If the analyzer is configured with the internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the internal Simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.
2. Run the CCC two times.	Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.
3. Update the CCC Usage Log.	The log is located on page 3 of the Technical Bulletin entitled “Instructions for Restoring Analyzers That Produce *** for Hematocrit and Quality Check Code 23”, which is shipped with the CCC. Updating the log allows the user to keep track of the number of pin conditioning cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use.
4. Return the analyzer to service.	

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QUALITY CONTROL 12

OVERVIEW

The Manufacturer's Quality System Instructions (MQSI) represent information necessary to ensure quality results (accurate, precise, and reliable) based upon the specific characteristics of the i STAT System.

Three key technological characteristics of the i-STAT System underlie the MQSI:

1. The unit-use cartridges are stable when stored properly.
2. The system has been designed so that any user influence on the analytical process is detected and flagged.
3. The performance of the handheld reader is verified by a combination of automated quality checks and procedural controls during each test event, supplemented by electronic quality control.

MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS

Perform Daily Quality Control with Electronic Simulator

Check each Handheld reader with the Electronic Simulator, using either the internal or external simulator, once on each day of use.

Check New or Replacement Handheld Readers with the Electronic Simulator

Use the Electronic Simulator, internal or external, to verify operation of a new or replacement handheld reader before use.

The internal Electronic Simulator will automatically activate the first time a new or replacement handheld is used and after every 24 hours of use thereafter. The handheld can be customized to remind the operator to perform the simulator test (i-STAT 1 Analyzer) or automatically run the simulator (i-STAT 1 Analyzer) more frequently as required or desired.

Check Temperature Strip for a New Shipment of Cartridges

Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.

Ensure Proper Cartridge Storage

- Ensure that refrigerator storage conditions for stored cartridges are between 2–8 °C (35–46 °F).
- Ensure that cartridges are not exposed to temperatures exceeding 30 °C (86 °F).
- Ensure that cartridges are not used after the expiration date printed on the individual package and box.
- Ensure that cartridges are not outside the refrigerator for longer than the time frame indicated on the cartridge box.
- Ensure that a cartridge is used immediately after it is removed from its package.
- Ensure that a cartridge taken from refrigerated storage is allowed to stand in its package at room temperature for 5 minutes before use, or that a box of cartridges stands at room temperature for one hour before use.

Ensure Thermal Probe Check is Performed

Ensure the thermal probe check is performed every 6 months on each handheld reader. This check may be performed in conjunction with the analyzer software updates. See *Thermal Probe Check—Procedure for Handheld* in this section.

Train Staff

Avoidance of Pre- and Post-analytical Errors:
Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).

Update Software

1. Update the i-STAT System software as provided by Abbott Point of Care (APOC).
2. Check the handheld with the external Electronic Simulator after software updates.
3. Verify thermal probe reading.

PROCEDURE FOR TESTING CONTROLS

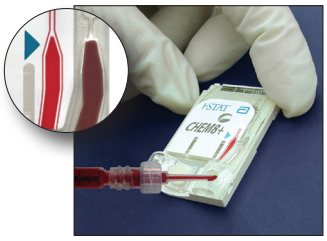
Prerequisites

- Ensure that quality control testing is performed from the Quality Test Menu for the purpose of documentation and review.
- Scan the cartridge barcode before opening cartridge pouch.
- Ensure controls, cartridges, and handhelds are at the same room temperature.

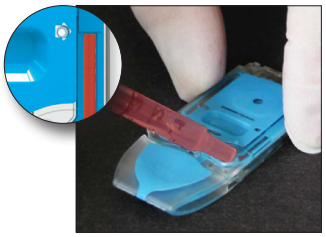
1. Press ⏻ to turn on handheld.



2. Press MENU → 3 → 1 for Control Samples.
3. Follow handheld prompts.
4. Scan the lot number on the cartridge pouch.
   - Position barcode 3–9 inches (8–23 cm) from scanner window on the handheld.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The handheld will beep when it reads the barcode successfully.



5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.



6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT, INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing.

7. Review results.

TROUBLESHOOTING OUT-OF-RANGE CONTROL OR CALIBRATION VERIFICATION RESULTS ON CARTRIDGES

Troubleshooting

Verify that the following conditions are met and then repeat the test:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly–see the directions for use.
- The analyzer being used passes the Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or cartridges. If the results are still out of range, refer to Support Services information in the Technical Bulletins section.

PERFORMING ELECTRONIC SIMULATOR TEST

Procedure for Internal Electronic Simulator

The internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays "ELECTRONIC SIMULATOR FAIL." If the analyzer is customized to block testing when it fails the simulator test, the same cartridge can be re-inserted immediately after the FAIL message is displayed. If the analyzer fails the simulator test again, see the Troubleshooting section that follows the Procedure. If less than three minutes has elapsed, the cartridge can be inserted into another analyzer. If the analyzer is not customized to block testing after a failed simulator test, the internal simulator test will not repeat until the programmed interval has elapsed.

PROCEDURE FOR EXTERNAL ELECTRONIC SIMULATOR



Display	Step	Analyzer Response / Comments
	Press the **On/Off** key to turn the analyzer on.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests Menu	Press **4** to select Simulator.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID and press **Enter**.	If enabled, the analyzer will validate ID and/or ask for the ID to be repeated.
Scan or Enter Simulator ID	Press **Scan** to scan the Simulator ID or manually enter the Simulator ID and press **Enter**.	The simulator serial number can be used as an ID. If the simulator does not have a barcode, one can be made on-site and affixed to the simulator (not near contact pads).
INSERT SIMULATOR	Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.	Inserting the simulator at an angle may cause a Quality Check message to be displayed.
Contacting Simulator Please wait… Time to Results bar Simulator Locked	Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.	
Result screen: ID of Simulator Date and Time ELECTRONIC SIMULATOR PASS or FAIL 1 - Test Options	Test Options Simulator 1 - Next Simulator 2 - Same Simulator 3 - History	If **PASS** is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case. If **FAIL** is displayed, see the Troubleshooting in this section of the manual.

Caution The analyzer will continue to initialize test cycles when the analyzer is customized to warn, but not block testing when a scheduled external Electronic Simulator test is missed, when a FAIL result for the external Electronic Simulator test is ignored, and when the analyzer fails the internal Electronic Simulator test and the lockout feature is not enabled.

TROUBLESHOOTING FAILED ELECTRONIC SIMULATOR TEST

Introduction With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.

External Simulator Run the test again or try another simulator, as it is possible that the test will pass on a second try. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped.

Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the electronic test and the failure code “L” will be displayed. Allow the analyzer to sit for half an hour to allow the moisture to evaporate, then insert the Electronic Simulator again. If the analyzer passes the second electronic test, continue using it. If the analyzer fails the second time, record the letter or Quality Check Code displayed with the FAIL message and refer to Support Services information in the Troubleshooting section.

Internal Simulator The cartridge or an external Electronic Simulator should be rerun to confirm the failure. The analyzer’s connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can fail if the contact pads have been contaminated in some way.

Lockout Enabled: Rerun the cartridge in the same analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. If the cartridge fails in more than one analyzer, use another cartridge. When Lockout is enabled, the analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.

Lockout Not Enabled: Rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When Lockout is not enabled, the analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed. Verify the analyzer using an external Electronic Simulator.

THERMAL PROBE CHECK

Overview

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature ± 0.15°C.

A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, APOC recommends that the thermal probe check be verified every six months.

Procedure for Handheld

Check the thermal probes on the i-STAT 1 Analyzer as follows:

1. 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, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. Insert the simulator into the analyzer.
3. When results are displayed, press the period key to view the difference between the thermal probes.
4. Interpretation of the thermal probe check value:
    - Acceptable: a value from -0.1 to +0.1, inclusive.
    - Repeat the procedure if a FAIL message with a “t” Quality Check Code or a value less than -0.1 or greater than 0.1 is displayed.
    - Repeat the procedure if “--.--” is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.
    - Contact your Technical Support representative if the **repeat** thermal check value is greater than 0.1 or less than -0.1 or if a Quality Check Code is displayed.

Documentation of Results

The results of the thermal probe check are stored in a data manager. If a data manager is not available, use the form included in this section of the manual to record the results.

PREPARATION OF CONTROLS

Visit www.globalpointofcare.abbott for instructions for use (IFU) related to products not listed in this section.

i-STAT CONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Control Solutions

Aqueous assayed control fluids are available for verifying the integrity of newly received cartridges. i-STAT Level 1, 2 and 3 Controls are formulated at three clinically relevant levels with known pH and with known concentrations of:

Sodium	$\boldsymbol{P}CO_2$	Glucose
Potassium	$\boldsymbol{P}O_2$	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box of 10 ampules. Control solutions are contained in 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	108	127	141	169	187
K (mmol/L)	2.3	3.1	4.0	6.8	8.5
Cl (mmol/L)	71	85	100	122	133
Glu (mmol/L)	1.8	2.5	7.3	17	35
Urea (mmol/L)	44.6	18	4	2.7	1.8
iCa (mmol/L)	2.5	1.6	1.3	0.8	0.2
Lac (mmol/L)	19.5	8.4	2.3	1	0.6
Crea (µmol/L)	1486	386	155	46	17
$\boldsymbol{P}O_2$ (mmHg)	43	61	100	140	400
$\boldsymbol{P}CO_2$ (mmHg)	95	66	30	22	18
H^+ (pH)	6.81	7.15	7.41	7.60	7.95

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and analyzer should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, $\boldsymbol{P}CO_2$, or $\boldsymbol{P}O_2$. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

Before Use

i-STAT control solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.

Procedure

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

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringe with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.globalpointofcare.abbott.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the target value table matches the software revision in the analyzer.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls.

Target Values are specific to the i-STAT System. Results obtained from these aqueous controls with other methods may differ due to sample matrix effects.

Correction of PO_2 for Barometric Pressure

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of red blood cells containing hemoglobin which binds oxygen molecules. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration which occurs in the cartridges at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values in the value assignment sheet included with each box of i-STAT controls.

Equations:

For PO_2 values below 150 mmHg:

PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

For PO_2 value 150 mmHg and above:

PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

i-STAT TRICONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Control Solutions

Aqueous-based control fluids are available for verifying the integrity of newly received cartridges. i-STAT TriControls Level 1, 2 and 3 are formulated at three clinically relevant levels with defined pH and hematocrit values and with known concentrations of:

Sodium	***P***CO_2	Glucose
Potassium	***P***O_2	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box containing 10 individual 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
PCO_2 (mmHg)	96	65	40	26	12
PO_2 (mmHg)	40	63	120	163	500
H^+ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 °C (35-46 °F) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 °C; 64-86 °F) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and handhelds should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not ***P***O_2 is to be measured. If ***P***O_2 is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If ***P***O_2 is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

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

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes (fresh 1 cc or 3 cc sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous control solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Ensure that the lot number printed on the Value Assignment Sheet matches the lot number on the label of the ampule and that the software full version above the target value table matches the software version in the handheld.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual.

Target Values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Correction of *P*O_2 for Barometric Pressure

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. ***P***O_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed ***P***O_2 values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Equations:

For ***P***O_2 values below 150 mmHg:

PO_2 corrected = ***P***O_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For ***P***O_2 values 150 mmHg and above:

PO_2 corrected = ***P***O_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

Precision

The additive used in the aqueous-based TriControls to simulate the effect of hematocrit in blood samples results in reduced precision in repeat measurement of electrolytes relative to the precision obtained when assaying with either standard control/calibration verification materials or whole blood. The imprecision is related to the concentration of additive. The increase is pronounced at higher levels of indicated hematocrit.

Internal testing of non-Abbott aqueous control materials on the i-STAT System which have hematocrit, blood gas and chemistry functionalities exhibit similar precision to that observed for TriControls.

The acceptance limits which have been established for these control solutions are wider than analogous limits established for the current i-STAT control and calibration verification solutions, reflecting the precision effect highlighted above.

The situation where better precision will be obtained in clinical samples than in control solutions is not unusual. A similar effect is observed in control solutions for the i-STAT measurement of PO_2.

The precision data shown below, including results for TriControls solutions, were collected during studies at an Abbott Point of Care facility. SD and %CV are typical of performance; current Value Assignment Sheets should be referenced for applicable mean data. Refer to the value assignment sheets posted on the APOC website at www.globalpointofcare.abbott.

Analyte	Level 1			Level 3		
	Mean	SD	%CV	Mean	SD	%CV
Na (mmol/L)	120	0.46	0.4%	158	1.39	0.9%
K (mmol/L)	2.85	0.038	1.3%	6.15	0.058	0.9%
Cl (mmol/L)	72.9	0.63	0.9%	113.6	2.30	2.0%
Glu (mg/dL)	289	2.4	0.8%	41.8	0.68	1.6%
Urea (mg/dL)	69.7	0.94	1.3%	5.5	0.45	8.2%
iCa (mmol/L)	0.84	0.012	1.4%	1.51	0.030	2.0%
Lac (mmol/L)	6.35	0.08	1.3%	0.810	0.03	3.7%
Crea (mg/dL)	4.16	0.123	3.0%	0.50	0.046	9.1%
PCO_2 (mmHg)	63.8	1.57	2.5%	19.6	0.40	2.0%
PO_2 (mmHg)	65.1	3.12	4.8%	146.5	6.00	4.1%
H^+ (pH)	7.165	0.005	0.07%	7.674	0.003	0.04%
Hct (%)	17.6	0.40	2.3%	57.1	1.00	1.75%
TCO_2 (mmol/L)	17.4	0.62	3.6%	30.4	0.70	2.3%

ACT CONTROLS

Intended Use

The i-STAT ACT Control Level 1 and ACT Control Level 2 are intended for use to verify the integrity of newly received i-STAT ACT cartridges. The controls produce clotting times expected for moderate and high level heparinization to indicate that the cartridges are functioning properly.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage

i-STAT ACT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature (18 - 30 °C or 64 - 86 °F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.globalpointofcare.abbott. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

PT/INR CONTROLS

Intended Use

The i-STAT PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used to verify the integrity of newly received PT/INR cartridges (List Number 03P89-24).

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage

i-STAT PT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30 °C or 64 to 86 °F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature 18-30 °C (64-86 °F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT/INR cartridge.
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional PT/INR cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet posted on the APOC website at www.globalpointofcare.abbott. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

i-STAT cTnI, BNP, AND CK-MB CONTROLS

Intended Use

i-STAT cTnI, BNP, and CK-MB Control Levels 1, 2, and 3 are intended for use as an assayed quality control material which can be used to verify the integrity of newly received i-STAT cTnI, BNP, and CK-MB cartridges.

Product Description

6 bottles, 1 mL each

Notes:

- These controls contain ≤ 0.09% sodium azide as a preservative.
- These controls do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Control material is a ready-to-use liquid control requiring no reconstitution or frozen storage. The controls are stable until the expiration date on the vial label when stored unopened at 2-8 °C (35-46 °F). Once opened, these controls are stable for 30 days when stored tightly capped at 2-8 °C (35-46 °F).

Procedure

1. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8 °C (35-46 °F).
4. Seal the cartridge and immediately insert it into the i-STAT 1 handheld.

Control Target Values and Ranges

See Value Assignment Sheets posted on the APOC website at www.globalpointofcare.abbott. The Value Assignment Sheet displays target values and ranges expected when cartridges, controls, and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the handheld.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

See Troubleshooting section below for procedures to follow if control results are out of range.

i-STAT TOTAL β-hCG CONTROLS

Intended Use

The i-STAT Total β-hCG Controls are used to monitor performance of the i-STAT Total β-hCG test.

Product Description

6 Bottles (1 mL each) of i-STAT control fluid prepared in human serum.

Note: These controls contain < 0.09% sodium azide as a preservative.

Warnings and Precautions

Handle the products using the same safety precautions used when handling any potentially infectious material. The human serum used in the preparation of these products has been tested by FDA approved test methods and found negative/non-reactive for HBsAg, anti-HIV 1 /2, anti-HCV, and HIV 1 Ag. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Do not use control material if it is received uncapped.

Bacterial contamination of the control material can cause an increase in turbidity. Do not use the materials if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

i-STAT Total β-hCG control materials are ready-to-use liquids requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2–8 °C. Once opened, these control fluids are stable for 30 days when stored tightly capped at 2–8 °C.

Procedure

1. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of fluid into the i-STAT Total β-hCG cartridge using the vial dropper tip. Tightly recap the control vial and store it at 2–8 °C.
4. Seal the cartridge and immediately insert into the handheld.

Target Values and Ranges

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT 1 analyzers that pass the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott. The Value Assignment Sheet displays target values and ranges expected when controls and equipment are performing properly. See Troubleshooting section below for procedures to follow if control results are out of range.

Always ensure that the control material lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software full version in the handheld.

Target values are specific to the i-STAT System. The values assigned to the control material are traceable to *WHO 5th International Standard for Chorionic Gonadotropin (NIBSC Code 07/364)*. Results may differ if used with other methods.

Analyze the control material in the Control pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration menu.

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i-STAT System Incoming Cartridge QC Log

Cartridge Type:_____ **Lot No.:**_____ **Rec'd Date:**_____ **Exp. Date:**_____ **Quant:**_____ **Temp. Strip:**_____

Control Name: _____ **Level:** _____ **Lot No.:** _____ **Exp. Date:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: _____ **Level:** _____ **Lot No.:** _____ **Exp. Date:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: _____ **Level:** _____ **Lot No.:** _____ **Exp. Date:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: _____ **Level:** _____ **Lot No.:** _____ **Exp. Date:** _____

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Rev. Date: 20-DEC-2024
Art: 714376-00AC
12-21

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i-STAT System QC Log: Expiration Date and Storage Conditions

				REFRIGERATED 2 TO 8° C (35 TO 46° F)			ROOM TEMPERATURE 18 TO 30° C (64 TO 86° F)				
DATE	LOCATION	CARTRIDGE TYPE	LOT #	QTY	EXP. DATE	TEMP	QTY	EXP. DATE	TEMP	ACTIONS	INSP.

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i-STAT Cartridge Quality Control Action Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	CARTRIDGE LOT	PROBLEM	CORRECTIVE ACTION	OPERATOR

Rev. Date: 20-DEC-2024
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i-STAT Electronic Simulator Log for Analyzer Serial Number:_____ Year:_____

DATE	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR

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i-STAT Electronic Simulator Action Log

DATE	TIME	ANALYZER	FAILURE CODE OR LETTER	SIMULATOR ID	ACTION	OPERATOR

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i-STAT Analyzer Thermal Probe Check

Year: _____

Rev. Date: 20-DEC-2024

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

Analyzer Serial No.: _____

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT Acceptable Range: -0.1 TO +0.1	COMMENTS	OPERATOR

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CALIBRATION VERIFICATION 13

OVERVIEW

Calibration Verification, also known as a linearity check, is a procedure intended to verify the accuracy of results over the entire measurement range of a test. Because of the inherent stability of the i-STAT System, Abbott Point of Care does not make any specific recommendations for the calibration verification procedure. Therefore, it is the responsibility of the laboratory to determine when and how this procedure should be performed.

Replacement and newly purchased analyzers are delivered with factory calibration. The Electronic Simulator is superior to calibration verification or control solutions in assuring that the analyzer's most important function is within factory specifications.

STABILITY OF CALIBRATION IN THE i-STAT SYSTEM

The i-STAT System is a unit-use testing system. Components that cause shifts and drifts in results in multi-use analyzers: sensors (electrodes), calibration solution, fluid-handling channels and pumps, are housed in a disposable test cartridge. The sensors are exposed to sample only once, so there is no protein build-up which is a major cause for deterioration of sensor slope and the need to calibrate and/or verify calibration on a frequent basis in multi-use analyzers.

The stability and consistency of the manufacturing process allow the slope of the sensors to be programmed into the analyzer's software. A one-point calibration to set the intercept accounts for any day-to-day variation in testing conditions. When stored according to directions, the cartridges are stable up to the expiration date.

The analyzer houses the mechanical and electrical systems necessary to control fluid movement within the cartridge, control the temperature when measurements are performed at 37 °C, measure barometric pressure, measure electrical signals generated by the sensors and display and transmit results. The analyzer's functions are factory calibrated to specifications that are programmed into the analyzer along with acceptability limits, which when exceeded cause the analyzer to display quality check messages or to display *** rather than results.

The accuracy of results and dependability of the internal quality check system depend upon the ability of the analyzer to take accurate and sensitive signal readings from the sensors. To check this function, i-STAT developed an electronic control device. The Electronic Simulator simulates two levels of electronic signals that stress the analyzer's signal detection function both below and above the reportable ranges. Injecting signals directly into the analyzer allows very tight control limits to be set. Control limits for liquid controls are set wide enough to allow for sensor-to-sensor variation. All analyzers that pass the Electronic Simulator test are equivalent and any variations in results are caused by within and between lot variations in the cartridges.

The combination of unit-use cartridges, inherently stable electronics of the analyzer, and reliability of the Electronic Simulator check provides the stability needed for a point-of-care testing system and reduces the need for frequent stability or calibration verification checks.

PROCEDURE FOR TESTING CALIBRATION VERIFICATION

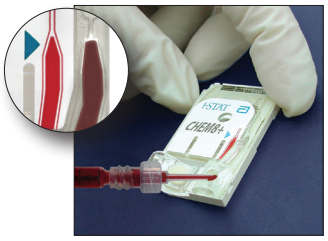
Prerequisites

- Ensure that calibration verification testing is performed from the Quality Test Menu for the purpose of documentation and review.
- Scan the cartridge barcode before opening the cartridge pouch.
- Ensure calibration verification ampules, cartridges and analyzers are at room temperature.
- Measurement limits are not applied to results in the calibration verification test path. Results above and below the measurement ranges will be reported.

Procedure

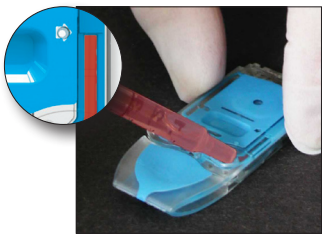
1. Press ⏻ to turn on analyzer.
2. Press MENU → 3 → 3 for Cal Ver Samples.
3. Follow analyzer prompts.
4. Scan the lot number on the cartridge pouch.
   - Position barcode 3 - 9 inches from scanner window on the analyzer.
   - Press and hold SCAN to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The analyzer will beep when it reads the barcode successfully.





5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.
6. Push the sealed cartridge into the analyzer port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT, INR, Hct and immunoassay testing, the analyzer must remain on a level surface with the display facing up during testing. A level surface includes running the analyzer in the downloader/recharger.



7. Review results.

Troubleshooting Cartridge Tests

Should results outside these ranges be obtained, refer to **TROUBLESHOOTING OUT-OF-RANGE CONTROL OR CALIBRATION VERIFICATION RESULTS ON CARTRIDGES** in Section 12 of the i STAT 1 System Manual.

PREPARATION OF CALIBRATION VERIFICATION MATERIALS

Visit www.globalpointofcare.abbott for instructions for use (IFU) related to products not listed in this section.

i-STAT CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/ METABOLITE CARTRIDGES

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	$\boldsymbol{P}CO_2$	Lactate
Chloride	$\boldsymbol{P}O_2$	BUN/Urea
Ionized Calcium	TCO_2	Creatinine

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients

See the table "Reactive Ingredients" in the Quality Control section of the i-STAT System Manual for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes.

Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.

3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck. Use caution to protect against cuts if scanning a barcode from an open glass control ampule.
4	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as calibration verification material lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 12. Target values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

Correction of *P*O_2 for Barometric Pressure (BP)

The partial pressure of oxygen in a solution will change as it equilibrates to the ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin, which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flow-path of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. ***P***O_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed ***P***O_2 values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Equations:

For ***P***O_2 values below 150 mmHg: ***P***O_2 corrected = ***P***O_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen. (Approximate change: for every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For ***P***O_2 values 150 mmHg and above: ***P***O_2 corrected = ***P***O_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen. (Approximate change: for every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

i-STAT CHEM8+ CALIBRATION VERIFICATION LEVEL 1B

Calibration Verification Solution for CHEM8+ Cartridges

i-STAT CHEM8+ Calibration Verification Level 1b is available for purchase to verify the calibration of the i-STAT CHEM8+ TCO_2 at the low end of the reportable range.

There are ten 1.7 mL glass ampules in each box.

Note: For testing all CHEM8+ cartridge analytes, use either the i-STAT TriControls Calibration Verification Set (includes hematocrit) or the i-STAT Calibration Verification Set (does not include hematocrit).

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

i-STAT CHEM8+ Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes.

Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

A separate ampule must be used for each cartridge being tested.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

Equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck. Use caution to protect against cuts if scanning a barcode from an open glass control ampule.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as calibration verification material lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1 mL or 3 mL sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 12. Target values are specific to the i-STAT System. Results obtained when testing these aqueous calibration verification materials with other methods may differ due to matrix effects.

i-STAT TRICONTROLS CALIBRATION VERIFICATION FOR BLOOD GAS/ ELECTROLYTE/ METABOLITE CARTRIDGES

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	***P***CO_2	Lactate
Chloride	***P***O_2	BUN/Urea
Ionized Calcium	TCO_2	Creatinine
pH		

There are four 1.7 mL glass ampules of each level in the set.

Reactive Ingredients for TriControls Materials

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
PCO_2 (mmHg)	96	65	40	26	12
PO_2 (mmHg)	40	63	120	163	500
H^+ (pH)	6.550	7.025	7.390	7.610	7.850

Storage

Refrigerated storage at 2-8 °C (35-46 °F) should be maintained until the printed expiration date on the box and ampule labels.

TriControls solutions may also be maintained at room temperature (18-30 °C; 64-86 °F) for up to 5 days.

Do not use TriControls solutions past the labeled expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, ***P***CO_2, ***P***O_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use residual TriControls solution that may be in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if that testing is performed within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

i-STAT TriControls solutions require different temperature stabilization times depending on whether or not ***P***O_2 is to be measured. If ***P***O_2 is to be measured, equilibrate the ampule to room temperature for 4 hours prior to use. If ***P***O_2 is not being measured, equilibrate the ampule for approximately 30 minutes at room temperature.

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck. Use caution to protect against cuts if scanning a barcode from an open glass control ampule.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as calibration verification material lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous calibration verification solution from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes (fresh 1 mL or 3 mL sterile syringe with 16 – 20 gauge needles) are recommended to transfer aqueous calibration verification solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

Should results outside these ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls in the System Manual in Section 12. Target values are specific to the i-STAT System. Results obtained when testing these aqueous calibration verification materials with other methods may differ due to matrix effects.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

Correction of *P*O_2 for Barometric Pressure (BP)

The partial pressure of oxygen in a solution will change as it equilibrates to the ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of hemoglobin, which binds oxygen. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flow-path of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration that occurs in cartridges tested at or near sea level. ***P***O_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed ***P***O_2 values should be corrected before comparing them to the values on the Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

Equations:

For ***P***O_2 values below 150 mmHg: ***P***O_2 corrected = ***P***O_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen. (Approximate change: for every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

For ***P***O_2 values 150 mmHg and above: ***P***O_2 corrected = ***P***O_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen. (Approximate change: for every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to the observed value.)

HEMATOCRIT VERIFICATION PROCEDURE

Preparation of Hematocrit Sample

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7 mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.
2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.
3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.
4. Transfer all of the plasma from tube 4 to tube 1.
5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.
6. Gently invert tubes 1, 2 and 3 to resuspend the cells.
7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 15 %. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75 %.

Measurement

1. Gently invert tubes 1, 2, and 3 to resuspend the cells.
2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.
3. Inspect the data for outliers. Repeat a measurement if necessary.
4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results

The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K_3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.
2. The adjusted i-STAT hematocrit mean should be within ±3 %PCV of the microhematocrit mean.

   For example: the microhematocrit method mean for the mid level sample is 36 %PCV. The i-STAT method mean is 34 %PCV. 34 x 1.0425 = 35.445. Acceptable range for the adjusted i-STAT mean: 33 - 39 %PCV.

Note: If your analyzers are customized for K_2EDTA/Heparin/None, the above calculation is unneccessary.

Notes on the Procedure

1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.
2. The highest hematocrit that should be tested on the i-STAT System is 75 %. Whole blood samples with hematocrit values greater than 75 % will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 15 %. Whole blood samples with hematocrit values less than 15 % will be flagged as <15.

Using Another Comparative Method

Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:

- Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.
- Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method

CLSI recommends that the blood samples anticoagulated with Na_2EDTA or K_2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.

* CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard–Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

ACT VERIFICATION PROCEDURE

See Technical Bulletin "i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure."

i-STAT cTnI, BNP, CK-MB, β-hCG CALIBRATION VERIFICATION

Intended Use

The i-STAT cTnI, BNP, CK-MB and β–hCG Calibration Verification Sets are intended for use as assayed materials to verify the greater portion of the Reportable Range for i-STAT cTnI, BNP, CK-MB and β–hCG cartridges.

There are two 1.0 mL plastic vials of each of the three levels in each set.

Notes:

- cTnI, BNP and CK-MB calibration verification materials contain ≤0.09 % sodium azide as a preservative, and β–hCG calibration verification material contains <0.09 % sodium azide as a preservative.
- These calibration verification materials do not require freezing.

Warnings and Precautions

Each plasma donor unit used in the manufacture of cTnI, BNP and CK-MB and human serum for β–hCG has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, HIV NAT, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the calibration verifiation material can cause an increase in turbidity. Do not use the calibration verification material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Calibration Verification material is ready to use and requires no reconstitution or frozen storage. The calibration verification materials are stable until the expiration date on the vial label when stored unopened at 2-8 °C (35-46 °F). Once opened, these calibration verification materials are stable for 30 days when stored tightly capped at 2-8 °C (35-46 °F).

Procedure

STEP	ACTION
1	Access the Cal Ver option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, gently mix the contents of the vial to ensure homogeneity. Avoid foaming of the sample.
3	Open the vial and transfer a drop of the fluid into the i-STAT cartridge using the dropper tip, a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the vial and store it at 2-8 °C (35-46 °F).
4	Seal the cartridge and immediately insert it into the i-STAT 1 analyzer.

Acceptable Criteria

Target values (determined by testing multiple vials of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the APOC website at www.globalpointofcare.abbott.

The Value Assignment Sheet displays target values and ranges expected when cartridges, calibration verification materials and equipment are performing properly.

Always ensure that the lot number and software revision on the Value Assignment Sheet match the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

Should results outside these ranges be obtained, refer to **TROUBLESHOOTING OUT-OF-RANGE CONTROL OR CALIBRATION VERIFICATION RESULTS ON CARTRIDGES** in Section 12 of the i STAT 1 System Manual.

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PROFICIENCY OR EXTERNAL QUALITY CONTROL 14

OVERVIEW

Proficiency, or external quality control, testing is the testing of unknown samples sent to a facility by an outside agency. After testing the unknown samples, the facility reports its results back to the agency. The agency grades the results and sends back scores that reflect how accurately the facility performed against its peers.

TESTING COMPLEXITY

Check with your state regulations for requirements.

- Moderate Complexity customers, refer to www.cms.gov for up-to-date information on CLIA Regulations Subpart H.
- Waived Complexity customers, refer to COLA at www.cola.org and/or CAP at www.cap.org for up-to-date guidelines.

  NOTE: With the i-STAT 1 System, the FDA has categorized the tests included on the i-STAT G and Crea cartridges as Waived when testing is performed using venous whole blood samples collected in lithium heparin evacuated tubes. Other venous whole blood samples, capillary, and/or arterial samples tested using these same cartridges on the i-STAT 1 System are categorized by the FDA as moderate complexity.

GENERAL PROCEDURE FOR TESTING

It is recommended that the Proficiency Test path be used on the i-STAT 1 analyzer when testing proficiency, or external quality control samples, especially those that include Hematocrit or ACT.

- The use of the Proficiency Test path will ensure that customization features enabled for patient testing are suspended. All analyzers will produce results using K_3EDTA, CPB-Never, and ACT PREWARM for survey reporting purposes.
- The same CLEW is used for both the Patient and Proficiency Test path.
- If the Patient Sample Test path is used instead of the Proficiency Test path, do not select CPB, and if the analyzer is customized for K_2EDTA, divide the Hematocrit results by 1.0425 before reporting. There is no reliable way of converting NONWARM ACT results to PREWARM ACT results

Sample Handling

Follow the agency's instructions for handling unknown samples.

Refer to the Quality Control section of the i-STAT 1 System Manual and follow the instructions for "Transfer with Capillary Tube" or "Transfer with Syringe" to ensure aqueous samples for blood gases and Ionized Calcium are not exposed to air.

Prerequisites

- Ensure that testing of unknown samples is performed from the Proficiency Test Menu for the purpose of documentation and review.
- Scan the cartridge barcode before opening the cartridge pouch.
- Ensure cartridges and handhelds are at the same room temperature.

Procedure

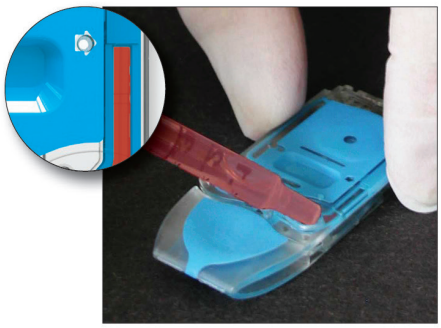


1. Press ⏻ to turn on handheld.
2. Press MENU → 3 → 2 for proficiency/external quality control samples.
3. Follow handheld prompts.
4. Scan the lot number on the cartridge pouch.
   a. Position barcode 3–9 inches from scanner window on the handheld.
   b. Press and hold SCAN to activate the scanner.
   c. Align the red laser light so it covers the entire barcode.
   d. The handheld will beep when it reads the barcode successfully.



5. Continue normal procedures for filling and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

   Note: For ACT, PT, INR, Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing.



7. Review Results.

REPORTING RESULTS

It is important to record the cartridge type and lot numbers used to test samples.

pH and ***P***CO_2 results from EC8+ cartridge lots with prefix letters F, H, J and K will not agree with pH and ***P***CO_2 results from other cartridges. When reporting results, select a separate peer group for these cartridge lot letters.

For creatinine results, select IDMS-Traceable Calibration, if available. If not available, make your selection based upon the cartridge type and lot letter.

Ensure that the correct method and/or peer group are selected when reporting results.

To prevent transcription errors, review all selections and numeric entries.

PO_2 Correction for Barometric Pressure

Section 12 of the i-STAT 1 System Manual, *Quality Control—i-STAT Controls for Blood Gas, Electrolyte/Metabolite Cartridges* contains the calculation to be used for barometric pressure correction.

TROUBLESHOOTING AND PROFICIENCY TEST FAILURES

Samples

The i-STAT System is designed to measure fresh whole blood samples. Matrix effects and interfering substances can be expected when measuring non-whole blood samples. The following points should be considered when selecting and testing external quality control samples:

- Aqueous samples intended to assess blood gases will not be measured by the i-STAT System unless electrolytes, or at least sodium, are present.
- Fluorocarbon samples are not compatible.
- Preserved-cell samples are not compatible.
- Aged serum and lyophilized serum may contain degradation products or preservatives that interfere with the measurements.
- Matrix effects between aqueous-based and protein-based samples may cause results from the i-STAT System to differ from reference methods or other comparative methods.
- Aqueous samples that contain a resistive substance to allow assessment of conductometric hematocrit measurements will cause the i-STAT System to extrapolate ambient temperature results to 37 °C results for pH and PCO_2 as if the sample were whole blood. Since extrapolation coefficients for aqueous and whole blood samples differ, results on the i-STAT System for these samples may not agree with other methods.

While the various cartridges give the same results for whole blood samples, there may be substantial differences between types (e.g., EC8+ vs CHEM8+) and generations (e.g., blue vs white) of cartridges for non-whole blood samples. Cartridge generations are identified by the prefix letter preceding the cartridge lot number.

Abbott Point of Care will work with Proficiency testing providers to prevent i-STAT System users from being unfairly penalized for Proficiency testing failures that can be attributed to manufacturing changes.

The CLEW software prevents manufacturing changes from affecting results when testing patient samples.

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CUSTOMIZATION 15

Overview

The i-STAT 1 analyzer (Model 300-G and 300W) is a fully-functioning analyzer with default customization. Customization options allow the healthcare organization to change the operating characteristics of each analyzer. This section describes the factory default settings and parameters that can be customized using the analyzer keypad for site-specific testing requirements.

For the procedure to customize using the i-STAT/DE see the i-STAT/DE User Guide located at www.globalpointofcare.abbott.

Caution

Analyzers that have been repaired and returned or replaced will have the factory settings as indicated by the DEFAULT0 customization profile name on the Customization screen (under the Administration Menu) of the analyzer.

- These analyzers must be customized, if applicable, before being put into use.
- These analyzers will also have the current standard CLEW and application software (JAMS). If a different version of CLEW or application software is in use, it must be downloaded to these analyzers.
- Verify the customization of the CPB function, if applicable. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery. If an analyzer customized for the CVOR as "Hct, CPB Adjustment: Always" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If an analyzer customized as "Hct, CPB Adjustment: Never" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

ANALYZER CUSTOMIZATION OPTIONS AND DEFAULT SETTINGS

Option	Description	Default
LANGUAGE	Language for text: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, and Finnish	English
UNIT SET	Reporting units for results. For analyzer default units and procedure for setting units, see SET UNITS (OF MEASURE) AND ANALYTE ENABLE OPTIONS in this section. To adjust settings with optional i-STAT/DE Software, see the i-STAT/DE User Guide located at www.globalpointofcare.abbott.	Unit Set 00
i-STAT 1 ANALYZER CLEW	Standardization data. All non-expired versions listed. The CLEW software has an expiration date. If an expired CLEW remains in a customization profile, a warning will be displayed.	
i-STAT 1 SOFTWARE	JAMS functionality data.	
PREFERENCES	Options and default settings are listed under six headings: Instrument, ID Entry, Test, Cartridge QC, Results, and Analyte Enable.	
STATNotes	Feature allows users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings. See the "i-STAT/DE User Guide" for more details.	CHART0
USE eVAS	This Feature can automatically determine if the results of a liquid QC test run on an i-STAT cartridge are within APOC's published quality control ranges. See the "i-STAT/DE User Guide" for more details.	Not enabled
USE OPERATOR LIST	4000 operator IDs can be stored in the analyzer along with certification start and end dates for cartridge testing. See the "i-STAT/DE User Guide" for more details.	Not enabled (no information stored)

FOR INSTRUMENT OPTIONS

Option	Description	Default
PASSWORD	0-5 digit password to access Set Clock, the Change function in Customization, and Utility under the Administration Menu. Password protection for the Set Clock function can be enabled or disabled. See below.	No password
DATE FORMAT	mm/dd/yy or dd/mm/yy For Clock Set function only.	mm/dd/yy
INACTIVITY TIMEOUT	Number of seconds after a result is displayed and no operator intervention that an analyzer will turn off. Allowable range is 45 to 1620 seconds.	120 seconds
SOUND	If enabled, the analyzer will emit a beep after each successful key press, when results are ready or when a Quality Check message is displayed. If Sound is disabled, the analyzer will only beep after a successful barcode entry.	Beep enabled
ENABLE WIRELESS CUMMUNICATION (U.S. CUSTOMER USE ONLY)	Enable the wireless functionality in an i-STAT 1 Wireless analyzer. See the "Procedure for Using the i-STAT 1 Wireless Analyzer" Technical Bulletin for full details.	Not Enabled
AUTO TRANSMIT	Analyzer transmits results when placed in Downloader or Downloader/Recharger.	Enabled
MEMORY FULL ACTION	Not enabled: over-write the oldest record without warning. Enabled: Warn user (start-up warning) or Lockout (testing disabled until upload occurs). Memory Full refers to when the unsent records as recorded on the Analyzer Status screen reaches 1000. Uploading does not erase the data from the analyzer’s memory.	Not enabled
BATCH MODE TIMEOUT	Not active at this time.	
DISPLAY PASSWORD FOR CLOCK PAGE	The default setting is enabled. However it may be useful to disable password protection for the clock page in the Spring and Fall when clocks are set forward and backward one hour.	Enabled
SYNCHRONIZE CLOCK TO CDS	Will synchronize or update the real time clock in the i-STAT 1 analyzer to the Central Data Station's clock at the time of each download. See the "i-STAT/DE User Guide" for more details.	Not Enabled
APPLY OPERATOR LIST TO VIEWING STORED PATIENT RECORDS	Requires operator to enter their operator ID number to access stored patient results on the i-STAT 1 analyzer. See the "i-STAT/DE User Guide" for more details.	Not Enabled
LIMIT NUMBER OF RECORDS IN TRANSMIT ALL	Allows the user to apply a date range limit to the Transmit All function in the i-STAT 1 analyzer. See the "i-STAT/DE User Guide" for more details.	Not Enabled
UPLOAD SCHEDULE	Options are Off, or every X hours, where X can be 1 to 65535 hours. If enabled, the behavior of the analyzer if the schedule is not met can be specified. Behavior Options are: Warn User (start-up warning message) or Lockout (testing disabled until upload occurs). See the "i-STAT/DE User Guide" for more details.	Off: no warning or lockout.

FOR OPERATOR AND PATIENT ID OPTIONS

Option	Description	Default
OPERATOR ID	Minimum and maximum allowed operator ID length (scanned or manually entered). If operator IDs are a fixed length, the min. and max. settings should both be equal to the ID length. See the "i-STAT/DE User Guide" for more details.	Min = 0 Max = 15
REPEAT ID ENTRY	Operator must enter ID twice. Analyzer prompts operator to start again if IDs do not match. This option can be set for manual and/or scanned ID Entry. See the "i-STAT/DE User Guide" for more details.	Enabled: repeat required
INCLUDE ID ON PRINTOUT	Enables/Disables printing of operator IDs on printouts from the Martel or i-STAT printer. Disabling the printing of operator IDs can prevent uncertified operators from learning the IDs of certified operators.	Enabled
BARCODE OPTIONS	The type of barcodes used for Operator ID. See table below.	All barcode types
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check. Check digit algorithms are given in HL7 Specification, Section 2.9.5.3	None
INVALID OPERATOR	Behavior of analyzer when Operator ID not in stored list or certification date expired Options are: Not enabled (continue without warning), Warn User (prompt to continue), and Lockout (block testing until a valid Operator ID is scanned/entered). This option should not be enabled if the Use Operator List option is disabled. Separate Actions can be chosen for Certification Expired or Operator Not On List. See the "i-STAT/DE User Guide" for more details.	Continue without warning
EXPIRATION NOTIFICATION	Allows a System Administrator to define a time period (1-255 days) in which the operator will be notified by a message on the i-STAT 1 analyzer display of their competency expiration date. See the "i-STAT/DE User Guide" for more details.	Off
PATIENT ID	Minimum and maximum allowed patient ID length (scanned or manually entered). If ID numbers are a fixed length, the min. and max. settings should both be equal to the ID length.	Min = 0 Max = 15
REPEAT ID ENTRY	Operator must enter patient ID twice. Analyzer prompts operator to start again if IDs do not match. This option can be set for manual and/or scanned ID entry.	Repeat ID enabled
PATIENT ID RECALL	Operator can recall last patient ID when analyzer prompts for Patient ID. The most recent patient ID is recalled by pressing the → key.	Enabled
BARCODE OPTIONS	The type of barcodes used for Patient ID. See table below.	All barcode types
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check. Check digit algorithms are given in HL7 Specification, Section 2.9.5.3	None

FOR TEST OPTIONS

Option	Description	Default
AUTO-CHART PRESENTATION	If enabled, the Chart Page will be displayed automatically. If any information on the Chart Page is mandatory for the site, Auto-Chart Presentation is recommended.	Not enabled: operator must press the → key to display the Chart Page.
CARTRIDGE PATIENT TEST	The behavior for the following features is set by the analyzer firmware and no longer requires customization: • Require Information before Running Cartridge • Enter Lot Number • Scan Cartridge Barcode Third Party Result Output and Require Analyzer to be in Downloader: These two options were instituted for the release of the RIBS data integration feature. Please see the "The RIBS (Results Integration at the Bedside) Feature for the i-STAT System" Technical Bulletin for full details. **These options SHOULD NOT be activated by users until the data integration process is complete, as misconfiguring your analyzers using these features can cause testing to be disabled.**	Not enabled
PATIENT TEST COMMENT CODE	Options are: No prompt or prompt as follows: • Prompt for Comment Code, All Results in Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • Prompt for Comment Code, Any Result out of Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • A comment code of up to 3 characters is allowed. Care should be taken to select combinations that make sense. In the case of a missed required Comment Code, the results will be stored and "_ _ _" will be entered as the Comment Code.	No prompt
SAMPLE TYPES FOR CARTRIDGE	Drop down menus for each sample type allow the six sample types to be re-ordered or changed. Up to 4 user-definable characters are allowed for each sample type. The sample type is stored with the test record and is included on the printout from the portable printer and in the record in the Data Manager.	1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR
CHART PAGE	Any item on the Chart Page can be deleted by clicking off the check mark in the Display column or be made mandatory by clicking a check mark in the Mandatory column. If any item is set as mandatory, the Chart Page will be displayed automatically after the Patient ID is entered. The items on the Chart page can also be rearranged by holding down the left mouse button and dragging the item to another location. See the "i-STAT/DE User Guide" for more details.	All items set to not mandatory.

FOR CARTRIDGE QC – ELECTRONIC QC SETTINGS

For the quality control of i-STAT analyzers, i-STAT recommends the use of the Electronic Simulator.

i-STAT's recommendation for the frequency of the Electronic Simulator is once every 24 hours. More frequent use or use according to number of patient tests may be required by accreditation and regulatory bodies.

Option	Description	Default
EXTERNAL SIMULATOR SCHEDULE	Options are Off (no prompt), an interval of specified hours (1 to 65535 hours), or an interval of specified patient tests (up to 99999). The behavior of the analyzer if the schedule is not met can also be specified: Warn or Lockout (testing disabled until Simulator used).	No prompt
INTERNAL SIMULATOR SCHEDULE	Time interval when the internal Electronic Simulator test will be run. Options are Off; an interval of specified hours (1 to 65535 hours); 8/24 (every 8 hours for blood gases, coagulation, hematocrit and immunoassays, and every 24 hours for other tests); an interval of specified patient tests (up to 99999). The behavior of the analyzer if the simulator test fails can also be specified. If the Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display "FAIL" on subsequent cartridges until the test passes. If Lockout is not selected, the simulator test will not be initiated again until next scheduled time.	Interval 24 hours. Lockout

FOR CARTRIDGE QC – LIQUID QC SETTINGS

Option	Description	Default
CONTROL PASS/FAIL DETERMINATION	Describes how the System Administrator will determine the acceptability of liquid QC results. Options are: **None:** Disables the QC Pass/Fail and QC Schedule feature. **Manual:** Can be customized via the analyzer keypad or with optional i-STAT/DE software. See Procedures for customization using the analyzer keypad in this section or the i-STAT/DE User Guide for more details. • The user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at https://www.globalpointofcare.abbott/us/en/support/istat-systemcustomers/vas-evas.html and indicate on the analyzer whether the QC run passed or failed. **Automatic via EVAS:** Requires optional i-STAT/DE software for customization. Choosing this option indicates that the analyzer will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 analyzer. See the "i-STAT/DE User Guide" for more details.	None
CONTROL TEST SETTINGS	If the System Administrator wants users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, they would check the appropriate box and then use the drop down menu to select whether entering the comment code is optional (Allow no comment) or Required (Require Comment). Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected. See the "i-STAT/DE User Guide" for more details.	Disabled
CONTROL RESULTS DISPLAY FORMAT	Options are: Numeric: liquid QC results are displayed in numeric format. Suppressed: the following symbol “<>” is displayed next to each liquid QC test name in place of the quantitative (numeric) results. The “Suppressed” option should only be chosen if “Automatic via EVAS” is chosen for the liquid QC Pass/Fail Determination. See the "i-STAT/DE User Guide" for more details.	Numeric
APOC FLUID LOT ENTRY METHOD	Options are: Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the analyzer, or scanning it from the barcode on the quality control vial being tested. Scan only: the fluid lot information must be entered by scanning the barcode on the vial being tested.	Scan or Enter
SCHEDULE STATUS	Displays the status of previously defined Liquid QC Schedules See the "i-STAT/DE User Guide" for more details.	Off

FOR CARTRIDGE QC - LIQUID QC SCHEDULE (1, 2, OR 3)

Option	Description	Default
QC FREQUENCY	Describes the frequency at which the System Administrator wants the liquid QC run under this schedule. Options are: Off: Disables the selected QC Schedule Daily Weekly: A particular day of the week (e.g. every Monday) Monthly: A particular day of the month (e.g. the second Tuesday of the month) See the "i-STAT/DE User Guide" for more details.	Off
QC TIME	The QC Time sets the time when the QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become “due to start”. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out. See the "i-STAT/DE User Guide" for more details.	Disabled
APPLY QC SCHEDULE TO	The months of the year to which this schedule will apply. Options are: All months Selected Months: Check the box next to the months to which this schedule will apply. See the "i-STAT/DE User Guide" for more details.	All months
CARTRIDGE QC PROFILE	The System Administrator defines a QC cartridge set consisting of: A QC cartridge type (i.e. the cartridge type to be test with specified liquid QC fluids during the QC procedure), as well as any number of dependent cartridge types (i.e. associated cartridge types that will be enabled by the analyzer if the QC requirements for a given cartridge set are met on that analyzer). The System Administrator then associates the defined cartridge set with up to six (6) specific QC fluids. A Cartridge QC Profile can only be edited or created if QC Frequency has been activated. See the "i-STAT/DE User Guide" for more details.	Disabled

FOR RESULTS REPORTING OPTIONS

Option	Description	Default
REFERENCE RANGES	Reference ranges can be defined for each test. The ranges will be depicted as tic marks on the bar graphs on the result pages. There are no bar graphs for blood gas, coagulation, and immunoassay tests. Ranges will be displayed on the Customization screen of the analyzer under the Administration Menu. Only one range is allowed for each test in a particular analyzer. However, different customization profiles can be set up in specific analyzers used for specific patient populations. Care should be taken to enter the same units as selected in the Unit Set Window.	Ranges are listed in the Cartridge and Test Information sheets (CTI) and Instructions for Use.
ACTION RANGES	High and low action ranges can be defined for each test. See the "i-STAT/DE User Guide" for more details.	Disabled (-99999.9 to 99999.9)
CUSTOM REPORTABLE RANGES	High and low custom Reportable Ranges can be defined for each analyte (except ACT). See the "i-STAT/DE User Guide" for more details.	Disabled (-99999.9 to 99999.9)
PRINT REFERENCE RANGES	Reference Ranges can be printed with results. Ranges will print only if the record to be printed is stored with the active Preference set in the analyzer. The active Preference set in the analyzer is listed as ”Custom” on the Analyzer Status page and the Preference set stored with the record is displayed on the Chart Page when the record is recalled and is printed with the results.	Disabled
OPERATOR TEST SELECTION	Requires the operator to select tests to be reported from a cartridge test panel. This option facilitates compliance with Medicare/Medicaid regulations in the USA. This option facilitates compliance with Medicare/Medicaid regulations in the USA.	Disabled
ACT OPTIONS (i-STAT 1 Analyzer Only)	The user can select between the current 37° (PREWRM) result calibration and a new "NON-PREWARM" (ambient temperature) result calibration for both Celite ACT and Kaolin ACT cartridges. Please see the Technical Bulleti "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT 1 Analyzer" for full discussion.	PREWRM for both cartridge types.
HEMATOCRIT OPTIONS	Reference anticoagulant used to calculate hematocrit result: K3EDTA or K2EDTA/ Heparin/None. (NaEDTA is included in this option and None means no anticoagulant.) CPB options are: 1. **Prompt:** asks user whether to apply CPB compensation when cartridge includes hematocrit sensor. 2. **Never:** CPB correction is never applied when running a cartridge with a hematocrit sensor.. 3. **Always:** apply CPB correction every time it runs a cartridge with a hematocrit sensor. See Theory section in this manual for explanation of CPB. Analyzers can be customized by location. Analyzers customized for "CPB: Always" should not be used for reporting Proficiency Testing results.	K3EDTA Prompt CPB
DECIMAL SEPARATOR	Select comma (,) or period (.)	Period
BASE EXCESS CALCULATION	Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb). See i-STAT Cartridge Instructions for Use (IFU) for $\boldsymbol{P}CO_2$ for formulas.	BEecf

FOR ANALYTE ENABLE

Option	Description	Default
APPLY GLOBALLY	Test(s) can be disabled for all cartridge types. To enable/disable a particular analyte on all cartridge types, simply check/uncheck the box next to the analyte name in the Apply Globally section. The global selection takes precedence over the cartridge type selection.	All tests enabled.
APPLY BY PANEL	Test(s) can be disabled for individual cartridge types. To enable/disable a particular analyte on a specific cartridge type, make sure the analyte is first checked under the Apply Globally section. Then click on the cartridge type under the Apply by Panel section, and then check/uncheck the box next to the analyte name.	All tests enabled for all cartridge types.

FOR BARCODES

Option	Description	Default
ID BARCODES *	The user can select any or all of the following as valid barcode formats for both the operator and patient ID: • I2 of 5 • Code 128 • Codabar • Code 93 • Code 39 • EAN 8, EAN 13 Barcode type Code 128 will support USS 128 and UCC/EAN 128, but not ISBT 128.	All barcode types
I2 OF 5 OPTIONS	No Check Digit USS Check Digit OPCC Check Digit	USS Check Digit
CODE 39 OPTIONS	Check Digit or No Check Digit Alphanumeric or Full ASCII	Check Digit, Full ASCII
TRUNCATE DIGITS	User can select how to truncate digits from a scanned operator and/or patient ID: First: enter number of leading characters to be stripped from the barcode. Last: enter number of trailing characters to be stripped from the barcode. The analyzer will accept up to 15 characters for operator and patient IDs.	No truncation

*** Note:** For fields other than Operator and Patient ID, only the default setting for the barcode type can be scanned. These are:

- Code I2 of 5 with USS Check Digit
- Code 39 Full ASCII with Check Digit

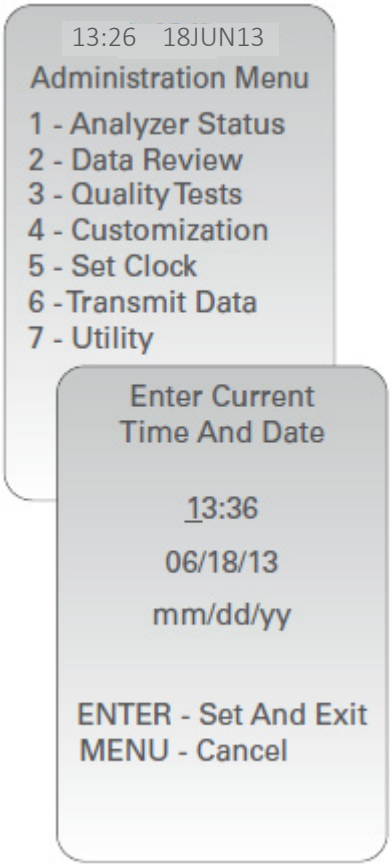
PROCEDURES FOR CUSTOMIZATION USING THE ANALYZER KEYPAD

The following procedures are provided in this section to assist with using the i-STAT 1 analyzer keypad to verify or change items as noted below:

- Verify/Change Date and Time
- Verify Software and Status
- Change Test Selection
- Analyzer Language Options and Data Format
- Decimal Separator Options
- Set Units and Analyte Enable Options
- Procedure for Setting Units and Disable or Enable Analyte(s)
- Sample Type Customization

Verify/Change Date and Time

1. Press  to turn on the analyzer.
2. Press  to change to the Administration Menu
3. Press  (Set Clock)
4. Press  (when enabled, enter password)
5. Use ⇠ or ⇢ arrow keys to move the cursor to a digit if it needs to be changed. Use number keys to change the digit.
6. Press the *Enter* key to accept changes, or the *Menu* key to cancel changes.

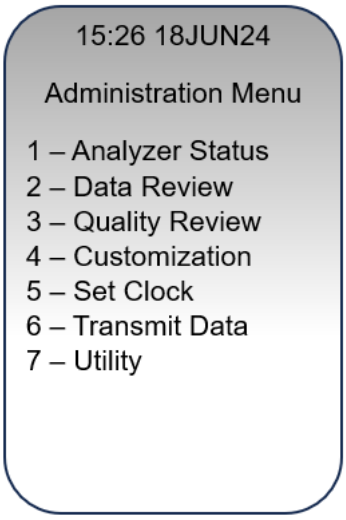


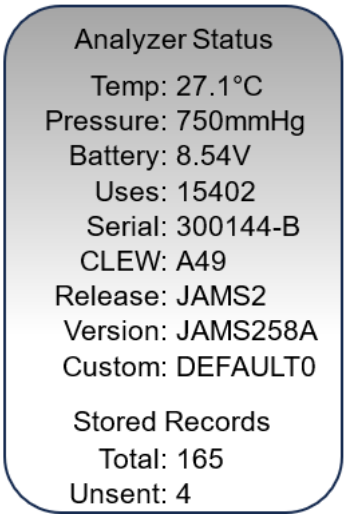
Verify Software and Status

1. From the Administration Menu, 1 (Analyzer Status)

2. Check that software (CLEW & Version) in the Analyzer is up to date by comparing the CLEW & Version to the latest software release details located at www.globalpointofcare.abbott.

For more details on the information displayed in the Analyzer Status page, please refer to *Analyzer Status*, located earlier in this chapter.

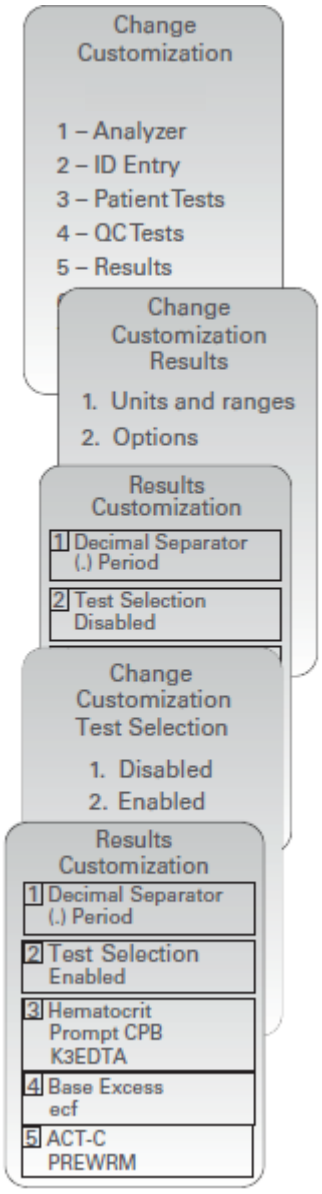




Change Test Selection

New analyzers or replacement analyzers will have the Operator Test Selection feature disabled by default. When enabled and the operator does not select a test, no results will be displayed with the analytes. There is no ability to retrieve results for tests that were not selected.

1. Press ⏻ to turn on the analyzer.
2. Press MENU to change to the Administration Menu
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (when enabled, enter password)
6. Press 5 (Results)
7. Press 2 (Options)
8. Press 2 (Test Selection)
9. Press 1 (Disabled), to disable test selection.
   Press 2 (Enabled) to enable test selection.
10. Once you have made your selection, press MENU twice to save and return to the Main Menu.



ANALYZER LANGUAGE OPTIONS AND DATE FORMAT

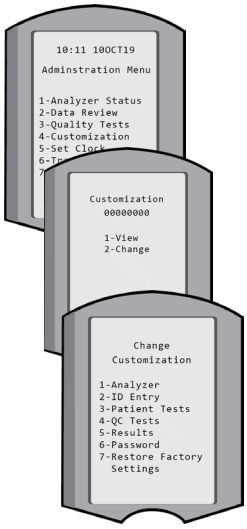
The default language and date format set for the analyzer is English and mm/dd/yy.

Below are the options available:

- Languages: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, and Finnish.
- Date format: mm/dd/yy or dd/mm/yy.

PROCEDURE TO SET LANGUAGE

To change the lanague and date format follow the steps below:



1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (Password)

Note: Abbott Point of Care recommends setting a password. For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORRT section of this

6. Press 1 (Analyzer)
7. Press 2 (Language)
8. Use ← → arrow Key to move to the next screen, if needed.
9. Press 1 - 9 number Key to select langauge.
10. Press 2 (Date Format) and select the corresponding number key to set the format.

11. After all items have been set, turn the analyzer off to save and activate the settings.

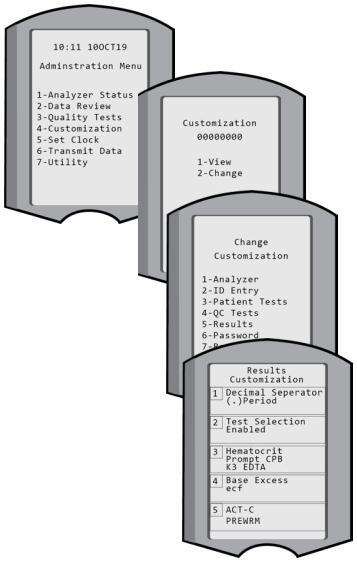
DECIMAL SEPARATOR OPTIONS

Customizes the analyzer keypad "." key to enter a decimal point (".") or a comma separator (",") between the integer and the fractional part of a decimal number.

PROCEDURE TO SET DECIMAL SEPERATOR

To change the decimal separator, follow the steps below:

1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (Password)



Note: Abbott Point of Care recommends setting a password. For more details, see SUPPORT in the TROUBLESHOOTING AND SUPPORT section of this guide.

6. Press 5 (Results)
7. Press 2 (Options)
8. Press 1 (Decimal Separator)
9. Select corresponding number key to set the format.
10. After all items have been set, turn the analyzer off to save and activate the settings.

SET UNITS (OF MEASURE) AND ANALYTE ENABLE OPTIONS

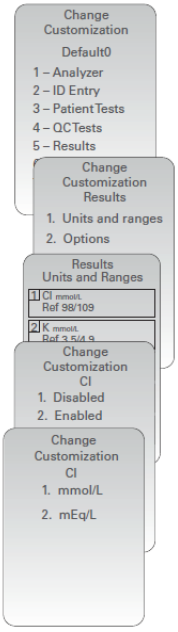
Analyzers will have default units set installed and all analytes enabled. **Note(s)**:

1. When setting the units of measure and/or disabling an analyte, the setting will apply to all i-STAT cartridge configruations with that test.
2. There is no option to set the units of measure based on the i-STAT cartridge panel using the analyzer keypad or by using the optional i-STAT/DE software.
3. There is no option to disable test by i-STAT cartridge panel using the analyzer keypad. Tests can be disabled by i-STAT test cartridge panel using the optional i-STAT/DE software. See the i-STAT/DE User Guide available at www.globalpointofcare.abbott for more details.

SET UNITS TABLE:			
Analyzer out-of-box default units of measure for each test are provided in this table, along with the options for setting a different unit of measure.			
Test/ Analyte	**Units (of measure) Default**	**Units (of measure) Options**	**Note(s)**
Na	mmol/L	mmol/L, mEq/L	
K	mmol/L	mmol/L, mEq/L	
Cl	mmol/L	mmol/L, mEq/L	
BUN	mg/dL	mg/dL	
UREA	N/A	g/L, mg/dL, mmol/L	
Crea	mg/dL	µmol/L, mg/dL	
Glu	mg/dL	mmol/L, mg/dL, g/L	
Lac	mmol/L	mmol/L, mg/dL, g/L	
AnGap	mmol/L	mmol/L, mEq/L	
Hct	%PCV	%PCV, [None]	There are no units for Hct when reported reported as a decimal fraction.
Hb	g/dL	mmol/L, g/dL, g/L	
iCa	mmol/L	mmol/L, mEq/L, mg/dL	
pH	[None]	[None]	There are no units for pH since its reported as decimal fraction.
PCO2	mmHg	kPa, mmHg	
PO2	mmHg	kPa, mmHg	
HCO3	mmol/L	mmol/L, mEq/L	
TCO2	mmol/L	mmol/L, mEq/L	
BE	mmol/L	mmol/L, mEq/L	
sO2	%	%, [None]	
ACT WBT	sec	sec	
PT	sec	sec	
INR	[None]	[None]	There is no unit selection for INR.
cTnI	ng/mL	µg/L, ng/mL	
hs-TnI	ng/L	µg/L, ng/mL, pg/mL	

PROCEDURE FOR SETTING UNITS AND DISABLE OR ENABLE ANALYTE(S)

To disable or set a different unit of measurement for a particular analyte, follow these steps:



1. Press ⏻ to turn on the analyzer.
2. Press MENU (Administration Menu)
3. Press 4 (Customization)
4. Press 2 (Change)
5. Press ENT (Password)

Note: Abbott Point of Care recommends setting a password.

6. Press 5 (Results)
7. Press 1 (Units and Ranges)
8. Press the number key corresponding to the analyte you wish to disable or change units for.
9. Press 1 (Disabled), to disable the analyte OR
   Press 2 (Enabled) to change the units.
10. When changing units, press the number key corresponding to the units in which you would like the analyte reported.
11. After all items have been set, turn the analyzer off to save and activate the settings.



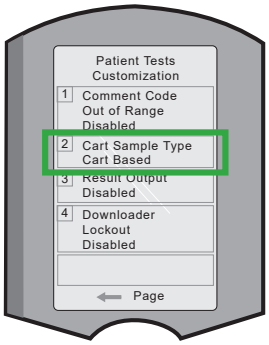
Note: When an analyte is disabled, units and ranges will not be displayed on the Results Units and Ranges screen.

SAMPLE TYPE CUSTOMIZATION

The analyzer by default, uses the i-STAT test cartridge based (Cart Based) sample types from the CTI sheet or IFU. When using the optional i-STAT/DE software, the analyzer may be set to use Custom samples types.

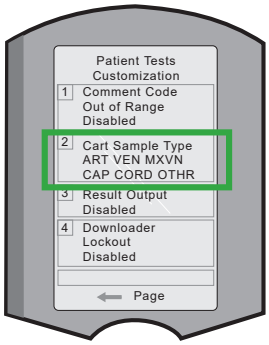
PROCEDURE FOR SETTING SAMPLE TYPE

1. Press ⏻ to turn on the analyzer.
2. Press MENU to go to the Administration Menu.
3. Press 4 to access the Customization screen.
4. Press 2 (Change).
5. Press ENT (when enabled, enter password).
6. Press 3 (Patient Tests), then press the → to go to the next page.
7. Press 2 (Cart Sample Type).
8. Press 1 (Cart Based) to display a sample-type selection list for the cartridge scanned.
   OR
   2 (Custom) if a custom sample-type selection list is preferred based on your facility's policies and procedures.
9. Once the selection has been made, press MENU twice to save and return to the Main Menu.



Step 8:
Patient Tests Customization Screen Cart Based Selection (DEFAULT)

OR



Step 8:
Patient Tests Customization Screen Custom Selection. Custom Selection will display sample types as in the image above.

Note: Cart Based Selection will display sample types that are noted in the Instructions for Use or Cartridge Test Information Sheet for the cartridge.

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ROUTINE CARE of the ANALYZER and DOWNLOADER 16

Drying a Wet Analyzer or Downloader

If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged:

- The electronics compartment
- The battery compartment
- The cartridge port

The Downloader may also be damaged by liquid contamination. Unplug the power supply from the outlet and dry the Downloader completely.

Cleaning the Analyzer and Downloader



Clean the display screen and the case with any of the following:

- A gauze pad moistened with:
  - Isopropyl alcohol (IPA) or
  - 10% bleach solution
- A PDI® Super Sani-Cloth®

Rinse the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam (A) between the display screen and the case.

The use of any unapproved product to clean the i-STAT System may result in damage to system components.

Wash hands throughly with soap and water after handling an analyzer or downloader.

Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.

Caution



The analyzer and downloader are NOT designed to be autoclaved or sterilized by any other method, including high heat, irradiation, or gaseous chemical processes. The analyzer and downloader MUST NOT be immersed in any liquid.

Dispose of analyzer, peripheral electronics, and batteries according to local, state, and/or national guidelines.

If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage.

Decontaminate the analyzer or Downloader whenever a specimen is spilled onto it or if the item is to be returned to APOC for repair. Wear gloves while performing the following procedure.

Procedure

STEP	ACTION
1	Prepare a 10% solution of household bleach by mixing one part of bleach with nine parts of tap water.
2	Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
3	Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
4	Clean the entire surface of the device twice with gauze pads soaked in the bleach solution.
5	Rinse the surface of the device with gauze pads moistened with tap water and dry.
6	If the device is to be shipped, place it in a plastic bag.

Removing and Replacing Disposable Batteries

Wait until any test in progress is completed, and turn off the analyzer before replacing the batteries or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the battery carrier which contains the two 9-volt batteries.
3	Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
4	Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient the new battery so it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the battery inward. The terminals of the battery should be underneath the protective bar on the carrier. Repeat for the second battery on the other side of the carrier.
5	Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the instrument first. Insert the carrier into the instrument as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.
6	Slide the battery compartment door back into place.

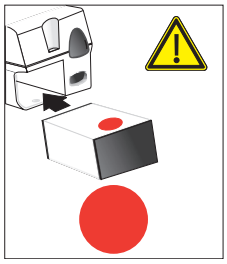
Caution

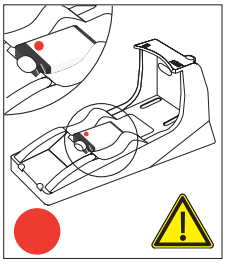
A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

Removing and Replacing the Rechargeable Battery

Wait until any test in progress is completed, and turn off the analyzer before replacing the battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the rechargeable battery pack.
3	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the pack into the analyzer as shown on the label. If the pack is inserted incorrectly, the battery door will not close.
4	Slide the battery compartment door back into place.





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UPDATING THE SOFTWARE 17

To access product software updates and related instructions, registration on the Abbott Point of Care website is required. Visit www.globalpointofcare.abbott to register and access content. Once logged in, select Support > i-STAT 1 and i-STAT Alinity Support > i-STAT 1 Resources login > Access Software (under i-STAT System Software Updates).

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i-STAT 1 SYSTEM TECHNICAL BULLETIN

Sample Type Customization

OVERVIEW

This technical bulletin describes the functionality of the i-STAT 1 Sample Type Customization feature.

With the release of CLEWA40/JAMS149A software, the Sample Type Customization feature of the i-STAT 1 analyzer provides the ability to choose between two options for the sample-type selection list displayed during a patient test.

Option 1, Cart Based: the analyzer will display only those sample types for the cartridge scanned. Information on i-STAT Cartridges may be found in the *Instructions for Use* (IFU), located at www.globalpointofcare.abbott.

Option 2, Custom: the analyzer will display the sample-type selection list provided by i-STAT/DE or CDS, or the following analyzer default selection list if none is provided: ART, VEN, MXVN, CAP, CORD, OTHR.

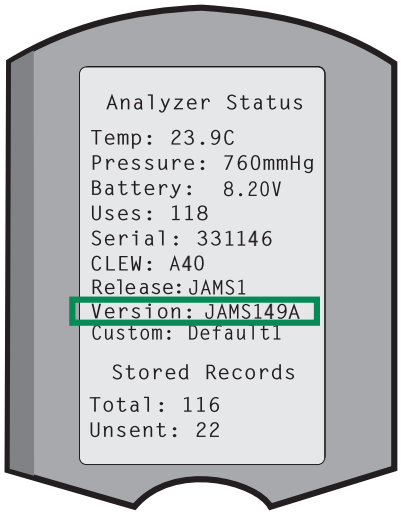
Minimum Analyzer Software Requirements

i-STAT Analyzer Software	Version
Application Software	JAMS149A

Perform the following steps on the analyzer keypad to verify the full version of the application software:

1. Press ⏻ to turn on the analyzer.
2. Press MENU to go to the Administration Menu.
3. Press 1 to access the Analyzer Status screen.
4. **Version:** will display the full version of the application (JAMS) in the analyzer.

   Details regarding other items within the Analyzer Status screen may be found in the *i-STAT 1 System Manual, Section 3, i-STAT 1 Analyzer*.



The i-STAT 1 System is for *in vitro* diagnostic use.

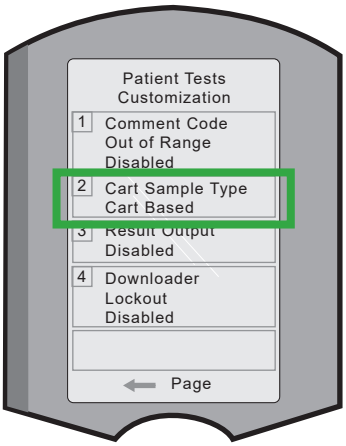
SAMPLE TYPE CUSTOMIZATION

Customization Using the Analyzer Keypad

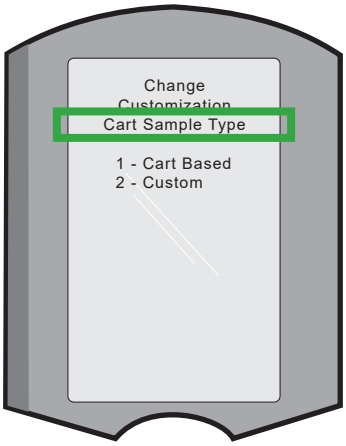
1. Press ⏻ to turn on the analyzer.
2. Press MENU to go to the Administration Menu.
3. Press 4 to access the Customization screen.
4. Press 2 (Change).
5. Press ENT (when enabled, enter password).
6. Press 3 (Patient Tests), then press the → to go to the next page.
7. Press 2 (Cart Sample Type).
8. Press 1 (Cart Based) to display a sample-type selection list for the cartridge scanned.

   OR

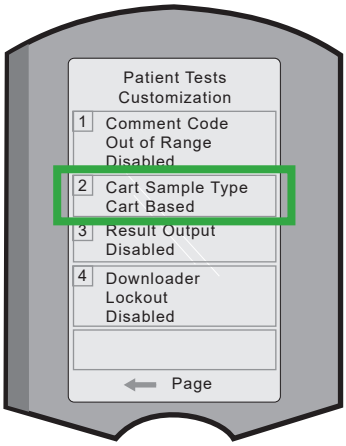
   Press 2 (Custom) if a custom sample-type selection list is preferred based on your facility's policies and procedures.
9. Once the selection has been made, press MENU twice, to save and return to the Main Menu.



Step 6:
Patient Tests Customization Screen Cart Sample Type

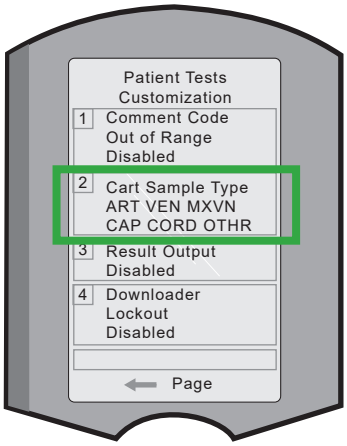


Step 7:
Change Customization Screen Cart Sample Type



Step 8:
Patient Tests Customization Screen Cart Based Selection (DEFAULT)

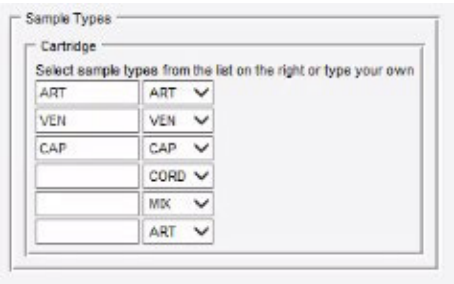
OR



Step 8:
Patient Tests Customization Screen Custom Selection

Sample Type Customization using i-STAT/DE or CDS

i-STAT/DE and CDS provide customers with the ability to customize the analyzer for sample type based on the options available within the Sample Types and Chart Page areas. In addition, i-STAT/DE and CDS provide a STATNotes feature that, when enabled, allows a sample-type and site-collection selection list.



Sample Types Area

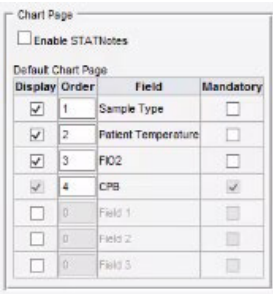


Chart Page Area

Note: images are for representational purposes only and may vary depending on the version of i-STAT/DE or CDS.

ANALYZERS CUSTOMIZED WITH STAT*Notes*

For analyzers customized with STAT*Notes*, the STAT*Notes* sample-type selection list will supersede the analyzer default selection list regardless of the analyzer Cart Sample Type customization. In this case, Cart Sample Type customization is not required.

ANALYZERS CUSTOMIZED WITH I-STAT/DE OR CDS

Once the analyzer software has been updated to CLEWA40/JAMS149A, a cartridge based sample-type selection list will be set as the default. If a custom sample-type selection list is preferred based on your facility's policies and procedures, perform the following before placing the instrument back into use:

1. Customize the analyzer for a Custom sample-type selection list using the analyzer keypad. Refer to "Customization Using the Analyzer Keypad" within this technical bulletin.
2. Place the analyzer(s) in a downloader to reapply the sample-type selection list based on the preference defined within i-STAT/DE or CDS.

For information on the customization workspace to customize options related to Sample Type, refer to the *i-STAT/DE User Guide* or the *i-STAT 1 System Manual, Section 9, Customization,* located at www.globalpointofcare.abbott.

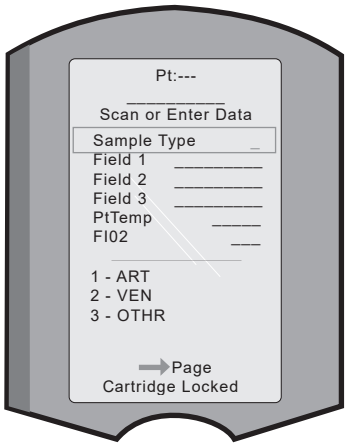
For information on STAT*Notes*, refer to the *i-STAT/DE User Guide* located at www.globalpointofcare.abbott or contact your local APOC sales representative.

ANALYZER DISPLAY SCREENS FOR SAMPLE-TYPE CUSTOMIZATION

When running a patient test, the screens shown below will display according to the Cart Sample Type customization setting.

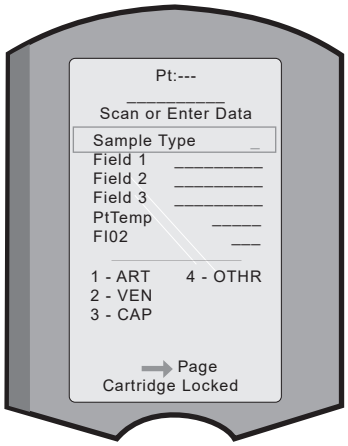
Cartridge Based (CART BASED) Sample-Type Selection List

The sample-type selection list presented in the display screen examples below are based on the i-STAT Cartridge Type indicated.



If the user performs a patient test with a CG4+ (blue) cartridge, the sample types displayed for selection are:

1 – ART
2 – VEN
3 – OTHR



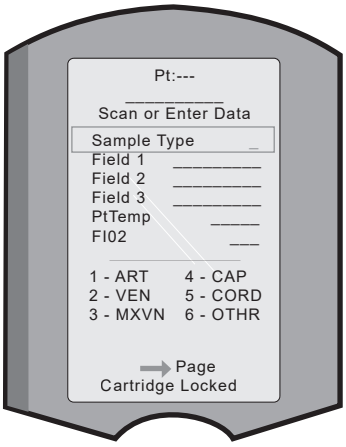
If the user performs a patient test with a CG8+ (white) cartridge, the sample types displayed for selection are:

1 – ART
2 – VEN
3 – CAP
4 – OTHR

Custom Sample-Type Selection List

The sample types presented in the examples below are based on the selection of Custom for the sample-type selection list.

Note: These examples do not apply to analyzers that use a STAT*Notes* sample-type selection list.

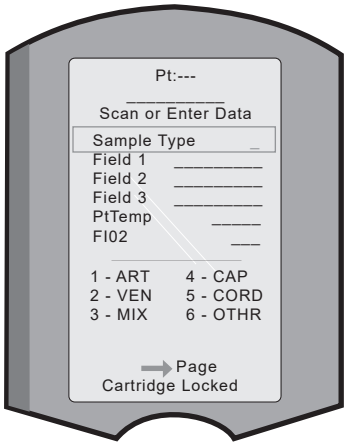


If the user performs a patient test and uses an analyzer with the following:

- Cart Sample Type customization option set to Custom and
- customization profile not applied via i-STAT/DE or CDS

the options for sample type displayed for selection are:

1 – ART
2 – VEN
3 – MXVN
4 – CAP
5 – CORD
6 – OTHR



If the user performs a patient test and uses an analyzer with the following:

- Cart Sample Type customization option set to Custom and
- customization profile applied via i-STAT/DE or CDS

the options for sample type displayed will vary based on customization made to those options within i-STAT/DE or CDS. For example:

1 – ART
2 – VEN
3 – MIX
4 – CAP
5 – CORD
6 – OTHR

NEW AND REPLACEMENT ANALYZERS

Prior to placing the analyzers into use, ensure preferred customization of the sample-type selection list.

TROUBLESHOOTING

Problem	Resolution
The analyzer does not display the preferred sample-type selection list during patient test.	The analyzer may not have been customized for the preferred cartridge sample-type selection list. Customize the analyzer for a Cart Based or Custom sample-type selection list according to “Customization Using the Analyzer Keypad”. If using i-STAT/DE or CDS, place the analyzer in the downloader; this action will apply the preferred customization preference to the analyzer.
The analyzer does not display (during patient test) the sample-type selection list provided by i-STAT/DE or CDS.	The analyzer may not have been customized for the preferred cartridge sample-type selection list. Customize the analyzer for a Custom sample-type selection list according to “Customization Using the Analyzer Keypad”. Verify that customization is enabled for the analyzer location within i-STAT/DE or CDS and place the analyzer in the downloader; this action will upload the customization and apply the preferred customization preference to the analyzer.

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i-STAT 1 SYSTEM TECHNICAL BULLETIN

Instructions For Restoring Analyzers That Produce *** For Hematocrit and Quality Check Code 23

Hematocrit star-out (***) results and Quality Check Code 23 may be reduced by restoring an analyzer with the reusable i-STAT Ceramic Conditioning Cartridge. This technical bulletin contains instructions for this restoration process.

QUICK REFERENCE

Using an i-STAT Ceramic Conditioning Cartridge (CCC)

Step	Action
1	Run an external Electronic Simulator
2	Run the CCC two times
3	Update the CCC Usage Log
4	Return the analyzer to service

DETAILED INSTRUCTIONS

Using an i-STAT Ceramic Conditioning Cartridge (CCC)

1. Run an external Electronic Simulator

If the analyzer is configured with the Internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the Internal Simulator cycle will not execute during the restoration cycle, which could lead to the premature termination of restoration cycle.

2. Run the CCC two times

Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e: rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.

3. Update the CCC Usage Log

Update the CCC Usage Log to keep track of the number of restoration cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use. Refer to sections below for the CCC Usage Log and maintenance instructions.

4. Return the analyzer to service

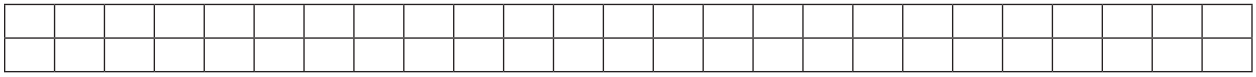
Ceramic Conditioning Cartridge Usage Log

Ceramic Cartridge Serial Number[1] _____

NEW STRIP

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer restoration.

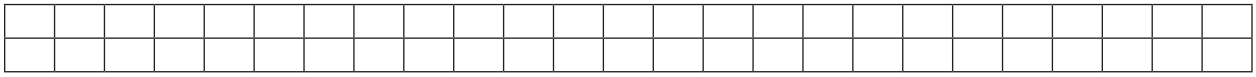


FIRST ROTATION

Rotate the strip 180 degrees, keeping the same side up.

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

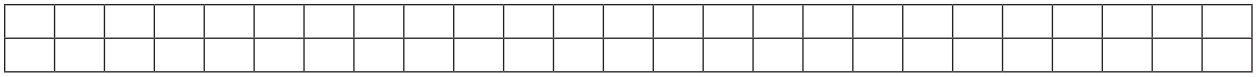


SECOND ROTATION

Flip the strip over, so the bottom side is now up.

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes immediately below are checked, rotate the strip as instructed and continue to check-off boxes for each analyzer repair.

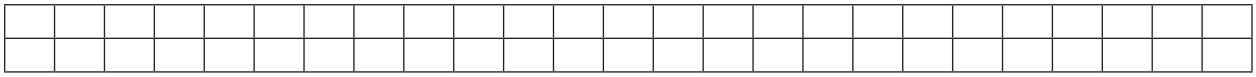


THIRD AND LAST ROTATION

Rotate the strip 180 degrees, keeping the same side up.

Check one box for each time the ceramic cartridge is run in the analyzer. Typically, this means two boxes are checked each time an analyzer is restored with the ceramic cartridge (serial number shown above).

There are 50 boxes. If the strip is damaged[2], replace the strip, start a new log. After all the boxes are checked, discard the strip as instructed below.



DISCARD STRIP

Replace the strip with a new strip, and start a new log

[1] Serial Number is etched on the cartridge base.

[2] Inspect the ceramic cartridge for damage. Check to make sure the ceramic strip is centered (i.e., is not hanging over either edge), that the screw is secure, and that the ceramic is not chipped or cracked. Wear marks (appearing as small lines on the ceramic) are normal.

MAINTAINING THE CERAMIC CONDITIONING CARTRIDGE

The Ceramic Conditioning Cartridge consists of an aluminum base that supports a ceramic "strip." The strip is a white strip of Alumina that is held down by a brass retainer and retainer screw. The ceramic cartridge may be used up to 50 times before the strip is worn and needs to be rotated or up to 200 times before the strip must be replaced as described below.

PROCEDURE FOR ROTATING THE STRIP

Note: Rubber gloves should be worn to perform the following procedure.

1. Using a small Phillips head screwdriver, loosen and remove the screw and retainer.
2. Remove the ceramic strip.

   Note: The ceramic strip is brittle and should be handled with care to avoid damaging or contaminating it.

3. Inspect the ceramic strip for damage. Replace if cracked or chipped. CRACKED STRIPS MUST BE REPLACED BEFORE USING THE CERAMIC CARTRIDGE IN AN ANALYZER.
4. Inspect the aluminum base. Clean if necessary with isopropyl alcohol and soft, lint-free cloth. Avoid using paper that might leave fibers on the ceramic cartridge which might be carried into the analyzer.
5. Rotate the ceramic strip to the next orientation (either spin around or flip over).

   Note: The ceramic cartridge may be used to perform 25 repairs before rotating or replacing the strip. The strip may be rotated 3 times before replacing it (i.e., the strip has a total of 4 positions; original position of the strip plus 3 rotations). In other words, a single strip may be used to repair 100 analyzers – 25 analyzers per orientation of the strip. The 4 orientations are:

   1. Initial position
   2. The strip rotated by "spinning it" 180 degrees, same side up.
   3. The strip rotated by turning it over, now back-side up.
   4. The strip rotated by "spinning it" again 180 degrees, back-side still up.

6. Place the ceramic strip in the base, making sure it sits flat in the recess and does not overhang either edge (i.e., the inner edges adjacent to the strip, not the wider edges back on the body of the cartridge).
7. Replace the retainer plate and retainer screw.

   Note: Over-tightening the screw may damage the threads in the base or crack the ceramic strip.

8. Record the strip rotation in the Use Log.

PROCEDURE FOR REPLACING THE STRIP

Follow the same procedure as rotating the strip, except discard the old strip and insert a new strip in its place.

Request replacement parts by contacting your i-STAT support provider and refer to the following i-STAT list numbers:

Description	List Number
Ceramic Cartridge, Packaged (with box, spare strips, etc.)	04J51-01
Ceramic Cartridge Strips, Replacement	06F21-39

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i-STAT 1 SYSTEM TECHNICAL BULLETIN

K_2EDTA and K_3EDTA Customization for Hematocrit on the i-STAT System

PURPOSE

This Technical Bulletin contains the information needed to select the K_2EDTA or K_3EDTA customization option for reporting hematocrit results on the i-STAT System.

HEMATOCRIT CALIBRATION

The reference method for hematocrit is the microhematocrit (MH) method. All instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference method.[1-3]

The microhematocrit reference method described in CLSI H7-A3[3] permits both K_2EDTA and K_3EDTA anticoagulant sample collection tubes. K_3EDTA anticoagulant shrinks red blood cells relative to K_2EDTA anticoagulant, causing microhematocrit results from K_3EDTA samples (MH-K_3EDTA) to be lower by approximately 2 – 4% than results from K_2EDTA samples (MH-K_2EDTA).[3,4]

Consequently, instruments calibrated to MH-K_3EDTA report lower hematocrit results than analyzers calibrated to MH-K_2EDTA.

SELECTION OF THE K_2EDTA OR K_3EDTA CUSTOMIZATION SETTINGS ON THE i-STAT SYSTEM

i-STAT provides two customization settings for reporting hematocrit results: The "K_3EDTA" customization reports hematocrit results traceable to MH-K_3EDTA. The "K_2EDTA" customization reports hematocrit results traceable to MH-K_2EDTA.

For best agreement of i-STAT and hematology analyzer hematocrit results, the i-STAT customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K_2EDTA or MH-K_3EDTA). (Note: The default setting on the i-STAT System is K_3EDTA.)

If the calibration of a comparative method is uncertain, determine the customization setting by minimizing the average bias between methods as follows:

- Check that the results from hematocrit controls for both i-STAT and comparative methods are acceptable.
- If i-STAT hematocrit results obtained using the "K_3EDTA" setting are consistently lower than those on the comparative method, the "K_2EDTA" setting may be a better choice. If agreement is better after multiplying the "K_3EDTA"-customized i-STAT results by 1.0425, the customization setting should be switched to "K_2EDTA".
- Conversely, if i-STAT hematocrit results obtained using the "K_2EDTA" setting are consistently higher than those on the comparative analyzer, the "K_3EDTA" setting may be a better choice. If agreement is better after dividing the "K_2EDTA"-customized i-STAT results by 1.0425, the customization setting should be switched to "K_3EDTA".
- If an unacceptable system bias still exists, contact i-STAT Technical Support at 1-800-366-8020, option 1.

HEMATOLOGY ANALYZERS AND K_2EDTA AND K_3EDTA SAMPLE COLLECTION TUBES

Hematocrit results on hematology analyzers from samples collected in K_3EDTA and K_2EDTA tubes will be equivalent. This is because the osmotically-balanced diluent reverses the red blood cell shrinkage caused by the anticoagulant.[5] It should be clear that results from K_2EDTA and K_3EDTA tubes will be equivalent, but lower, on an analyzer calibrated to MH-K_3EDTA than on an analyzer calibrated to MH-K_2EDTA.

i-STAT has become aware that some customers have selected their i-STAT hematocrit customization according to the type of EDTA anticoagulant in the collection tube used for samples for the hematology analyzer. As explained above, the selection of the "K_2EDTA" or the "K_3EDTA" customization for i-STAT analyzers is based upon the microhematocrit method (MH-K_2EDTA or MH-K_3EDTA) to which the hematology analyzer is calibrated, rather than on the collection tube used for the hematology analyzer.

EXPECTED LEVEL OF METHOD AGREEMENT

Average i-STAT hematocrit results over a group of samples should normally agree with those from the comparative method within ± 2 %PCV at 29 %PCV and below, ± 3 %PCV from 30 to 50 %PCV, and within 10% above 50 %PCV when the following conditions are met:

- i-STAT analyzers are customized correctly.
- Comparative analyzer is calibrated correctly.
- Sample handling is optimal for both i-STAT and comparative methods.
- Samples are unaffected by factors listed in the i-STAT Cartridge and Test Information sheet for Hematocrit or in the user documentation for the comparative method.

REFERENCES

1. Bull BS, van Assendelft OW, Fujimoto K, et al (International Council for Standardization in Haematology Expert Panel on Cytometry). Recommendations for Reference Method for the Packed Cell Volume (ICSH Standard 2001). Lab Hematol. 7:148-170 (2001).

2. CLSI. *Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard.* CLSI document H38-P [1-56238-398-1]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 1908 –1898 USA, 1999.

3. CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third Edition.* CLSI document H7-A3 [ISBN 1-56238-413-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 1908 –1898 USA, 2000.

4. Gotch F, Torres L, Evans M, Keen M, Metzner K, Westpal D, Polascegg H. Comparison of Conductivity Measured Hematocrit to Microhematocrit. ASAIO Transactions 37:M138-139 (1991).

5. Parikh, M. Evaluation of BD Vacutainer™ Plus Plastic 4.0mL K_2EDTA, 2.0mL K_2EDTA and Glass 5.0mL K_3EDTA Tubes for CBC, WBC Differential Count and Reticulocyte Count. (Technical Literature). Becton, Dickenson and Company, 2003.

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i-STAT 1 SYSTEM TECHNICAL BULLETIN

ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration

BACKGROUND

The Activated Clotting Time (ACT) test has been in existence for over 30 years. It is the most popular test for measuring the effect of heparin administered during an interventional procedure. By placing an activator in the test chamber, the blood sample is "activated" to promote clotting. When heparin is present in the sample, the clotting is delayed in proportion to the amount of "anticlotting" effect of the heparin.

Since its inception, numerous changes have taken place to ACT tests, including increased automation and decreased sample volume. Today, there are many new, fully automated, low blood volume ACT tests on the market, in addition to the older, macro blood volume, semi-automated tube-based systems (*i.e.*, Hemochron, Actalyke™). The micro sample ACT systems typically employ test cartridges or cards (instead of tubes), and all have incorporated an automatic test cycle prewarming step that brings the ACT testing chamber to 37 °C prior to initiating the clotting reaction. As blood clotting is an enzymatic process, the temperature at which the clotting cycle takes place has a marked impact on the rate at which the blood clot forms. The ACT tests that incorporate a prewarming step allow the entire clotting reaction to take place at 37 °C. ACT tests that do not use a prewarming step are subject to a delay before the blood specimen reaches (and stabilizes at) 37 °C; the actual time needed to reach 37 °C is dependant on the starting temperature of the sample test tube. For example, a 30 °C blood sample placed into a (non-prewarmed) 25 °C ACT tube will take a few minutes before the test environment (blood, reagent, tube) stabilizes at 37 °C. The result of this thermal delay is an increase in the reported ACT clot time that will depend on sample tube temperature.

ACT Instruments WITH an automatic prewarming step	ACT Instruments WITHOUT an automatic prewarming step
Medtronic ACT Plus	Hemochron 801/401/8000/Response
Medtronic HMS Plus	Actalyke
Bayer/TAS HMT	
Roche ACT	
Hemochron Jr. (Signature/PCL)	
i-STAT 1	

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Art: 715617-00F Rev. Date: 18-OCT-2021

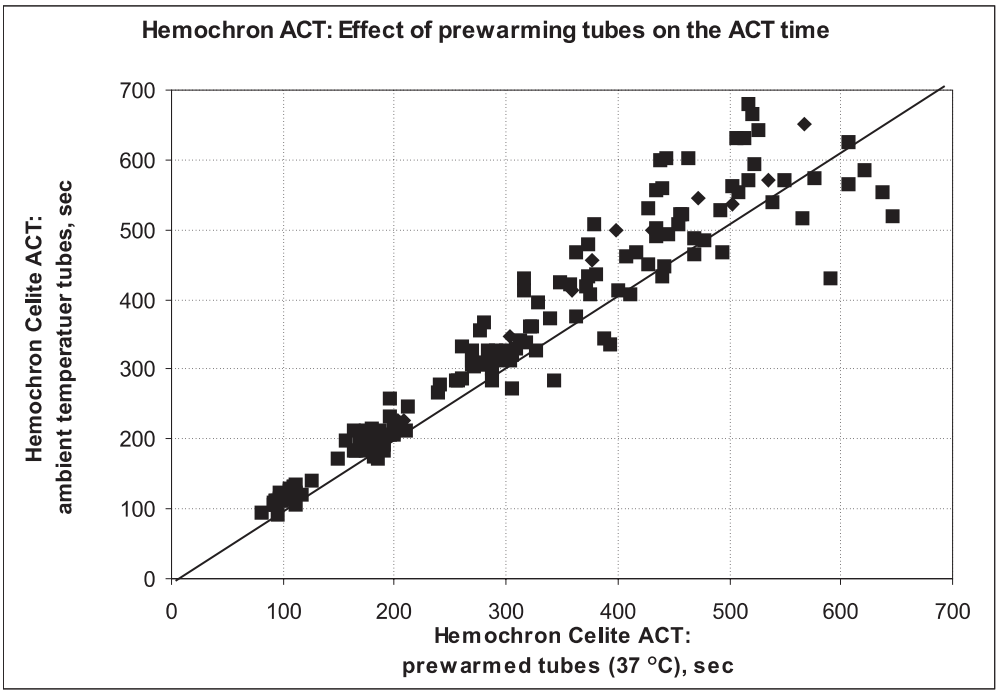
i-STAT ACT CALIBRATION

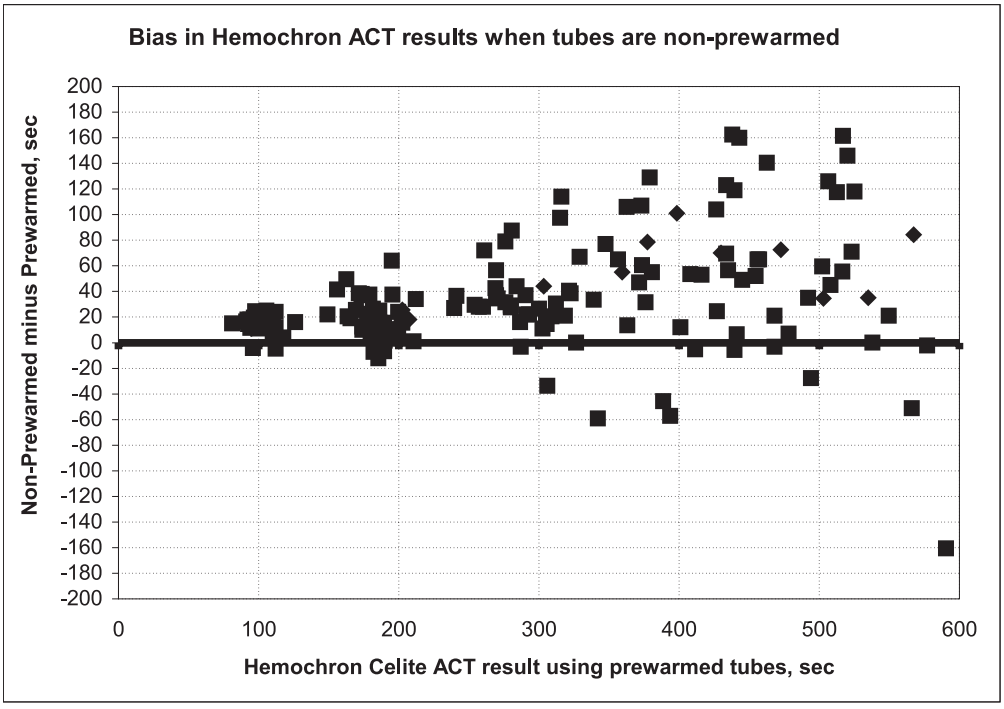
Currently, the i-STAT Celite ACT and i-STAT Kaolin ACT tests are factory calibrated by mathematically adjusting the raw i-STAT "clot time" to match the Hemochron Celite tube result. This calibration is performed by testing cartridges and Hemochron Celite tubes side by side, using a range of heparinized, non-hemodiluted whole blood samples, and using **Hemochron tubes prewarmed to 37 °C**.

Customers who are familiar with macro-sample ACT methods like Hemochron and Actalyke™, and who do not preheat their tubes prior to each test, have found that the bias in results between their previous ACT method and the i-STAT ACT may require changing familiar clotting time target values. In order to ease the changeover to the i-STAT ACT method under these circumstances, i-STAT now provides a choice between the current 37 °C result calibration and a new "non-prewarm" (or ambient temperature) result calibration. The additional calibration mode allows an i-STAT ACT cartridge to deliver results that will be a closer match for those users who are familiar with macro-sample methods without automatic prewarming cycles, and should reduce the need to make large changes to ACT target times or ranges. Since micro-sample methods (Medtronic HR-ACT, Hemochron Jr. ACT+) already incorporate preheating of the test cuvettes, users with ACT target times and ranges based on these methods should continue to use their current i-STAT 37 °C calibration.

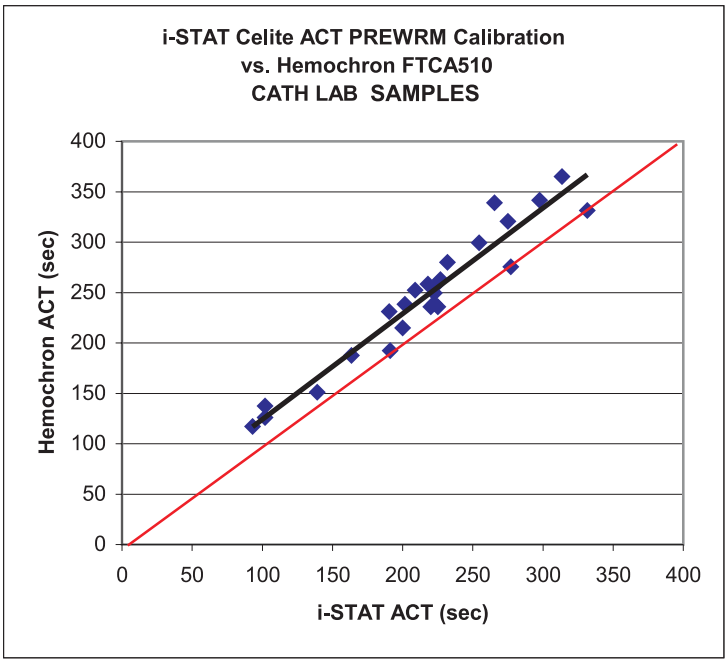
REPRESENTATIVE DATA

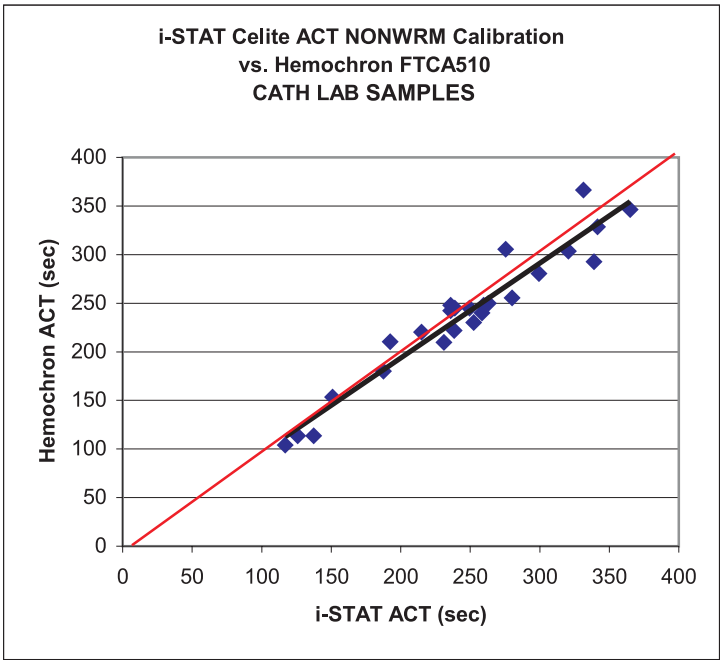
Effect of Sample Tube Temperature on Hemochron ACT Results using Paired Samples: prewarmed sample tubes vs. non-prewarmed sample tubes.





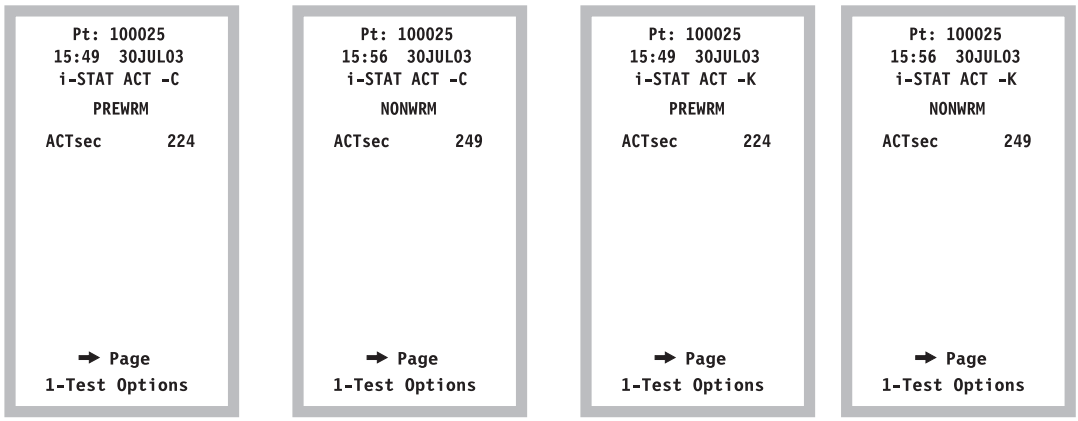
i-STAT Celite ACT vs. Room Temperature Hemochron FTCA510: prewarmed **(PREWRM)** vs. non-prewarmed **(NONWRM)** calibration modes.





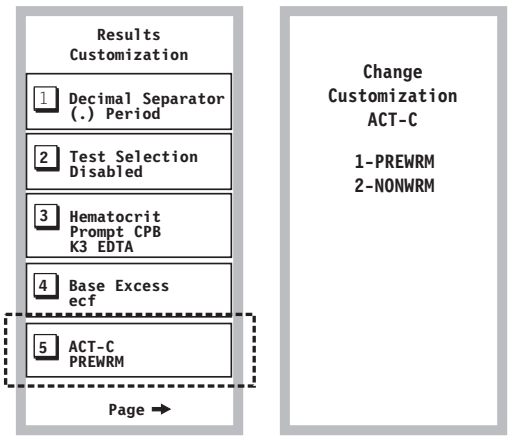
i-STAT 1 ANALYZER DISPLAY

The ACT test results displayed on the i-STAT 1 Analyzer show the calibration setting that was used to perform the ACT calculations.

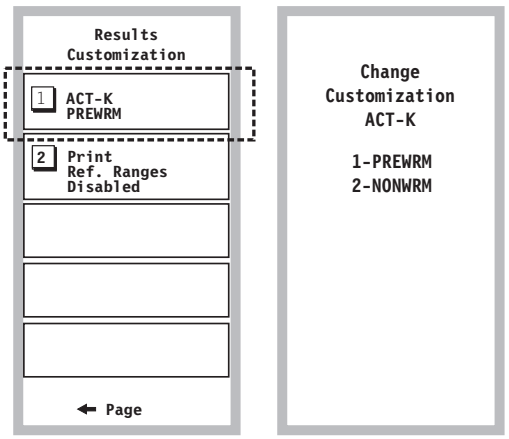


CUSTOMIZATION

- The i-STAT 1 Analyzer is capable of offering both the **NONWRM** and **PREWRM** ACT customization settings. These customizations can be viewed, selected and changed via the RESULTS CUSTOMIZATION section on the i-STAT 1 Analyzer.

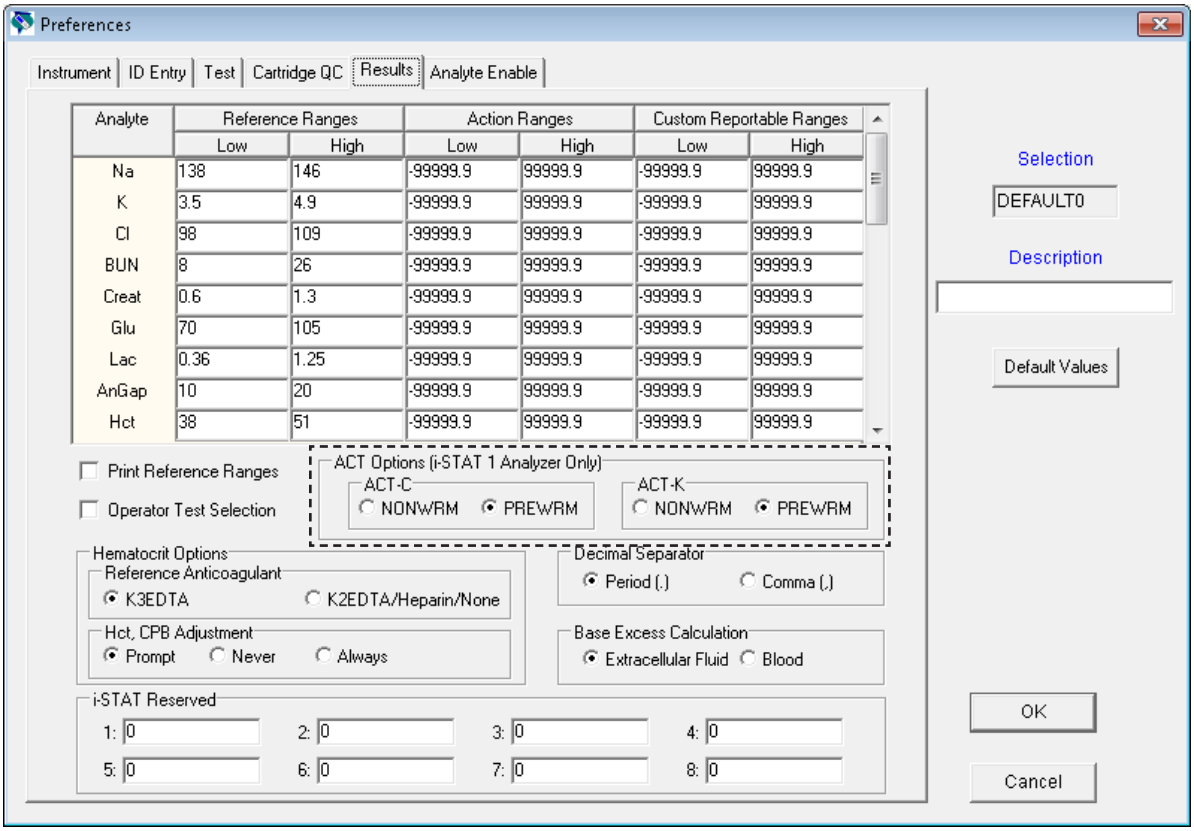


Celite ACT handheld customization.



Kaolin ACT handheld customization.

- For i-STAT 1 Analyzers used in conjunction with CDS Version 5 or i-STAT/DE, the ACT customization options are located on the RESULTS tab of the Preferences section of the individual customization profile (see highlight below). Users should select the desired calibration mode for each i-STAT ACT cartridge type (Celite and/or Kaolin).



LIMITATIONS AND WARNINGS

- The NONWRM calibration mode applies to the Patient Path only, and will not be applied to the Control or Proficiency Testing pathway. *Control or Proficiency samples run in the Patient Pathway may produce erroneous results.*
- Different locations within a given hospital may utilize different calibration modes/customization profiles. Prior to testing patient samples, ensure the appropriate calibration mode is employed.

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i-STAT 1 SYSTEM TECHNICAL BULLETIN

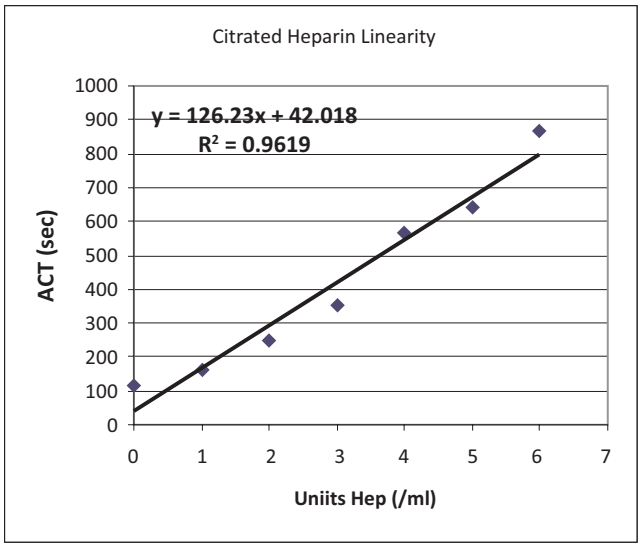
i-STAT Celite® ACT* and i-STAT Kaolin* ACT Heparin Linearity Procedure

INTRODUCTION

The i-STAT Celite ACT and the i-STAT Kaolin ACT tests are intended for *in vitro* diagnostic use. This test can be performed at the bedside using venous or arterial whole blood. The i-STAT Celite ACT is commonly used for heparin anticoagulation monitoring for adults during cardiopulmonary bypass (CPB) surgery and percutaneous transluminal coronary angioplasty (PTCA). The i-STAT Kaolin ACT is used for heparin anticoagulation monitoring during cardiopulminary bypass (CPB) surgery, and can be used in the presence of aprotinin. The i-STAT ACT tests can be performed using the i-STAT Portable Clinical Analyzer or i-STAT 1 Analyzer. The reportable range of the i-STAT ACT test is from 50-1000 seconds.

The i-STAT ACT tests have demonstrated linearity between 0.0 and 6.0 units of heparin in blood samples from normal, healthy volunteers.

An *in vitro* heparin sensitivity curve was generated by adding increasing amounts of heparin to aliquots of normal donor blood (See graph below which serves as an example only. Each patient demonstrates a unique dose-response curve.)



* Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

If an attempt is being made to reproduce and demonstrate the manufacturer's claims as they relate to the linearity and sensitivity of an ACT test, the following procedure may be used. An *in vitro* laboratory assay of heparin sensitivity is a universally accepted method of evaluating the ACT assay performance. An acceptable degree of linearity in a heparin dose-response sensitivity curve is an indication of ACT performance validation. Heparin sensitivity curves are generated using either citrated or fresh donor whole blood, where incremental concentrations of heparin are added to aliquots of the blood specimen. The i-STAT ACT tests can be performed using these specimens.

When performing the procedure on an i-STAT Analyzer, run the samples in the Patient Mode, as there are too many levels to run them in the Calibration Verification Mode.

LINEARITY PROCEDURE FOR USING CITRATED WHOLE BLOOD

Materials

- i-STAT Celite ACT cartridges or i-STAT Kaolin ACT cartridge (14). Note: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.
- Plastic test tubes, no additives (7)
- Large collection tube for heparin dilution, 10 mL minimum, no additives (1)
- Large plastic collection tube for blood pooling, 10 mL minimum, no additives (1)
- 1,000 units/mL USP Heparin (beef lung or porcine)
- Isotonic Saline (9.0 mL)
- 0.025M Calcium Chloride
- Precision pipettes (1,000 µL)
- 3.2 or 3.8% Sodium Citrate evacuated blood collection tubes (blue top) for 9mL collection (i.e., 2 x 4.5mL tubes).

Procedure

Note: *Although clinical testing utilizes fresh whole blood exclusively, for the purposes of the linearity assessment, citrated whole blood can be substituted.*

Note: *When using a citrated whole blood source clotting times may be slightly higher than when using fresh whole blood.*

1. Obtain 14 i-STAT ACT cartridges and two i-STAT Analyzers of the same model.
2. Using a standard pharmaceutical heparin preparation (either beef or porcine derived material from any manufacturer), dilute the heparin using saline to a concentration of 100 units/mL of total volume. This can be accomplished by adding 9.0 mL of saline to 1.0 mL of standard USP heparin supplied at 1,000 units/mL.
3. Label seven (7) plastic test tubes in the following manner: "A", "B", "C", "D", "E", "F", and "G". Dispense the following quantities of the diluted heparin into the respective test tubes. The final concentration of heparin in the plastic test tubes after the addition of blood and calcium can be found in the table below.

Tube	Amount of Heparin (µL)	Final Heparin Concentration (units/mL)	Total Heparin Units
A	0	0	0
B	10	1.0	1.0
C	20	2.0	2.0
D	30	3.0	3.0
E	40	4.0	4.0
F	50	5.0	5.0
G	60	6.0	6.0

4. Obtain at least two 4.5 cc blue top (3.8% or 3.2% sodium citrate) tubes. Gently mix the tubes end to end 10 times. (Note: a total of 9.0 mL of citrated whole blood is needed and pooled in the larger collection tube)
5. Accurately dispense 0.70 mL of the citrated blood sample to each one of the seven test tubes prepared in step 3. ("A", "B", "C", "D", "E", "F" and "G"). These are the tubes to which the heparin has previously been added. After adding the blood sample, gently mix the tubes by inversion.
6. Starting with test tube "A" add 0.30 mL of 0.025M Calcium Chloride to the tube. Mix thoroughly. (Do not add Calcium Chloride to the tube until ready to run the cartridge(s) for that heparin level.)
7. Immediately, use a plastic transfer pipet or a syringe to dispense the mixture into the sample well of 2 ACT cartridges. Begin the test.
8. Record the ACT results.
9. Repeat steps 6 through 9 for all tubes "B", "C", "D", "E", "F" and "G".

   Note: Before testing tubes B – G, mix gently by inversion.
10. Record the clotting times and graph the results using, "Avg. ACT seconds" on the y-axis and "Heparin Concentration" (units/mL) on the x-axis.

Result Interpretation

Inspection of the dose-response curve will identify a linear sensitivity response. Linearity is defined statistically by the correlation coefficient (r value) of the assay, which should be ≥ 0.88.

Notes:

Due to the variability of heparin sensitivity, high levels may yield out of range high results. An intermediate amount of heparin can be used to perform linearity (e.g. 35 µL). The actual values obtained for a given heparin level will vary among donors. The heparin type (beef or porcine), manufacturer source and lot number of the heparin preparation will also affect results. The maximum concentration of heparin at which a donor's blood will clot is dependent upon physiologic characteristics of the donor. Extremely elevated clotting times can be excluded from the analysis.

LINEARITY PROCEDURE FOR USING FRESH WHOLE BLOOD

Materials

- i-STAT Celite ACT or i-STAT Kaolin ACT cartridges (14). Note: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.
- Plastic test tubes, no additives (7)
- Large plastic collection tube for heparin dilution, 20 mL, no additives (1)
- 1,000 units/mL USP Heparin (beef lung or porcine)
- Isotonic Saline (9.0 mL)
- Precision pipettes (1,000 uL)

Procedure

1. Obtain 14 i-STAT ACT cartridges and at least two i-STAT Analyzers of the same model.
2. Using a standard pharmaceutical heparin preparation (either beef or porcine derived material from any manufacturer), dilute the heparin using saline to a concentration of 100 units/mL of total volume. This can be accomplished by adding 9.0 mL of saline to 1.0 mL of standard USP heparin supplied at 1,000 units/mL.
3. Label seven (7) plastic test tubes in the following manner: “A”, “B”, “C”, “D” “E”, “F” and “G”.
4. Dispense the following quantities of the diluted heparin into the respective test tubes. The final concentration of heparin in the plastic test tubes after the addition of 1.0 mL fresh whole blood can be found in the table below.

Tube	Amount of Heparin (µL)	Final Heparin Concentration (units/mL)	Total Heparin Units
A	0	0	0
B	10	1.0	1.0
C	20	2.0	2.0
D	30	3.0	3.0
E	40	4.0	4.0
F	50	5.0	5.0
G	60	6.0	6.0

5. Using a butterfly needle and a 10 cc syringe, obtain 9.0 cc of fresh whole blood from a normal healthy donor who is not currently taking medications.
6. Accurately dispense 1.0 mL of the fresh whole blood sample to each of the seven (previously prepared) plastic test tubes A to G and gently mix by inversion.
7. Immediately using plastic transfer pipet or a syringe withdraw about 0.3 mL of the unheparinized blood from tube A and dispense into 2 ACT cartridges. Begin the test.
8. Record the ACT results.
9. Repeat steps 7-9 for blood samples “B”, “C”, “D” “E”, “F” and “G”.

   Note: Before testing tubes B – G, mix gently by inversion.
10. Record the clotting times and graph the results, using “Avg. ACT seconds” on the y-axis and “Heparin Concentration” (units/mL) on the x-axis.

Result Interpretation

Inspection of the dose-response curve will identify a linear sensitivity response. Linearity is defined statistically by the correlation coefficient (r value) of the assay, which should be ≥ 0.88.

Note: Due to variability of heparin sensitivity, high levels may yield out of range high results. An intermediate amount of heparin can be used to perform linearity (e.g. 35 µL). The actual values obtained will vary among donors. The heparin type (beef or porcine), manufacturer source and lot number of the heparin preparation will also affect results. The maximum concentration of heparin at which donor blood will clot is dependent upon physiologic characteristics of the donor. Extremely elevated clotting times can be excluded from the analysis.

Heparin Linearity Data Collection Sheet

Operator Name	

Sample Type	Citrated Whole Blood ❑ Fresh Whole Blood ❑

Date	**Facility Name**	
	Analyzer Serial Number	
	i-STAT ACT Lot#	

Hep Conc (U/ml)	**Clotting Time (sec)**		
	ACT 1 (sec)	**ACT 2 (sec)**	**Average (sec)**
0			
1			
2			
3			
4			
5			
6			

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The i-STAT System and Waived Status

OVERVIEW

The FDA has granted waived status for the following two i-STAT test cartridges:

- Crea (L/N 03P84-25) and G (L/N 03P83-25) (granted November 13, 2008).

Waived status is applicable only when testing venous samples collected in evacuated tubes with lithium heparin (green top tubes) with any of the above listed cartridges with the i-STAT 1 Analyzer (Handheld). These new test categorizations can be found on the list of waived tests available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm.

Waived testing may be performed under all types of CLIA certificates: Certificate of Waiver (CW), Certificate of Provider-Performed Microscopy Procedures, Certificate of Compliance (COC), and a Certificate of Accreditation (COA). If you are currently maintaining a COC or COA because you are drawing venous samples collected in evacuated tubes with lithium heparin (green top tubes) and performing testing using the i-STAT Crea and G cartridge(s) with the i-STAT 1 Analyzer, you may "downgrade" to a CW the next time your Certificate is renewed.

THE i-STAT 1 SYSTEM MANUAL FOR WAIVED TESTS

The i-STAT 1 System Manual for Waived Tests is intended for facilities with a Certificate of Waiver. If you have a standard i-STAT System Manual and are using the i-STAT System under a Certificate of Compliance (COC) or a Certificate of Accreditation (COA), it is not necessary to order the Waived Manual. This Technical Bulletin is intended as an update to the standard i-STAT System Manuals for the use of the waived cartridges.

You do not need to have the Waived Manual if you maintain this Technical Bulletin in your current i-STAT System Manual. If desired, you can purchase the i-STAT 1 System Manual for Waived Tests (Abbott List Number 06F20-03) at no charge by contacting your Abbott Point of Care sales representative or customer service representative.

The Centers for Medicare and Medicaid Services (CMS), The Joint Commission, the College of American Pathologists, COLA and the American Association of Laboratory Accreditation (A2LA) Healthcare Facilities Accreditation Program (HFAP) will expect a facility to follow the instructions in the Waived Manual and summarized in this Technical Bulletin when using i-STAT waived cartridges to test venous samples as previously described. Laboratories will be expected to follow the instructions in the standard i-STAT Manual and the regulations for Moderate Complexity tests when using other i-STAT cartridges (other than Crea and G) or if testing sample types other than venous with the Crea and G cartridges.

Note: If the manufacturer's instructions are not followed for any test categorization, the test defaults to high complexity.

PROFICIENCY TESTING

The Proficiency Testing Providers listed in the Technical Bulletin "Proficiency Testing and the i-STAT System," have been informed of which cartridge types have waived status. It will take time for the providers to update their survey forms.

Note that Accrediting Organizations and certain States may have additional waived testing requirements including those for the laboratory director and personnel requirements, policies and procedures, operator competency, specimen handling, results and control reporting and instrument maintenance. Some states may restrict the list of approved waived tests.

The following are **additional** manufacturer's quality system instructions for i-STAT cartridges granted waived status. A list of **all** of the manufacturer's instructions are included in both the i-STAT 1 System Manual for Waived Tests and the standard i-STAT 1 System Manual.

Additional Manufacturer's Quality System Instructions for Waived Tests	
New Shipment of Cartridges	Check one cartridge from each newly received lot with the appropriate i-STAT control: • Crea Cartridges: use i-STAT or Tri Controls Level 1 Control, • G Cartridges: use i-STAT or Tri Controls Level 3 Control.
Ensure Proper Cartridge Storage (Including Monthly Check)	Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which cartridges are stored is in doubt, use a liquid control to verify that the cartridges are performing properly. Check storage conditions monthly by testing the one cartridge from refrigerated storage with the appropriate i-STAT level control. Select the one cartridge to be tested using the following order: Creatinine, and Glucose. If the cartridge being tested is a: • Crea: use i-STAT or Tri Controls Level 1 Control. • G: use i-STAT or Tri Controls Level 3 Control. • Test the cartridge on any Handheld.

Note on control testing: Cartridges and controls have been selected based on sensitivity to thermal stress. Other control levels and hematocrit controls will not enhance the detection of thermal stress and are therefore not required.

If both moderate complexity and waived tests are performed in same unit/area:

- Handhelds could be identified as "waived testing only" or "moderate complexity testing only" to make it easier to comply with the regulatory requirements;
- You still need to follow the manufacturer's requirements for the waived test(s), which include for example monthly quality control testing as outlined above, even if you decide to comply with moderate complexity requirements for the waived test(s),

CPT CODE INFORMATION

Please refer to the website www.codemap.com/abbott for the updated CPT (Current Procedural Terminology) codes for the waived cartridges.

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THE PRESENCE OF LATEX RUBBER IN i-STAT SYSTEM COMPONENTS

Introduction

This technical bulletin provides information on the presence of latex rubber in the components of the i-STAT 1 and i-STAT 1 Wireless Analyzers, i-STAT Cartridges, and the i-STAT Dispensing Tip.

i-STAT 1 and i-STAT 1 Wireless Analyzers

The exterior parts of the i-STAT 1 and i-STAT 1 Wireless Analyzers are not made with natural rubber latex. No natural or synthetic rubber latex is used anywhere on the exterior of this product, the product packaging, or the accessories.

i-STAT Dispensing Tip

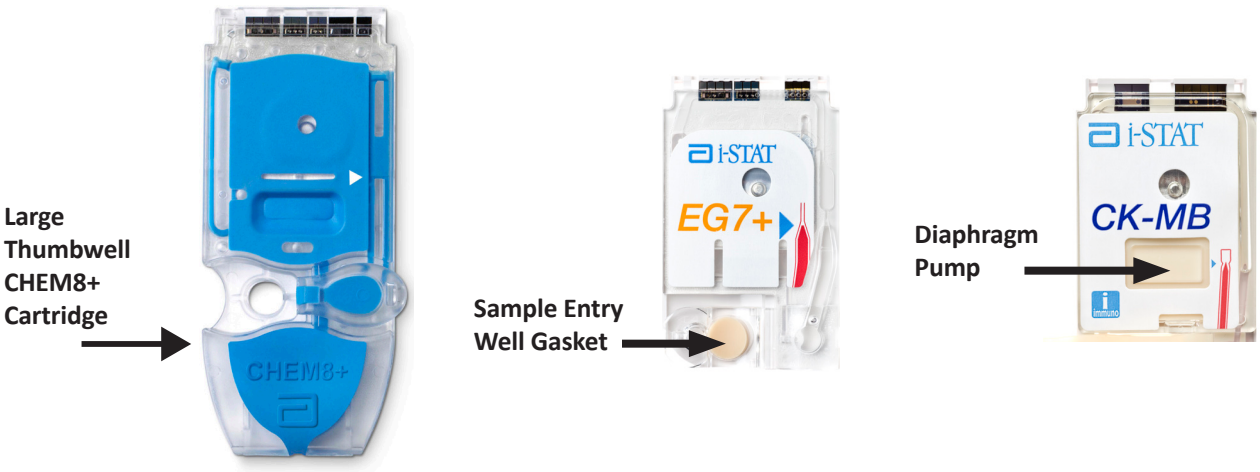
The components of the i-STAT Dispensing Tip are not made with natural rubber latex. No natural or synthetic rubber latex is used anywhere in this product, the product packaging, or the accessories.

i-STAT Cartridges

The large thumbwell CHEM8+ cartridge is not made with natural rubber latex.

The 'Sample Entry Well Gasket' contains natural rubber latex and is used on the following cartridges with the original thumbwell: EC8+, CG8+, EG7+, EG6+, CG4+, G3+, G, Crea, ACTk, ACTc, PT^{plus} and PT/INR. The location of the 'Sample Entry Well Gasket' is shown below.

A diaphragm pump on the following cartridges (all having the original thumbwell) contains natural rubber latex: hs-TnI, cTnI, CK-MB, Total β-hCG, BNP, TBI and TBI Plasma. The location of the diaphragm pump is shown below.



Not all cartridges are available in all regions. The i-STAT TBI Plasma test is not intended for use as a Point-of-Care device. For *in vitro* diagnostic use only.

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