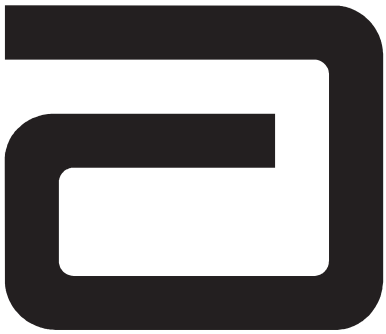
i-STAT
System Manual



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Patents

CA 1,281,072; CA 1,303,175; CA 1,330,888; CA 2,002,848; CA 2,087,720; CA 2,087,966; CA 2,175,228; CA 2,193,000; CA 2,194,795; CA 2,221,178; EP 0408575; EP 0412119; EP 0434742; EP 0442969; EP 0505169; EP 0540691; EP 0543916; JP 2113412; JP 2521826; JP 2833809; JP 2948321; JP 3093274; JP 3105919; JP 3105922; JP 3137612; JP 3269553; JP 3392871; US 4,864,229; US 4,933,048; US 4,954,087; US 5,008,616; US 5,096,669; US 5,112,455; US 5,121,050; US 5,124,661; US 5,200,051; US 5,447,440; US 5,466,575; US 5,514,253; US 5,554,339; US 5,605,664; US 5,609,824; US 5,614,416; US 5,628,961; US 5,789,253; US 5,821,399; US 5,837,446; US 6,030,827; US 6,379,883; US 6,438,498; US 6,750,053; US D332,833; US D337,164

Symbol Technologies Corporation is the owner of US Patent Nos. 4,758,717; 5,130,520; 5,262,628; 5,396,055; 5,532,469.

Trademarks

i-STAT is a registered trademark of i-STAT Corporation. MediSense is a registered trademark of Abbott Laboratories. Precision and PCx are trademarks of Abbott Laboratories. Windows is a registered trademark of Microsoft Corporation.

SYSTEM MANUAL CONFIGURATION

Please ensure that the contents of your System Manual are complete and up to date. In the event that your System Manual does not contain the current configuration, it is recommended that you contact your i-STAT support provider.

As of October 2005, your i-STAT® System Manual (for the i-STAT Portable Clinical Analyzer) should be configured with the contents as listed below and in the order shown. The listings under the Art# column are valid.

ITEM	Art #
Cover Sheet	715001-01C
Configuration Sheet	715029-01H
Table of Contents	715002-01C
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CARTRIDGE AND TEST INFORMATION

TECHNICAL BULLETINS

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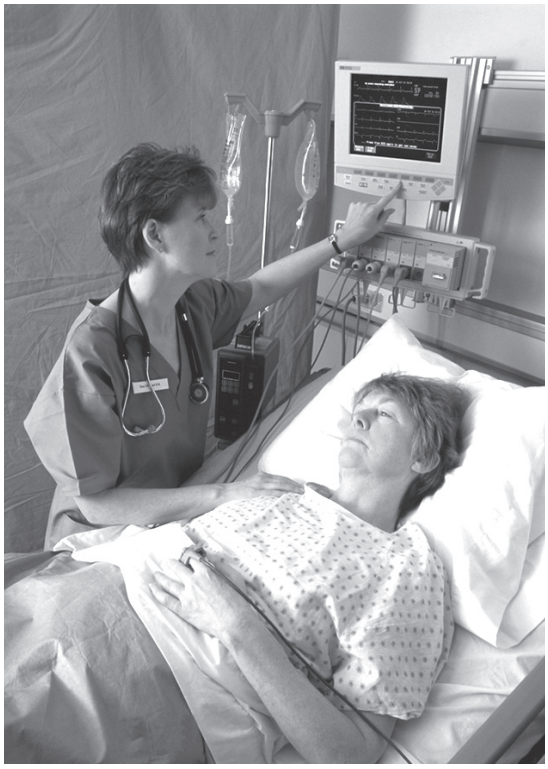
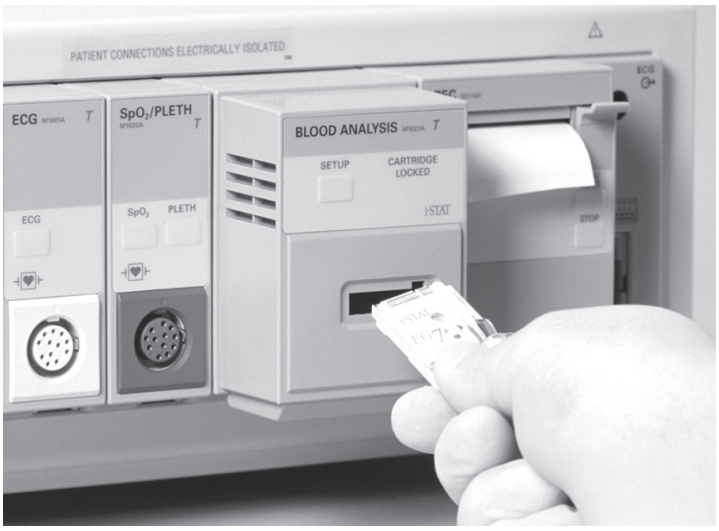
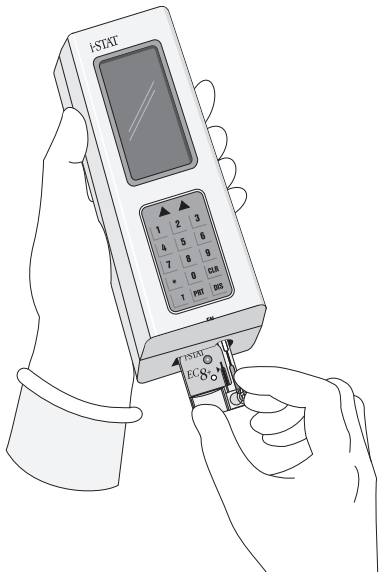




This Manual

This manual describes the i-STAT® Portable Clinical Analyzer, the Philips Medical Systems* Blood Analysis Module, i-STAT Cartridges and the i-STAT Central Data Station Version 5 program. Related sections are grouped behind tabs. The i-STAT Portable Clinical Analyzer and Philips Blood Analysis Module perform the same basic functions, although some elements of the Blood Analysis Module's user interface have been adapted for a patient monitoring environment. Except were noted, operating instructions apply to both pieces of equipment. For specific information on the Blood Analysis Module, refer to the Blood Analysis Module section of this manual.



The i-STAT®1 Analyzer is described in a separate manual.

* Formally distributed by Hewlett-Packard and Agilent Technologies

Intended Use

The i-STAT Portable Clinical Analyzer and Philips Blood Analysis Module are intended for use with i-STAT cartridges for the *in vitro* quantification of various analytes and coagulation times in whole blood. Analyzers and cartridges should be used by healthcare professionals trained to use the system and should be used according to the facility's policies and procedures.

In the USA, for the purpose of CLIA compliance, the i-STAT System is categorized as Non-Waived 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 handheld Portable Clinical Analyzer or a Blood Analysis Module, a cartridge with the required tests, and 2 to 3 drops of blood will allow the caregiver to view quantitative test results for blood gas and chemistry tests in approximately 2 minutes as well as quantitative times for coagulation tests.

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 Central Data Station (CDS) program provides system management tools.

Components

The i-STAT System consists of:

- i-STAT Cartridges
- Abbott MediSense Precision PCx and PCx Plus Blood Glucose Test Strips (for i-STAT1 Analyzer)
- i-STAT Portable Clinical Analyzer
- i-STAT 1 Analyzer
- Philips Medical Systems Blood Analysis Module (used in conjunction with Philips CMS and 24/26 Patient Monitors)

- Portable Printer
- Quality Assurance Materials
  - Electronic Simulator
  - Control Solutions
  - Calibration Verification Set
- Data Management System
  - Downloader and/or Downloader/Recharger for i-STAT 1 Analyzer
  - IR Link for Portable Clinical Analyzer
  - Data Manager
    - Central Data Station Version 5, software for cartridge management
    - QC Manager software for PCx glucose tests strip management
    - Data Manager Printer
  - i-STAT Central Data Station
    - Central Data Station, version 4, software for cartridge management
- LIS/HIS Interface Software

Selection of Components

The selection of 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 administrative requirements

Summary of the Procedure

To perform cartridge testing, the operator fills a cartridge with sample, seals the cartridge with its snap closure, and inserts the cartridge into the analyzer. Inserting the cartridge activates the analyzer. The unit-use cartridge contains all components necessary to perform one or more tests including: calibrating solution for blood gas and chemistry tests or reagents for coagulation tests, a sample handling system, and sensors. The analyzer automatically controls all steps in the testing cycle, which may include: fluid movement, calibration, reagent mixing, and thermal control. Quality checks are performed continuously throughout the testing 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. This degree of automation, along with the ability to test fresh whole blood, eliminates many sources of error as well as time-consuming and costly steps inherent in other methods.

Data Management

Test records can be transmitted to the Data Manager or Central Data Station 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 Central Data Station 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 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, i-STAT recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

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.

Symbol	Definition
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	Model number. The model number will appear adjacent to this symbol.
	Date of manufacture.
	Manufacturer
IVD	In vitro diagnostic medical device.
EC REP	Authorized Representative for Regulatory Affairs in the European Community.
	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 61010A-1 CAN/CSA C22.2 No. 1010.1-92
	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).
	Separate waste collection for this electrical/electronic item indicated.

Symbol	Definition
	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).
BODxxxx-xx	Born On Date: the label BODxxxx-xx defines the year and month of manufacture.

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.

Symbol	The following symbols are used on the i-STAT Portable Clinical Analyzer Keypad
DIS	Key used to activate the display.
ENT	Key used to enter information.
PRT	Key used to print a test record.
CLR	Key used to clear an incorrect entry.

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*CO2**	Partial pressure of carbon dioxide.
***P*O2**	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/INR	Prothrombin Time / International Normalized Ratio
Hb	Hemoglobin
TCO2	Total carbon dioxide concentration.
HCO3	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extra cellular fluid)
AnGap	Anion Gap
sO2	Oxygen saturation
cTnI	Cardiac Troponin I
CK-MB	Creatine Kinase MB Isoenzyme
BNP	B-type Natriuretic Peptide

Warranty

i-STAT warrants this medical product (excluding disposable or consumable supplies) against defects in materials and workmanship for one year from the date of shipment. If i-STAT receives notice of such defects during the warranty period, i-STAT shall, at its option, either repair or replace products which prove to be defective. With respect to software or firmware, if i-STAT receives notice of defects in these products during the warranty period, i-STAT shall repair or replace software media and firmware which does not execute their programming instructions due to such defects. i-STAT does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free. If i-STAT 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 i-STAT.

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 i-STAT,

3 Buyer-supplied software or interfacing,

4 Unauthorized repairs, modifications, misuse, or damage caused by disposable batteries, or rechargeable batteries not supplied by Abbott.

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.

Selling or Leasing the i-STAT System

If you sell an i-STAT analyzer, please notify i-STAT so that we can enter the new owner into our software update database. If you rent an i-STAT analyzer and do not intend to provide software updates to the leaser, please notify i-STAT so that we can enter the leaser into our software database.

PORTABLE CLINICAL ANALYZER 2

INTRODUCTION

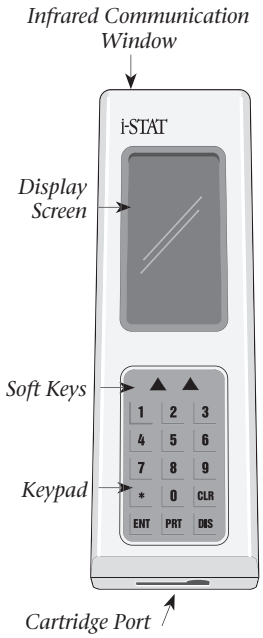
The i-STAT Portable Clinical Analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of various analytes and coagulation times in whole blood.

Refer to the Cartridge and Test Information section of this manual for information on tests that can be performed using i-STAT cartridges.

Please read the paragraph "Before You Use the Analyzer" in this section before you use a new, repaired or replaced analyzer.

DESCRIPTION

Specifications



Dimensions	Width Length Depth	6.41 cm (2.52 in.) 20.97 cm (8.26 in.) 5.21 cm (2.05 in.)
Weight	520 grams (18.34 oz.)	
Power	Two 9-volt lithium batteries	
Calibration	Factory: electronic, mechanical, thermal, pressure	
Memory/Clock Back-up Power	Lithium battery	
Display	Dot matrix super twist liquid crystal	
Communication Link	Infrared transmitter and receiver	
Operating Temperature	16-30 °C (61-86 °F)	
Transport Temperature	-10-50 °C (14-122 °F)	
Relative Humidity	0-90% non-condensing	
Barometric Pressure	300-1000 mmHg	

Software

All analyzer functions are controlled by 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 four months.

Power

The analyzer is powered by two 9-volt batteries. The lifetime for a set of new batteries is dependent on the type of battery (lithium batteries last longer than alkaline) and the types of cartridges used (cartridges that are thermally controlled use more energy). About 400 thermally controlled or about 100 coagulation cartridge test cycles can be expected from two 9-volt lithium batteries. The analyzer will display the message "BAT" when battery replacement is needed.

Caution: The BAT message warns that there is sufficient power for approximately 50 more non-coagulation cartridges when using lithium batteries. Because the power usage curve for alkaline batteries differs from that of lithium batteries, the warning may not be accurate for alkaline batteries.

A separate lithium battery internal to the analyzer maintains the clock/calendar and stored results.

The analyzer has no on/off switch. It is automatically activated when a cartridge is inserted. The analyzer automatically deactivates after 45 seconds of inactivity. Pressing the display key activates the display screen for viewing results and accessing the menu.

Cartridge Port

Cartridges and the Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer. When properly inserted, the cartridge or simulator activates the analyzer.

Infrared Communication Window

The Infrared Communication Window provides the analyzer with two-way communication to the Central Data Station program via the IR Link, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication.

Display Screen

Test results, operator prompts and other messages are displayed on the display screen.

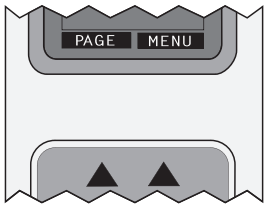
Keypad

There are 15 labeled keys and two smaller unlabeled keys (soft keys) located directly below the display screen:

KEY	FUNCTION
DIS	The DIS (display) key is pressed to activate the display screen in order to recall the most recently displayed test results to the screen or to access the Menu page. The display key can be pressed when the Enter Patient ID prompt is displayed to recall the most recent Patient ID. (This function may be useful during operations where samples from the same patient are tested on the same analyzer several times in a row.) This function can be disabled in the customization profile.
ENT	The ENT (enter) key is pressed in response to a prompt to complete an action, such as entering an operator or patient ID.
CLR	The CLR (clear) key is pressed to erase an incorrectly entered number. Pressing the CLR key backs the flashing cursor (-) one space and erases the number in that space.
Numbered	The "0" through "9" keys are used to enter operator and patient identification numbers, to change the time and date, and to make selections from menu options.
PRT	The PRT (print) key is pressed to send displayed or selected stored test records from the analyzer to the portable printer.
*****	The * key is pressed to enter a decimal when entering information on the chart page (such as Patient Temperature), send all stored records to the Central Data Station, exit a page and return to the results page when indicated by the prompt at the bottom of the screen, and

stop transmission of test records from the analyzer to the portable printer as indicated by the PRINTING… *(STOP) prompt.

SOFT KEY LABELS



▲ The soft keys are activated by the software when needed. When activated, the soft key's function or label will appear in an inverse video box (dark background, light letters) on the bottom of the screen, directly above the key. The soft keys functions are described below.

PAGE Accesses the chart page where additional information can be entered and accesses additional results screens.

MENU Accesses the MENU page screen. The Menu soft key is activated after a patient ID is entered or after the beep when the display key is pressed to activate the analyzer's display screen.

CLKSET Activates the clock-setting function on the Status page.

← → The arrow soft keys are activated when the clock-setting function is activated. Each time a key is pressed, the cursor moves forward (→) or backward (←) one position.

PAGE ↑ PAGE ↓ The Page arrow keys are activated when option 1 or 2 is selected from the Stored Results page. This allows the operator to page forward (↑) and backward (↓) through the 10 pages of stored test records.

Thermal Control

The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and the 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 PO_2 sensor calibration.

Cartridge Test Cycle

An operator starts a test cycle by inserting a cartridge into the analyzer.

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 applicable)
- measures electrical signals generated by the sensors and the calibration fluid
- displaces the calibration fluid with sample
- measures electrical signals generated by the sensors and the sample
- accepts the operator and patient IDs entered by the operator
- accepts chart page information
- calculates and displays results
- stores results

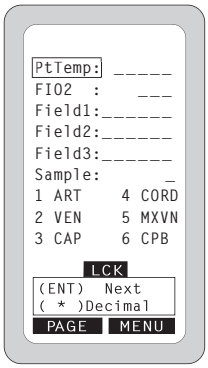
DATA ENTRY

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

IDs

- Operator ID: 0 to 7 digits
- Patient ID: 0 to 12 digits

Chart Page



- 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.

  Note: Input of PT temperature and FIO2 is only possible when a cartridge contains pH, $\mathbf{P}CO_2$, and $\mathbf{P}O_2$ sensors.

- FIO2: Enter values from 0 to 100 for liters or percentage of oxygen patient is receiving.
- Free fields: Three fields, up to 6 digits each including a decimal point.
- Sample Type: Enter the number corresponding to the sample type:

1	ART (arterial)	2	VEN (venous)
3	CAP (capillary)	4	CORD (umbilical cord blood)
5	MXVN (mixed venous)	6	CPB (cardiopulmonary bypass)

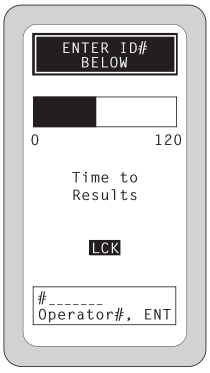
  When 6 is chosen as the sample type, an algorithm is used to adjust the hematocrit result for the dilutional effect of the pump priming solution. An adjusted hematocrit result is reported as Hct_{CPB} on the display and printout. For more information on the CPB sample type see the Theory section of this manual.

To Enter Data

Step	Action
1	Use the number and * keys to enter the desired data.
2	Press the ENT key to move to the next field. The active field name is surrounded by a box.
3	To return to a previous field, press the ENT key until the desired field name is boxed. The ENT key must be pressed twice to return to the first field from the last field.
4	Data entered on the chart page can be edited until results are printed or transmitted, or until another cartridge is inserted, or another test record is recalled to the screen.

PROMPTS AND MESSAGES

Prompts



The analyzer prompts the operator when a certain action is required. There are two types of prompts:

- Simple input prompts, such as ENTER ID# BELOW
- Alert prompts that are displayed in a reverse video box above the operator and patient ID entry box:

LCK LCK appears on the display screen during the test cycle to indicate that the cartridge or Electronic Simulator is locked in the analyzer and should not be removed.

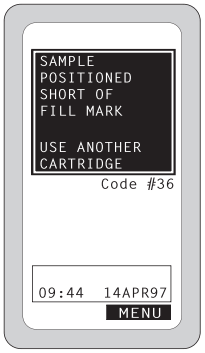
Caution: A cartridge or simulator should be removed only after the LCK prompt disappears from the screen. Attempting to remove a cartridge or simulator while LCK is displayed will damage the anlayzer.

BAT BAT will appear when the disposable lithium battery voltage drops below 7.5. At this point there is sufficient power to test approximately 50 more cartridges before a DEAD BATTERIES message is displayed.

SIM SIM will appear if the analyzer is customized to warn the operator that it is time to use the external Electronic Simulator. Analyzers with Default1 listed as the CFG (configuration) on the Status page will display the SIM prompt every 8 hours.

SFT SFT will appear 15 days before the expiration date of the analyzer's CLEW software. Contact your technical support representative if new software has not been received when this prompt appears.

Quality Check Codes and Messages



If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear identifying the problem and the next step to be taken. Quality check codes and messages are described in the Troubleshooting Section of this manual.

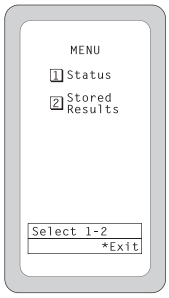
MENU OPTIONS

The Menu page has two numbered options: Status and Stored Results.

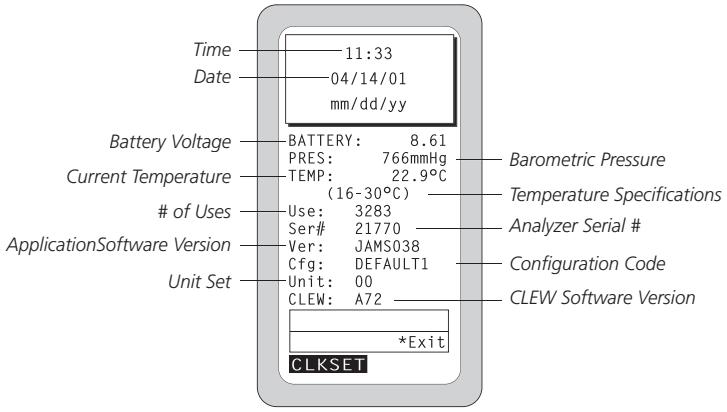
Status Page

The "1" key is pressed to display the Status page which contains information about the condition or "status" of the analyzer. The date and time are changed on the Status page (explained later in this section).

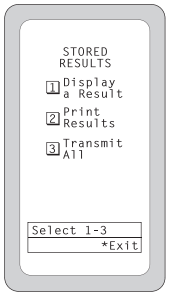
MENU PAGE



STATUS PAGE



Stored Results



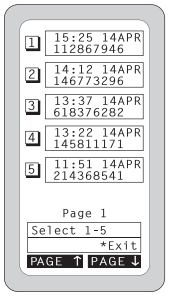
The "2" key is pressed to display the Stored Results menu. The analyzer can store 50 test records, including those for the Electronic Simulator (both internal and external) and those with quality check codes. Test records are listed by the time and date the test was performed, the patient identification number and the cartridge type to make it easy to find a specific test record. The display key is used to toggle between patient ID and cartridge type. Five test records are listed on each of 10 pages. The most recent test record is always stored in position 1 on page one. When the storage capacity is reached, the oldest test record (position 5 on page 10) is removed each time a new test record is added. If a storage position in empty or if the test record is corrupted, the message INVALID or NO DATA will appear in the position.

Electronic Simulator tests are stored as PASS or FAIL with the failure code letter(s). If a test cycle was not completed, the quality check code will be stored.

Display a Result

The "1" key is pressed to access the test records for this option. The PAGE soft keys are used to page forward (↑) or backward (↓). The test record to be displayed is selected by pressing the numbered key ("1" through "5") corresponding to the record's position. Electronic Simulator and quality check codes cannot be recalled to the screen.

Print Results



The "2" key is pressed to access the test records for this option. Any number of records can be selected for printing on the portable printer. The PAGE soft keys are used to page forward (↑) or backward (↓). The test records to be printed are selected by pressing the numbered key ("1" through "5") corresponding to their positions. A reocord can be de-selected by pressing the numbered key again. Printing is initiated by pressing the PRT key. (See the Portable Printer section of this manual for instructions.) Quality check codes cannot be printed.

Transmit All

The "3" key is pressed to transmit all stored test records to the Central Data Station via an IR Link. Transmission does not erase the test records from the analyzer's memory. The Central Data Station recognizes and ignores test records that have been transmitted before. Note: Pressing the ***** key when results are on the screen is the same as using Transmit All. (See the IR Link section of this manual for instructions on transmitting results from an analyzer to a Central Data Station.)

SPECIAL FUNCTIONS

Utility Menu

The Utility Menu allows the operator to:

1 clear all stored results in the analyzer's memory

2 change the default HP portable printer to the Seiko printer

3 send software to another analyzer

4 test calibration verification or linearity samples

5 test proficiency or external quality control samples

To access the Utility Menu:

Step	Action
1	Insert the Electronic Simulator and wait for PASS to be displayed.
2	While pressing the DIS key, press the Menu soft key.

Transmitting Diagnostic Files

For troubleshooting purposes, a technical support representative may request the diagnostic file for a test record.

Step	Action
1	The results from the desired test record must be fresh; that is, they must be the most recent and must be transmitted before results are printed or before reviewing other pages via the Menu.
2	Transmit the results to the Central Data Station by holding down the DIS key and then pressing the * key.
3	The diagnostic file can either be copied to a disk and mailed to the support representative or the support representative can retrieve the file using a remote link to the CDS computer.

BEFORE YOU USE THE ANALYZER

Install Batteries

Two disposable lithium batteries are supplied with the analyzer. Install the batteries according to the instruction below.

Check Date and Time

Press the DIS key, then the Menu soft key, then the "1" key for Status to check the date and time of the analyzer. Change the time if necessary according to the instructions below.

Perform Quality Check

Use the Electronic Simulator to verify the performance of new, replaced or repaired analyzers. (See Quality Control Section for instructions.)

Check Software

New analyzers or analyzers that have been repaired and returned or replaced will have the factory default settings as indicated by the DEFAULT1 on the analyzer status screen and 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. If analyzers in your facility do not use the default customization profile, the appropriate customization profile should be installed before the analyzers are put into use.

Customization

Analyzers can be customized for many site-specific testing requirements. A Central Data Station or an Analyzer Programming Kit is required to customize analyzers. (See the Customization section of this manual which lists the customizable parameters and the default values.)

Note: In the USA, the Analyzer Programming Kit can only be used for software updates.

Note: Outside the USA, the following changes should be considered: language, unit set, decimal separator, and Electronic Simulator schedule.

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.

PROCEDURES

Replacing the Batteries

Wait until any test in progress is completed before replacing the batteries or results will be lost. Stored results will not be lost when replacing the batteries.

Battery compartment opening.

Step	Action
1	Place the analyzer upside down and slide the battery compartment door off.
2	Remove the old batteries. Remove the protective cover from the contact points of the new batteries.
3	Orient the + and – poles of the new batteries with the + and – labels in the battery compartment and slide the new batteries into place.
4	Slide the battery compartment door back into place. (Press down slightly while sliding the door on.)

Caution: Do not insert a single battery, particularly so that it will connect with the two center holes since this will short circuit the battery and cause damage to the analyzer. Use 9 volt lithium batteries.

Changing the Time and Date

Changing the time and date of the clock will not change the time and date of stored test records.

Caution: The analyzer's software recognizes when February has 29 days every four years, but does not automatically change the time for daylight savings time. The analyzer's clock must be set forward and backward for daylight savings time.

Step	Action
1	Press the soft key for Menu.
2	Press the "1" key for Status.
3	Press the soft key for CLKSET. The current time and date will be displayed and a cursor (-) will be flashing under the first digit of the hour. Both soft keys are activated as arrows to move the cursor. The clock is a 24 hour clock; therefore, AM or PM is not specified. The format for time is hours and minutes (hh:mm). The format for the date is month, day and year (mm/dd/yy) as indicated on the display.
4	Press an arrow key until the cursor is under the digit to be changed. To change the digit, press the correct numbered key. The new digit will appear and the cursor will move to the next position. If an invalid number is pressed, the cursor will not move to the next position but will remain in the current position until a valid number is pressed.
5	When all changes have been made, press the ENT key to set the clock. If an invalid number was not changed before the ENT key is pressed, the clock will revert to its original setting

Drying a Wet Analyzer or IR Link

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 IR Link may also be damaged by liquid contamination. Unplug the cable and dry the IR Link completely.

Cleaning the Analyzer and IR Link

Clean the display screen and the case using a gauze pad moistened with any of the following:

- ✧ A mild non-abrasive cleaner
- ✧ Detergent
- ✧ Soap and water
- ✧ Alcohol
- ✧ 10% bleach solution
- ✧ PDI® Super Sani-Cloth® (solution of IPA, n-Alkyl dimethyl ethylbenzyl- and benzyl- ammonium chloride)

Rinse the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam between the display screen and the case.

(PDI and Sani-Cloth are registered trademarks of Sani-System™ Brand Products, the Health Care Division of Nice-Pak Products, Orangeburg, NY, USA.)

Caution

Exercise universal safety precautions at all times when handing the analyzer, cartridges, and peripherals to prevent exposure to blood borne pathogens.

The analyzer is NOT designed to be sterilized or autoclaved by any method, including those using gas (e.g. steam, ethylene oxide, ect...) high heat, bead, radiation, or other chemical processes. The analyzer is splash resistant, but should not be immersed in any liquids.

Dispose of analyzer and peripheral electronics according to local, state, and/or national guidelines.

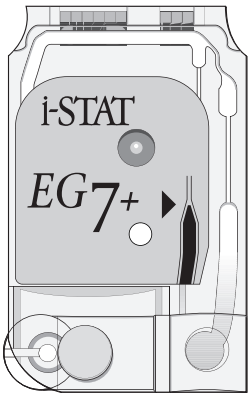
If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage.

Decontaminate the analyzer or IR Link whenever a specimen is spilled onto it or if the item is to be returned to i-STAT for repair. Wear gloves while performing the following procedure.

Step	Action
1	Prepare a 1:10 solution of household bleach by mixing one part of bleach with nine parts of tap water. This solution will maintain its germicidal action for a week.
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 in a plastic bag.

i-STAT CARTRIDGE

Contents

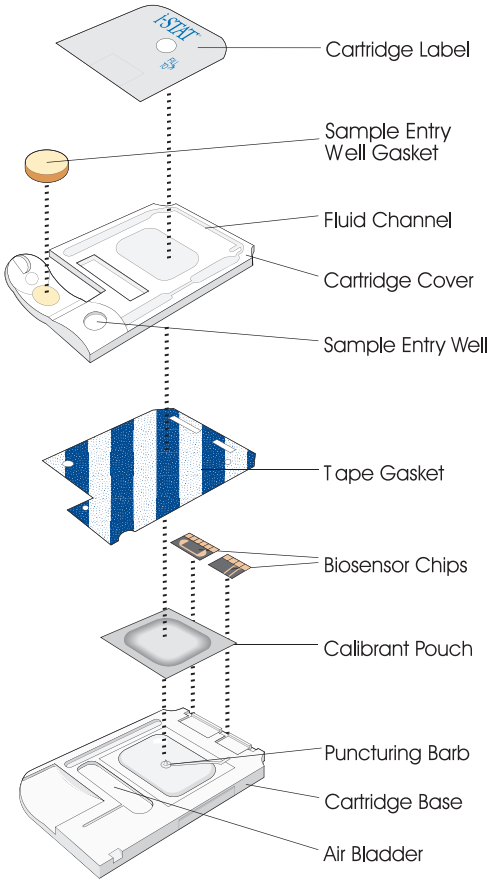


The unit-use disposable cartridge contains many of the subassemblies typically found in complex laboratory systems. Microfabricated thin film electrodes or sensors are assembled in unit-use cartridges containing:

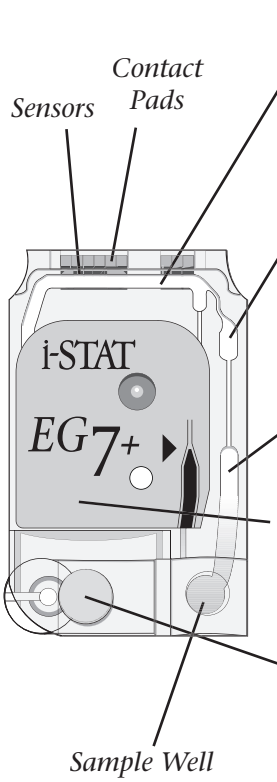
- calibrant solution in cartridges with sensors for blood gases, electrolytes, chemistries and hematocrit
- reagents in cartridges with sensors for coagulation
- sample handling system
- waste chamber
- an array of miniaturized sensors
- conductive pads to make electrical contact with the analyzer
-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

See the Cartridge and Test Information Sheets for test-specific details.

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 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 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 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 and sample remain contained within the cartridge during the testing cycle and subsequent disposal.
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 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

Cartridges that require thermal control at 37°C include heating elements on the underside of the sensor chips which are contacted and heated by the analyzer'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 three 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.

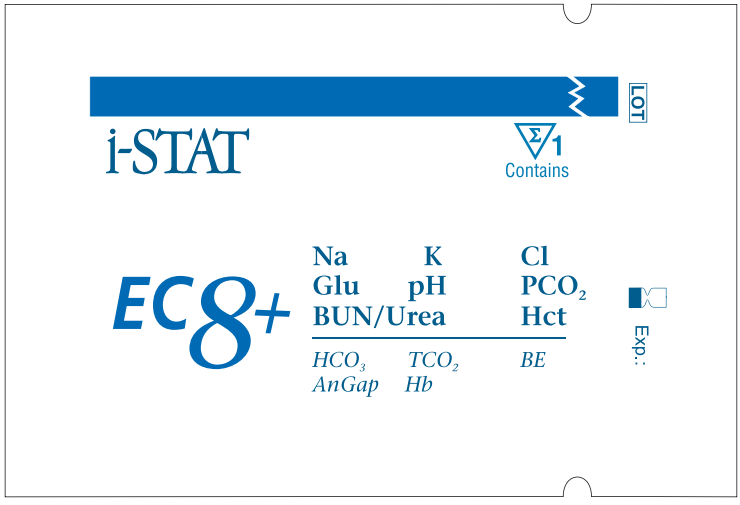
Packaging

Each cartridge is sealed in a foil pouch for protection during storage.

Labeling on the carton, box and pouch identify:

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

If the pouch 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 25 cartridges to come to room temperature. Cartridges in use may be stored at room temperature (18-30°C or 64-86°F) for two weeks. The cartridge box contains a line used to indicate the two-week 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.

BLOOD ANALYSIS MODULE 4

Overview

The Philips Medical Systems Blood Analysis Module* is a component for the Philips Medical Systems CMS and 24/26 Patient Monitors. Caregivers can perform blood analysis in real time right at the bedside using i-STAT cartridges, and see testing results along with other physiological parameters on the patient monitor's screen. The Blood Analysis Module performs the same basic functions as the i-STAT handheld analyzer, although several features of the user interface have been optimized or appropriately adapted for a patient monitoring environment.

For instructions on the installation and configuration of the module, refer to the CMS Installation and Site Preparation and the CMS Configuration manuals. The module can be customized via the Central Data Station for certain site specific testing characteristics. Refer to the Customization section of this manual for more information.

A server running a Blood Analysis Module interface is required to transmit test results from a Blood Analysis Module to the Central Data Station. Refer to Philips Medical Systems technical documentation and the Technical Bulletin: "Installation Guide for the Central Data Station to Receive Data from a Philips Clinical Data Server" in this manual for more information.

For care and cleaning of the module refer to the CMS User's Reference Guide.

For instructions on how to perform a test on the Blood Analysis Module refer to the Procedure for Cartridge Testing section in this manual.

* Formerly distributed by Hewlett-Packard and Agilent Technologies.

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 Electronice 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 on the i-STAT Portable Clinical Analyzer and by the 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 on the i-STAT Portable Clinical Analyzer and by the hours or tests on the i-STAT 1 Analyzer. For details and lockout options, see the Customization section of this manual.

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.

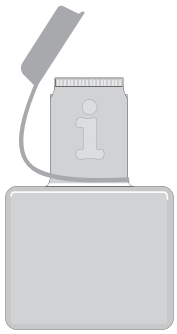
External Simulator

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.) Users should take care to firmly grasp the simulator during use and transport, to avoid drop damage.

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	0-90% 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.
- to access the Proficiency and Calibration Verification test paths on the i-STAT Portable Clinical Analyzer.

The external Electronic Simulator should be stored in the static-free 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 Central Data Station.

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.

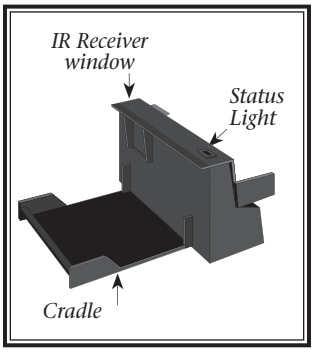
Clean the simulator with a gauze pad moistened with any of the cleaning agents approved for the analyzer, listed on page 2-11 of this manual.

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.

Introduction

The IR receiver in the IR Link converts the infrared signals from the i-STAT Portable Clinical Analyzer to electrical signals which are transmitted to the computer on which the Central Data Station program resides via cable. The IR Link also receives transmission of software or a customization profile from the Central Data Station or PC with Analyzer Programming software which it converts to infrared signals that are transmitted to the analyzer. The IR Link's cradle ensures proper alignment during transmission.



Specifications

Size	Length with printer arm: 6.17in (15.7cm) Width: 3.77in (9.6cm) Height: 2.35in (5.9cm)
Weight	3.49oz (98.9gm)
Power	Direct cable: Data Manager with power connector from Software Update Kit Ethernet: AC Power Adapter (output 5V DC)
Operating Temperature	15 - 40°C (59 - 104°F)
Storage Temperature	-20 - 50°C (-4 - 122°F)
Communication Link to and from Analyzer	Infrared transceiver
Communication Link to and from Data Manager	Serial (RS232) or Ethernet (using Network Downloader, Terminal Server, or Co-box)
LED Status Light	Off: no power or connection Red: power but no connection Green: power and connection Blinking: communication in progress
Indicator Sound	One high pitched beep: communication successful Three low pitched beeps: communication not successful

Power Requirements

Direct cable: The IR Link is powered from the Data Manager with the power connector from the Software Update Kit.

Ethernet: The IR link is powered by a separate 5V DC power adapter.

Note: the AC Power Adapter for the IR Link (5V) looks identical to the power adapter for the HP Printer (12V). They are NOT interchangeable.

Connections

Direct cable: IR Links can be connected to the Data Manager computer with the power connector from the Software Update Kit. A diagram of this connection can be found on page 15-5 of this manual.

Ethernet: The IR Link can be connected to a terminal server, a co-box, or a Network Downloader and connected to the Data Manager computer via ethernet. (Connections and programming specifications can be obtained from your Support Representative.)

Other computers: An IR Link can be connected to a computer running Windows 95 or above for the purpose of software updates using a Software Update Kit.

Caution: Be sure to install all cables and power supplies so they do not pose a trip hazard. When the IR Link is powered by an AC adapter, the socket outlet must be installed or located near the IR Link and must be easily accessible.

Transmitting Results from a Handheld Analyzer to the Central Data Station

Step	Action
1	Place the analyzer in the cradle of an IR Link..
2	Check that the status light on the IR Link is green.
3	Press the display key if the analyzer is not activated.
4	Press the * key.
5	Do not move the analyzer for the few seconds that TRANSMITTING is displayed.
6	Listen for a single high pitched beep that indicates successful transmission to the CDS.

The status light on the IR Link is green when the Data Manager is ready to receive transmissions, red when the CDS is not ready and, blinks red and green when transmission is in progress. A fast clicking sound will be heard during transmission. If a customization profile is being transmitted, the fast clicking will be followed by slow clicking. The receiver emits a single high pitched beep when the transmission is successful and three low pitched beeps when transmission was not successful.

Transmitted Information

The following information is transmitted from the analyzer for each test record:

- The date and time the test was performed
- Operator and Patient ID numbers
- All information entered by the operator
- Results
- Serial number of the analyzer
- Uses count of the analyzer
- Application software version in the analyzer
- CLEW standardization software in the analyzer

Troubleshooting

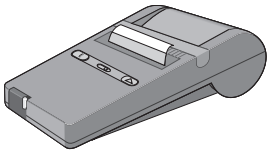
Condition	Problem	Solution
No status light (no power)	The computer with the Central Data Station software is off.	Turn the computer on.
	The cable at the computer or at the IR Link is loose.	Check cables.
	The 5V DC power supply to the power adapter on the terminal server, co-box or Network Downloader may be un-plugged.	Check that the 5V DC power supply is plugged in and that the wall outlet is active.
	The IR Link is damaged.	Substitute another IR Link and see if the status light turns red or green. If it does, replace the original IR Link.
Status light red	The computer is on but the Central Data Station software is not active.	Activate the Central Data Station program.
	A power surge has interrupted communication between the computer and the terminal server, co-box, Network Downloader, and/or the IR Link.	Exit the Central Data Station (CDS) application and turn the computer off. Disconnect and reconnect the cables on the terminal server, co-box, or Network Downloader at the computer and IR Links. Reboot the computer and local terminal server.
Status light green but no transmission occurs	A power surge has interrupted communication between the computer and the terminal server, co-box, Network Downloader and/or the IR Link.	Exit the Central Data Station application and turn the computer off. Then reboot the computer.
Status light indicates that transmission occurred but no results on Central Data Station	Analyzer: Date may be wrong.	Check status page and change date and time if neccessary.
	CDS 5: New data is not displayed automatically.	Click on the Refresh button.
	The data may be sorted by another column other than date and time.	Click on the Date and Time column.
	There may be no data in the specified date range.	Check the date range.

Wet or Contaminated IR Link

The IR Link may be damaged by liquid contamination. Unplug the power supply from the outlet and dry the IR Link completely. Use the procedure described for the analyzer to decontaminate an IR Link.

HEWLETT PACKARD PORTABLE PRINTER

Overview

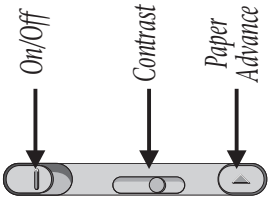


A Hewlett-Packard HP 82240B Infrared Portable Printer can be used with the i-STAT Portable Clinical Analyzer to obtain a printout of a test record at the point of care. The printer can be attached to an i-STAT IR Link or an i-STAT Printer Cradle (IR Link without receiver) to ensure proper alignment between analyzer and printer.

The printer can be powered by four 1.5 volt alkaline batteries or an AC adapter. Battery life for the alkaline batteries is approximately 450 test records. After about 10 minutes of inactivity, the printer (without AC adapter) will switch to low power mode to conserve batteries. To reactivate the printer, press the paper advance button.

To prolong battery life, set the print contrast to the lightest comfortable setting, turn the printer off when not in use, and use the optional AC adapter when possible. Because the printer may require supplemental power during heavy printing, batteries should be installed when using the AC adapter.

Specifications



Dimensions	Height: 2 in (5 cm) Width: 3.5 in (8.9 cm) Depth: 7.25 in (18.4cm) Weight: 0.95 lbs (431 gm)
Power	Four 1.5 volt alkaline batteries Power adapter for AC outlet
Communication Link	IR light-emitting diode
Paper	Thermal, 2.25 in x 80 ft roll
Indicator	Red power on light
Switches	On/Off, Contrast, Paper Advance
Printing method	Thermal line printing
Printing speed	24-character line per second, maximum
Temperature	Operating: 0 - 50°C (32 - 122°F) Storage: ¯40 - 60°C (¯40 - 140°F)
Humidity	5 to 95% relative humidity at 40 °C (104 °F)

Supplied with Printer

- Four 1.5 volt alkaline batteries
- One roll of paper

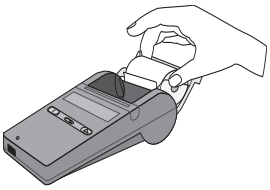
Can be Ordered

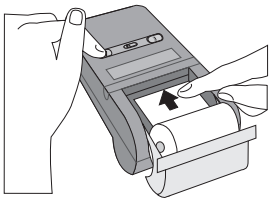
- AC adapter
- Printer Cradle or IR Link

Paper

Paper can be ordered from the manufacturer/distributor or purchased locally: HP 82175 black-printing thermal paper is recommended. Paper that is not attached to the roll is recommended.

Loading the Paper





Step	Action
1	Open paper compartment door.
2	Make sure that leading edge of paper in cut evenly.
3	Position paper in door as shown in illustration.
4	Turn the printer on by switching the on/of switch to the on (|) position.
5	While pushing paper into slot, hold down the paper advance switch until paper emerges. If paper jams, pull backwards very slowly.
6	Place paper in compartment and close the door.

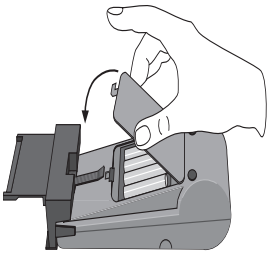
Caution

- Do not operate printer without paper.
- Do not pull paper through mechanism, use the paper advance switch.
- Do not pull paper backward through printer.
- Do not run paper to end of roll if paper is attached to its inner core. Paper supplied by i-STAT is not attached.

Replacing the Batteries

Install fresh batteries when any of the following conditions occur:

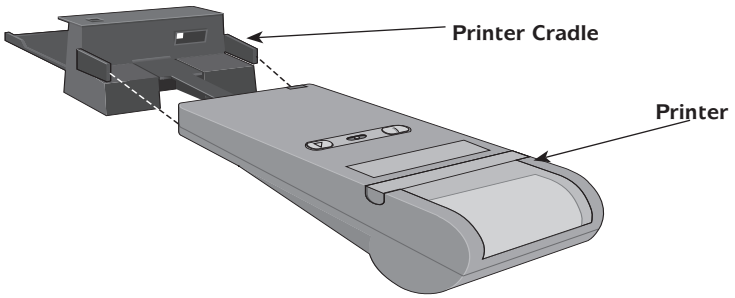
- Print contrast is uncomfortably low, even when the print control is set to highest contrast.
- Printing slows because the print head moves across the paper at a much slower speed. (When a large amount of information—more than 200 characters—is transmitted by the analyzer, printing slows because the printer pauses momentarily before printing each new line. However, the print head moves across the paper at normal speed. This is not a symptom of low batteries.)
- Printing halts before all information on a line has been printed.
- Battery condition index printed at the end of the self test is 1 or 0.



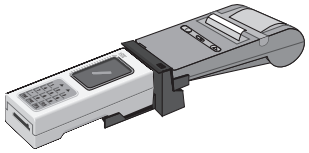
Step	Action
1	Turn the printer upside down and open the battery compartment as shown in the illustration.
2	Remove old batteries.
3	Align fresh 1.5 volt alkaline batteries with the + and - symbols in the battery compartment and insert the batteries.
4	Replace the battery compartment door.

Attaching Printer to Printer Cradle or the IR Link

Slide the Portable Printer into the Printer Cradle.



Printing Displayed Results



Step	Action
1.	Place analyzer in IR Link cradle or align the IR window of the printer with the IR window of the analyzer.
2.	Turn the printer on by switching the on/off switch to the on (|) position. The red indicator will light. If the printer is on but the indicator light is off, press the paper advance key to reactivate the printer.
3.	Display the test record to be printed.
4.	Press the PRT key on the analyzer.
5.	Do not move the printer or the analyzer until the PRINTING... message is removed from the screen.

Printing Stored Results

Step	Action
1	Press the Menu soft key, press the "2" key for Stored Results, then press the "2" key for Print Results.
2	Use the soft keys to page up (↑) or down (↓) through the 10 pages of stored results. Press the 1 to 5 keys to select the desired record(s) to be printed from each page. When a numbered key is pressed, the number selected will be displayed in reverse video (dark background with light number). To deselect a record, press the number key again.
3	When all test records are selected, place the analyzer in IR Link cradle or align the IR window of the printer with the IR window of the analyzer.
4	Turn the printer on by switching the on/off switch to the on (|) position. The red indicator will light. If the printer is on but the indicator light is off, press the paper advance key to reactivate the printer.
5	Press the PRT key on the analyzer.
6	Do not move the printer or the analyzer until the PRINTING... message is removed from the screen.

WHAT IS PRINTED

```
i-STAT EG7+
Pt: 973621150
Pt Name: _____________
Na ________141 mmol/L
K __________4.4 mmol/L
TCO2 _______ 41 mmol/L
iCa _____ 1.24 mmol/L
Hct _______39%
Hb* ________ 13 g/dL
      *via Hct
At 37C
pH_______ 7.380
PCO2 _____ 38.4 mmHg
PO2 ________ 95 mmHg
HCO3 _______ 40 mmol/L
BE_________ 17 mmol/L
sO2* _______95 %
     *calculated
At Patient Temp
pH_______ 7.415
PCO2 _____ 34.5 mmHg
PO2 ________ 85 mmHg
Patient Temp   36.2C
Sample Type_ : ART
   07MayO2  16:41
Oper: 852
Physician:___________
Ser#  37106
Ver:  JAMS043B
      CLEW A23
```

Caution

- Use only the AC adapter supplied by manufacturer/distributor.
- Do not allow the power supply to become a trip hazard.
- Do not disturb either the analyzer or the printer until printing is complete since this may cause corruption the printout. If printing is interrupted, reprint the resutls.
- When the battery index approaches 1, the printer may skip one or more lines of printing. Take care when reading results from the printout.

Aborting Printing

To stop printing before all test records are printed, press the * key.

What is Not Printed

Test records with quality check codes or INVALID OR NO DATA can not be printed.

Self-test and Battery Condition

If the printer is not operating properly, run the self-test. If the printer fails the self-test, rerun the test to verify the results. If the printer fails again, it requires service. The self-test can be run using the optional AC adapter; however, the battery condition index will not be accurate. To test the battery condition, disconnect AC adapter, turn off printer, and then hold down the paper advance indicator while turning the printer on, then release.

SELF-TEST

The battery condition index is a number from 0 to 5 (0,1 = low, 4,5 = high) that describes how much useful battery life remains. Regardless of the battery condition index, install new batteries when any of the symptoms of low batteries appear. If the printer is to be operated from batteries without interruption for an extended period of time, it is recommended that new batteries be installed before the index has dropped to 1.

Controlling Printhead

If the printer is turned off while it is printing, the print head may stop in the middle of a line. To return the printhead to the left side of the paper, turn the printer on, then off. Leaving the print head in the middle of a line causes temporary lightening of characters in that column; continued printing restores the print contrast in that position.

Incorrect Character

A hatched-box character is printed if the printer detects incorrect data due to interference with or interruption of the stream of incoming information. Common causes for incorrect data are improper positioning of the printer with respect to the analyzer, obstruction of the infrared beam, or interference from another infrared source. Occasionally, the printer will print hatched-box characters when the analyzer is transmitting to the Central Data Station.

If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the analyzer. 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 analyzer data, the printer requires service and the printed results must not be used.

Potential for Radio/ TV Interference

The printer generates and uses radio frequency energy and may cause interference to radio and television reception. The unmodified printer has been tested and found to comply with the limits for a Class B computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference in a residential installation. However, there is no guarantee that interference will not occur in a particular installation. In the unlikely event that there is interference to radio or television reception (which can be determined by turning the printer off and on, disconnecting the AC adapter, or removing the batteries), correct the interference by one or more of the following measures:

- Relocate the product with respect to the receiver.
- Plug the AC adapter into an outlet on a different branch line than the receiver.

PORTABLE PRINTER TROUBLESHOOTING

Not Printing

If the power-on indicator light is not lit, turn the printer on by moving the off-on switch to the right. If the switch is in the on (|) position, press the paper advance switch to reactivate the printer. If the indicator light does not light, change the batteries.

If the power-on indicator light is lit, the most recent set of test results cannot be printed unless patient identification number is entered or actively bypassed by pressing the ENT key twice. If the identification numbers have been entered, reseat analyzer in cradle with the analyzer's LED facing the IR Interface's receiver.

Stops Printing

If the power-on indicator light goes out, change batteries as described earlier. If the power-on indicator light is lit, do not lift the analyzer out of cradle until printing is completed.

Light Print

Move Print Contrast switch to right. If the switch is all the way to right, change the batteries as described earlier.

Garbled Print, Missing Characters or Symbols

If the analyzer is moved (lifted out of the cradle momentarily) while the printer is still printing, the printed information may be garbled, may be missing letters and numbers, or may include hatched box symbols. If the cradle is not used to align the printer and analyzer, other infrared signals, including those from other analyzers, can interfere with the transmission. Occasionally the printer will print hatched box symbols when the analyzer transmits to the Central Data Station.

MARTEL MCP8850B INFRA-RED THERMAL PRINTER

Overview

The Martel MCP8850B Infra-Red Thermal Printer can be used with the i-STAT Portable Clinical Analyzer to obtain a printout of a test record at the point-of-care. The printer can be attached to an i-STAT IR Link or an i-STAT Printer Cradle (IR Link without receiver) to ensure proper alignment between analyzer and printer.

The printer can be powered by four 1.5 volt alkaline AA batteries or an AC adapter. After about 10 minutes of inactivity, the printer will switch to low power mode to conserve the batteries. To reactivate the printer, press the Mode button.

To prolong battery life, turn the printer off when not in use, and use the optional AC adapter when possible. Because the printer may require supplemental power during heavy printing, batteries should be installed when using the AC adapter.

Specifications

Dimensions	Height: 2.3 in (58 mm) Width: 3.6 in (91 mm) Depth: 7.3 in (185 mm) Weight: 0.94 lbs (425 gm)
Power	Four 1.5 volt alkaline AA batteries Power adapter for AC outlet: 6V, 2A
Communication Link	IR light-emitting diode
Paper	Thermal, 2.25 in (57 mm) x 80 foot (24.4 m) roll
Status Indicator	Green power-on light
Button	Mode button used to power printer on or off, to feed paper through the printer, or to signal the printer to perform the Self Test.
Printing Method	Thermal line printing
Printing speed	3 lines per second (typical)
Temperature	Operating: 0 - 50°C (32 -122°F) Storage: -20 - 60°C (-4 - 140°F)

Supplied With Printer

- Four 1.5 volt alkaline AA batteries
- One roll of paper

Can Be Ordered

- AC adapter
- Printer Cradle or IR Link
- IR Link Printer Adapter

Paper

Paper can be ordered from your local representative. The Abbott list number for the thermal paper is 06F17-11.

Loading Paper

The printer will automatically detect when the printer paper has run out. The Status indicator will flash repeatedly to denote that the paper has run out.

Step	Action
1	Open the paper cup lid and remove the remaining paper using the Mode button. **Do not pull paper through the printer mechanism.**
2	Reel off a few centimeters from a new roll of paper and check that the end has a clean, straight edge.
3	Slide the leading edge of the paper through the paper entry slot, with the leading edge of the paper feeding forwards from the bottom of the roll, until you feel resistance.
4	Press the Mode button and feed the paper through the printer mechanism. Keep the Mode button depressed until enough paper is fed through the printer mechanism to pass through the paper exit slot.
5	Sit the new paper roll in the paper cup and close the lid.
Note:	Should the paper become creased or out of line when feeding in a new roll, cut the end off the paper roll, feed out the creased paper using the Mode button, and reload ensuring the paper has a clean straight edge.

Caution

- Do not operate printer without paper
- Do not pull paper backward through the printer
- Do not run paper to end of roll if paper is attached to its inner core. Paper supplied by i-STAT is not attached.

Paper Tear Procedure

When removing 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.

Replacing the Batteries

Power is supplied to the printer from 4 alkaline AA batteries. The Status indicator will flash three times repeatedly to show that the batteries are nearly exhausted. Install fresh batteries if this occurs.

Step	Action
1	Ensure the printer is switched off. The printer is off if the Status light is not lit.
2	Unclip battery cover and remove old batteries.
3:	Align fresh 1.5 volt alkaline AA batteries in the orientation shown in the battery compartment.

Batteries should be removed if the printer is to be left unused for long periods of time.

Attaching Printer to the Printer Cradle or the IR Link

Slide the Adapter onto the Portable Printer until "click" is obtained. Then slide Adapter/printer into the printer cradle. See below:



Detaching Printer from the Printer Cradle and Adapter

Turn assembly over. Gently lift up on black cradle tab. Slide printer/Adapter out. To remove Adapter from printer, lift center tab and slide Adapter away.



Power On and Off Procedure

When the Status indicator light is off, the printer is off. A brief press of the Mode button turns the printer on, the Status indicator light will illuminate green, and the printer mechanism will reset. A brief press of the Mode button will turn the printer off. After about 10 minutes of inactivity, the printer will switch to low power mode to conserve the batteries. To reactivate the printer, press the Mode button.

Power On Self Test

The self test procedure will check most of the printer functions, except for the infrared interface, i.e. printer mechanism, control circuitry, firmware version, and print quality. When the printer is off, press and hold the Mode button depressed for approximately 2 seconds. Release the Mode button and the printer will power on and print a self-test report.

Printer Mechanism – Head Thermal Limit

After extensive printing, the print head temperature may rise to an unusable level. If this occurs, the Status indicator light will flash twice repeatedly and printing will be suspended until the print head temperature returns to normal levels.

Printing Displayed Results

Step	Action
1	Place analyzer in IR Link cradle or align the IR window of the printer with the IR window of the analyzer.
2	Turn the printer on by pressing the Mode button. The green Status indicator will light.
3	Display the test record to be printed on the analyzer.
4	Press the PRT key on the analyzer.
5:	Do not move the printer or the analyzer until the PRINTING… message is removed from the analyzer's display screen.

Printing Stored Results

Step	Action
1	Press the Menu soft key, press the "2" key for Stored Results, then press the "2" key for Print Results.
2	Use the soft keys to page up (↑) or down (↓) through the ten pages of stored results. Press the 1 to 5 keys to select the desired record(s) to be printed from each page. When a numbered key is pressed, the number selected will be displayed in reverse video (dark background with light number). To deselect a record, press the number key again.
3	When all test records are selected, place the analyzer in IR Link cradle or align the IR window of the printer with the IR window of the analyzer.
4	Turn the printer on by pressing the Mode button. The green Status indicator will light.
5	Press the PRT key on the analyzer.
6:	Do not move the printer or the analyzer until the PRINTING… message is removed from the screen.

Cleaning the Printer

Clean the printer with a gauze pad moistened with any of the following approved cleaning agents:

- 10% bleach solution
- Isopropyl alcohol (IPA)
- PDI® Super Sani-Cloth® (solution of IPA, n-Alkyl dimethyl ethylbenzyl- and benzyl- ammonium chloride)

Rinse the printer using another gauze pad moistened with water and dry.

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

Caution

- Use only the AC adapter supplied by the manufacturer/distributor for this particular product.
- Always place the printer on a stable surface or in a location where it will not cause injury if dropped.
- Do not allow the power supply to become a trip hazard.
- Do not disturb either the analyzer or the printer until printing is complete since this may cause corruption of the printout. If printing is interrupted, reprint the results.
- If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the analyzer. 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 analyzer data, the printer requires service and the printed results must not be used.

DATA MANAGEMENT 8

Introduction

The i-STAT System provides comprehensive data management capabilities to ensure that blood analysis results obtained at the patient bedside can be integrated into the hospital's various information systems. The Data Manager computer system is capable of receiving simultaneous transmissions from several different types of blood analysis instruments. The instruments may include, but are not limited to:

- i-STAT Portable Clinical Analyzer (PCA)
- i-STAT-1 Analyzer
- AccuData GTS
- Philips Blood Analysis Module via the Clinical Data Server

This section describes the information management capabilities of the i-STAT System and how the components can be integrated to meet the needs of point-of-care data management.

Components

The i-STAT 1 Analyzer

With each cartridge use, the analyzer allows entry of:

- operator identification number
- patient identification number
- proficiency identification number
- simulator serial number
- cartridge lot number
- glucose strip lot number (if applicable)
- control lot number
- calibration verification lot number
- comment codes for patient and control results
- chart page information
  - sample type
  - patient temperature
  - FIO_2
  - free fields: three fields, up to 9 characters each

The Portable Clinical Analyzer

With each cartridge use, the analyzer allows entry of:

- ❑ operator identification number
- ❑ patient identification number
- ❑ chart page information
  - patient temperature
  - FIO_2
  - free fields: three fields, up to 6 characters each
  - sample type

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

The Data Manager

A validated and qualified Data Manager computer system may be purchased from i-STAT Corporation for use with the Central Data Station 5 software application. The end user also has the option to purchase the computer system from another hardware vendor. In those cases, i-STAT Corporation will provide a minimum requirement specification to ensure proper operation and functionality of the Central Data Station 5 software application.

i-STAT Corporation and its distributors can supply the following hardware:

- i-STAT Data Manager computer system and its peripherals
- IR Downloader (Serial and Network) and required components
- IR Link and required components

i-STAT Central Data Station Version 5 Software

This is i-STAT's primary data management application. It supports all blood analysis instruments mentioned above via a combination of serial and/or network communications.

Please see the "Central Data Station 5" section of this System Manual for additional information on installation, setup, and configuration of this application.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Records, Control Results, Calibration Verification Results, and Proficiency Results (external quality control).

Note: All data (regardless of type) downloaded from the Portable Clinical Analyzer and the Philips Blood Analysis Module will only appear in the Results Data Viewer.

Additional features include the ability to:

- ❑ view patient and quality results by patient identification number, operator identification number, date/time chronological order, location, department, or analyzer serial number.
- ❑ edit identification numbers associated with results (original numbers are automatically retained for reference)
- ❑ add comments to records
- ❑ send results (automatically or by manual selection) to another information system such as an LIS or HIS

- archive records
- export records to ASCII text files
- manage instruments
- manage operators
- manage inventory
- manage policy exceptions
- monitor operator competence
- monitor LIS entry exceptions
- monitor download compliance

Downloader and Downloader/ Recharger

The Downloader and Downloader/Recharger are available for use with ethernet cabling (network format) and direct wiring (serial format). The Network Downloaders convert serial data transmitted from the i-STAT 1 Analyzer via infrared transmission to TCP/IP, which then delivers the data to the Data Manager using the hospital's ethernet system.

Through a customizable feature, transmissions can be performed automatically when an analyzer is placed in the Downloader or Downloader/Recharger.

Please contact your i-STAT Support Representative for additional information related to specifications and configuration requirements for your facility.

IR Link

A Portable Clinical Analyzer communicates to the Data Manager via an Infrared Interface Link (IR Link). The IR Link converts infrared signals received from the analyzer to electronic signals, and passes them to the Data Manager. To transmit results, place an analyzer in the IR Link and press the star (*) key. A single IR Link can be used to collect results from a limitless number of Portable Clinical Analyzers, one at a time. Transmission time is usually less than 15 seconds.

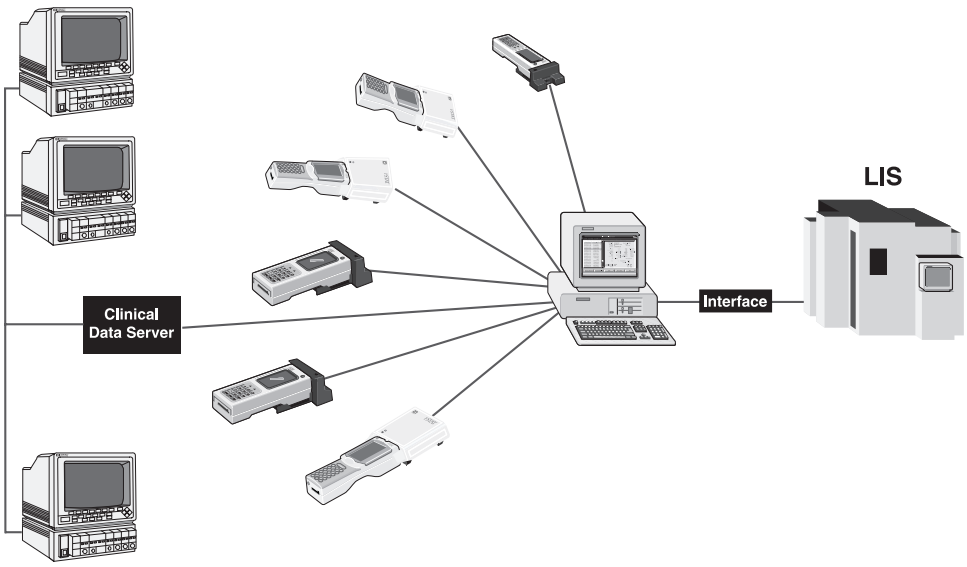
LIS/HIS Interface

The Data Manager typically connects to the Laboratory or Hospital Information System. The user can manually select records to send or the Central Data Station application can be configured to automatically transmit records to the alternate system as they are received. There are four data transmission protocols available:

- AME (US only): this protocol is used to simulate manual keystrokes when connected to a hospital's LIS or HIS. This protocol is installed and configured only by i-STAT Interface Operations department.
- ASTM: Data transmission conforms to ASTM E1381-95 and E1394-97 standards. Specifications for this protocol can be obtained from your i-STAT Support Representative.
- HL7: This is a robust Electronic Data Interchange (EDI) interface. Data transmission conforms to HL7 v2.4 and is based upon the CIC observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science (NCCLS) in the US under Document POCT-1-A. An activation key is required to use this protocol. Contact your i-STAT Support Representative to obtain this license key. This interface requires a receiver software from the LIS vendor.
- Data File: Formats the CDS file for third party use.

Standard Data Management Configuration

The figure below shows the standard i-STAT Data Management configuration. Downloaders, Downloader/Rechargers, and IR Links are placed in end-user departments and allow handheld analyzers to transmit results to the Data Manager. The results from the Philip Medical Systems Blood Analysis Module can also be interfaced via the Philips Clinical Data Server. The Data Manager then interfaces to the LIS/HIS.



Connecting Components

There is only one option available for physically connecting remote Downloaders, Downloader/Rechargers, and IR Links to a Data Manager. That option is:

- Ethernet Connection

  The i-STAT System connects terminal servers to Ethernet ports to allow a Local Area Network (LAN) or Wide Area Network (WAN) to transport data from a Downloader, Downloader/Recharger, or IR Link to the Data Manager using the TCP/IP protocol. Often, no additional wiring needs to be installed, but network ports or 'drops' may need to be installed in walls at appropriate locations. Also, power outlets will need to be available at each location in order to provide power to the Downloaders, Downloader/Rechargers or terminal servers. Using this method allows an unlimited number of Downloaders, Downloader/Rechargers, and IR Links to be connected to the Data Manager.

SAMPLE COLLECTION 9

SPECIMEN COLLECTION

Overview

The specimen used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient's current status.

Only fresh whole blood samples are recommended for use with the i-STAT System.

Specimens should be collected according to the facility's policies and procedures. The following precautions (taken from the references at the conclusion of this section) can help avoid potential sources of error prior to filling a cartridge.

VENIPUNCTURE - GENERAL

Overview

Venipunctures are typically performed for:

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

Observe the following precautions:

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 to prevent changes in ionized calcium and pH results.

Muscle Activity

Avoid extra muscle activity, such as clenching and unclenching the fist, which may increase potassium results.

Hemolysis

Avoid hemolysis (bursting of red cells) by

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

Hemolysis will cause an increase in potassium results and a decrease in calcium results.

Tube 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
- ✧ Heparin
- ✧ EDTA - Na_2, K_3 or K_2
- ✧ Oxalate, fluoride, iodoacetate

If a citrate tube is drawn, draw a 5mL plain discard tube before drawing the heparin tube.

VENIPUNCTURE - pH, PCO2, ELECTROLYTE, CHEMISTRY, AND HEMATOCRIT TESTS

Anticoagulants

If the sample can be tested in a cartridge immediately, a plain syringe can be used. If a cartridge cannot be filled immediately the sample should be collected in a blood collection tube with sodium heparin or 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. Blood collection tubes contain approximately 15 U/mL when filled to capacity.

Samples collected in EDTA anticoagulant may be used with the i-STAT Glucose cartridge. 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 cartridge.** 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.

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 with *and without* anticoagulant may also cause decreased PCO_2 (and calculated 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 analysis because of the potential for decreased PCO_2 (and calculated 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.

Mixing

Gently mix blood and anticoagulant 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 when testing venous samples for ionized calcium, pH and PCO_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.

Time to Test

For the most accurate results, test samples immediately after drawing. Samples for lactate must be tested within 3 minutes. Samples for blood gases and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.

If testing is not immediate, remix blood collection tubes by gentle inversion at least 10 times. Roll syringes 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. 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 mix a sample in a 1.0 cc syringe.

VENIPUNCTURE - COAGULATION TESTS

Blood Flow

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

Plastic

The sample for testing should be drawn into a **plastic** collection device (syringe or blood collection tube) containing **no anticoagulant**, **clot activators**, or **serum/plasma separators.** Any transfer device (dispenser, capillary tube, pipette or syringe) **must be plastic** and must **not contain anticoagulant**.

Samples collected into glass tubes or syringes, or in tubes containing anticoagulants, activators, or separators cannot be used with the i-STAT coagulation cartridges.

Note: NCCLS 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.

Time to Test

The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.

Repeat Test

If a repeat measurement is needed, a fresh sample must be obtained.

ARTERIAL PUNCTURE - GENERAL

Overview

Arterial punctures are performed to access gas exchange status.

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 PUNCTURE - BLOOD GAS, ELECTROLYTE, CHEMISTRY, AND HEMATOCRIT TESTS

Evacuated Tubes

Evacuated or other blood collection tubes are not recommended for blood gas analysis.

Syringes and Anticoagulant

If the sample can be tested in a cartridge immediately, a plain syringe can be used.

If a cartridge cannot be filled 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).

If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.

Fill syringes to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under filling syringes will cause higher heparin-to-blood ratios which will decrease ionized calcium results due to binding. Under filling syringes with liquid heparin will also dilute the sample causing results to be affected.

Mix

Mix blood and anticoagulant 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. Discard the first 2 drops of blood.

Exposure to Air

Avoid or remove immediately any air drawn into the syringe and maintain anaerobic conditions.

Time to Test

For the most accurate results, test samples immediately after draw. Samples for lactate must be tested within 3 minutes. Samples for blood gases and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.

If testing is not immediate, remix the syringe 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, then discard the first two drops of blood. 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 mix a sample in a 1.0 cc syringe.

Sample on Ice

Fill the cartridge before icing the sample for transport. Icing will increase the potassium and will affect oxygen levels in samples collected in plastic syringes.

ARTERIAL PUNCTURE - COAGULATION TESTS

Blood Flow

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

Plastic

The sample for testing should be drawn into a **plastic** collection device (syringe or blood collection tube) containing **no anticoagulant**.

Samples collected into glass tubes or syringes, or in tubes containing anticoagulants, cannot be used with the i-STAT coagulation cartridges.

Note: NCCLS guidelines recommend 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.

Time to Test

The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.

Repeat Test

If a repeat measurement is needed, a fresh sample must be obtained.

INDWELLING LINE

Blood Gas, Electrolyte, Chemistry

Back flush 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.

Coagualtion Cartridges

If blood **must** be drawn from an indwelling line, possible heparin contamination should be considered. The line should be flushed with 5mL of saline and the first 5mL of blood or six dead space volumes of the catheter should be discarded.

SKIN PUNCTURE

Device

Use a puncture device that provides free-flowing blood. Inadequate blood flow may produce erroneous results.

Hemolysis

Avoid hemolysis (bursting of red cells) due to vigorous massaging or "milking."

Hemolysis will cause an increase in potassium results and a decrease in calcium results.

To increase blood flow, massage a finger gently from about three inches from the tip to the fleshy portion of the tip.

Avoid hemolysis by allowing residual alcohol to dry over the puncture site.

Tissue Fluid For tests other than PT/INR cartridges, 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.

Air Avoid drawing air into the capillary tube.

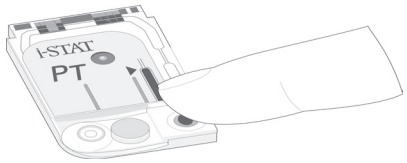
Anticoagulant Most heparinized capillary tubes are not suitable for electrolyte measurements, especially ionized calcium, due to the high concentration of heparin (50 U/mL or more). Use balanced heparin tubes or plain tubes.

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.

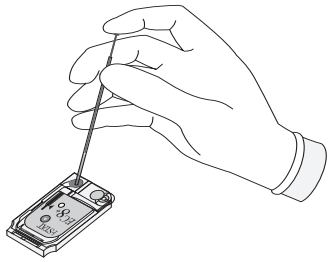
ACT Cartridges Skin puncture samples are not recommended for ACT measurements.

PT/INR Cartridges i-STAT PT/INR 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.



SAMPLE TRANSFER DEVICES

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



Do not use dispensers that would introduce air into the sample when ionized calcium, pH, or PCO_2 are being measured.

For coagulation testing the dispenser **must be plastic** and must **not contain anticoagulant**.

Capillary Tube While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred.

Capillary tubes can be used to transfer sample from a tube to a cartridge. For coagulation testing, the capillary tube **must be plastic** and must **not contain anticoagulant**.

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

Take care not to draw air with the sample when ionized calcium, pH or PCO_2 are being measured.

For coagulation testing, the syringe **must be plastic** and must **not contain anticoagulant**.

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PROCEDURE FOR HANDLING CARTRIDGES 10

PREPARATION FOR TESTING

Select the Cartridge Select the appropriate cartridge for the test or tests required. While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling and Quality Check failures.

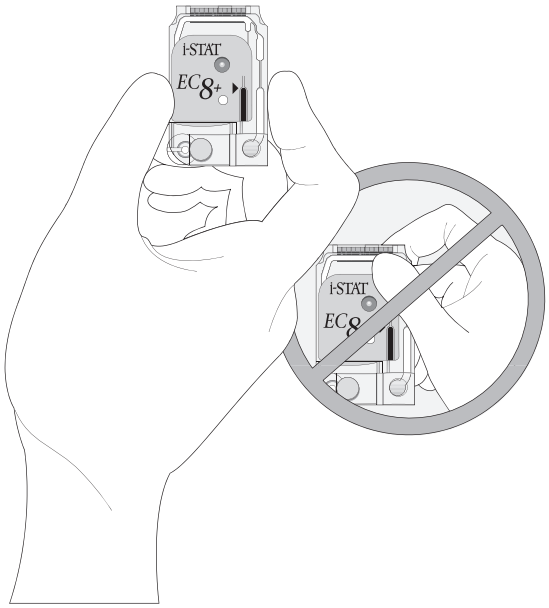
Room Temperature A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at the temperature of the room where they are to be used. Condensation on a cold cartridge may prevent proper contact with the analyzer. Allow a single cartridge to stand for 5 minutes and a box of cartridges for 1 hour at room temperature before use. Use a cartridge immediately after removing it from its protective pouch — prolonged exposure may cause a cartridge to fail a Quality Check. If the pouch 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. Cartridges may be stored at room temperature for two weeks.

Contact Pads Do not contaminate the contact pads with fingerprints or talc from gloves as the analyzer may not be able to make proper contact with the cartridge.

Calibrant Pack Do not apply pressure to the central area of the label as the calibrant pack inside could burst prematurely.

Air Vent 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.

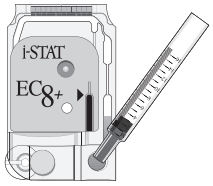
Contamination To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.

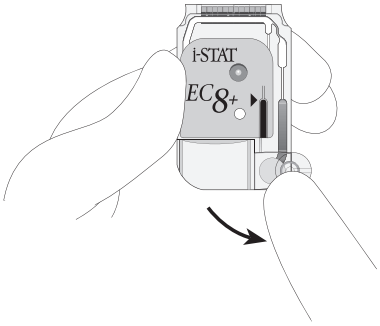


FILLING AND SEALING CARTRIDGE USING TRANSFER DEVICE

Procedure

STEP	ACTION
1	Place the cartridge on a flat surface or hold it in a horizontal position.
2	Direct the tip of the syringe, capillary tube or dispenser into the sample well.
3	Dispense sample slowly and steadily until it reaches the fill mark indicated on the cartridge label. Leave some sample in the sample well.
4	Fold the snap closure over the sample well.
5	Press the rounded end of the closure until it snaps into place.

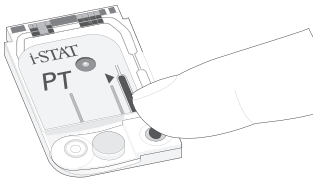




Caution Do not hold cartridge between the fingers if using a syringe with needle to fill.

FILLING AND SEALING PT/INR (PROTHROMBIN TIME) CARTRIDGES USING DIRECT FINGERSTICK SAMPLING

STEP	ACTION
1.	Remove cartridge 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. Allow finger to dry thoroughly before sampling.
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.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge 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 cartridge port.
2	Push the cartridge slowly and smoothly into the 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.

PATIENT AND CONTROL SAMPLE TESTING 11

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.

- 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 LCK message will remain on the screen until the analyzer unlocks the cartridge.
- The analyzer may be contaminated with blood from prior use. Whenever handling the analyzer, cartridges, and peripherals exercise universal precautions to protect yourself from blood-borne pathogens. Universal precautions are those procedures and practices, such as the wearing of gloves, designed to protect personnel from blood-borne pathogens as well as pathogens from other body substances. These precautions are based on the assumption that blood, body fluids or tissue can contain infectious agents and, therefore, should be treated as a biohazard. For more detailed information, please refer to either the CDC/NIH manual, "Biosafety in Microbiological and Biomedical Laboratories", Fourth Edition, 1999, or the WHO "Laboratory Biosafety Manual", Second Edition, 2003.

  To protect from nosocomial infections, decontaminate analyzers periodically and whenever blood is spilled or transferred to an analyzer. See instructions under "Cleaning the Analyzer and IR Link" in section 2 of this manual.
- 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 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.
- 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.

PROCEDURE FOR THE PORTABLE CLINICAL ANALYZER

The following procedure is used to test patient samples and quality control samples on the i-STAT Portable Clinical Analyzer. See the sections on Calibration Verification/Linearity and Proficiency Testing/External Quality Control for testing procedures for these sample types.

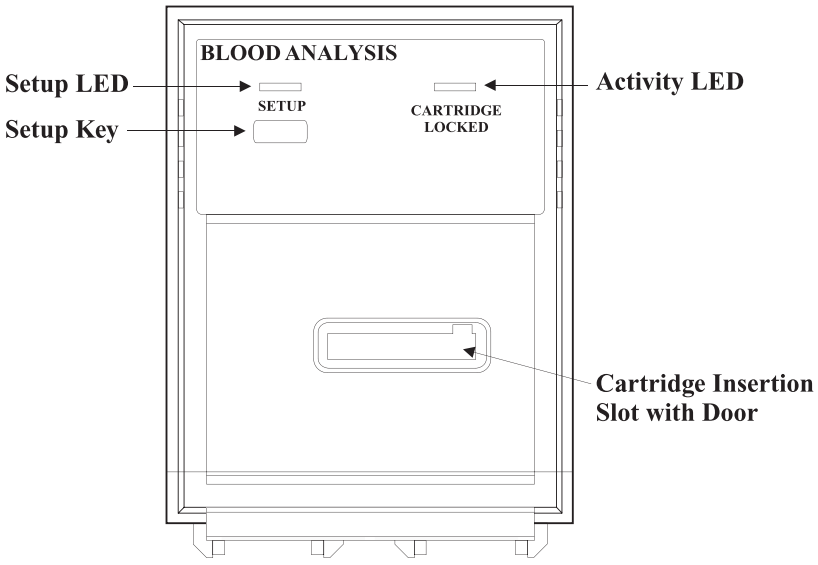
Display	Action	Analyzer Response/ Comments
The display may be blank or a result may be displayed.	Insert filled cartridge into analyzer's cartridge port.	Test cycle initiated. If at any point during the test cycle a quality check fails, the test cycle will halt and a message will be displayed indicating the condition and the corrective action.
LCK Enter Operator ID	Enter Operator ID number and press the ENT key.	If enabled, the analyzer will prompt for the ID number to be repeated. If the repeat number does not match, the ID numbers must be entered twice again.
LCK Enter Patient ID	Enter Patient ID number and press the ENT key.	If enabled, the analyzer will prompt for the ID number to be repeated. If the repeat number does not match, the ID numbers must be entered twice again. If enabled, the most recent patient ID can be recalled by pressing the DIS key.
i-STAT (cartridge panel number) Time to Results LCK Page	If the Test Selection page is displayed, use the numbered keys to select tests to be reported. (Press the number a second time to deselect a test.) If the chart page is automatically displayed, enter the required information. If not, press the Page soft key to go to the chart page.	

Procedure for the i-STAT Portable Clinical Analyzer (continued)

Display	Action	Analyzer Response/ Comments
Pt Temp (cartridges with PO2) FIO2 (cartridges with PO2) Free Fields Sample 1 ART (arterial) 2 VEN (venous) 3 CAP (capillary) 4 CORD (umbilical cord blood) 5 MXVN (mixed venous) 6 CPB (cardiopulmonary bypass)	Enter required or optional information on the chart page. Use the ENT key to move from field to field. Use the Page key to return to the results page.	Information entered on the chart page can be edited until results are printed or transmitted or until another cartridge is inserted or another test record is recalled to the screen. To edit the chart page, press the ENT key until the field to be edited is boxed.
Results or Results Ready message	If not on results page, press the Page key to return to the results page. Remove the cartridge and discard in biohazard container. Print or transcribe results.	Analyzer unlocks cartridge and is ready for another cartridge. See IR Link section for transmitting results. Care should be taken when transcribing results since most mistakes in patient testing occur during this step.

PROCEDURE FOR BLOOD ANALYSIS MODULE

The following procedure is used to test all sample types on the Blood Analysis Module (BAM).



Display	Action	Analyzer Response/ Comments
Main screen	Push the cartridge into the slot on the front of the BAM until it clicks into place. Note: If the Blood Analysis Setup Task window is not automatically displayed, press the Setup button on the BAM.	Test cycle initialized. Blood Analysis Setup Task window displayed. Light above the Cartridge Locked label on the BAM blinks. Light above setup button lights. Caution: Do not attempt to remove cartridge or unplug the module until the Cartridge Locked light stops blinking.
Blood Analysis Setup Task window	If required, enter the patient and operator ID blood sample type, patient temperature, FIO2, and any additional information in the free fields.	See Using the Blood Analysis Task Window below. Note: If the patient has been pre-admitted to the monitor, the patient ID will automatically be entered. Note: an external keypad can also be used to enter patient information.
Results	If still in the Setup window when results are ready, press the Analysis Results key on the BAM	Cartridge Locked light stops blinking. The cartridge may now be removed. Remove the cartridge and discard in biohazard container. The BAM is ready for another cartridge.

Procedure for Blood Analysis Module (continued)

Results	Confirm or Reject the results.	Both confirmed and Rejected results will be transmitted to the Central Data Station. Only confirmed results are transmitted to the laboratory or hospital information system. Note: Confirm can be programmed to automatically transmit results after a specified time interval.
Results	To change the information entered in the Setup window, press the Analysis Setup key.	Changes can be made up until the time results are transmitted to the Central Data Station. **Caution**: The settings selected will be applied a few seconds after leaving the setup window. Removing the module or inserting a cartridge before leaving the setup window will cause the previous settings to remain active.
	To review past results, press the Blood Review key.	Results are displayed chronologically.
	To return to the standard screen, press the MAIN hard key.	
	To obtain a printout from the module recorder, press the Record key.	This key is only active if a set of results has been confirmed.

USING THE BLOOD ANALYSIS SETUP TASK WINDOW

Operator ID

Press the Select Oper. ID soft key on the monitor to access the Operator ID selection screen. Use the cursor keys to select one of the ID numbers on the screen or press the Manual Entry key to enter an ID number. If preconfigured Operator ID selections do not appear on the monitor, this functionality has been configured off. Enter an ID number using the cursor keys or use the numeric keys on an external keypad. If Select Oper. ID does not appear on the monitor, this functionality has been configured off.

Blood Sample Type

Press the Select Sample soft key on the monitor to access the Sample Type selection screen. Use the cursor keys to select a sample type. CPB should be selected if the patient is on the pump in cardiopulmonary bypass surgery. (See the Theory section for an explanation.) Select Control when testing control solutions so that control results are not stored in the patient's record on the CMS. Control results will be transmitted to the Central Data Station.

Patient Temperature

When blood gases are included in the analysis, results are automatically reported at 37 °C. If a measured patient's temperature is available, the blood gas results are also reported at the patient's temperature.

Press the Select Pat. Temp soft key on the monitor to access the Patient Temperature source selection screen. If the patient's temperature is being measured by a Temp module or Cardiac Output module you can select the appropriate module as temperature source by pressing the Select Pat. Temp key. To enter a temperature value, press the Manual key. Adjust the value shown using the Change Value key or the cursor keys or enter a value with the external keypad. Values must be in degrees Centigrade. If Off is selected or if the selected module is not providing a valid temperature value, there will be no value shown after Patient Temp. in the Blood Analysis Setup task window.

FIO2 and Free Fields

Press the O2/Field soft key on the monitor to access the O2 and Free Field screens. For FIO2, enter a value by using the cursor keys to adjust the initial value shown, or directly using the numeric keys on an external keypad. Values can be entered in % or decimal form. Press the SelectO2/Field key again (or repeatedly) to access the field screens. In the free fields, facility-specific information of up to 6 digits can be entered.

Transmitting Results

The results must be transmitted before a recording can be made and in order for the system to include the results in the Blood Analysis trend data, and to pass the results to the Central Data Station.

The monitor can be configured to automatically transmit the results after a designated time has passed. If auto-transmit is enabled, the time remaining until transmission will be displayed in the Blood Analysis Results task window. The transmission will only occur at that time if you have left the Results or Setup task windows.

Even if Auto-transmit is not enabled, the system will automatically transmit results if any of the following occurs:

- A new measurement is started
- The module is unplugged
- The Blood Analysis parameter is switched off

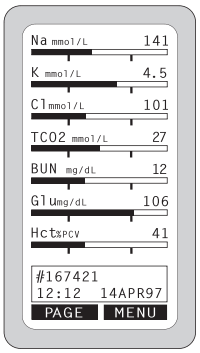
Results can be manually transmitted by pressing the Confirm hard key on the monitor.

Step	Action
1	Check the results and associated setup information.
2	If setup corrections are necessary, press Analysis Setup and go to the setup task window and make corrections. Return to the Analysis Results window.
3	To transmit results, press Confirm. To reject results, press Reject Results to mark results with -?- and press Confirm.

INTERPRETATION OF DISPLAYED RESULTS

Results Displayed

Test results are displayed with numerical concentration values in the units selected for the customization profile.



On the Portable Clinical Analyzer, bar graphs depicting the values in relation to reference ranges are also displayed with chemistry and hematocrit results. If a value exceeds the reference range, the bar graph may be rescaled to show the reference ranges and value in relation to the measurement range.

If result are rejected on the BAM, "-?- " will appear before each result. Note that the "-?-" symbol, indicating rejected results, will over ride the <, > and *** described below.

Calculated and Temperature Corrected Results

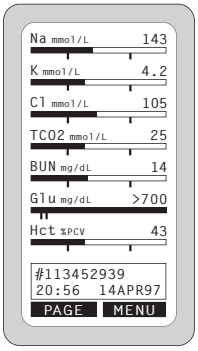
On the BAM, calculated results are displayed with a ' in front of the name of the calculated test. For example 'HCO_3. On the BAM, temperature adjusted results are displayed with an &. For example & **P**CO_2.

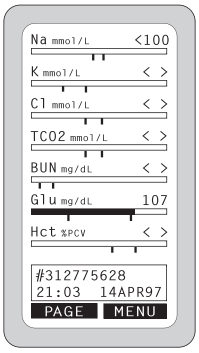
On the Portable Clinical Analyzer, calculated results are not marked as such and temperature corrected results are displayed under the 37° C results with the user entered temperature.

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 section.

When the analyzer detects an out-of-range result, the condition is indicated by the following symbols:

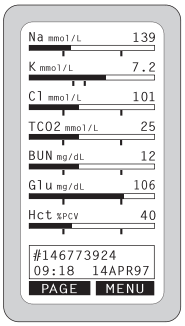




>	The ">" (greater than) sign indicates that a result falls above the displayed concentration value which represents the high end of the reportable range for the test. For example, if glucose results are reported in mg/dL and a result is displayd as >700, the result should be reported as "greater than 700 mg/dL".
<	The "<" (less than) sign indicates that the result falls below the displayed concentration value which represents the low end of the reportable range for the test.
< > **(-?- on the BAM)**	"< >" on the handheld analyzer or "-?- " on the BAM indicates that the calculation for the test is dependent upon another test which has been flagged either "<" or ">". For example, if the sodium is <100, then potassium, chloride, BUN/urea and hematocrit are flagged "< >" since the calculation of these results are dependent on the sodium result. "< >" or "-?" will also be displayed for TCO_2, pH, **P**CO_2, HCO3, anion gap, base excess and SO_2 if the TCO_2 result is outside the reportable range. Because the values outside the reportable range for TCO_2 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**CO_2 results.

Reference Ranges

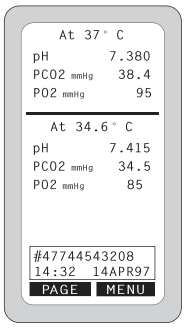
Reference ranges (sometimes referred to as normal ranges) are programmed into the analyzer and cannot be changed. The reference ranges are listed in the Cartridge and Test Information sheets and are derived from the literature cited on the sheets. Variables such as sex, age, heritage and other demographic factors of a population may cause a shift in these ranges. Therefore, it is generally recommended that each facility determine its own reference ranges.



Potassium outside reference range

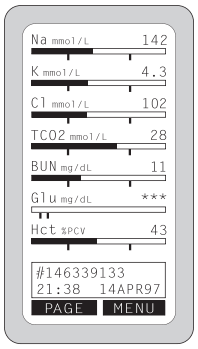
On the Portable Clinical Analyzer, reference ranges are marked under the bars by tic marks. When all tests are within their reference ranges, the tic marks will be centrally aligned. The bar graphs can be used as a visual cue for distinguishing between "normal" and "abnormal" results. Bar graphs and tic marks are not applied to blood gas results

On the BAM, results outside the reference ranges are displayed in yellow (or inverse video on monochrome display). To display reference ranges, press the Range/Units key repeatedly until they appear.



****

"***" (stars) on the Portable Clinical Analyzer or "-?-" on the BAM will appear in place of a concentration if the signals from a particular sensor are uncharacteristic. Uncharacteristic signals can be caused by:



- a compromised sensor
- an interfering substance in the sample
  - › exogenous: wrong anticoagulant, aged sample
  - › endogenous: contamination by I.V. fluid, medication
  - › See Cartridge and Test Information sheets for known interfering substances.
- a compromised lot of cartridges
- a condition that increase noise in the sensor signals, such as debris on the analyzer connector pins
- Stars will also appear for any tests that depend on another test which is itself flagged with stars.

  *Note that the *** symbol is replaced with the -?- symbol in the Blood Review window on the BAM.*

TROUBLESHOOTING

***** Instead of Results**

- Draw a fresh sample and use the same lot of cartridge to repeat the test.
- If stars reappear, check the lot of cartridges using liquid controls.
- If the controls are in-range and do not display stars, the sample may have an interfering substance and should be tested by another method.
- If the controls are out-of-range and/or display stars, use another lot of cartridges and report the problem lot to your technical support representative.
- If stars are displayed with a control sample and a second lot of cartridges, there may be debris on the analyzer connector pins. Contact your Support Representative for instructions on how to condition the pins in your analyzer.

Unexpected Results

When results do not reflect the patient's condition:

- Repeat the test using a fresh sample and cartridge.
- If results are still suspect, check the lot of cartridge using liquid controls. If the controls are in-range, there may be an interfering substance in the sample.
- Check the Cartridge and Test Information sheets and any Technical Bulletins related to the tests for any known interfering substances. Test by another method if any interfering substance applies.
- If an applicable interfering substance is not listed, test by another method to verify the result.
- If the control results are out-of-range, use another lot of cartridges or test by another method. Report the problem to your local technical support representative.

QUALITY CHECK MESSAGES AND CODES

Quality Check Messages and Codes appear when there is a cartridge-related problem. See the Troubleshooting section of this manual for an explanation of these messages and actions to be taken.

On the BAM, INOP (inoperative) messages appear when equipment-related problems prevent the monitor from processing signals properly. The INOP message is sometimes accompanied by an audible alarm which can be silenced with the Silence/Reset key. A numerical error code may be displayed with the INOP message that may be helpful to a service engineer. A BAI (Blood Analysis Interface) message indicates that results cannot be sent to the CDS - contact the Point-of-Care Coordinator.

QUALITY CONTROL 12

Overview

This section describes the steps to be taken to verify the performance of the analyzer and cartridges. The rationale for the i-STAT catridge and analyzer quality regimen is described in the Theory section of this manual.

Customization

The quality control behavior of the analyzer can be customized via the Central Data Station to:

- turn the external Electronic Simulator reminder on or off.
- prompt the operator to use the external Electronic Simulator at scheduled intervals.
- turn the internal Electronic Simulator on or off , and select the simulator test cycle intervals.
- disable further cartridge testing when the internal Electronic Simulator test fails.

See the Customization section for default values.

Data Retention

Quality control data is transmitted to the Central Data Station. If a Central Data Station is not being used, the charts at the end if this section can be used to record liquid and electronic control results.

QUALITY CONTROL FOR i-STAT CARTRIDGES AND THE ANALYZER'S CARTRIDGE TEST CYCLE

Verify Newly Received Cartridges

1. Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container.
2. From each lot in each shipment of cartridges, analyze multiple levels of i-STAT controls (and Meter Trax™ controls if testing for hematocrit) using any verified analyzer.

Verify Performance of Analyzers Daily

Verify the performance of each analyzer on site using the Electronic Simulator (external or internal) once a day on the days the analyzers are in use. Note that regulatory or accreditation requirements may dictate more frequent intervals.

Check Refrigerator Storage Daily

Verify that the cartridges stored in the refrigerator are within the expiration date printed on the boxes.

Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8 °C (35 to 46 °F). If storage conditions are in doubt, use controls to verify that the cartridges are performing properly. This is especially important if freezing conditions are suspected at the back of the refrigerator.

Check Room Temperature Storage Daily

Verify that the cartridges stored at room temperature are within the expiration date and that the cartridges have been out of the refrigerator less than two weeks. If the temperature at which the cartridges are stored is in doubt, use controls to verify that the cartridges are performing properly.

Check Thermal Control System Twice a Year

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, i-STAT recommends that the thermal probe check be verified twice a year.

Check the Analyzer Ambient Temperature Reading Once a Year

The analyzer uses ambient temperature measurements to ensure that the temperature is within the operating range and in the extrapolation of ambient temperature measurement results for ionized calcium, pH and PCO_2 to 37 °C results.

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 Control are formulated at three clinically relevant levels with known pH and with known concentrations of:

Sodium	PCO_2	Glucose
Potassium	PO_2	Lactate
Chloride		BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box of 10 ampules with a sheet with target values and acceptable ranges. 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
PO_2 (mmHg)	43	61	100	140	400
PCO_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, PCO_2, PO_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, PCO_2, or PO_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	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.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
4	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 included with each box of control ampules.

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 at Extreme Altitude

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 above 150 mmHg:

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.)

CONTROLS FOR HEMATOCRIT SENSOR

Meter Trax™ Whole Blood Reference Control for Glucose, Hemoglobin and Hematocrit (Meter Trax is a trademark of Hematronix, Inc.) is recommended as a control solution for the hematocrit sensor. Meter Trax is available in three levels: Low, Mid and High in boxes of one level (6x2mL) or boxes of three levels (6x2mL or 3x2mL).

CONTROLS FOR ACT CARTRIDGES

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 8ºC (35 to 46ºF) 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 - 30ºC or 64 - 86ºF) 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 included in each box of control vials. 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 (page 12-8). 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.

CONTROLS FOR PT/INR CARTRIDGES

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.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of calcium chloride diluent. The Level 1 control vials contain 9.5 ± 1.5 mmol/L calcium chloride, while the Level 2 control vials contain 12 ± 2.0 mmol/L calcium chloride.

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 8ºC (35 to 46ºF) 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 18-30ºC (64-86ºF) 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 included in each box of control vials. 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 (page 12-8). 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.

TROUBLESHOOTING OUT-OF-RANGE RESULTS

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 Troubleshooting section.

INTERNAL ELECTRONIC SIMULATOR

Procedure for the 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 reinserted 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.

EXTERNAL ELECTRONIC SIMULATOR

Procedure for External Electronic Simulator on Analyzer

Display	Step	Analyzer Response and Notes
Enter ID# Below Contacting Cartridge LCK #------- Operator #, ENT	Insert the simulator into the analyzer with the "i" facing up. Do not touch the contact pads,	If the simulator has a blue cover over the contact pads, remove it. The simulator will activate the analyzer when properly inserted
Enter ID# Below Time to Results LCK #------- Operator#, ENT	Enter an Operator ID	Do not attempt to remove the simulator until the LCK prompt disappears from the screen.
ELECTRONIC SIMULATOR PASS READY FOR USE Operator ID # Time and Date	Remove the simulator. If PASS is displayed, continue to use the analyzer.	If FAIL is displayed, see Troubleshooting section below. Record results in log or transmit results to Central Data Station. Replace the blue cap if applicable. Replace the simulator in a protective box or plastic bag.

Caution

The analyzer will continue to initialize test cycles when the external Electronic Simulator reminder is missed, when a FAIL result for an external Electronic Simulator 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

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.

CHECKING THE THERMAL PROBES IN THE I-STAT ANALYZERS

Verification for Portable Clinical Analyzers

Verify the thermal probe check for the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer as follows:

- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 4: On the CDS, click on **System**, then on **Simulator Results**. Look under the Delta column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.
- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Look under the Probe Delta column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.
- External Electronic Simulator used routinely, results not transmitted to a Central Data Station: Use the procedure below to check the thermal probes on each analyzer twice a year.
- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each analyzer twice a year.

Procedure for Portable Clinical Analyzers

Check the thermal probes on the i-STAT Portable Clinical Analyzer and 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, the difference between the thermal probes can be viewed on the analyzer's screen:
   - Portable Clinical Analyzer: while holding down the DIS key, press the 1 key.
   - i-STAT 1 Analyzer: press the period key.
4. Interpretation of the thermal probe check value:
   - Acceptable: a value equal to or less than 0.1 (≤ 0.1)
   - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
   - 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.

Verification of BAMs

Verify the thermal probe check on a Philips Medical Systems Blood Analysis Module (BAM) and Central Data Station Version 5 as follows:

- External Electronic Simulator used daily and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Click on **Record** in the Main Menu, then click on **Extended Electronic Simulator Report**. Look under the Pot6P column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each BAM in use in the last 30 days. No recorded value indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any BAM that does not have a numeric value listed.
- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each BAM twice a year.

Procedure for BAMS Check the thermal probes on a BAM as follows:

1. Insert the simulator partially into the BAM and wait for 15 minutes before inserting the simulator all the way into the BAM. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. When results are displayed, transmit the results to the Central Data Station.
3. View the probe check value on the CDS:
   1) Click on Data Viewer
   2) Click on Simulator
   3) Click on Record in the Main Menu task bar
   4) Click on Extended Electronic Simulator Report
   5) Look under the Pot6P column
4. Interpretation of the thermal probe check value:
   - Acceptable: a value equal to or less than 0.1 (≤ 0.1)
   - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm the results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
   - No value: repeat the procedure. Take care to handle the simulator as little as possible. It may help to increase the time in step 2 to 30 minutes.

Documentation of Results The results of the thermal probe check are stored in the Central Data Station. If the Central Data Station is not available, use the form included with this Technical Bulletin to record the results.

PROCEDURE TO CHECK ROOM TEMPERATURE MEASUREMENT

Step	Action
1	Place the analyzer with a calibrated thermometer suspended near the analyzer and away from air currents for one hour.
2	Check the temperature reading on the Analyzer status page. The temperature should be ± 1 °C of the thermometer's reading.

i-STAT System Incoming Cartridge QC Log

CatridgeType:__________ **Lot No.:**__________ **Rec'd Date:**__________ **Exp. Date:**__________ **Quat:**__________ **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

Lot/Shipment accepted by:__________ **Date:**__________

*OK or indicate blue window(s)

i-STAT System QC Log: Expiration Date and Storage Conditions

				REFRIGERATED 2 TO 8° C (35 TO 46° F)			REFRIGERATED 2 TO 8° C (35 TO 46° F)				
DATE	**LOCATION**	**CARTRIDGE TYPE**	**LOT #**	**QTY**	**EXP. DATE**	**TEMP**	**QTY**	**EXP. DATE**	**TEMP**	**ACTIONS**	**INSP.**

Rev. Date: 07/12/04

Art: 715014-01B

i-STAT Cartrdige Quality Control Action Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	CARTRIDGE LOT	PROBLEM	CORRECTIVE ACTION	OPERATOR

i-STAT Analyzer Thermal Probe Check

Year: ________

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT	COMMENTS	OPERATOR

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

i-STAT Electronic Simulator Action Log

DATE	TIME	ANALYZER	FAILURE CODE OR LETTER	SIMULATOR ID	ACTION	OPERATOR

CALIBRATION VERIFICATION FOR ANALYTES 13

NOTE: IN COUNTRIES WHERE LABORATORY REGULATIONS DO NOT REQUIRE ROUTINE LINEARITY CHECKS, i-STAT DOES NOT RECOMMEND THIS PROCEDURE, BELIEVING IT TO BE UNNECESSARY FOR A FACTORY CALIBRATED SYSTEM.

CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure

i-STAT recommends that each sensor type be included in the Calibration Verification procedure using a selection of the analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

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		Creatinine

There are four 1.7mL glass ampules of each level in the set.

Reactive Ingredients

See the table on page 12-2 of the Quality Control section 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.

i-STAT CALIBRATION VERIFICATION SET

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	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.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	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 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 1cc or 3cc sterile syringes 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 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) and acceptable ranges are printed on a Value Assignment Sheet included with each Calibration Verification Set.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If the result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

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.

If testing at extreme altitude refer to Correction of $\boldsymbol{P}O_2$ at Extreme Altitude under Controls for Blood Gas/Electrolyte/Metabolite Cartridges in the Quality Control section of the manual.

VERIFICATION PROCEDURE FOR HEMATOCRIT

Preparation of Hematocrit Samples

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7mL 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, 10%. 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 unnecessary.

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 10%. Whole blood samples with hematocrit values less than 10% will be flagged as <10.

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

NCCLS 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.

* NCCLS. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard– Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

VERIFICATION PROCEDURE FOR ACT

See Technical Bulletin: i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure

Procedure for Cartridges

Calibration Verification and linearity solutions can be tested via a test path accessed from the Utility menu on the i-STAT Portable Clinical Analyzer. (This test path is not available on the BAM.) The same standardization CLEW is used to calculate both patient sample results and calibration verification/linearity sample results. The difference is that in the Calibration Verification test path, the application software does not apply measurement range flags so that results for samples below and above the measurement ranges can be reported.

Note: Because the Utility menu also includes a Clear Stored Results option, it may not be wise to give end users access to the Utility menu.

The ID # (corresponds to Patient ID # in the standard test path) can be used to identify these samples and the cartridge lot number. Note that each of the five levels in the i-STAT Calibration Verification kit has its own lot number. The lot number for Level 1 can be used to identify the kit or each lot number can be used to identify each sample. The letters in the Calibration Verification and cartridge lot numbers can be ignored. For example: Cal Ver level 1 and lot number 1109 plus cartridge lot 02089: 1110902089.

Note: Samples should be prepared and ready to test before starting this procedure since the analyzer will wait for only 5 minutes after the "INSERT CARTRIDGE" message is displayed before powering down.

Display	Action	Analyzer Response
OFF (blank) or ON with a result displayed.	Insert Electronic Simulator	Electronic Simulator test cycle will commence.
Electronic Simulator PASS result displayed.	Hold down the DIS key and press the MENU soft key.	Utility Menu will be displayed.
Utility Menu 1 Clear Stored Results 2 Printer Setup 3 Send Software 4 Cal Ver 5 Proficiency	Press 4 for Cal Ver	Insert cartridge prompt will be displayed.
Cal Ver INSERT CARTRIDGE	Insert filled cartridge into analyzer cartridge port. If the display turns OFF before the cartridge is inserted, turn the analyzer ON using the DIS key. You must re-enter the Utility menu and select the Cal Ver option before inserting the filled cartridge.	Test cycle will commence. If at any point during the test cycle a quality check fails, the test cycle will halt and a message will be displayed indicating the condition and the corrective action.
_ _ _ _ _ _ _ Operator #, ENT	Enter Operator ID and press ENT.	
#_ _ _ _ _ _ _ Repeat #, ENT	Repeat Operator ID and press ENT.	Repeat of Operator ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.

#_ _ _ _ _ _ _ _ _ _ _ _ _ ID, ENT	Enter sample ID and Press ENT.	
#_ _ _ _ _ _ _ _ _ _ _ _ _ Repeat #, ENT	Repeat the sample ID number and press ENT.	Repeat of sample ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
Select Tests (Available tests will be dependent on cartridge type).	Use the number keys to select tests to be reported. (Press a number key a second time to deselect a test.) Press PAGE key when all desired tests are selected.	Test selection may not be required depending on analyzer customization settings.
Chart Page	Use the number and ENT keys to enter test information if desired. Press PAGE key when all information entry is complete.	Automatic display of the Chart Page is dependent on analyzer customization settings.
Results Displayed	If results are not displayed, but RESULTS READY message is visible, press the PAGE key until the results page is shown. Remove the cartridge and discard in a biohazard container. Print or transcribe results.	Analyzer unlocks cartridge and is ready for another cartridge. If another cartridge is inserted into the analyzer without pressing DIS and MENU, it will be run as a patient sample. To run another Cal Ver sample continue to next instruction.
Results Displayed	To run another Cal Ver sample, hold down the DIS key and press the MENU key.	Utility Menu will be displayed.
Utility Menu 1 Cal Ver 2 Proficiency	Press 1 for Cal Ver	Insert Cartridge prompt will be displayed. Follow sequence from the Insert Cartridge screen as shown above to complete the test cycle.

Troubleshooting Cartridge Tests

See the Troubleshooting Out-of-Range Results paragraph in the Quality Control Section in this manual.

PROFICIENCY TESTING/EXTERNAL QUALITY CONTROL 14

Purpose

Samples from proficiency testing or external quality control providers can be used to assess consistency of results for a particular method or system across testing sites. Due to matrix effects and additives, these samples should not be used as an indication of the system's true accuracy.

Selection of a Provider

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. In the USA, see the Technical Bulletin "Proficiency Testing and the i-STAT System" for recommended providers. For other countries, 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, other than Meter Trax (Hematronix, Inc) whole blood controls for glucose and hematocrit, are not compatible. (The i-STAT System will report only hematocrit for Meter Trax controls.)
- 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 small differences between generations and types of cartridges for non-whole blood samples. Generation means major manufacturing changes such as making the chips smaller. Cartridge types means those that make measurements at ambient temperature and those that make measurements at 37 °C.

Procedure for Cartridges

Proficiency Testing (PT) and External Quality Control (EQA) samples can be tested using the patient sample test path or the test path accessed from the Utility menu on the Portable Clinical Analyzer. (This test path is not available on the BAM.) The same CLEW (standardization software) is used in both test paths. However, in the test path accessed via the Utility menu, hematocrit results are calculated using coefficients for K3EDTA even if the analyzer is customized for K2EDTA. This ensures that hematocrit results are consistent across all sites.

If using a BAM, or the Portable Clinical Analyzer and the patient test path to test PT or EQA samples, customize for K3EDTA before testing.

Important! In order for hematocrit results to be consistent across all sites, do not select the CPB sample type.

The ID # (same as Patient ID # in standard test path) can be used to identify these samples and the lot number of cartridges used. For example, if the sample identification number is 12 and the cartridge lot number is M02089B, the ID# would be 1202089.

Note: Because the Utility menu also includes a Clear Stored Results option, it may not be wise to give end users access to the Utility menu. The person responsible for the PT or EQA program could access the Utility menu and select **5 – Proficiency** on the analyzer before presenting the analyzer and the sample to the end user.

Note: Sample should be prepared and ready to test before starting this procedure since the analyzer will wait for only 45 seconds after the "INSERT CARTRIDGE" message is displayed.

Display	Step	Analyzer Response
OFF (blank) or ON with a result displayed.	Insert Electronic Simulator	Electronic Simulator test cycle will commence.
Electronic Simulator PASS result displayed.	Hold down the DIS key and press the MENU soft key.	Utility Menu will be displayed.
Utility Menu 1 Clear Stored Results 2 Printer Setup 3 Send Software 4 Cal Ver 5 Proficiency	Press 5 for Proficiency.	Insert cartridge prompt will be displayed.
Proficiency INSERT CARTRIDGE	Insert filled cartridge into analyzer cartridge port. If the display turns OFF before the cartridge is inserted, turn the analyzer ON using the DIS key. Re-enter the Utility menu and select the Proficiency option before inserting the filled cartridge.	Test cycle will commence. If at any point during the test cycle a quality check fails, the test cycle will halt and a message will be displayed indicating the condition and the corrective action.
#_ _ _ _ _ _ _ Operator #, ENT	Enter Operator ID and press ENT.	
#_ _ _ _ _ _ _ Repeat #, ENT	Repeat Operator ID and press ENT.	Repeat of Operator ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
#_ _ _ _ _ _ _ _ _ _ _ _ ID, ENT	Enter the sample ID number and press ENT.	

#_ _ _ _ _ _ _ _ _ _ _ _ Repeat #, ENT	Repeat the sample ID number and press ENT.	Repeat of sample ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
Select Tests (Available tests will be dependent on cartridge type).	Use the number keys to select tests to be reported. (Press a number key a second time to deselect a test.) Press PAGE key when all desired tests are selected.	Test selection may not be required depending on analyzer customization settings.
Chart Page	Use the number and ENT keys to enter test information if desired. Press PAGE key when all information entry is complete.	Automatic display of the Chart Page is dependent on analyzer customization settings.
Results Displayed	If results are not displayed, but RESULTS READY message is visible, press the PAGE key until the results page is shown. Remove the cartridge and discard in a biohazard container. Print or transcribe results.	Analyzer unlocks cartridge and is ready for another cartridge. If another cartridge is inserted into the analyzer without pressing DIS and MENU, it will be run as a patient sample. To run another Proficiency sample continue to next instruction.
Results Displayed	To run another Proficiency sample, hold down the DIS key and press the MENU key.	Utility Menu will be displayed.
Utility Menu 1 Cal Ver 2 Proficiency	Press 2 for Proficiency	Insert Cartridge prompt will be displayed. Follow sequence from the Insert Cartridge screen as shown above to complete the test cycle.

Troubleshooting Cartridge Tests

If results are considered unsatisfactory by the provider, consider the following:

- Transcription errors.
- Result reported under wrong method or peer group.
- Matrix effects.
  - › Split sample testing of both the control samples and patient samples can be performed on the i-STAT System and a comparative method. If patient results agree but control samples do not agree, the presence of a matrix effect or interfering substance in the control samples is very likely.
  - › Petition the provider for a peer group for the i-STAT method.
- See also the Troubleshooting Out-of-Range Results paragraph in the Quality Control Section in this manual.

UPDATING THE SOFTWARE 15

CLEW

The i-STAT System is designed to eliminate operator influence on delivered results. Unlike other unit-use systems, the user is not required to enter lot-specific calibration information into the instrument. The micro-fabricated sensor technology produces very repeatable devices from lot to lot which allow the Analyzers to use the same set of standardizing values for extended periods of time.

Nevertheless, the continuous manufacturing process improvements by i-STAT necessitate re-establishing standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. New CLEW re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

Application Software

The "Application" software, listed under Version on the Analyzer Status page, is updated to enable the analyzer to recognize new cartridges and to enable new features. These updates typically occur at the same time as the CLEW updates.

Software Updates

Software update packages are mailed to each site three times a year and approximately two months before the current CLEW expires. The package includes a diskette with new versions of CLEW or both CLEW and application software, a Product Update explaining any changes, directions for updating software, and new value assignment sheets for control solutions. The procedure for updating software includes transferring the new software from the diskette to the Data Manager, updating one or a few analyzers from the Data Manager, and updating other analyzers around the facility from the ones updated at the Data Manager. A PC with Windows 95 or higher can be used in place of the Data Manager. Note: The COM ports of certain laptops may need to be reconfigured to communicate with the Downloader. If communication cannot be established, a standard PC should be used.

UPDATING ANALYZER SOFTWARE: JAMMLITE UTILITY

The JammLite Utility must be used to update software in the i-STAT®1 Analyzer and can be used to update the i-STAT Portable Clinical Analyzer and the Blood Analysis Module. The JammLite procedure is simple with just one screen for all analyzer types and software versions.

To use this utility, you must have a computer with Windows® 95 or higher. An i-STAT Central Data Station Version 5 or a Point of Care Central Workstation meet this requirement and can be used. An i-STAT/DE server is not recommended for use with this utility.

If this is the first time you are updating your analyzer, follow the Detailed Procedure. If you just need reminders, follow the Summary of the Procedure.

SUMMARY OF THE PROCEDURE

How to	Step	Page
Check battery voltage Save the data on Portable Clinical Analyzers	1	15-3
Disable Customization on the Central Data Station	2	15-3
Shut down all programs on the computer	3	15-3
Connect an IR Link or Downloader* to the computer	4	15-4
Access the C:\> prompt	5	15-5
Transfer the files from the JAMS disk to the computer	6	15-5
Access the JammLite Utility	7	15-6
Select the instrument (analyzer) type to be updated	7	15-6
Select the local port or select TCP\IP and enter the IP address	7	15-6
Select the Application software and CLEW	7	15-6
Click on Update and follow the directions on the screen	7	15-6
DO NOT move analyzer during update	7	15-7
Click on Close	7	15-7
Click on Exit or X in upper right corner of screen	7	15-7
Re-start the CDS, update CLEW, re-eanable Customization	8	15-7
Insert an Electronic Simulator into each updated analyzer	9	15-7

* It is not neccessary to connect a serial Downloader if using network protocol to update i-STAT 1 Analyzer.

DETAILED PROCEDURE

Step	Action

Step (1)

Save Stored Results & Check Battery Voltage

Save Data: All test records are erased in the i-STAT Portable Clinical Analyzer (series 200) when the application software is updated. Download each analyzer to the Central Data Station (CDS) program or ensure that all test records have been transcribed before updating a Portable Clinical Analyzer. Test records are not erased from the i-STAT1 Analyzer (series 300).

- There are two types of software in the analyzers: application (JAMS) and CLEW.
- The Product Update lists the software that is to be updated.
- Test records will not be erased if only the CLEW software is updated.

Check Battery Voltage: Analyzers consume power during the software update. For the software update, the battery voltage should be well above the 7.5 V point at which the low battery message is displayed.

Step (2)

Disable Customization on CDS

If you do not use Customization and Customization is disabled, skip this step. If you are not sure if Customization is disabled, follow the steps below. The steps to disable customization differ for the Central Data Station Version 4 and Central Data Station Version 5. If you are not sure which CDS you have, click **Help** on the main menu bar, then click on **About....**

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on File on the menu bar.
4. Click on Disable Customization.
5. Click Yes to the confirmation messages and the Utility will close.

Central Data Station Version 5:

1. Click on Administration in the main menu bar.
2. Click on Customization.
3. Type in the Password. The default password is istat.
4. Click off the checkmark in the box beside Enable Customization at the top left of the window.

Step (3)

Shut Down All Programs

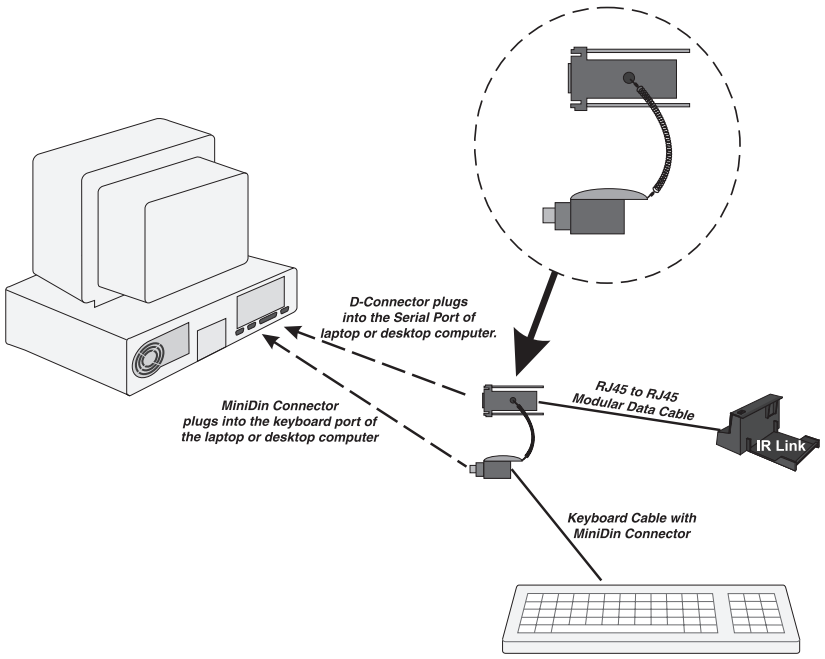
Exit the CDS and all other open programs.

Step (4)

Connect the IR Link and/or Downloader

IR Link connection:

- If using a Central Data Station Version 5, a Central Data Station Version 4 with digiboard, or any other computer using Windows 95 or above, connect the IR Link to a 9 pin COM port using an i-STAT Software Update Kit as illustrated below.



- If using a Central Data Station Version 4 with quad cards: Connect the IR Link to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors). COM5 is first port from the inside on the lower row.

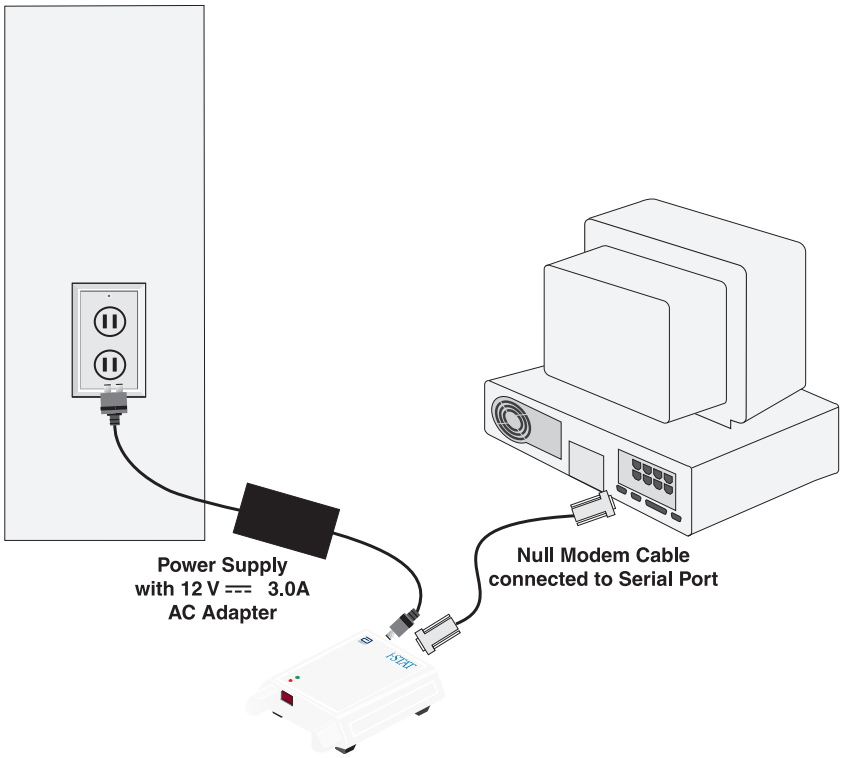
Blood Analysis Module connection:

- If using a Central Data Station Version 4, connect the BAM to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors).
- If using a Central Data Station Version 5 or another computer, connect the BAM to a 9 pin COM port using the D-Connector and Mini Din Connector from an i-STAT Software Update Kit.

Note: Do not connect the BAM until instructed to do so by the JammLite program.

Serial Downloader connection:

- Connect a serial Downloader to a COM port using a DB9-DB9 Null Modem cable and plug the Downloader's power adapter into a wall outlet.



Network Downloader connection:

- Connect a network Downloader to the network using a network patch cable and plug the Downloader's power adapter into a wall outlet. The computer must also be connected to the network. The computer must support the TCP/IP network protocol.

Step (5) *Access the Command Prompt*

- Click Start in the lower left corner of the window.
- Click Run.
- Type: **command** and press the Enter key.

Note: If you do not have access to the **Run** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

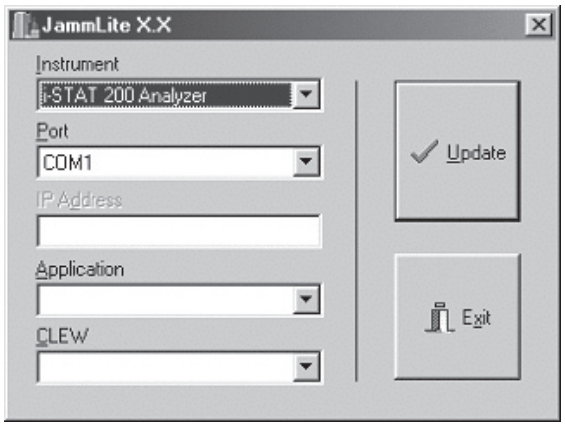
Step (6) *Transfer the Files*

Place the JAMS diskette into the A:drive. At the Command prompt, type **A:transfer** and press the Enter key.

Step (7)

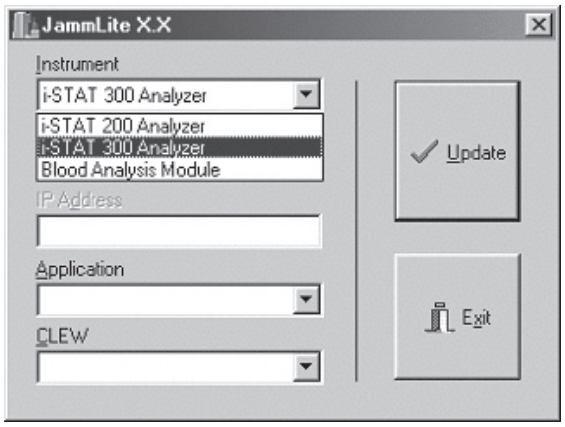
Using the JammLite Utility

1. At the C:\>bins prompt, type **jammlite** and press the Enter key. The following screen will be displayed with the new application and CLEW.



X.X is the current version of JammLite software.

2. Select the appropriate instrument from the Instrument drop-down list.



Note: i-STAT 200 Analyzer is the Portable Clinical Analyzer and the i-STAT 300 Analyzer is the i-STAT 1 Analyzer.

3. Select the port for the instrument being updated from the "Port" drop-down list. The JammLite program will list only available ports on the computer. For updates using a network Downloader, select TCP/IP. (The TCP/IP option is available only if i-STAT 300 is selected from the "Instrument" drop down list.) Enter the IP address of the Downloader in the "IP Address" box.

4. Select the appropriate Application and CLEW from the Application and CLEW drop-down lists. Refer to the update package for the correct Application and CLEW. If the update is for CLEW only, select None for Application. Note that there are different application versions for the i-STAT 1 Analyzer, the Portable Clinical Analyzer and the Blood Analysis Module. JammLite will display all application software and CLEW appropriate for the selected instrument.

5. Click on the Update button to start the update. Appropriate instructions will be displayed. Follow the directions on the screen. The selected application and CLEW will be displayed on the Update Line.

6. During the update, do not move the analyzer or unplug the Blood Analysis Module until a screen is displayed indicating the update was successful.
7. Click on Close. The JammLite program will return to step 7 to allow any selections to be changed before starting another update.
8. When all analyzers have been updated, click on Exit or the X in the upper right corner of the DOS window.

Step (8) ***Restarting the Central Data Station***

If using a Central Data Station, re-start the software, update the Customization Profile(s) with the new CLEW and enable Customization if desired.

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on Setup Mode.
4. Click on NEXT for the Language window.
5. Click on the new CLEW in the CLEW window and click on NEXT.
6. Click on NEXT in the Unit Set window.
7. Click on FINISH in the Preference window.
8. Click on FILE and Exit Program or click on the x in the upper right corner of the Utility window.
9. Click on the Central Data Station icon.

Central Data Station Version 5:

1. Click on the Central Data Station icon.
2. Click on Administration.
3. Click on Customization.
4. Type in the Password. The default password is istat.
5. Click the i-STAT Analyzer CLEW button.
6. Click the new version of CLEW and click OK.
7. If "Use Default Profile" is not check-marked beside any localization-based customization profiles, double click the box with the CLEW under the i-STAT Analyzer column (or Agilent BAM CLEW) and click the new version of CLEW.
8. Click a checkmark in the box beside Enable Customization at the top left of the window.
9. Click the x in the upper right corner of the Customization window to close it.

Step (9) ***Verifying the Update***

Run an external Electronic Simulator on updated analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

PROBLEM	RECOMMENDED ACTION
The Com port to be used for the update is not listed in the Port List	Exit the JammLite program and ensure that there are no other programs running which may be using the port (such as the Central Data Station). Restart the JammLite program to determine if the port is now listed.
A message appears on the screen that the port specified for the update could not be opened.	Verify that no other programs are using the port and that the correct port was selected.
A message appears on the screen that the specified application file could not be opened, has an error, or is not a valid application file.	Verify that all other programs are closed and that the proper application was selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the application update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that there was an error encountered during communication with the analyzer.	Ensure that the instrument is located properly in the IR Link or Downloader, and this it is not removed before the update is completed.
A message appears on the screen that the specified CLEW file could not be opened, has an error, or is not a valid CLEW file.	Ensure that all other programs are closed and that the correct CLEW is selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the CLEW update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that the Downloader could not be configured to perform the update	Verify that the Downloader is connected to the COM port, the Downloader is powered, and that the proper port is selected.
A message appears on the screen indicating that nothing was selected for the update.	Select an Application and/or a CLEW prior to clicking on the Update button.

Quality Check Code 13 - Invalid or Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Update CLEW in the customization profile(s) and download the analyzers. The new CLEW will be installed in the analyzers.

Unsuccessful with Windows 95

Some computers with Windows 95 will not run JammLite. In this case, Jammit must be used to update analyzers. Before accessing the Jammit Utility, the computer must be rebooted.

ANALYZER-TO-ANALYZER SOFTWARE UPDATES

i-STAT 1 Analyzer

Step	Action
1	Any updated analyzer can be used as the sending analyzer. Select the Utility option under the Administration Menu on the sending analyzer. The Utility menu can be password protected. Enter the password or press the Enter key if no password has been specified. From the Utility Menu select **1-Send Software**. Select **1 – JAMS and CLEW** or **2-CLEW** as required for the update. The message "Waiting to Send" will be displayed.
2	Ensure that the receiving analyzer is off.
3	Place the sending and receiving analyzers facing each other on a flat surface about 30cm (1 foot) apart and align their IR windows. Move one analyzer toward the other until the message "Sending…" is displayed on the sending analyzer and a scrolling banner appears on the receiving analyzer.
4	Do not move the analyzers until the "Sending…" message is removed from the sending analyzer's display. The sending analyzer will return to the Send Software option and will display the result of the last software update as "Successful" or "Unsuccessful."
5	Select the Analyzer Status option under the Administration menu on the receiving analyzer and check that the new JAMS and/or CLEW are listed.

Step	Action
1	Any updated analyzer can be used as the Sending Analyzer. Run the external Electronic Simulator on the Sending Analyzer.
2	Transmit all data from the analyzer being updated (the Receiving Analyzer) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.
3	With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.
4	In the Utility Menu, select 3 - Send Software. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".
5	Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-1 of the i-STAT System Manual for the location of the IR LED.)
6	On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the DIS key. The Sending Analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed. Note: Do not move the analyzers while the software is being sent.
7	When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. Do not press the DIS key on the Receiving Analyzer. Run the Electronic Simulator on the Receiving Analyzer.
8	To update software in another analyzer, repeat these instructions from Step 2.

TROUBLESHOOTING THE ANALYZER 16

Introduction

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.

Note: The Technical Bulletin "Analyzer Coded Messages" included in this manual lists the Quality Check Code numbers as well as additional troubleshooting details

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)
- Displayed message and code number
- Frequency of problem
- Software version
- Environmental conditions
- Result of last Electronic Simulator test
- Battery voltage from Analyzer Status page

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 offending condition is corrected.

Message on Display	Cause	Action
Date Invalid	The analyzer will not allow a date that precedes or exceeds the six months lifetime of the CLEW software.	Press the **Menu** soft key, press the "1" key for Status, press the **CLKSET** soft key and correct the time and/or date.
Dead Batteries	There is insufficient battery power to complete a test cycle.	Change the Lithium Batteries
Temperature Out of Range	The analyzer makes a temperature measurement before initiating a test cycle.	Check the temperature reading on the Analyzer Status screen. 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.
Invalid or Expired CLEW	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 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 batteries are inserted correctly. Check the battery voltage on the Status page and replace if low (below 7.5) Insert the Electronic Simulator to take the analyzer through a test cycle to ensure that the conditions has been corrected.

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 the 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. Single or sporadic 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).	Use another cartridge. If the same code repeats more than twice, 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 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.
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 at the end of this section.

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.	Push cartridge or Simulator straight through the cartridge port. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?). Try another Simulator. If the analyzer passes the Electronic Simulator check, continue to use it. If not, 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.
Cartridge Type Not Recognized Use Another Cartridge	This error could be due to use of a cartridge type that is not compatible with the version of software in the analyzer.	If this is a new cartridge type being used, update the software. If the cartridge type has been used before, check to see if the cartridges have expired. Otherwise, if this dose not fix the problem, reinstall the current software in the analyzer. Finally, if the condition persists, contact Support Services, as the analyzer may need repair.

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 batteries. If the problems persists, the analyzer should be returned for repair.

"LCK" 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. 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 the batteries 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 at the end of this section.

THEORY 17

ANALYZER FUNCTIONS

Introduction

The i-STAT Portable Clinical 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.

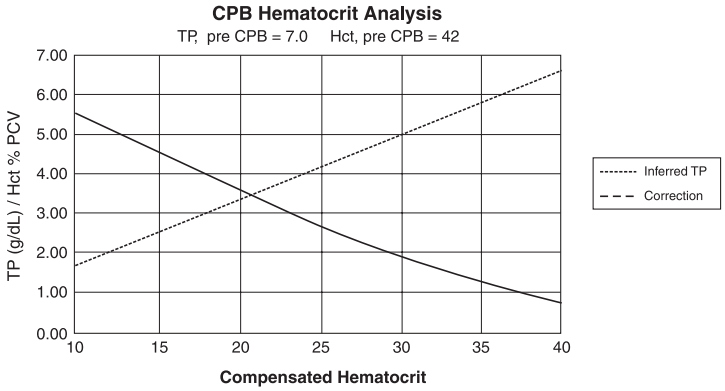
Direct measurement of hematocrit by the conductometric technique gives a result related to the non-conducting excluded volume fraction of the sample fluid. Red blood cell volume is the predominant component of the non-conducting volume, but proteins, lipids, and white blood cells also contribute. Elevated 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.

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. i-STAT Corporation 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 or Blood Analysis Module (as part of the Agilent Viridia Patient Monitoring System).

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).

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 regimen uses an analogous approach to monitor the part of the testing process which persists from run to run – the handheld analyzer or Blood Analysis Module.

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

The software in the analyzer and module 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.

An important aspect of the Simulator is that it mimics the sensitive nature of the sensor's signals to ensure that adjacent input channels within the analyzer or module maintain the required degree of electrical isolation from each other to prevent "crosstalk" (see US Patent #5124661 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 and module 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 analyzer or module 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. The response of the sensors' signals to the fresh calibrant fluid 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 or Blood Analysis Module's 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 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)	Every cartridge use
Calibration Fluid	
• 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 or module 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 or Blood Analysis Module	
• verify electrical contact pads (that allow access to sensor signals) are unoccluded	Every cartridge use
• verify internal element of cartridge that allows the analyzer or module to control the release of calibration fluid over the sensors is functioning properly	Every cartridge use
• verify internal element of cartridge that allows the analyzer or module to control the replacement of calibration fluid with sample is functioning properly	Every cartridge use

Handheld Analyzer and Blood Analysis Module

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	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
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 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 snap 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.

i-STAT LICENSE AGREEMENT AND WARRANTY FOR CENTRAL DATA STATION PROGRAM

EULA

For new users of CDS software the license and warranty information in the End User License Agreement (EULA) will be in effect.

License

The i-STAT Central Data Station software is licensed to the authorized user by i-STAT Corporation. Portions of the software are licensed to you by i-STAT Corporation under sublicense from other original software providers. By accepting and using this software, the user/licensee agrees to the following:

- The user/licensee will not make copies of the software programs or any of the program software files generated by the programs, the manual or other documentation except for archive copies made as part of user/licensee's regular back-up procedures.
- The user/licensee will protect the programs from unauthorized use, illegal reproduction (including reproducing any of the software files generated by the programs) or illicit distribution.
- The user/licensee will not change or reverse engineer the programs or any of their software files by debugging, decompiling, disassembling, reprogramming, rewriting the programs' macros, revising the programs' forms or any other means.

If the user/licensee makes any use, transfer or disclosure of the programs in violation of any of the foregoing, the sub-license will, at the option of i-STAT, immediately terminate without demand or notice and the user/licensee will immediately give to i-STAT the programs, the manuals and all copies thereof in the user/licensee's possession.

Warranty

i-STAT warrants the licensed software and accompanying physical documentation to be free of defects for a period of thirty days from the date of installation. If notified of defects within the warranty period, i-STAT will replace the defective software or documentation as soon as practical for the nature of the defect. The remedy for breach of this warranty is limited to replacement and shall not encompass any other damages including but not limited to loss of profit, and special, incidental, consequential or other similar claims. i-STAT specifically disclaims all other warranties, expressed or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software, accompanying documentation and the license granted herein.

INSTALLATION OF THE CENTRAL DATA STATION

Hardware

The PC on which the CDS software resides must meet specifications provided by i-STAT Corporation and should be installed following the PC manufacturer's directions. Install the printer if applicable.

Software Installation: License Key

A license key is required to install the Central Data Station software. The license key ensures that the end user agrees to the License Agreement which is displayed during installation. To obtain the license key, follow the instructions on the screen and listed below.

1. Insert the CDS CD and the installation will begin automatically.
2. Click **Next>** in the Welcome dialog.
3. The End-User License Agreement will be displayed. Read the agreement and if you agree to abide by the agreement, click **Yes** to proceed with the installation. If you do not agree, click **No** to abandon the installation.
4. Record the serial number of the CDS displayed in the *Enter License Key* dialog.
5. Go to the i-STAT web site at http://www.i-stat.com and click on the link under **CDS Key Generator** in the right hand column. You can also access this link directly at http://www.i-stat.com/cdslicense. (In the USA, the license key can also be obtained from Technical Support.)
6. If you are already registered, skip to step 8. If you are not registered, fill out the required information, select Basic Access, and click **Register.**
7. Go back to the i-STAT web site as directed in step 5.
8. Enter your username and password and click **Login**.
9. You may now enter the serial number recorded in step 4, and click **Submit**.
10. If successful, a message will appear indicating that your key has been e-mailed to the address with which you registered.
11. Obtain the key from the e-mail and enter it in the space provided on the CDS.
12. Click **Next** to proceed with the installation.

Caution

The use of other software that was not provided as part of the system on the same PC with the Central Data Station software may compromise the system, including permanent loss of patient records.

Site Specific Customization of the CDS

During installation, the CDS must be customized to properly communicate with i-STAT 1 Downloaders and Downloader/Rechargers, i-STAT IR Links and Philips Medical Systems Blood Analysis Modules throughout the hospital. The procedure to customize the CDS is described under the Customization section below.

The date displayed with results can be changed to any Short Date format and separator listed in the computer's Control Panel under Regional Options (or something similar, depending on the version of Microsoft Windows in use). If an unsupported format or separator is detected, the user will be notified and given the opportunity to change to a supported format/separator combination.

Connectivity

Basic information needed to connect the Downloaders, Downloader/Rechargers, and the portable printer to the PC are in the Downloader Wiring and Programming section of this manual.

For assistance in programming the Downloader, Downloader/Recharger and IR Links, contact your i-STAT support representative.

Interface

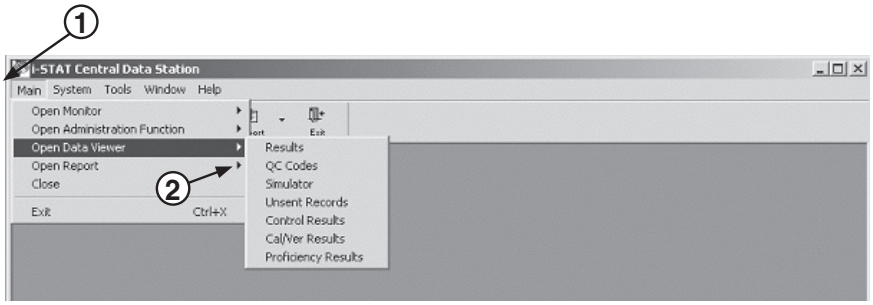
Basic information on interfacing can be found in the "Interface" paragraph under "Customization of the Central Data Station" in this section of this manual and in section 8.

Overview

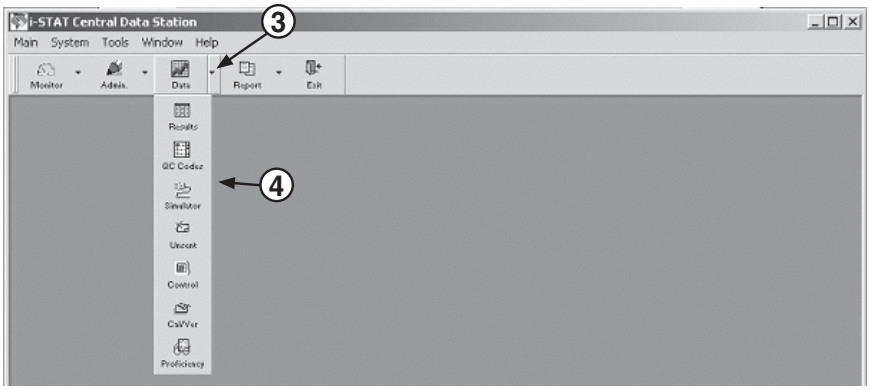
The CDS software follows typical Microsoft® Windows® conventions and procedures. The illustrations below are used to point out the use of the menu bar, toolbars, tabs and buttons.

Selecting Menu Options

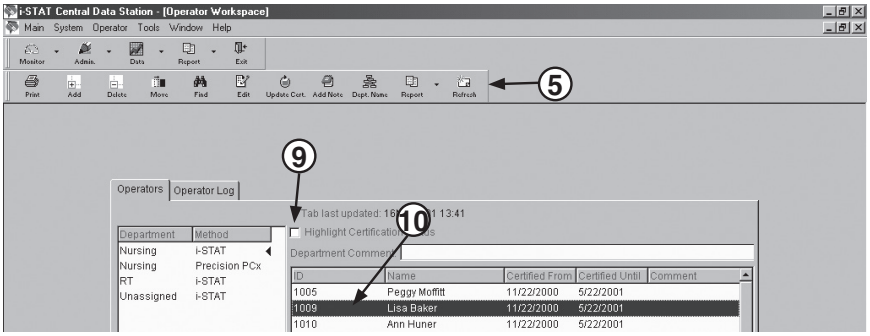
Clicking an item on the menu bar (1) will drop down the menu for that item. If any of the items in the drop down menu has a submenu, the submenu will open to the right of the ▶symbol next to the item when the item is highlighted (2).



Clicking the ▼ beside a toolbar button (3) will drop down a submenu toolbar (4).



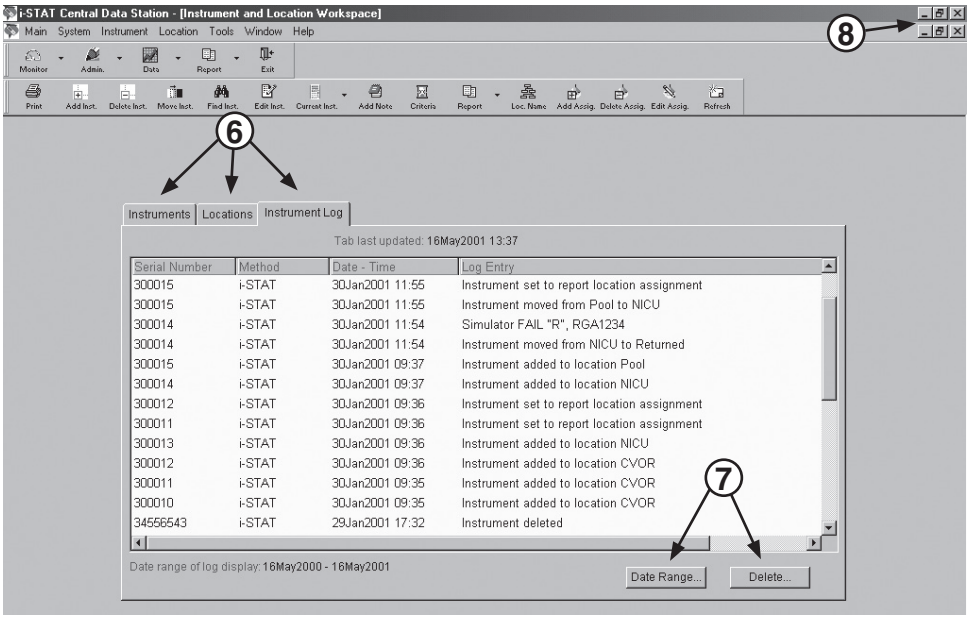
Clicking the desired menu option will open the item's window or will perform the item's function. The menu items and toolbar for the active window will be displayed (5).



Selecting Functions in a Window

Tabs: A window may have several functional groupings that are contained in tabs (6) with multiple pages. Clicking the text on the tab will display the corresponding page.

Buttons: Use to activate a function within a window (7) or to confirm (OK) or cancel a function or to manipulate a window. All windows can have the following buttons in the upper right hand corner (8):



 This button causes the window to be maximized.

 This button causes the window to be minimized.

 This button causes the window to be moveable and resizable.

 This button causes the window to close.

If a window does not have a close button, it can be closed by selecting **Main** then **Close** on the menu bar.

Check boxes: Click the box to enable or disable a single option (9).

Radio buttons: Click the circle to select from a list of mutually exclusive options.

Highlight bar: Use to select the line or lines on which to apply a function (10).

Drop down list: Click the ▼ button to drop down a list or scroll downward in a window.

Refreshing/Updating the Data in a Window

The **Refresh** toolbar button  refreshes the data content in the active window with the most recent data available. The refresh function is also available under the Window option on the menu bar. Pressing **F5** will also refresh the data.

Sorting Data in a Window

In most cases, when data is presented in a table, clicking a column header will sort the display based on the data in that column. In the Data Viewers, repeating values, such as a patient ID, will be sorted in descending Date/Time order. Clicking the header again will reverse the order of the sort. To return the data to chronological order, click the Date-Time column header.

Selecting Multiple Lines

In many functions, multiple lines can be selected for the desired action. To select consecutive multiple lines, click the first line and, while holding down the **Shift** key, click the last line. To select multiple lines that are not consecutive, click the desired lines while holding down the **Ctrl** key.

Opening Multiple Windows

Multiple windows can be open at the same time. The **Windows** item on the menu bar can be used to select the desired window from the list of open windows and bring it to the forefront. Close windows by clicking the **Close** button at the top right of the window or by selecting **Close** from the **Main** menu.

Column Ordering

Columns in the Data Viewers can be placed in any order. Use the mouse to grab a column header and drag the column to the desired position.

Column Widths

To adjust a column's width in Data Viewers, place the mouse pointer on the edge of the column header. When the mouse pointer turns into two arrows, hold the left mouse key and drag column to the desired width.

Toolbars

Helpful Hint!

Select **Tools ⇨ Customize Toolbars...** to select options for the way toolbars appear. Checking **Large Buttons** displays descriptive text under toolbar buttons. This may be helpful while learning the application. Checking **Show Tooltips** displays a description of a button when the mouse pointer is placed over a toolbar button.

CUSTOMIZATION OF THE CENTRAL DATA STATION

Overview

The Customization options are:

Site Information	Institution name and technical support phone number
Serial Ports	Enables/Disables serial communications and allows individual ports to be selected and configured
Network	Enables/Disables network communications and allows specification of TCP port numbers
Interface	Enables/Disables external interfacing and allows protocol to be selected
Options	Allows various general system behaviors to be specified
Security	Enables/Disables the CDS Security features which allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application.

To access the Customization screen, close the CDS application, access the Run dialog box by clicking **Start** ⇨ **Run....** Type **wcds32 config** at the **Open:** prompt, then click **OK**.

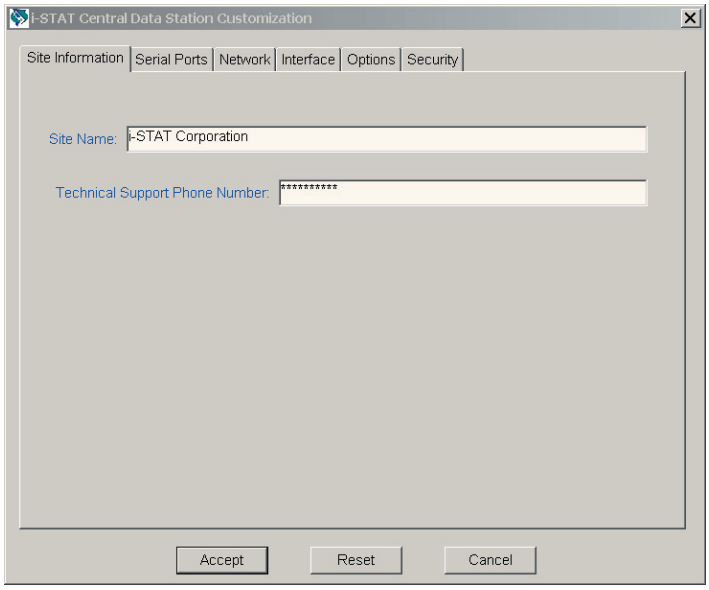
If **Run...** is not on the **Start** menu, double click the **Command Prompt** shortcut. At the **C:\>** prompt in the window that opens, type **c:\istat32\bin\wcds32.exe config** and press **Enter**.

When the Customization screen appears, click a tab to display the desired tab page. The information in each field can be specified. When all tabs are customized as desired, click the **Accept** button to save the information. Click the **Reset** button to disregard changes and restore the previous information. Click the **Cancel** button to ignore any changes and retain the current settings. When customization is complete, the CDS application will open automatically.

Site Information

A site name and address of up to 60 characters can be entered into this field.

The appropriate Technical Support Phone Number for the country will be listed or can be entered.



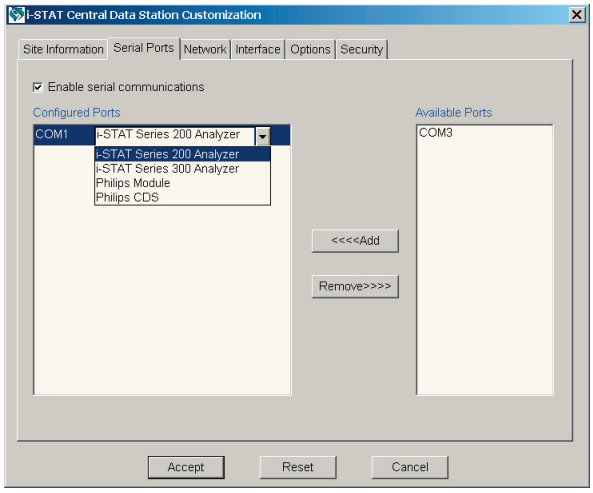
Serial Ports

The Central Data Station program resides on a PC with multiple serial ports (DB9). Available ports will automatically be listed under **Available Ports** on the Serial Ports tab page. The following components can be connected to the Central Data Station via serial ports:

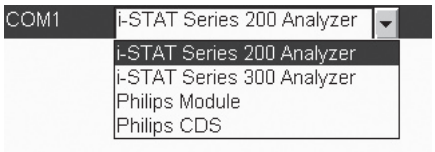
- **i-STAT Series 200 Analyzer:** IR Link transmits data to and from the i-STAT Portable Clinical Analyzer.
- **i-STAT Series 300 Analyzer:** Downloader or Downloader/Recharger transmits data to and from the i-STAT 1 Analyzer.
- **Philips Module:** a local connection to the CDS is needed to transmit software updates and customization profiles to the Blood Analysis Module.
- **Philips CDS:** The CDS server transmits patient data from the Blood Analysis Module to the Data Manager.

Click the **Enable serial communications** box to check it and enable serial communications.

Click the desired port(s) under **Available Ports** and click the **<<<<Add** button. The port(s) will now be listed under **Configured Ports.**



Click the port and select an instrument for that port.



Serial ports on the PC might also be needed for a local PCx Docking Station and connection to an interface.

Network

Click the **Enable network communications** box to check it and enable network communications.

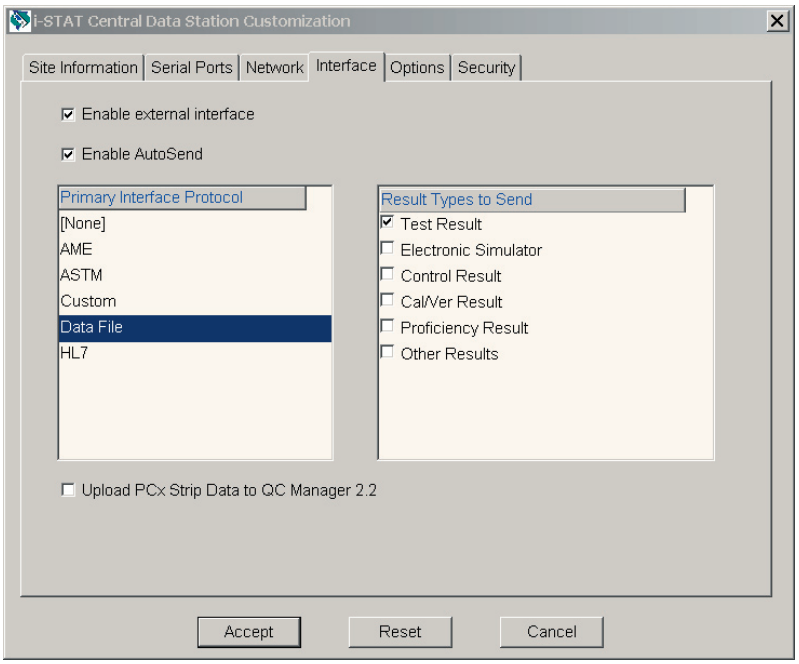
The default TCP service port assignments are listed in the Network tab page. If not using the default ports, click the port and type in the new assignment. Port numbers must be unique and in the range of 1024 to 65535.

Note: If a PCx Docking Station is sharing the ethernet port with an i-STAT Downloader, the PCx port assignment is made in QC Manager.

Interface

The appropriate interface protocol and the types of records to be sent to another data management system are selected in the Interface tab page. This configuration will typically be done by the interface provider.

Select the desired primary interface protocol. Then select the result types to be sent to the interface.



- ❑ **NONE:** Indicates no primary protocol in use. Select when no external interface is used and PCx glucose test strip data is to be uploaded to QC Manager 2.2.
- ❑ **AME:** Automatic Manual Entry – installed by i-STAT Corporation.
- ❑ **ASTM:** Data transmission conforms to ASTM E1381-95 and ASTM E1394-97 standards.
- ❑ **Custom:** Not supported at this time.
- ❑ **Data File:** Formats the CDS data for third party use.
- ❑ **HL7:** Data transmission conforms to HL7 (version 2.4) and is based on the CIC Observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science in the USA under Document POCT-1-A. This option is installed by i-STAT Corporation.

Click **Enable external interface** box to check it and enable this function.

Click **Enable AutoSend** box to check it and enable this function. When AutoSend is enabled, new records will be automatically sent from the Central Data Station to another data management system whenever they are received by the Central Data Station. Checking this box will cause the CDS program to start up with AutoSend enabled on startup. AutoSend can be temporarily enabled/disabled from the CDS program as well. Records can also be sent manually from the Data Viewers.

When MediSense Precision PCx glucose test strips are being run on the i-STAT 1 Analyzer, the glucose test strip data can be made available to QC Manager data management program. Click the **Upload PCx Strip Data to QC Manager 2.2** box to enable this function.

Options

Confirmation message on exit: When this option is enabled, a confirmation message is displayed prior to exiting the CDS program.

Enable use of IR Link IDs: When enabled, the IDs programmed into the IR Links are used in determining the download location of the results instead of the actual serial port or IP address. To use this function, all IR Links must be of the self-identifying type. This option is not typically used but is available in case the functionality is needed.

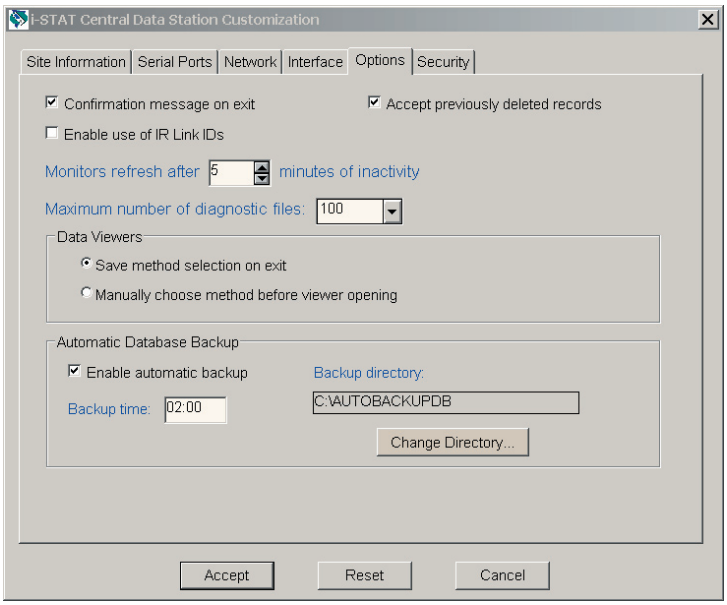
Accept previously deleted records: When disabled, this option prevents previously deleted records from being stored when re-transmitted to the Central Data Station.

Monitor refresh: The status reports in the Download and Interface Monitors will be updated after the period of inactivity specified.

Maximum diagnostic files: Diagnostic files contain information that can be useful in troubleshooting cartridge problems. The default number is 100 and is changed at the request of a Customer Support representative.

Data Viewers: Selecting **Save method selection on exit** will cause each Data Viewer to save whichever method was selected when the viewer is closed or the **Exit** button clicked. The next time the viewer or CDS software is opened, the saved method will be displayed. When **Manually choose method before viewer opening** is selected, the user will be prompted to choose a method before a data viewer is opened.

Automatic Database Backup: When enabled, the CDS database files will be backed up to the selected location at the time of day entered. Should there be a malfunction resulting in the corruption of the database, a Customer Support representative may be able to retrieve the lost data from the backup copy. Each backup replaces the previous one. Backup time depends on the size of the database but usually does not take longer than 15 minutes.

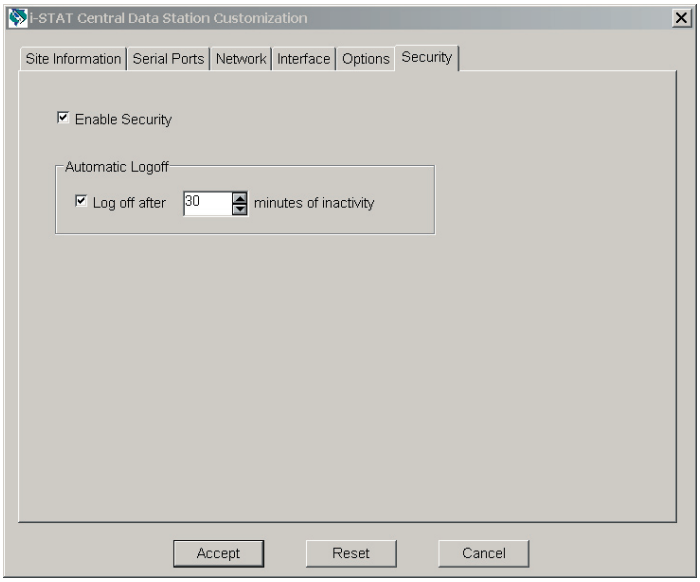


Security

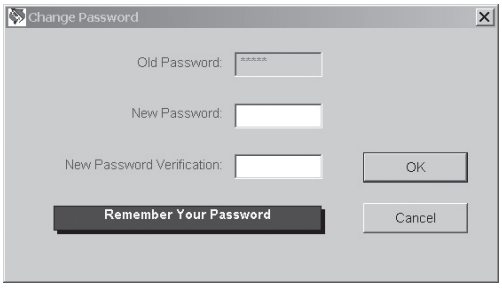
The security features allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application. Individual users can then be assigned to a security profile, and then choose their own individual CDS log-on password. The system also has capabilities for manual and automatic logoffs.

The security features should only be activated by the administrator of the System; i.e. the person ultimately in charge of the CDS who will be creating the security profiles and assigning users to them.

The security features can be activated by performing the following steps:



1. Check the box next to "Enable Security".
2. After enabling security, the user also has the option of selecting an inactivity interval after which the CDS will log off the current user. Simply click on the "Log Off" box and use the up/down arrows to choose the desired log off interval.
3. Click **Accept** at the bottom of the window.
4. A password dialog will then appear asking for a User Name and a Password. Type the User Name of **admin**, and the password **istat**. Then click on **OK**.
5. Another dialog box will appear prompting you to change your password.



6. Type in a New Password of your choosing in the space provided. Then retype that same password on the New Password Verification line and click **OK**. This will automatically bring you to the CDS application.

INTERFACE PROGRAM CUSTOMIZATION

Overview

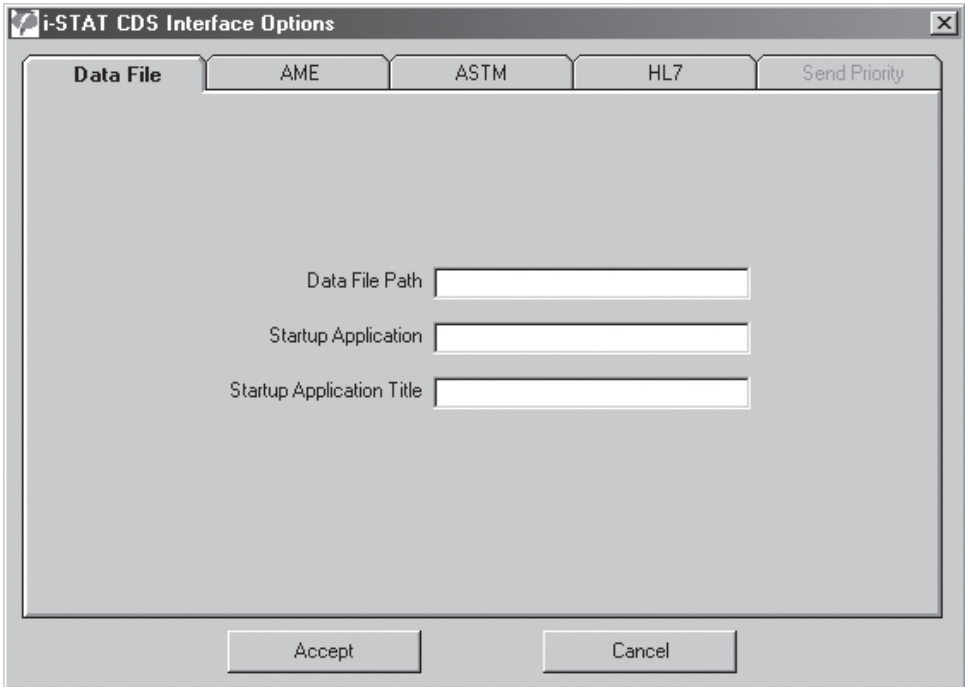
The Central Data Station can output results to an external computer system such as an LIS or HIS. The Central Data Station also provides a function that, when enabled, will also transmit all of the Precision PCx results generated on the i-STAT 1 Analyzer to QC Manager so they can be managed as part of the overall Blood Glucose Testing program.

The Central Data Station needs to be customized for the interface type using the procedures below. Tabs are presented for the options available. Each tab represents a protocol that the Interface Component of the CDS supports. Depending on the particular installation, one or more of these will be used.

Procedure

Exit the CDS application. Access the Run dialog box by clicking **Start ⇨ Run...** Type **c:\istat32\bin\interface32.exe** at the **Open:** prompt, then click **OK**. If **Run...** is not on the Start menu, double click the **Command Prompt** shortcut. At the C:\> prompt in the window that opens, type **c:\istat32\bin\interface32.exe** and press **Enter**. Click **File ⇨ Options**. The following screen will be displayed.

These tabs are used by the interface provider to configure the interface Component of the CDS for the protocol that will be used.

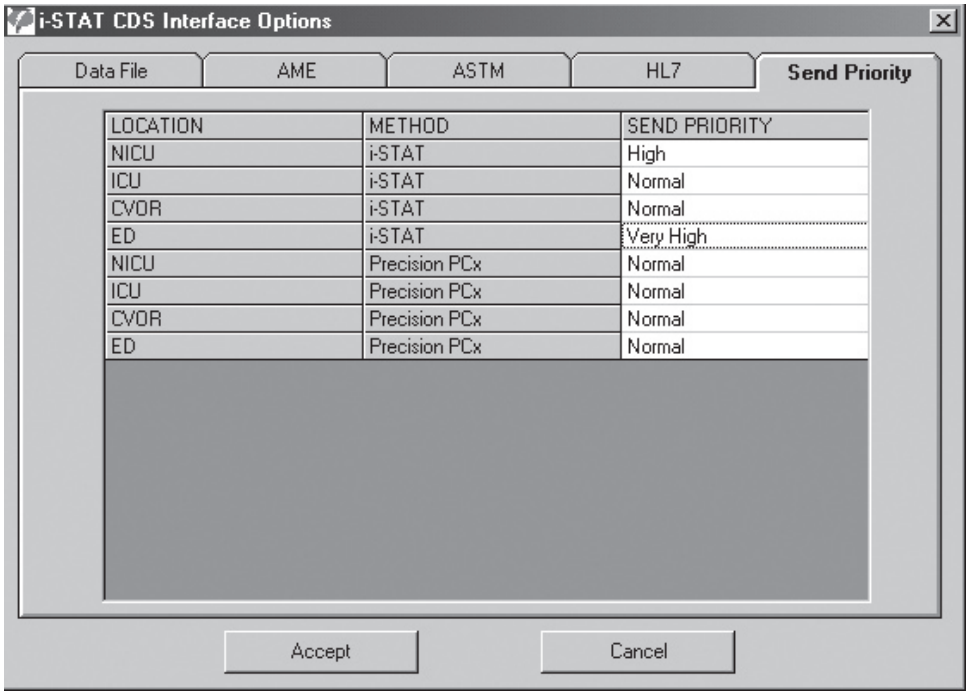


Send Priority

This function will prioritize the queue of results in the CDS database being processed by the Interface Component of the CDS program. This capability can be used by the interface provider to prioritize handling of results from one location over another.

Procedure

1. The CDS program must be running and the external interface must be enabled.
2. Double click the i-STAT interface icon in the system tray (next to the clock in the lower right hand corner of the screen) to open the interface program's main screen.
3. Click **File** ⇨ **Options**...
4. Click the **Send Priority** tab. (The other tabs will be available for viewing only.)
5. Click the Location/Method line to prioritize.
6. Right click under the **Send Priority** column and select the priority: Normal, High, Very High, from the drop down list.
7. Click **Accept** to finish.



OVERVIEW OF THE CENTRAL DATA STATION PROGRAM

The Central Data Station (CDS) software includes the following point-of-care testing process management functions:

- Managing Instruments
- Managing Operators
- Managing Inventory
- Managing Policy Compliance
- Monitoring Operator Competence
- Reviewing Patient and Quality Results
- Managing Analyzer Customization Profiles
- Maintaining Database Contents and Size
- Monitoring External Interface Activities
- Monitoring Analyzer Download Intervals
- Managing LIS entry exceptions

These functions are listed under the main menu option in four main groupings: monitors, viewers, workspaces and reports.

Central Data Station Software Function Overview and Toolbar Buttons

 Monitor

 Download

 Interface

 Administration Tools (Workspaces)

 Instrument/Location

 Operator

 Database Maintenance

 Inventory

 Customization

 User Administration

 Data Viewer

 Results (patient)

 QC Codes

 Simulator

 Unsent Records

 Control Results

 Calibration Verification

 Proficiency Tests

 Report

 Reagent Management

 Method Competence

 Method Compliance

ADMINISTRATION TOOLS

Overview

Administration Tools include Workspaces for Instruments and Locations, Operators, Database Maintenance, Inventory, Customization, and User Administration.

INSTRUMENT AND LOCATION WORKSPACE

Overview

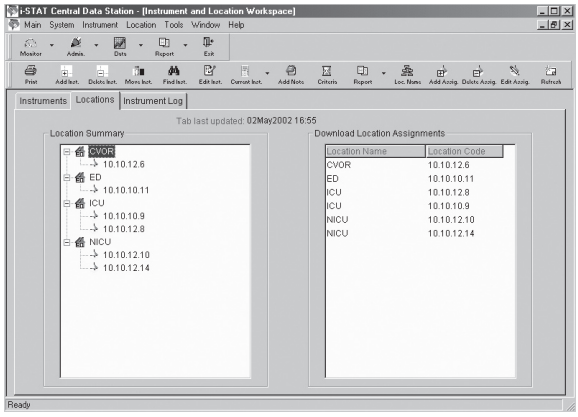
This workspace is used to:

- assign names to download locations,
- assign instruments to locations,
- configure the reporting and monitoring options for each instrument, and
- set required download intervals for each location.

The following sequence of tasks is used to set up the Central Data Station's management function for instruments:

1. Assign Location Names to Location Codes. Location Codes are the physical port addresses for the download devices.
2. Assign Instruments to Download Locations.

Locations



❑ Edit Location Name

The location name can be changed from a letter/number code to the name of a nursing unit, department, site, etc.. Up to 17 characters can be used to identify a location. Click **Location ⇨ Edit Location Name...** in the menu or click **Loc. Name** in the toolbar.

Note: Interface logic should be considered before editing.

❑ Add New Download Location Assignment

Download locations can be added manually. Click **Location ⇨ Add Download Location Assignment...** in the menu or click the **Add Assig.** in the toolbar. Download locations will also be added automatically when a transmission is received from a download device with a location that is not already on the list. The name assigned is A_xx, where xx is the download device's IP address or serial port. This name can be changed as described under **Edit Download Location Assignment**.

To assign instruments to a location without a download device, enter a Location Name or another descriptive word as the Location Code.

❑ Delete Download Location Assignment

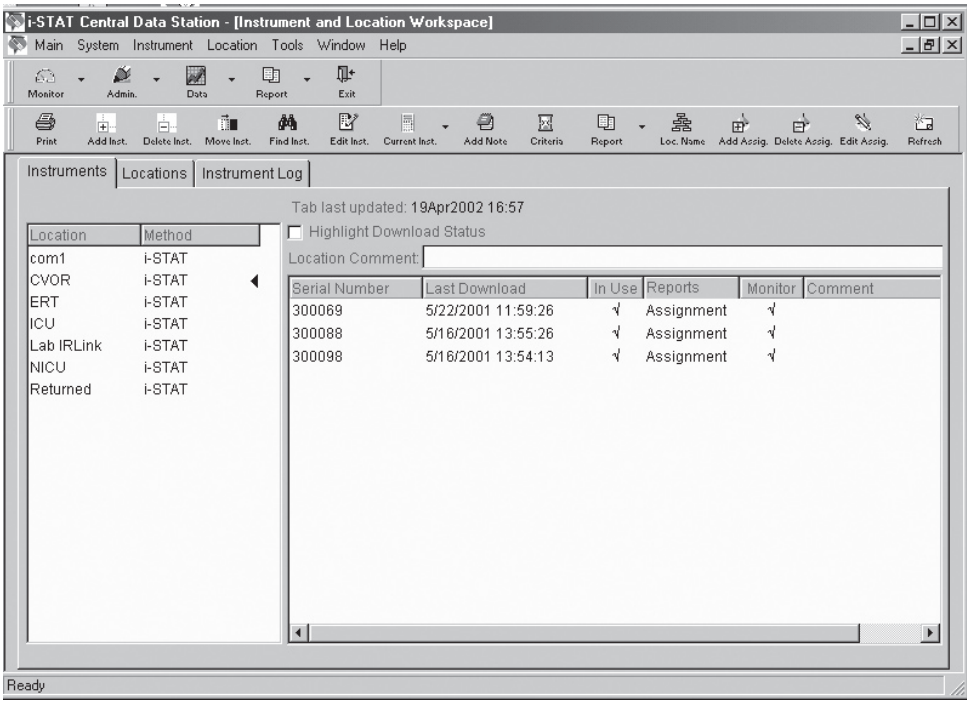
Click **Location ⇨ Delete Download Location Assignment...** from the menu or click **Delete Assig.** in the toolbar.

❑ Edit Download Location Assignment

Click **Location ⇨ Edit Download Location Assignment...** from the menu or click **Edit Assig.** in the toolbar.

Instruments

Once physical download locations have been given location names, the Instruments tab page will be the focus of management activities.



Location: Instruments are assigned to locations. This assignment is made when an instrument is manually added in the Instruments page or when an instrument downloads to the Central Data Station for the first time.

Method: The CDS is designed to accept results from any instrument that can be downloaded to the CDS program. The i-STAT method in the Instrument window refers to the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer (both i-STAT cartridge and MediSense Precision PCx and PCx Plus Glucose Test Strips) and the Philips Blood Analysis Module.

Clicking a Location/Method on the left side of the window will list the status of all instruments for that location and method in the right side of the window. A ◄ symbol indicates which location and method has been selected.

Highlight Download Status: Checking this box will highlight locations with instruments that have exceeded the required interval for downloading as well as noncompliant instruments within the location selected.

❑ Add Instrument

The Add instruments window is used to add an instrument to the system. Click **Instrument ⇨ Add...** from the menu or click **Add Inst.** in the toolbar. Select a method from the drop down list.

Note: If using the i-STAT 1 Analyzer for cartridge and/or test strip runs, select i-STAT as the method.

Select a location from the dropdown list. If the location is not listed, add the location using the instructions under Add New Download Location Assigment. If the location does not have a download device associated with it, such as an instrument used for transporting patients, a location name can be typed in. (In this case the Location Code on the Locations tab page will be SYSCODExxxxxx.) Up to 17 characters can be used.

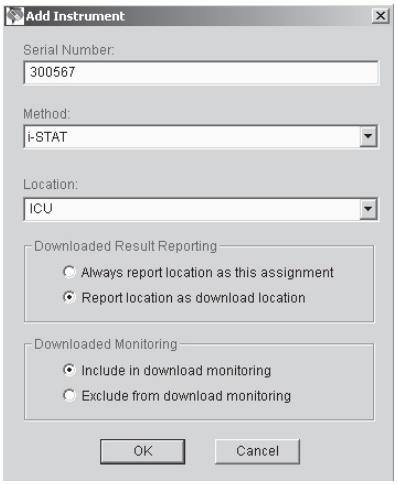
There are two options for Download Result Reporting, both of which apply to the i-STAT PCA, i-STAT 1 Analyzer, and the Philips Blood Analysis Module:

1. **Always report location as this assignment:** The results from this instrument will appear with the location of the instrument's assignment regardless of the download device used to transmit the results. This option is useful when an instrument is assigned to a functional group that may download from various areas in the institution. The instrument will be designated "Assignment" under the Reports column in the Instruments tab page.
2. **Report location as download location:** The results from this instrument will appear with the location for the download device that was used to transmit results to the Central Data Station. The instrument will be designated "Download" under the Reports column on the Instruments tab page.

   If the instrument is not manually added to the list and it transmits to the CDS, it is automatically assigned to the location of the download device and is set to report "Download." If the download device location has not been manually added, a default location A_xx (B_xx, C_xx, etc.), where xx is the IP address or serial port of the download device, will be used.

There are two options for Download monitoring:

1. **Include in download monitoring:** Includes this Serial Number in download monitoring.
2. **Exclude download monitoring:** The download status of the instrument will not be reported by the Download Monitor. (Blood Analysis Modules and infrequently used or spare analyzers might be exempted from the Download Monitor report).



❑ Delete Instrument

Click the Location/Method for the instrument to be deleted and then the serial number of the instrument to be deleted. Click **Instrument ⇨ Delete...** from the menu or click **Delete Inst.** in the toolbar.

❑ Move Instrument

Click the Location/Method for the instrument to be moved and then on the serial number of the instrument to be moved. Click **Instrument ⇨ Move...** from the menu or click **Move Inst.** in the toolbar. Select the new location from the drop down list or type in a new location.

❑ Find Instrument

Click **Instrument ⇨ Find...** from the menu or click **Find...** in the toolbar. Enter the serial number of the instrument and select the Method from the drop down list.

❑ Edit Instrument Comment

Click the instrument serial number, click **Instrument ⇨ Edit Comment** from the menu or click **Edit Inst.** in the toolbar. Enter a comment of up to 16 characters.

❑ Change Current Instrument Setttings

Reporting: Click the instrument serial number. Click **Instrument ⇨ Current Instrument ⇨ Change Reporting** from the menu or click the down arrow next to **Current Inst.** and then **Reporting** in the toolbar to toggle between **Download** and **Assignment**.

In Use: Click the instrument serial number. Click **Instrument ⇨ Current Instrument ⇨ Toggle In Use** from the menu or click the down arrow next to **Current Inst.** and then **In Use** in the toolbar to check (in use) or un-check (out of use) the analyzer in the In Use column.

Instruments that are not checked "In Use" do not have a download criteria applied to them. You would use this for instruments you do not expect to be downloaded. When an analyzer that is not marked "in use" downloads, it is set back in use and the download criteria is applied.

Monitoring: Click the instrument serial number. Click **Instrument ⇨ Current Instrument ⇨ Change Monitoring** from the menu or click the down arrow next to **Current Inst.** and then **Monitoring** in the toolbar to check or un-check the analyzer in the Monitoring column.

❑ Add Instrument Note

Click **Instrument ⇨ Add Note...** from the menu or click **Add Note** in the toolbar. A note of up to 50 characters can be entered. The note will appear as a Log Entry in the Instrument Log tab page.

❑ Change Download Monitoring Criteria

Compliance to download policy can be monitored by the CDS program. Click on the Location/Method. Click on **Instrument ⇨ Download Criteria...** from the menu or click **Criteria** in the toolbar. Enter the required download interval. An interval of up to 1000 hours is allowed.

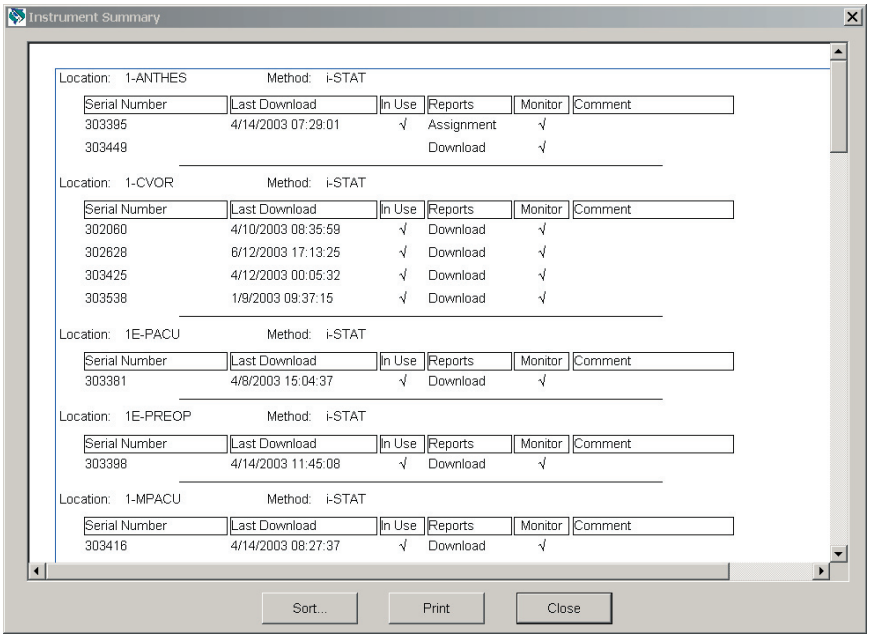
Compliance with the criteria can be observed by checking the Highlight Download Status check box or by going to the Download Monitor. Individual Download criteria can be set for each location and method pair.

Note: The i-STAT 1 Analyzer can also be customized either to warn the end users that a download is required or to lockout end users if the time for a download has been reached or exceeded. The download criteria for analyzers and for the CDS monitor should be selected to make sense.

❑ Instrument and Location Summary

The Instrument and Location Summary provides a report of the current instrument assignments and the last download for each instrument. Click **Main ⇨ Open Report ⇨ Instrument Summary** from the menu or click the down arrow next to **Report** and then **Summary** in the toolbar. Summaries can be viewed and printed by:

- This method and location only (location and method selected with ◄ symbol)
- This method, all locations (method selected with ◄ symbol)
- All methods, all locations



Instrument Log

The Instrument Log tracks all changes made in the Instruments tab page. Additional comments can be added to the log by clicking **Add Note** in the toolbar.

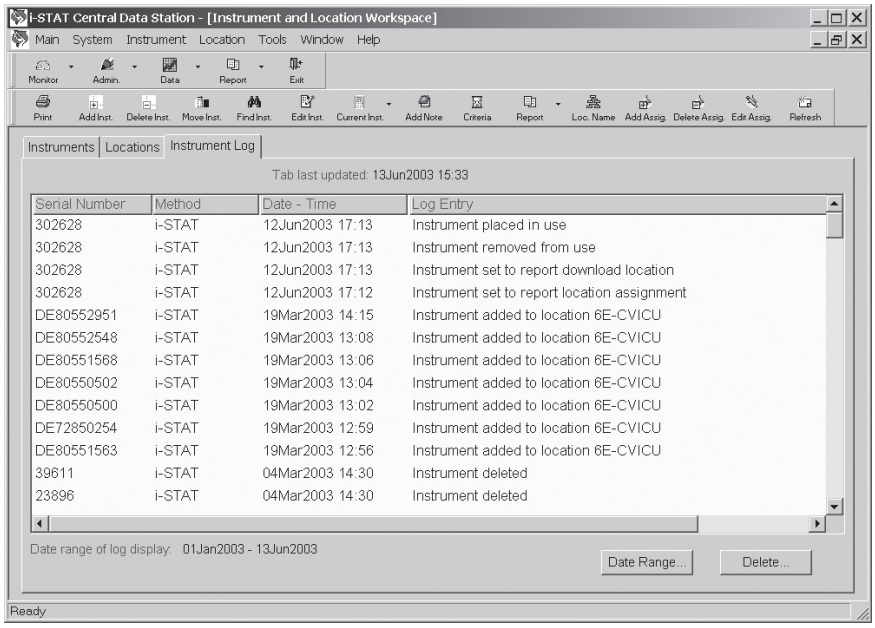
- ❑ Date Range...

Data can be viewed within a user defined default range or by a manually entered range.

- ❑ Delete...

The **Delete** button allows selected or all entries within the date range selected to be deleted.

To print the log press the **F2** key or select **Print** from the Main menu or toolbar.



OPERATOR WORKSPACE

Overview

This workspace is used to:

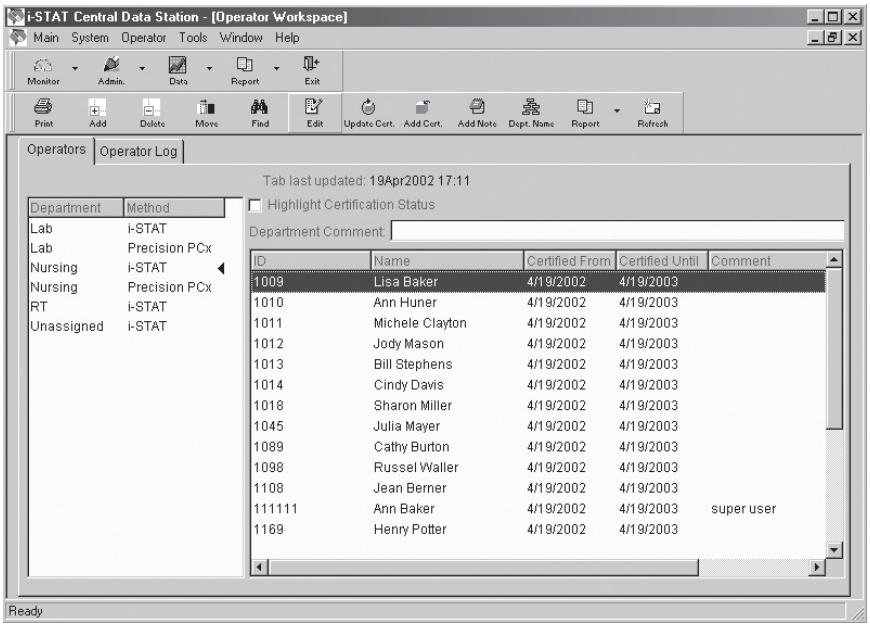
- Record operator names and identification numbers
- Record certification dates and certification expiration dates
- Assign operators to departments
- Add comments

When the i-STAT 1 Analyzer is customized to use the operator list created here, the analyzer can be customized to warn or lockout operators if they are not on the list or their certification has expired.

Operators

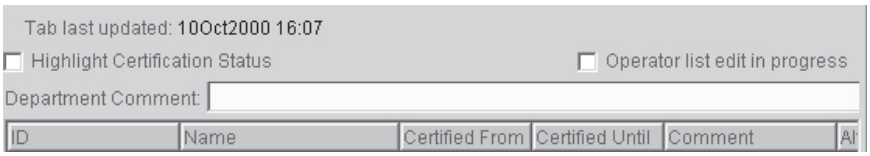
Operators are listed by Department and Method as indicated by the◄symbol. Operators are added to the operator list by department and by method.

When a record is received with an Operator ID that is not listed in any Department, the operator is placed in the “Unassigned” department.



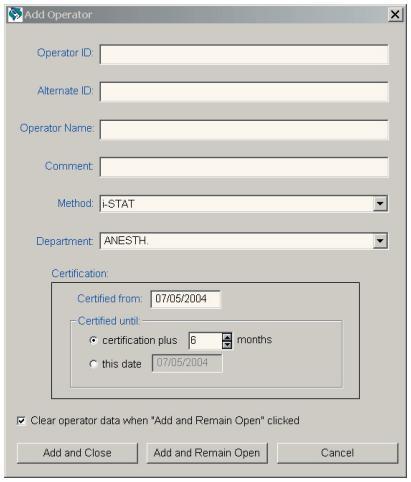
❑ Operator list edit in progress

When editing the operator list, check this box to delay updating i-STAT1 analyzers until all editing is complete. When editing is complete, click the box to remove the checkmark. This box will appear when Serial or Network Communications are enabled, Customization is enabled and Use Operator List is enabled.



❑ Add Operator

This function is used to add new operators to the list of operators. Alternatively, operator lists can be imported (see Operator List Import at the end of this section). Click **Operator ⇨ Add**... from menu or **Click** on **Add** in the toolbar.



Enter the ID number that the operator will enter into the analyzer on the Operator ID line. If a different ID number is used to access the LIS, this number should be recorded on the Alternate ID line. An Operator Name of up to 40 characters can be entered. A comment of up to 16 character can be added. If operators are to be certified for more than one method, such as for the i-STAT cartridge and the PCx glucose test strip, certify each operator for one method and use the **Add Cert.** toolbar button to certify all applicable operators at one time for the method. To add the first operator to a department, type the department name (up to 10 characters). Once a department has been added, it can be selected for additional operators from the drop down menu.

Check the **Clear Operator data when "Add and Remain Open" clicked** box to specify whether or not the operator information fields should be cleared when the Add and Remain open button's clicked.

❑ Delete Operator

Select the operator or operators. Click **Operator ⇨ Delete...** from the menu or click **Delete** in the toolbar to delete the operator or operators. When the last operator from a department is deleted, the department is removed from the system.

❑ Move Operator

Select the operator or operators. Click **Operator ⇨ Move...** from the menu or click **Move** in the toolbar, and select a new department from the drop down list. If the department is not in the list, type in the new department name.

❑ Find Operator

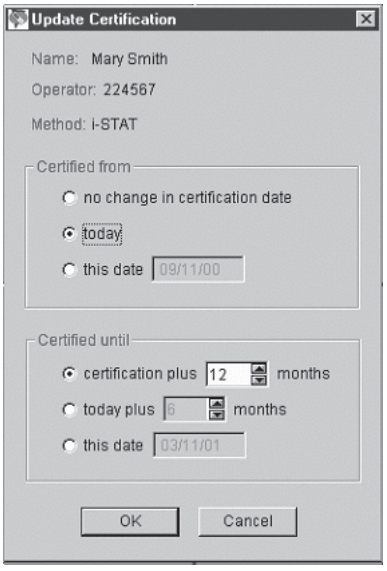
Click **Operator ⇨ Find...** from the menu or click **Find** in the toolbar, select the method for which the operator is certified, and type in the operator ID. A box will appear around the found operator.

❑ Edit Operator Data

Click the operator. Click **Operator ⇨ Edit** from the menu or click **Edit** in the toolbar. The operator ID, name, comment and alternate ID can be edited.

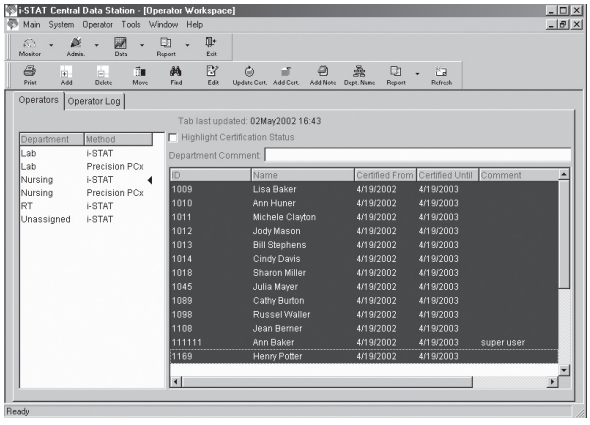
❑ Update Certifications

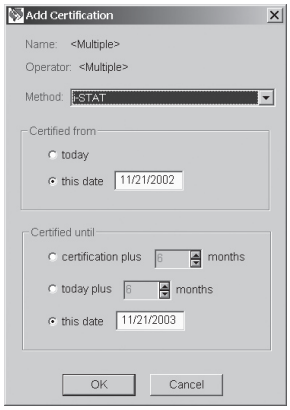
Select the operator or operators. Click **Operator ⇨ Update Certification...** from the menu or click **Update Cert.** in the toolbar and complete the Update Certification form.



❑ Add Certification

The Add Certification button allows operators who are certified for one method to be certified for another method without having to complete a new Add Operator form. Highlight the operator or operators in the Operator tab window that are to be certified for another method. Click **Operator ⇨ Add Certification...** from the menu or click the **Add Cert**. button on the toolbar. Select the other method for which these operators are to be certified, then specify the certification dates.





❑ Add Note

Click the operator. Click **Operator ⇨ Add Note...** from the menu or click **Add Note** in the toolbar. An Operator Log Note of up to 50 characters can be typed.

❑ Edit Department Name

Click the department name to edit. Click **Operator ⇨ Edit Department Name** from the menu or click **Dept. Name** in the toolbar. The Unassigned designation cannot be changed.

❑ Operator and Certification Reports

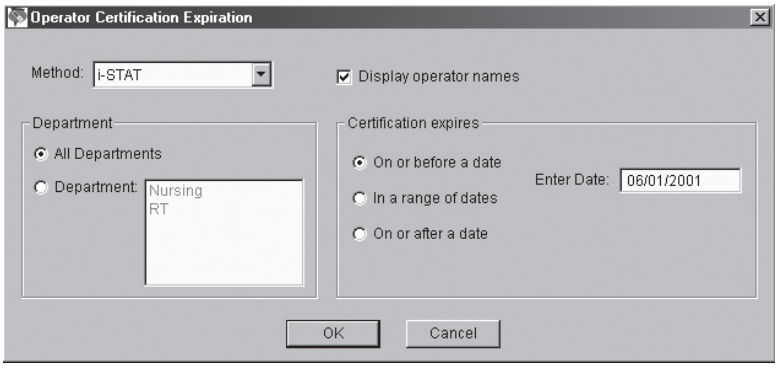
Click on the down arrow next to **Report** in the Operator Workspace toolbar and click on **Summary** or **Expiration**.

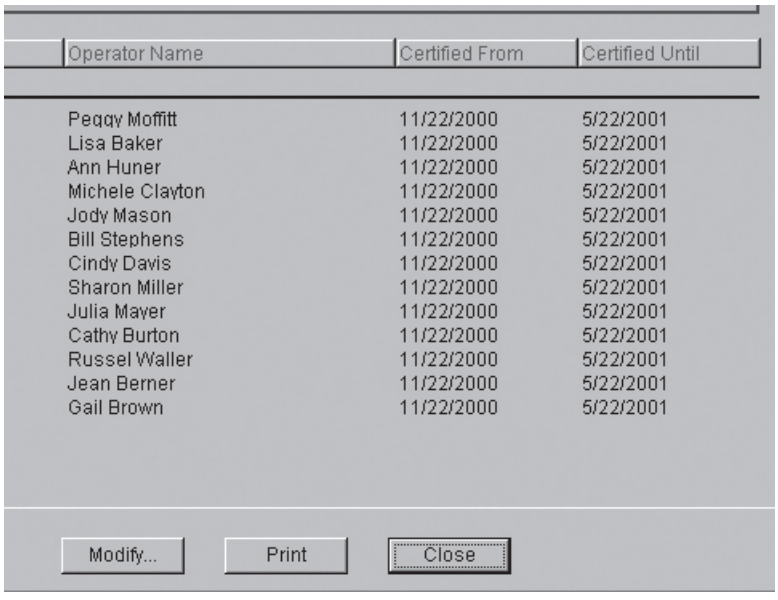
Operator Summary: Summaries of operators can be viewed and printed by:

- This method and department only (department and method selected with ◄ symbol)
- This method, all departments (method selected with ◄ symbol)
- All methods, all departments

  The reports include operator IDs, operator names, certified from date, certified until date, comments, a checkmark if certification has expired and the operator's alternate IDs grouped by department and method.

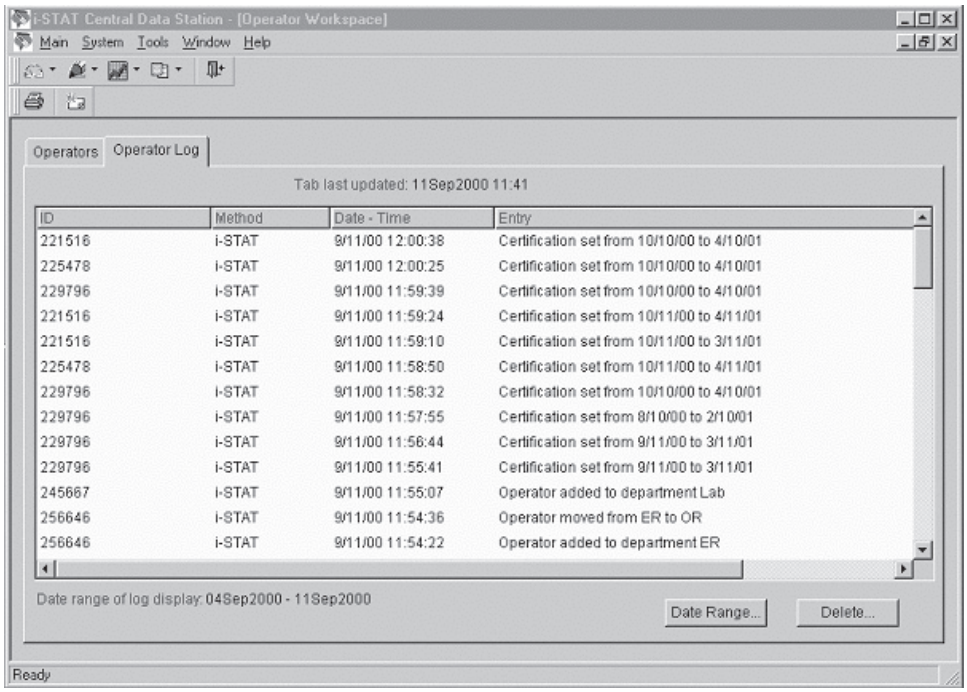
Operator Certification Expiration: This report allows the certification status of operators to be viewed.





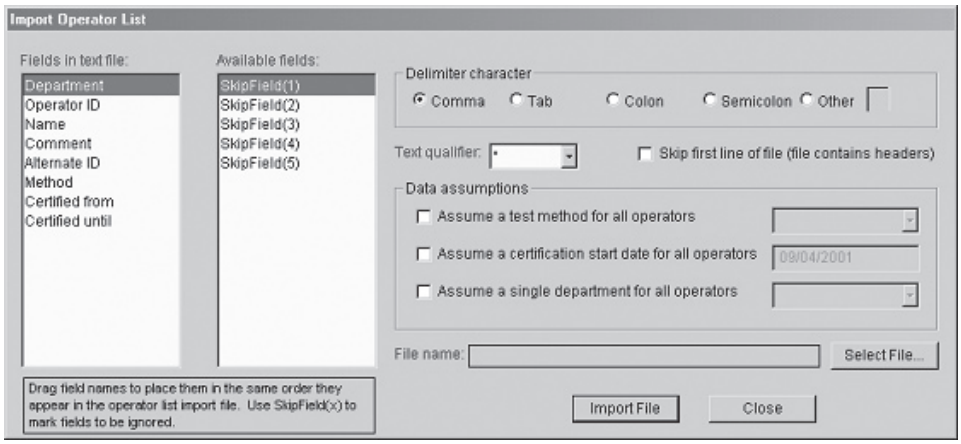
Operator Log

The Operator Log tracks changes made and "Add Note" entries made in the Operator tab page. The **Date Range...** button can be used to specify a time period to be viewed and the **Delete...** button to delete entries. To print the log press the **F2** key or select **Print** from the Main menu.



OPERATOR LIST IMPORT

This function in the Operator Workspace on the CDS5 allows an operator list to be imported from a text file. To access this function, click on **Main ⇨ Open Administration Function ⇨ Operator** from the main menu to open the Operator Workspace. Select **Operator ⇨ Import List...** from the main menu to open the Import Operator List window. This window is used to describe the format of the text file containing the list to be imported into the CDS.



Import List Instructions

1. Under **Fields in text file:**, use the mouse to drag and drop the field names so they match the order in which the fields appear in the text file containing the list to be imported. If a field does not appear in the text file, drag it to the **Available fields**: list. If the text file contains a field that should be ignored, drag a **SkipField(x)** field to the **Fields in text file:** list to mark where that field appears.
2. Fields in the text file containing the list to be imported must be separated by a comma or other delimiter character. Specify the separator in the **Delimiter character** box.
3. If a qualifier character is used to enclose the data contained in each the field in the text file containing the list to be imported, select this character from the **Text qualifier:** list.
4. If the first line of the text file is a header line listing the names of the fields in the text file containing the list to be imported, click **Skip first line of file (file contains headers)**. The import function cannot process header lines.
5. If all operators in the text file containing the list to be imported are to be certified for one method, click **Assume a test method for all operators** and select **i-STAT** for cartridge testing or **Precision PCx** for the MediSense Precision PCx or PCx Plus Glucose Strip testing on the i-STAT1 Analyzer. If this option is selected, the text file does not need to contain a **Method** field. If this option is selected and the text file does contain a **Method** field, its contents will be ignored
6. If all operators will be certified from the same date, click on **Assume a certification start date for all operators** and enter the start date. If this option is selected, the text file does not need to contain a **Certified from** field. If this option is selected and the text file does contain a **Certified from** field, its contents will be ignored.
7. If all operators are to be assigned to the same department, such as Nursing or Perfusion, click on **Assume a single department for all operators** and enter or select the department from the drop down list. If this option is selected, the text file does not need to contain a **Department** field. If this option is selected and the text file does contain a **Department** field, its contents will be ignored

Example from list to be imported:

"ICU", "12345", "Smith, Judy", "none", "98765", "i-STAT", "2001-08-08", "2002-08-08"

8. Click **Select File…** and select the name of text file containing the list to be imported.
9. Click **Import File** to import the list from the text file.

Note: operator data that already exits in the CDS5 database takes precedence over any data imported from a text file.

Export List

After a list has been imported or created, it can be exported for backup purposes.

DATABASE MAINTENANCE

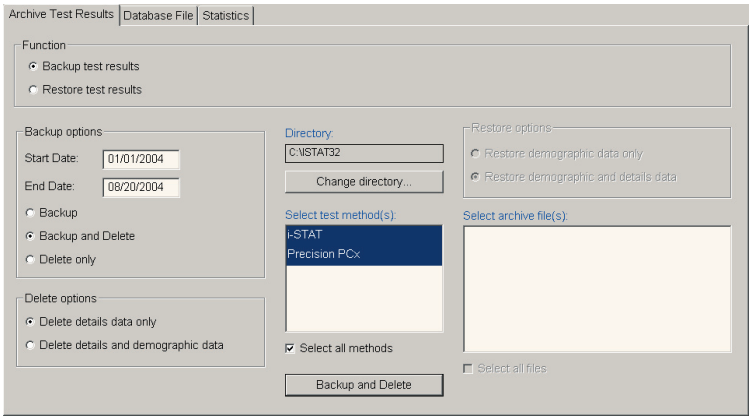
Overview

This workspace allows the database to be backed up, deleted and restored. A "Statistics" tab page also allows users to view a summary page of Result Types contained in the database.

Archive Test Results

Backup test results: This function allows test results to be backed up onto a disk, CD or other directory. (Note: a 1.44MB disk will only store about 1000 test records.)

1. Click on **Main ⇨ Open Administration Functions ⇨ Database Maintenance.**
2. After the workspace opens, click the **Archive Test Results** tab.



3. Click the **Backup** test results radio button.
4. Specify a date range for the function.
5. Select a Backup Option: **Backup**, **Backup and Delete**, or **Delete only**.
6. If an option that includes Delete is selected, then select a Delete Option: **Delete details data only** or **Delete details and demographic data**. Details data includes:

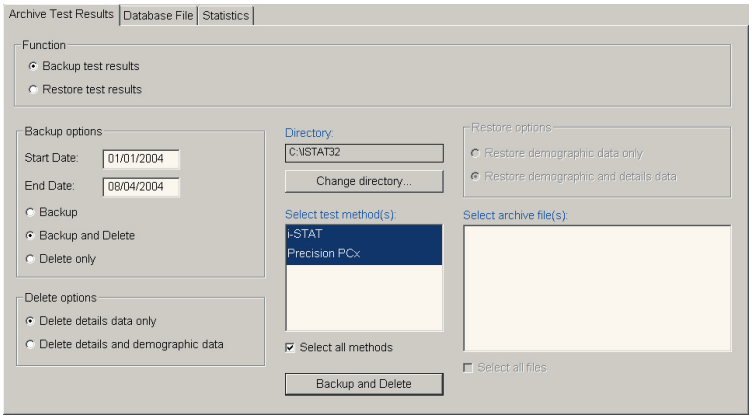
   - Original Operator and Patient ID
   - Patient Name
   - LIS order number
   - Sent status
   - Analyte values
   - Extra data

   Demographic data can be used to generate reports. Demographic data includes:

   - Test type (test result, simulator, proficiency,...)
   - Test panel (such as EC8+, CG8+, PCx Glucose)
   - Test Method (i-STAT, Precision PCx...)
   - Patient ID
   - Operator ID
   - Test date/time
   - Location

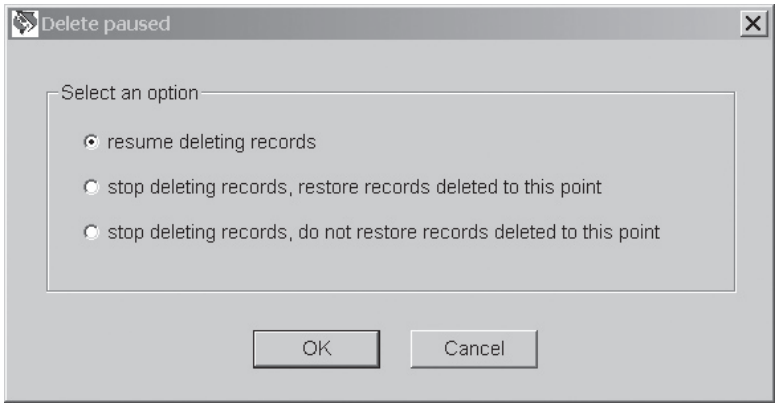
- Comment
- Interface comment
- Serial number
- Department

7. Select a Directory.
8. Select a method or methods to back up or click **Select all methods**.



9. Click the button marked **Backup** or **Backup and Delete** and follow the prompts.

Note: When results are being deleted as part of a backup and delete or a delete only operation, the deletion can be cancelled. Simply click on the **Cancel** button to stop the operation. Once the **Cancel** button is clicked, depending on the amount of data being deleted and the size of the database, there may be a significant lag time of a few minutes before a dialog box appears indicating that the deletion has been paused, asking you to select one of three options:



The reason for the lag time is that the program needs to complete whatever portion of the deletion operation it was performing when the **Cancel** button was clicked before it can display the dialog box. Once the dialog box is displayed, simply click on the desired radio button and then click **OK**.

Restore test results: This function allows test results that have been deleted from the CDS but backed up elsewhere to be restored to the database.

1. Click on **Main ⇨ Open Administration Functions ⇨ Database Maintenance**.
2. Insert disk or CD where files are located.
3. Click the **Restore test results** radio button.
4. Select the directory for the stored results.
5. Select the method or methods to be restored.
6. Select a restore option: **Restore demographic data only** or **Restore demographic and details data**. (Demographic data can be used to generate reports.)
7. Select the files to be restored or select all files.
8. Click the **Restore** button.

Database File

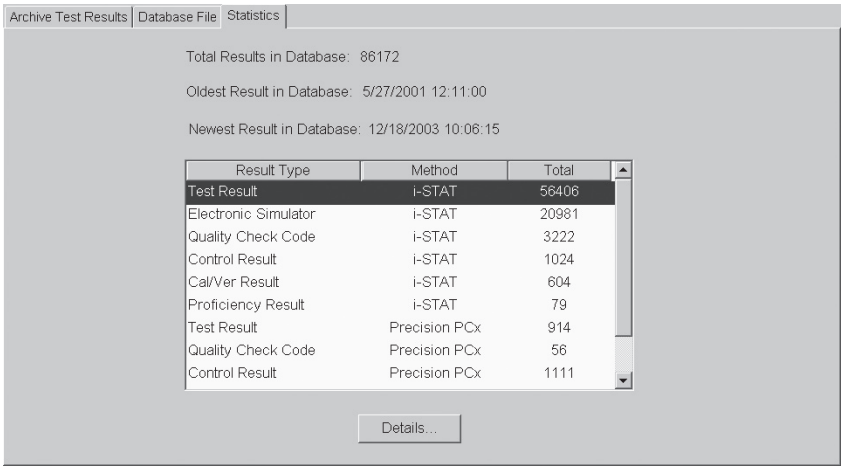
Backup Database File: This function allows the user to manually perform the same operation that occurs when the automatic database backup occurs. It creates a complete backup of the database file to the specified drive/directory.

Compact Database File: When the backup and delete or delete only functions are executed, the deleted data is removed from the database but the disk space the data occupied in the database file is not. The compaction function creates a new copy of the database with the excess space removed, creating a smaller, better organized and, therefore, more responsive database. If CDS functions such as opening or refreshing a data viewer grow noticeably less responsive over time, compaction of the database may help. It is recommended that compaction function be executed at least once a year.

Statistics

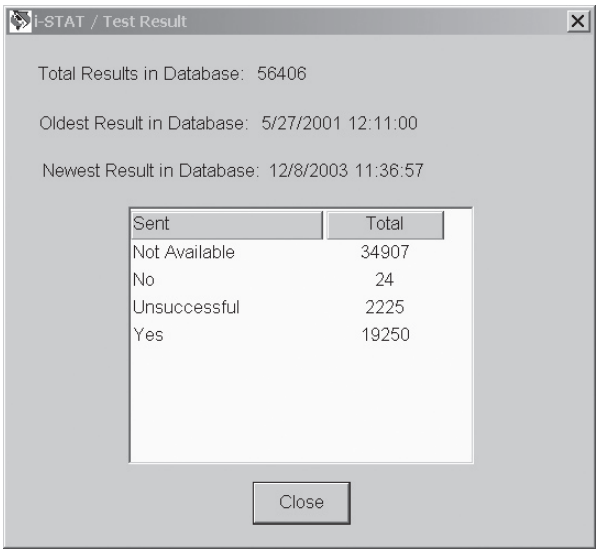
A "Statistics" tab page allows users to view a summary page that lists:

1. The total results in the database,
2. The date and time of the oldest result in the database,
3. The date and time of the newest result in the database, and
4. A breakdown of the total results in the database by Result Type and Method.



Selecting an individual Result Type and then clicking on Details allows you to view a similar statistical breakdown for that particular Result Type:

1. The total number of that particular Result Type in the database,
2. The date and time of the oldest result of that type in the database,
3. The date and time of the newest result of that type in the database,
4. A breakdown of the number of this particular result type that have been sent successfully (Yes), unsuccessfully, or not sent at all (No) to the LIS/HIS. Note: a listing in this window for "Not Available" indicates that there are records of this type in the database where the details data have been deleted, so the application cannot determine whether that particular record was sent or not.



INVENTORY WORKSPACE

Overview

The Inventory Workspace is organized under five tabs with the following functions:

- Stock: define reorder triggers, view and edit inventory
- Distribution: track items distributed from central stock to different locations
- Items: define inventory items
- Orders: track pending and received orders, view reports on received items
- Inventory log: view a log of major user actions

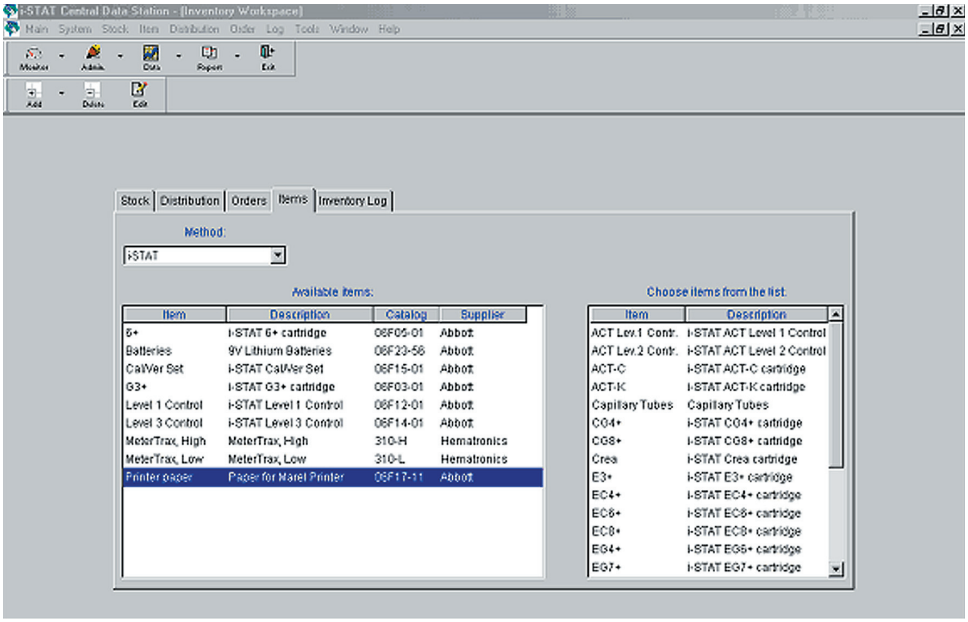
Populate the Items tab first, followed by the Stock tab where current inventory should be entered and reorder triggers defined.

Items

The Items tab is used to define the inventory items for the i-STAT System and other point-of-care tests.

To select an item available from i-STAT and its distributors, highlight the item in the **Choose items from the list** on the right side of the window, then click the arrow next to the **Add** button in the tool bar and click the **Selected** button. The item will move to the **Available items** list on the left side of the window.

To add an item not available from i-STAT and its distributors, click the arrow next to the **Add** button in the tool bar, then click the **New** button and complete the displayed information form.



To delete an item from the Available items list, highlight the item, then click the **Delete** button in the tool bar. If the item was selected from **Chose items from the list**, the item will be moved from **Available items** back to this list.

To edit information under the **Available items** list, click the **Edit** button in the tool bar.

Stock

The Stock tab includes both Inventory and Estimated Inventory statistics.

Inventory: The number of given items as counted and entered by the user. The inventory is automatically updated when new orders are received under the Orders tab.

Estimated Inventory: The number of i-STAT cartridges and MediSense PCx and/or PCx Plus glucose test strips as estimated by the workspace software. The initial Estimated Inventory is taken from the Inventory column. Every time a cartridge or glucose test strip result is transmitted to the Central Data Station software, the count of the estimated inventory decreases by 1. The Estimated Inventory is automatically updated when new orders are received under the Orders tab. The Estimated Inventory item count is adjusted to the Inventory count whenever the Inventory column is manually edited.

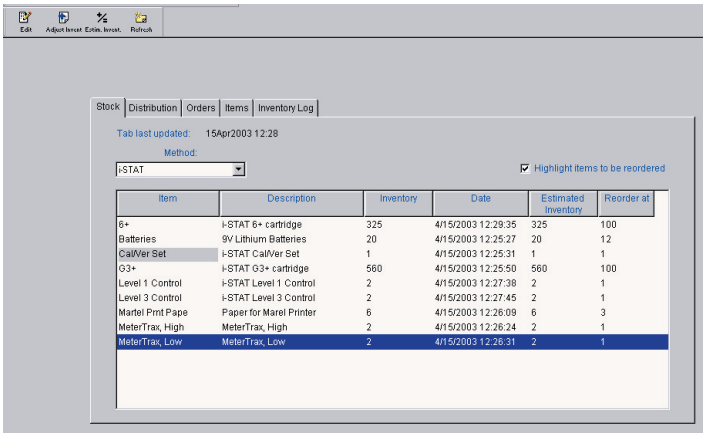
Startup Option

The items added under the Items tab will be listed under the Stock tab with **Inventory** and **Reorder** set to 0. There are two ways to populate the Inventory column.

1. Count current stock. Go to the Stock tab, click on the **Edit** button in the tool bar, and enter the current inventory. Lot numbers and Expiration dates will not be tracked for inventory entered by this method.
2. Count current stock along with lot numbers, expiration dates and locations. Go to the Order tab and enter and receive the POs for the existing stock. Go to the Stock tab and manually adjust the Inventory to the current stock count. (Alternatively, receive only the current stock count.) This option allows the user to take advantage of the lot number and expiration date tracking capabilities of the workspace.

Click on the Edit button on the tool bar and enter the reorder trigger numbers.

Click a check mark next to **Highlight items to be reordered**. Items that need to be reordered will be highlighted. (See CalVer Set in illustration below.) Reorders are highlighted based on the **Estimated Inventory**.



The inventory can be edited by highlighting the item and clicking the **Edit** button or by clicking the **Adjust Invent** button, selecting the item from the drop down menu, and adding or subtracting units. When the **Inventory** is edited, the **Estimated Inventory** is automatically made equal to the **Inventory**.

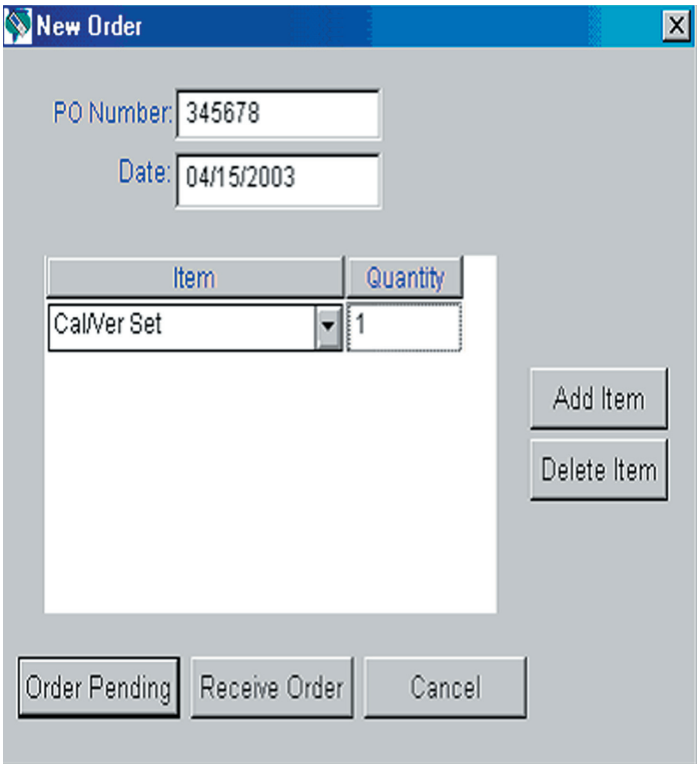
The **Estimated Inventory** for i-STAT cartridges and MediSense PCx glucose test strips will automatically begin updating with the next analyzer transmission. Click the **Refresh** button to update the workspace for transmitted data. Both the **Inventory** and the **Estimated Inventory** are updated automatically when orders are received under the Orders tab.

Periodically, the **Estimated Inventory** should be updated manually. This is necessary to account for other consumables as well as for cartridges and strips that are discarded before testing, such as expired inventory. Click the **Estim. Invent.** button in the tool bar to adjust the **Estimated Inventory**.

Orders

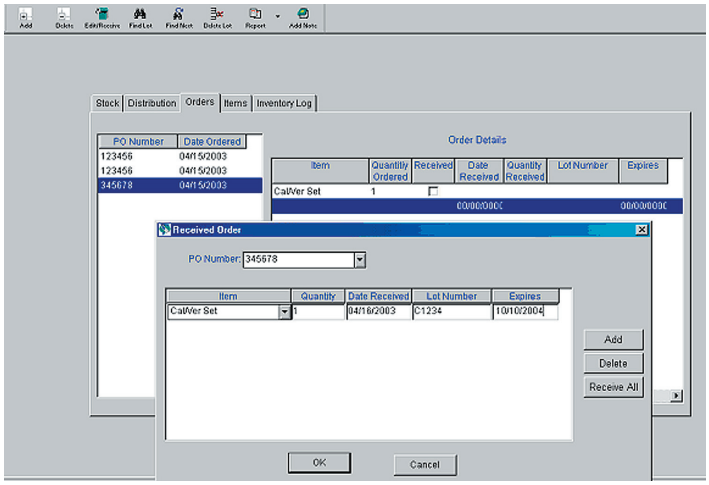
To record a new order, click on the **New** button in the tool bar. Select the item from the drop down menu under **Item** and enter the quantity. Click the **Add Item** button to add another item or the **Delete Item** button to delete an item.

To enter information about a received order right away, click on the **Receive Order** button. To enter information about a received order later, click the **Order Pending** button.

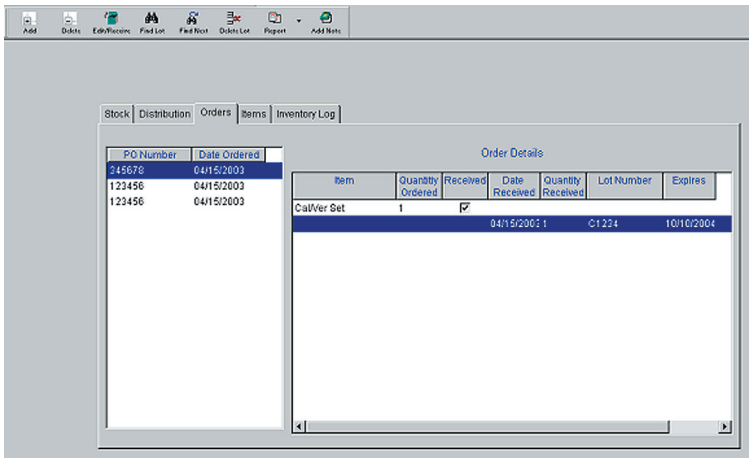


To receive an item or to edit order information, click the **Edit/Receive** button in the tool bar. Highlight the PO Number and enter the **Order Details**.

Note: The lot number and expiration date are used in the Distribution tab. Therefore, PO, lot number and expiration date information for consumables in inventory should be entered here. The PO number field can accommodate up to 20 characters.



Click the **Add** Button to add another item or the **Delete** Button to delete an item. Click the **Receive All** Button to automatically enter items and quantities, as they were ordered.



Use the **Delete** button on the tool bar to delete an order.

Use the **Find Lot** and **Find Next** buttons on the tool bar to find the PO associated with a received lot.

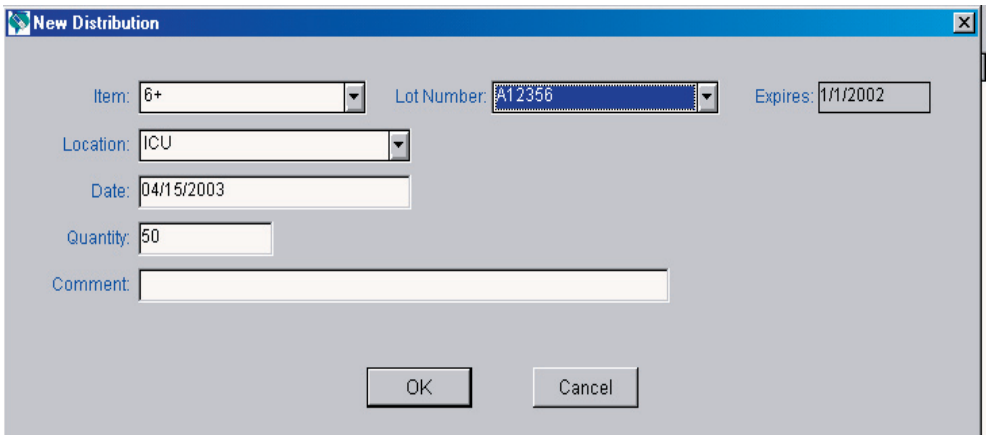
Use the **Delete Lot** button on the tool bar to delete a lot number that has expired or has been used up.

The **Report** button on the tool bar is used to view all received items by date range.

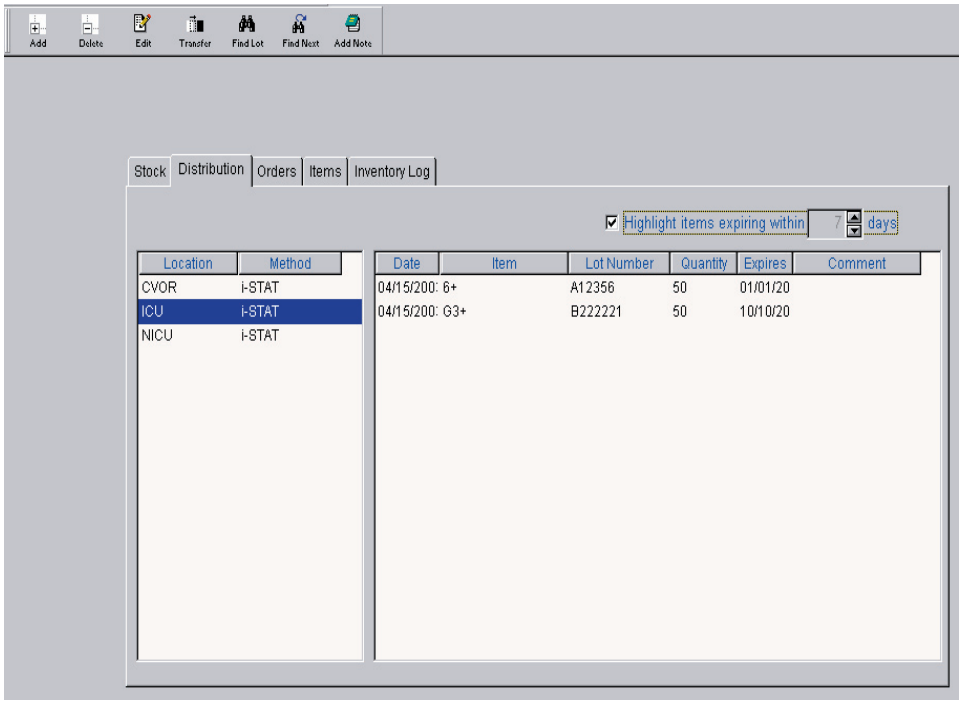
Use the **Add Note** button on the tool bar to add a note to the **Inventory Log**.

Distribution

Use the **Add** button in the tool bar to record the distribution of consumables. The Item drop down menu includes all consumables entered in the Items tab. The Location drop down menu includes all locations entered in the Instrument and Location Workspace. The Lot Number drop down menu includes lot numbers for the selected items received in the Order tab. The expiration date is entered automatically. A comment of up to 16 characters can be entered.



The Distribution tab will list each location with its consumables. Define an alert date and click a check mark next to **Highlight items expiring within xx days** to alert you to transfer stock to a different location where it can be used before its expiration date.



Use the **Delete** button on the tool bar to delete a distribution.

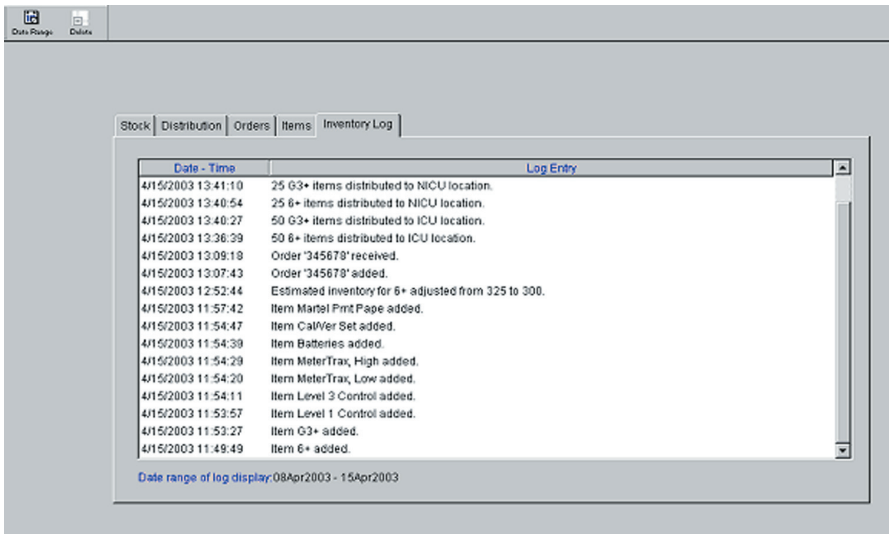
Use the **Transfer** button in the toolbar to move consumables from one location to another.

Use the **Find Lot** button to find a location where a consumable of a specific lot has been distributed. Click the **Find Next** button to find other locations for this lot.

Use the **Add Note** button to add a note to the Inventory Log.

Inventory Log

The Inventory Log documents each action taken in the Items, Stock, Distribution and Orders tabs. Click the **Date Range** button in the toolbar to select the a Default date range or a Start and End date for this report. Click the Delete button to delete entries in the log.



CUSTOMIZATION WORKSPACE

Overview

This workspace is used to create profiles with site specific test characteristics for the analyzers. See the Customization section of this manual for details of items that can be customized and their default settings.

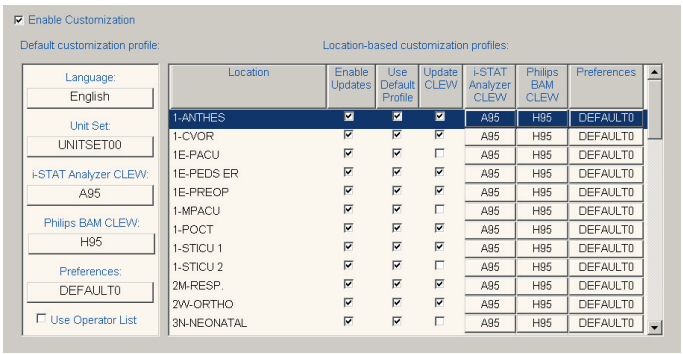
Password

The Customization Workspace is password protected. If the Security feature is disabled, the default password is **istat**. If the Security feature is enabled, the user uses the same password as their CDS application logon password. To change the password, select **Tools** and **Change Password** from the menu bar. A password from 3 to 8 characters can be used.

Enabling Customization

To enable customization, click the box to check it. When customization is enabled, the Central Data Station will check the Customization Profile for the location each time an analyzer is downloaded. If the location has the **Enable Updates** option checked, the Central Data Station will update the analyzer with the current Customization Profile for that location as noted below.

- Analyzers designated to Report location as download location in the Instrument workspace will be updated with the Customization Profile assigned to the download location, regardless of the location to which the instrument is assigned. Care should be taken when downloading instruments from locations other then their assigned location.
- Analyzers designated to Always report location as this assignment in the Instrument workspace will always be updated with the Customization Profile for the instrument's assigned location, regardless of the physical location from which it downloads.

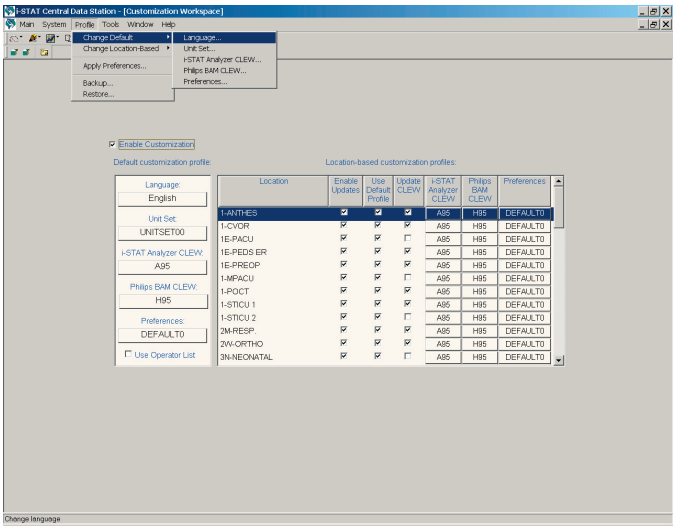


If a location has the **Enable Updates** option unchecked, downloading from that location will result in no customization changes being made to analyzers designated to **Report location as download location.** Analyzers designated to **Always report location as this assignment** will not be updated if the assignment location for the instrument has the **Enable Updates** option unchecked, regardless of the setting associated with the physical location from which it downloads.

User can also disable/enable CLEW updates by location. The default setting is to have the CLEW updates occur automatically for all locations. To disable a particular location, simply click on the corresponding check box under **Update CLEW** to remove the check mark. Disabling CLEW updates may help protect users from getting Code 13-Invalid or Expired CLEW on their analyzers following a software upgrade, should they forget to update the CLEW in the Customization Workspace following the software upgrade procedure.

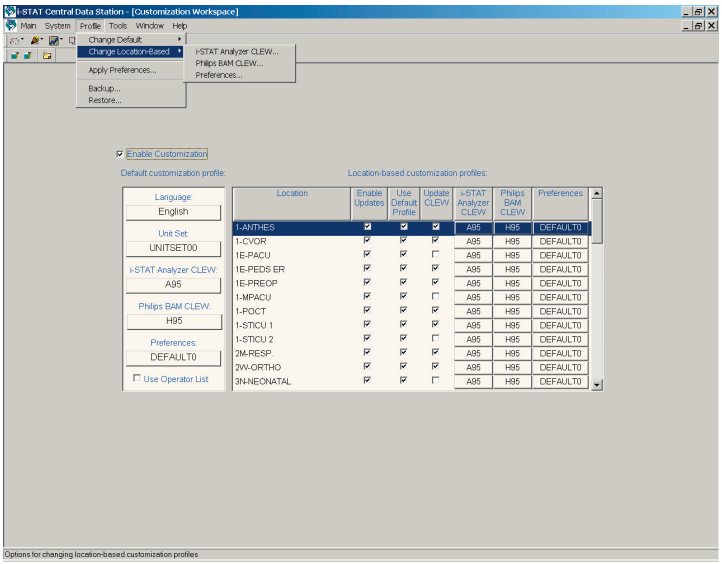
Default Customization Profile

The first step in customization is to create a default customization profile. This is the profile initially assigned to every new location. To change the default profile, use the directions under Making Selections or click the menu option **Profile ⇨ Change Default** and the item to be changed. The changes in the default profile are automatically applied to every location using the default profile.

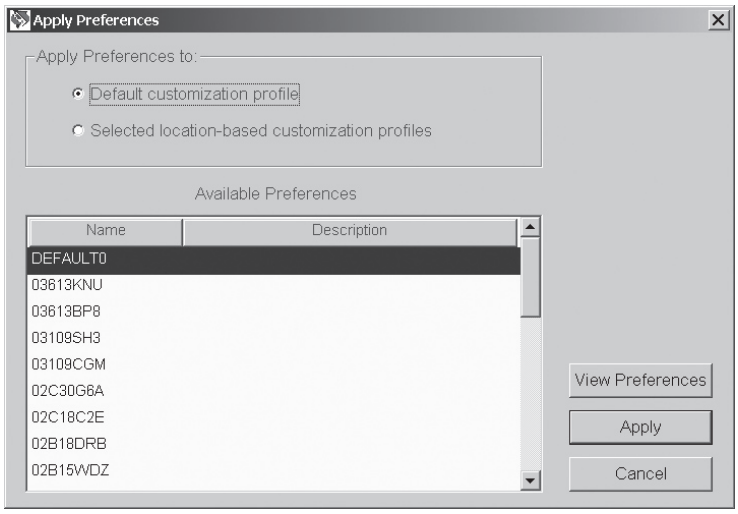


Location-based Customization Profiles

Different customization profiles can be created for different locations. Uncheck the **Use Default Profile** box for the location and double click **i-STAT Analyzer CLEW** or **BAM CLEW** to change the CLEW or double click **Preferences** to change any of the preferences. Alternately, select the menu option **Profile ⇨ Change Location-Based** and the item to be changed. Changes in the customization profile can be made for several locations at once by selecting the locations and then selecting the appropriate option from the Profile Menu. If a location has the **Use Default Profile** option checked, its customization settings will not be changed even if it is selected. Note that Language and the Unit Set from the default customization profile are always used.



Preferences for locations can also be changed by selecting an existing preference from the Apply Preferences submenu. Select the location or locations to be changed. Click **Profile ⇨ Apply Preferences.** Select the desired preferences and click **Apply**. Click **View Preferences** to review a set of preferences.



Making Selections

Selections are made from options in the following ways:

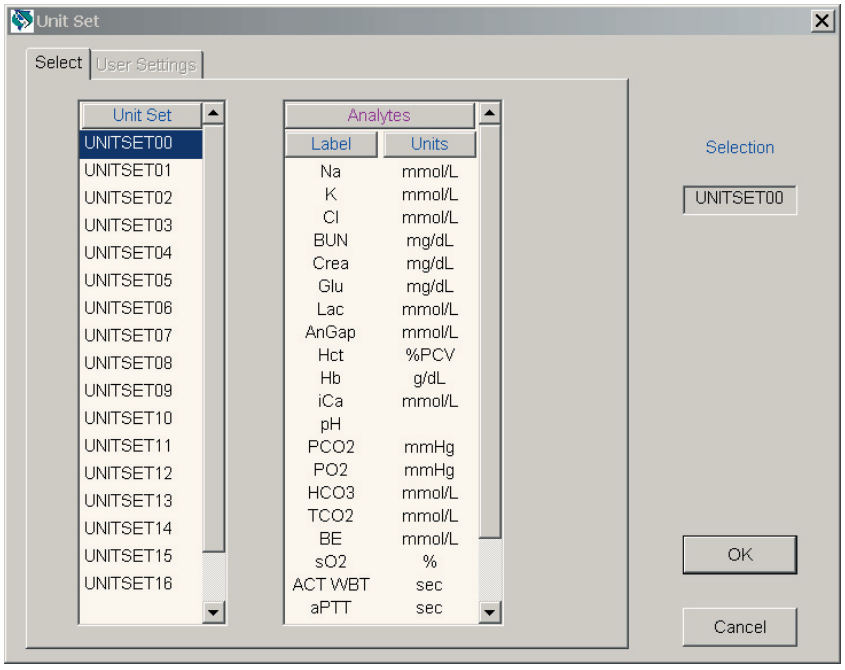
- Select one of the five main Customization options by double clicking the box for **Language**, **Unit Set**, **i-STAT Analyzer CLEW, BAM CLEW** or **Preferences**.
- After making a selection in the Language, Unit Set and CLEW window, click the **OK** button to save the selection or click the **Cancel** button to return to the previous selection.

Language Window

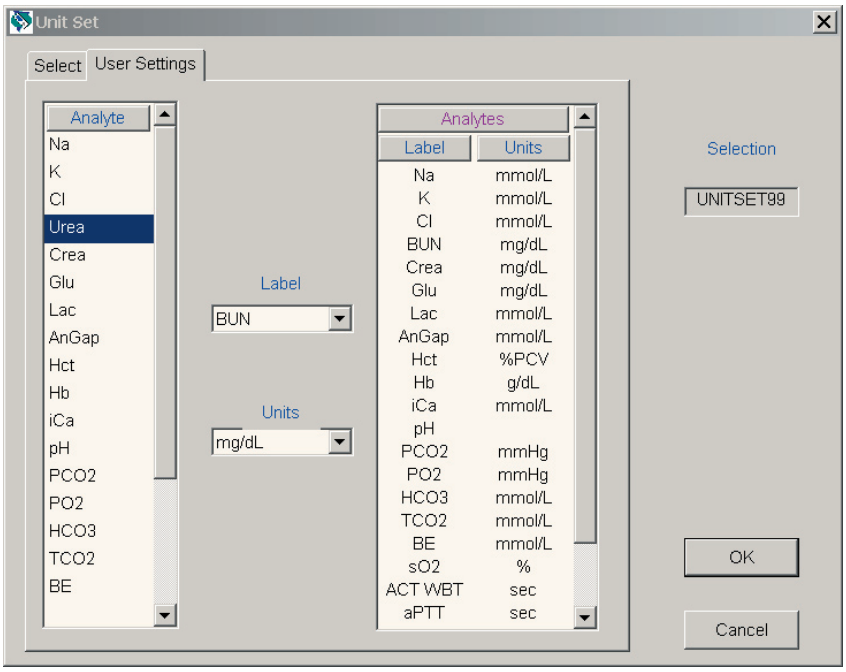
Note: Russian is available only on the i-STAT Portable Clinical Analyzer and Portuguese, Danish, and Finnish are available only on the i-STAT 1 Analyzer.

Unit Set Window

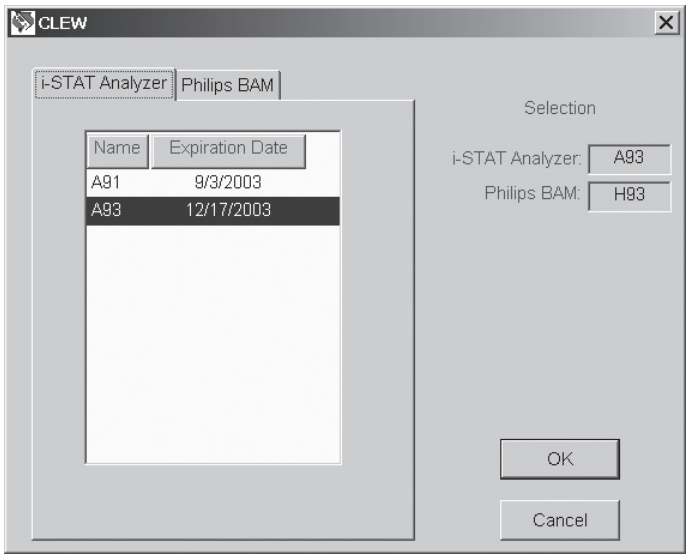
Details of each unit set are displayed under the Analytes column. Details are also listed in the Customization section in this manual.



To create a unique unit set, click **UNITSET99** and then the **User Settings** tab. Then select the name and units for each analyte or test.



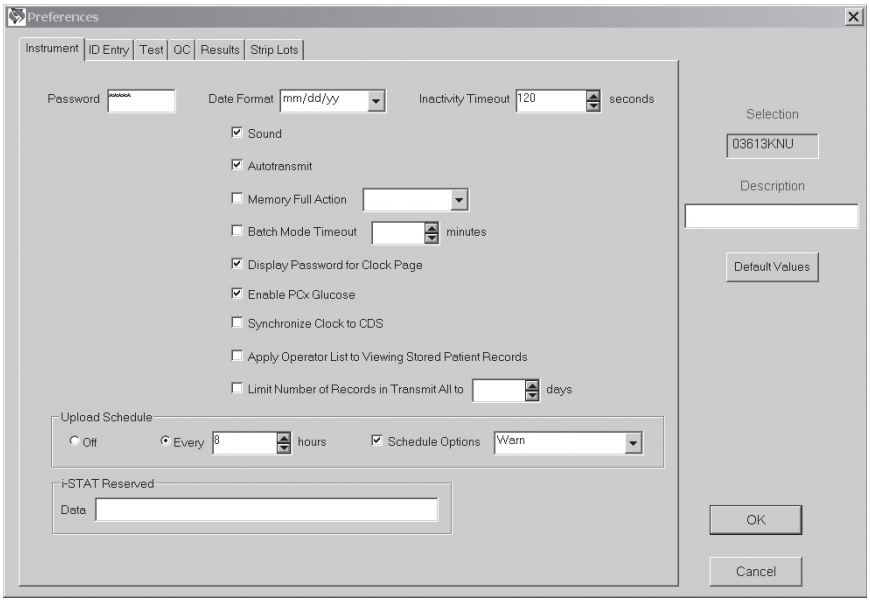
CLEW Window



A new CLEW is added to the window via the software update process three times a year. If the **Update CLEW** feature is active, the Default customization profile must be updated after each new CLEW is added. Click the new CLEW and click OK. Note that there are separate CLEW for the i-STAT analyzer and the Philips Blood Analysis Module.

Note: Before changing to a new CLEW ensure that all analyzers have been updated to a compatible application software version.

Preferences Window



For detailed descriptions of the preferences, see section 9, Customization. The Preferences Window has six tab pages. Click the tab to display the desired page. The following conventions are used in the Preferences pages:

- Enable/disable an option by clicking the check box to check/uncheck it.
- Change a numeric setting by clicking and holding the ▲ or ▼ symbol or manually entering the number.

- Select an option from a list by clicking the ▼, and selecting the option from the list.
- Select from multiple options by clicking the radio button next to the desired option.
- Enter values into fields, such as for Reference Ranges and Strip Lot Numbers.

When all information has been entered, a button is pressed:

- **Default Values** will restore the default settings to the open window.
- **OK** will store the new settings.
- **Cancel** will ignore any new settings and restore the current settings.

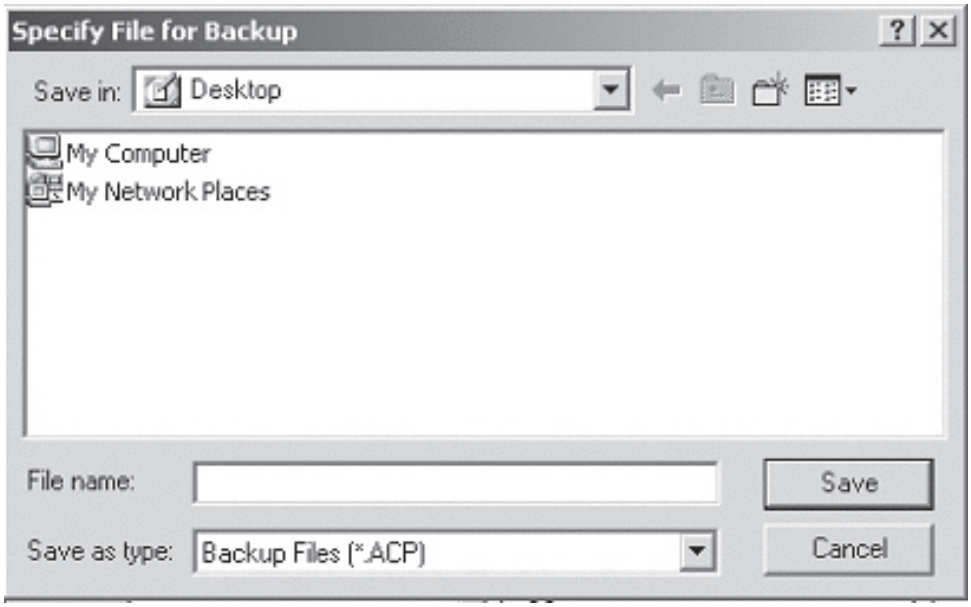
Each Customization Profile is assigned a unique name by the CDS program. This name appears under the Preferences column in the Customization Workspace window, on the Customization screen on the i-STAT 1 Analyzer, on the Analyzer Status screen on the i-STAT Portable Clinical Analyzer and on the Blood Analysis Setup screen of the Blood Analysis Module.

A description can be associated with a profile using the **Description** field in the Preferences Window.

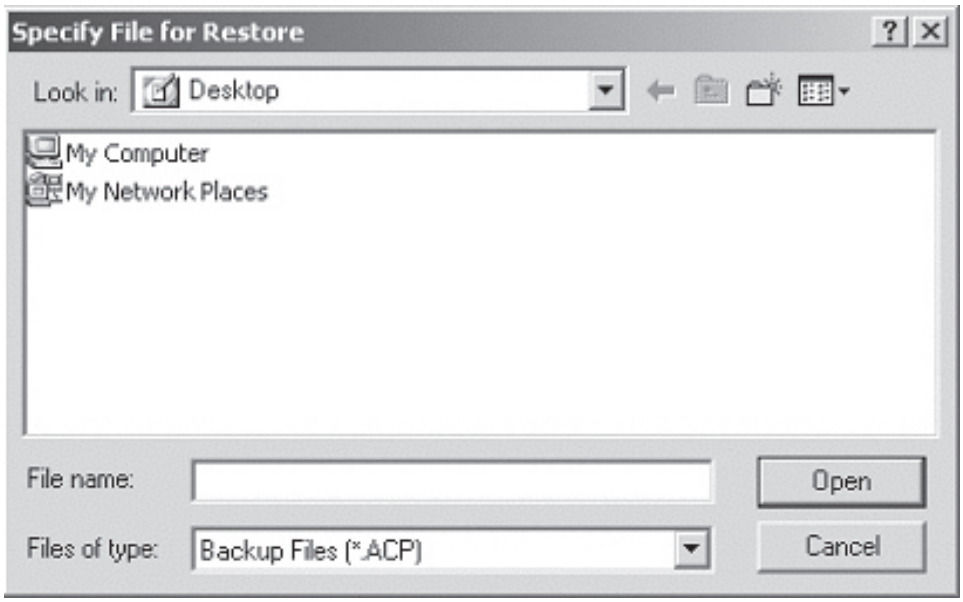
Caution: Close the Customization Workspace when finished to prevent inadvertent changes.

Backup and Restore Profile

The current customization profile can be stored by selecting **Profile ⇨ Backup...** from the menu bar or by clicking the **Backup** toolbar button, selecting the directory where the profile is to be stored, typing in a file name for the profile, and clicking the **Save** button.



To restore a profile to the CDS, click **Profile** ⇨ **Restore…** or the **Restore** toolbar button. Select the directory and backup file to restore and click the **Open** button.



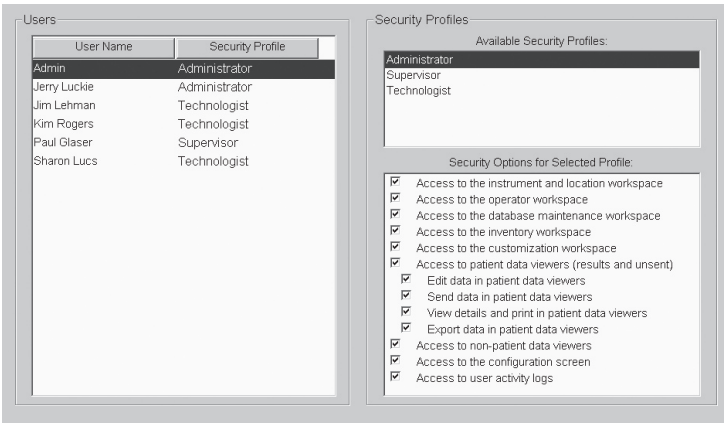
USER ADMINISTRATION WORKSPACE

Overview

The User Administration Workspace is designed as a tool for system administrators. It allows administrators to manage security profiles (a set of security settings determining the access to different CDS screens and functions), manage users, and assign users to security profiles.

Access

Only users designated as administrators can access the User Administration Workspace in the CDS by clicking on **Main ⇨ Open Administration Function ⇨ User Administration**. A Password dialog will then appear. Type in your CDS log-in password and click on **OK**.

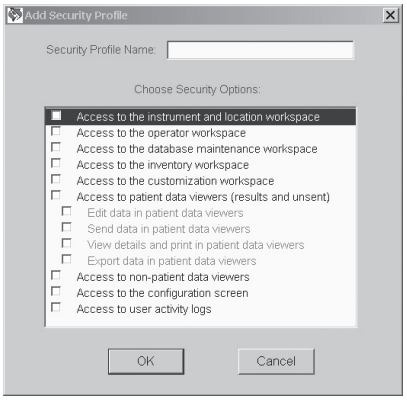


Creating Security Profiles

Once the User Administration Workspace is activated, the Administrator will need to determine how many different security profiles are needed for their facility, and what workspaces and functions should be available to users at those different security levels. Once those decisions have been made, the next step is to create the desired security profiles in the User Administration Workspace.

Please note that an Administrator profile will always exist in the User Administration Workspace. It cannot be edited or deleted, and allows access for those designated users to all CDS Workspaces and functions.

To create a new security profile: click on **Profile ⇨ Add**. An "Add Security Profile" dialog will then appear.



Type in the name of the new Security Profile, then check off the different workspaces and functions users assigned to that security level will be allowed to access, and then click **OK**. The newly created security profile will then be added to the Available Security Profile list.

Deleting Security Profiles

To delete an existing Security Profile, click on the profile you want to delete in the Available Security Profiles window. Click on **Profile ⇨ Delete**, and answer "**Yes**" to the confirmation message that appears on the screen.

Please note that a Security Profile can only be deleted if all of the Users assigned to that particular profile have first been deleted from the Users window. If all of the users have not first been deleted, "Error Accessing Database" and "Error Deleting Profile" messages will appear.

The Administrator Security Profile is permanent and cannot be deleted.

Editing Security Profiles

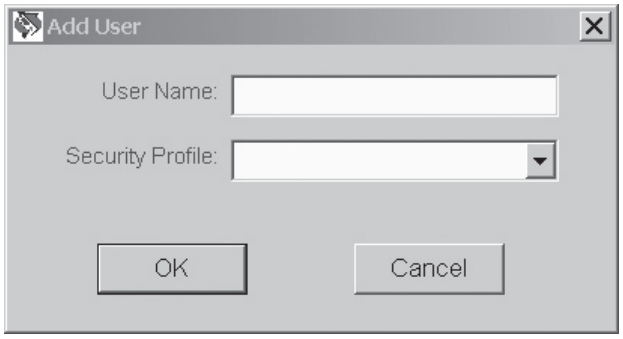
To edit an existing Security Profile, click on the profile you want to edit in the Available Security Profiles window. Click on **Profile ⇨ Edit**. The name of the profile will then be highlighted in blue. If you wish to edit the profile name, simply type in the new profile name. Then select or deselect the desired listings under the "Security Options for Selected Profile" window by clicking on the corresponding check box.

When all edits are complete, simply click on **Profile ⇨ Edit**, and answer **Yes** to the confirmation message that appears about saving the new changes.

Adding Users

Once all the Security Profiles have been created, the next step is to create users and assign them to the various security profile levels.

To add a user to a security profile when in the User Administration Workspace, click on **User ⇨ Add...**. An Add User box will then appear on the screen.



Type in the User Name in the first line, then choose the appropriate Security Profile from the drop down list and click **OK**. The new user listing will then appear in the User window.

Deleting a User

To delete a user, select the user to be deleted, click on **User ⇨ Delete**, and answer **Yes** to the confirmation message. Note: the user who is currently logged on cannot be deleted.

Assigning a User to a Different Profile

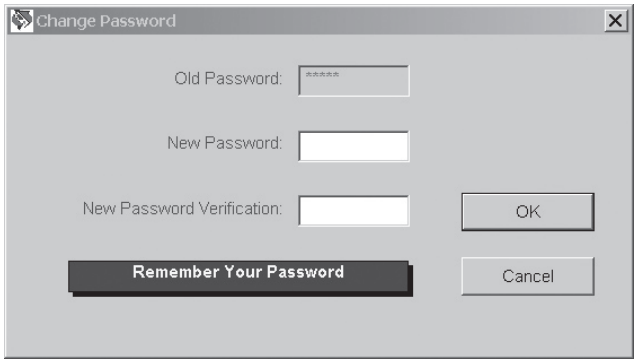
To assign an existing user to a different Security Profile, click on **User ⇨ Assign Profile**. A drop down menu will appear next to the user's name. Simply click on the desired Security Profile, then click on **User ⇨ Assign Profile**, and answer **Yes** to the confirmation message that appears asking if you want to save changes.

PASSWORD MANAGEMENT

Passwords

Once all the Security Profiles are created, and all CDS users are assigned to the appropriate Profiles, the Administrator should provide the users with their assigned User Names. Their initial password is **istat**.

When a user logs on to the CDS application for the first time, a dialog box asking for a User Name and Password will appear. They should input their assigned User Name supplied by the Administrator, and the password **istat**. A dialog will then appear indicating that they must change their password. After clicking on **OK**, the following dialog will appear:



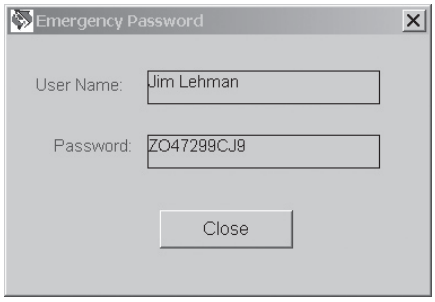
The user should type in a unique password of their choosing in the space provided, then retype that same password on the New Password Verification line and click **OK**. The password must have a minimum length of 3 alphanumeric characters, and a maximum length of 12 alphanumeric characters.

Once the password is changed, the user will then use their new password for all subsequent CDS log-ons.

Emergency Passwords

If a user forgets their User Name or Password, they have two options for accessing the CDS application:

1. If available, the Administrator can log onto the User Administration Workspace and look up the User Name from the User Window. An Emergency Password for this particular user can then be obtained by performing the following:
   a. Click and highlight this particular user's listing in the User Window.
   b. Click on **User ⇨ Emergency Password**. A box will appear with an Emergency Password that this particular user can use. Note: Once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.



2. If the Administrator is not available, the user can contact their local Support Representative for an emergency User Name and/or password. As with option 1 above, once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.

Changing a Password

If a user is logged on to the CDS application, they can choose to change their password at any time by clicking on **Tools ⇨ Change Password**. A dialog box will appear asking them to enter their Old Password, as well as their New Password (twice). After entering this information, the user clicks on **OK** and answers Yes to the question that appears asking if they really want to change password.

SYSTEM LOGOFFS

Overview

The CDS provides the capability for manual and automatic user logoffs. In the logged off state, the majority of CDS screens and functions are not available. However, analyzer and BAM data can continue to be transmitted to the application, and subsequently sent to the LIS/HIS (if applicable). Also, the monitors remain open if they were open prior to logoff.

Manual Logoff

Once a user has completed their CDS tasks, they can log off by clicking on **System ⇨ Log Off**. A box will then appear on the screen indicating that the current user has logged off.

Automatic Logoff

Automatic logoffs are optional and can be enabled in the i-STAT CDS Customization screen, as described in the Security section above on page 22-13.

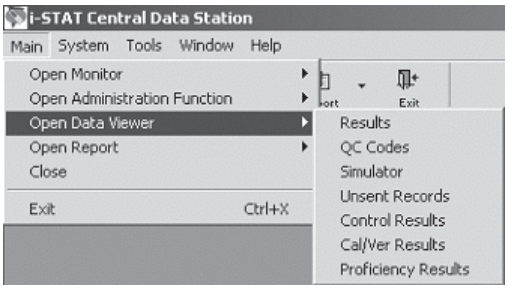
DATA VIEWERS

Overview

Data from instruments downloaded to the CDS are viewed in the Data Viewers.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Results, Control Results, Calibration Verification (or Linearity) Results and Proficiency Results (external quality control).

Control, Calibration Verification and Proficiency Results from the Portable Clinical Analyzers and Blood Analysis Modules will appear in the Results Data Viewer.

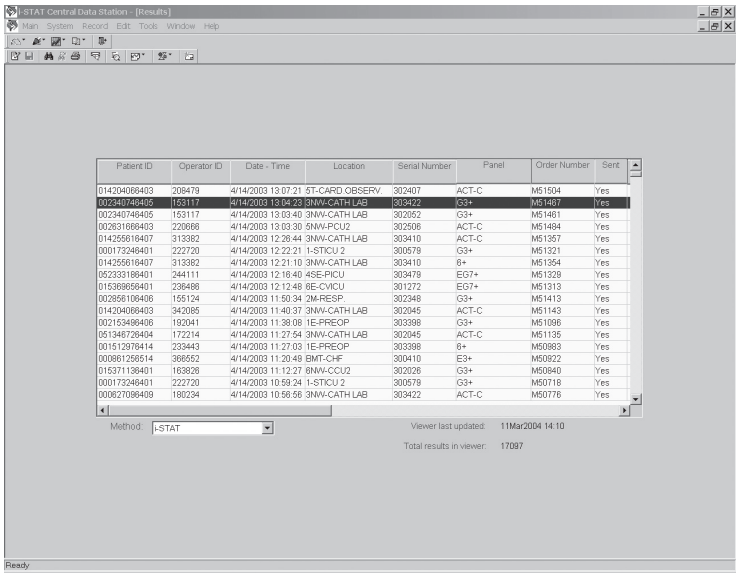


Data from the Medisense Precision PC*x Plus* Glucose Test Strips can now be viewed in the Data Viewers, alongside the data from the Precision PC*x* strip. To determine which strip type was used on a particular testing run, look at the column entitled **Panel**. Precision PC*x* Plus strip runs will be labeled **PCx Plus Glucose**, while Precision PC*x* strip runs will be labeled **PCx Glucose**.

Information in Data Viewers

Data for only one method at a time, such as the i-STAT cartridges, is displayed in a viewer. To switch to a different method, select the method from the selection list in the lower left corner of the viewer. The exception is the Unsent Results Data Viewer which displays results from all methods. Records are listed based on which column is being sorted. Data can be displayed in ascending or descending order by clicking a column as described above.

Example: Results Data Viewer



Refreshing the Data

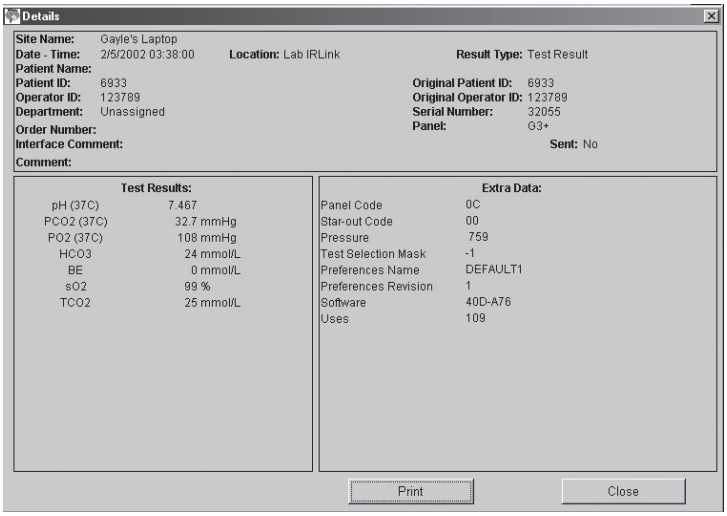
Data is received continuously by the CDS. Updating the viewers with the continuous incoming stream of data would make viewing the data difficult. Therefore, new data is not added to a viewer until the **Refresh** button is pressed. The window can also be refreshed by pressing **F5** or selecting **Refresh** from the **Window** option menu on the menu bar. The date and time of the latest refresh are listed on the bottom right of the window.

Viewing Details

The details of records in the Results, Control, Cal/Ver, Proficiency and Unsent Results Viewers can be viewed by double clicking the record, by selecting the record and clicking the **Details** toolbar button, or by selecting **Record ⇨ View Details...** from the Menu.

Many of the Extra Data details may be helpful to the Customer Support representative in troubleshooting.

Example of Details for Results Viewer

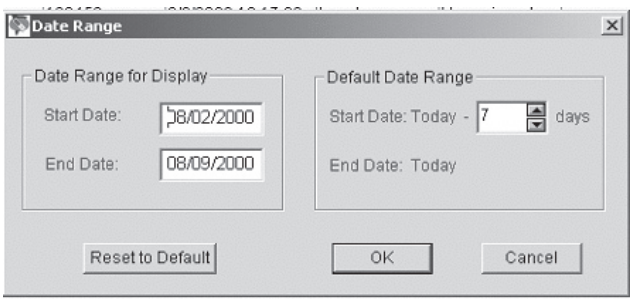


Customizing the Data Viewers

The viewers can be customized for individual preferences. The following aspects of the viewers are user configurable.

❑ **Selecting a Date Range**

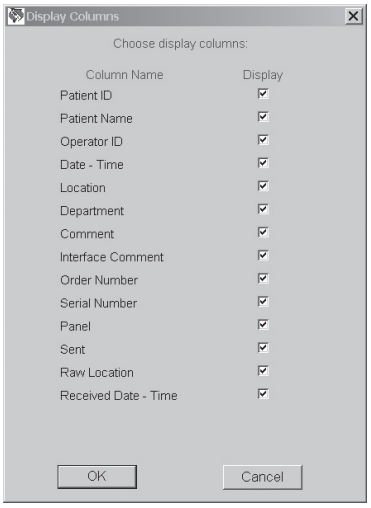
The initial default date range for data in a viewer is the current date and back 7 days. The initial default range can be changed by selecting **Tools ⇨ Customize Viewer ⇨ Date Range...** from the text menu, or by clicking the arrow next to the **Customize** toolbar button, then the **Date Range** button. A default date range can be set but overridden by entering a different date range for display. The maximum default date range allowed is 999 days.



The selection of a shorter date range enhances the system performance by limiting the amount of information needing to be presented. It is always possible to expand the range to view results from earlier and then reset to a more limited default period. The date range function only limits what is presented, not what is in the database.

❑ Selecting Columns to View

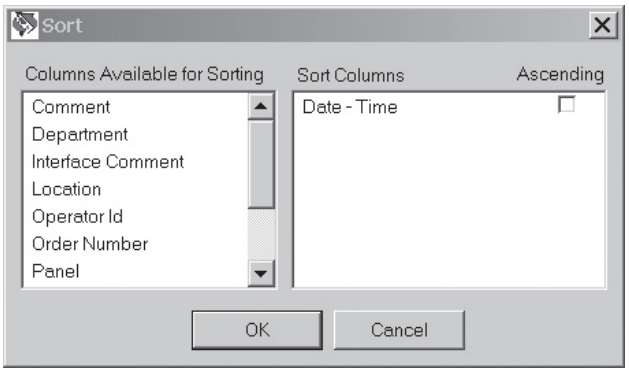
Columns can be hidden. Select **Tools ⇨ Customize Viewer ⇨ Display Columns** or click the arrow next to the **Customize** toolbar button, then the **Columns** button. To hide a column, click the box following the column's name to uncheck it and then click **OK**. To make the column visible again, click the empty box following the column's name to check it and click the **OK** button.



The Raw Location and the Receive Date/Time columns allow users to track the location where particular analyzers are being downloaded, plus the time intervals in which users are transmitting data to the Central Data Station.

❑ Sorting Data

For customers who want to sort data in the Data Viewers by multiple column criteria, a new multilevel sorting feature has been added. To access this feature, open the desired Data Viewer, click on **Tools ⇨ Customize Viewer ⇨ Sort**..., or click the arrow next to the **Customize** toolbar button, then the **Sort** button.



A two-sided Sort dialog will then appear, listing **Columns Available for Sorting** on the left, and **Sort Columns** on the right. Simply click the listing under **Columns Available for Sorting** that you wish to sort your data by, and then drag that column title to the right hand side of the screen under the **Sort Columns section**. Once all of the columns you wish to sort by are under the **Sort Columns** section, check whether you want that particular column to be sorted by ascending or descending order, by placing or removing the check mark in the **Ascending** box.

Once all selections have been made, simply click on **OK** and the sort process will be completed, taking you back to the Data Viewer screen.

Note: By default, the Date/Time column is automatically placed under the **Sort Columns** section with descending order selected. If you do not wish to sort by Date/Time, simply click on that column listing and drag it back to the left side of the screen under **Columns Available For Sorting**.

Editing a Record

To edit a record, highlight the record to be edited, click **Record ⇨ Edit Record** in the menu bar or click the **Edit** toolbar button.

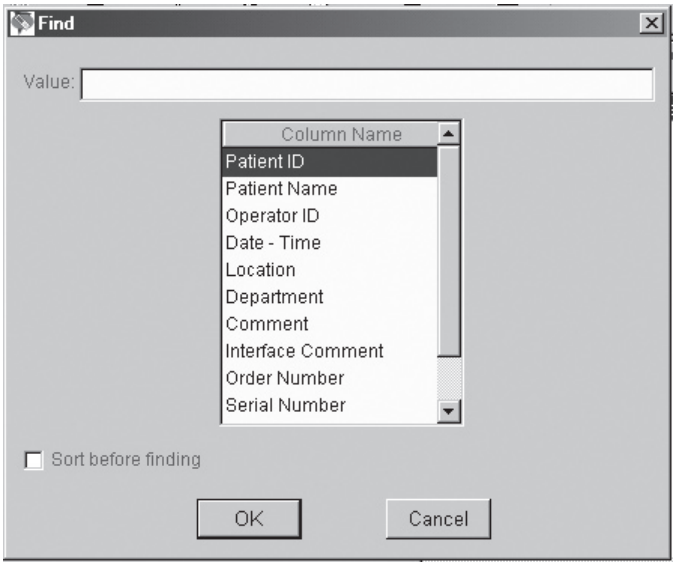
Different viewers have different editable items. Results that have been successfully sent to the LIS or HIS have only an editable Comment. Results marked as **Pending** or **In Progress** cannot be edited.

The Patient ID, Patient Name, Operator ID, Comment, Interface Comment and Order Number can be edited in the Results Viewer. Use the **Tab** key or the mouse to move across the line. The original Patient and Operator IDs will appear along with the edited IDs in the Details window.

Finding a Record

Different viewers have different lists from which to select for a search based on the data presented. Click **Record ⇨ Find...** on the menu bar or click the **Find** toolbar button. Selecting **Sort before finding** before clicking **OK** will present the records in ascending order for the value after the first record matching the search is found.

Type on the Value line the desired parameter then highlight that parameter and click **OK** to find.



Printing Selected Records

With a Data Viewer open, highlight the records to be printed, click **Record** ⇨ **Print Selected Records** or click the **Print** toolbar button.

Send Selected Records

With a Data Viewer open, highlight the records to be sent, click **Record** ⇨ **Send Selected Records** or click the **Send** toolbar button.

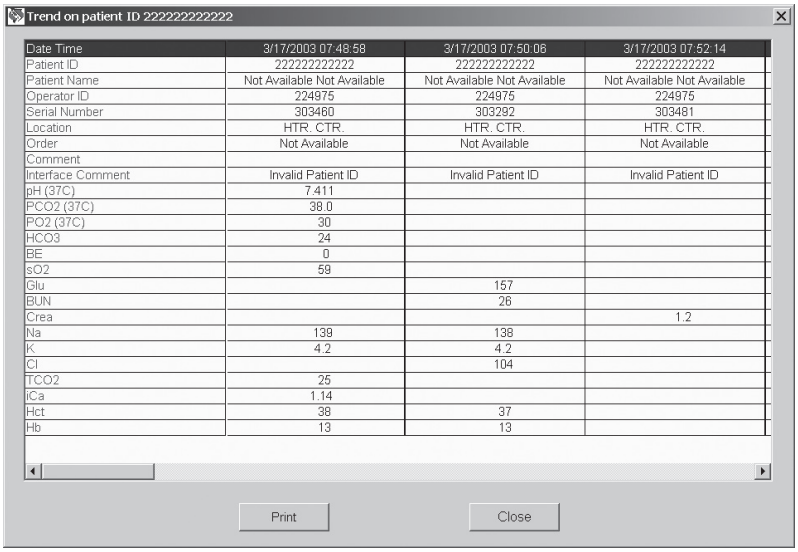
Trending Results

Results records in the Results, Control Results, Cal/Ver Results, Proficiency Results and Unsent Results Viewers can be selected for Trend reports. Trends can be performed on Patient ID, Control Lot Number, Calibration Verification Kit Number, Proficiency ID, Operator ID, Analyzer Serial Number or by a selection of records.

With the Data Viewer open, click **Record** ⇨ **Trend**, then the trend option from the menu bar or click the arrow beside the **Trend** toolbar button and click the desired trend option. Up to 25 records are presented from oldest to newest data.

To trend by selection, highlight the records to be included in the trend report then perform the Trend function.

Example of a Result Trend by Patient ID


Trend on patient ID 2222222222222

Date Time	3/17/2003 07:48:58	3/17/2003 07:50:06	3/17/2003 07:52:14
Patient ID	222222222222	222222222222	222222222222
Patient Name	Not Available Not Available	Not Available Not Available	Not Available Not Available
Operator ID	224975	224975	224975
Serial Number	303460	303292	303481
Location	HTR. CTR.	HTR. CTR.	HTR. CTR.
Order	Not Available	Not Available	Not Available
Comment			
Interface Comment	Invalid Patient ID	Invalid Patient ID	Invalid Patient ID
pH (37C)	7.411		
PCO2 (37C)	38.0		
PO2 (37C)	30		
HCO3	24		
BE	0		
sO2	59		
Glu		157	
BUN		26	
Crea			1.2
Na	139	138	
K	4.2	4.2	
Cl		104	
TCO2	25		
iCa	1.14		
Hct	38	37	
Hb	13	13	

Print Close

QC Codes Viewer

All Quality Check Codes are listed in chronological order. To add a comment, click the record, then **Record** ⇨ **Edit Record** on the menu bar or click the **Edit Record** toolbar button. To sort the Quality Check Codes by type, click the Quality Code column header. To list again in chronological order, click the Date-Time column header.

Note: Panel is a binary code for the cartridge types.

Operator ID	Date - Time	Location	Serial Number	Sent	Comment	Quality Code	Pa
3148	12/12/2003 14:04:12	M. CDS	300007	No		CODE 147	26
35789	12/8/2003 13:47:13	M. CDS	300007	No		CODE 147	26
486	12/8/2003 13:40:11	M. CDS	300007	No		CODE 147	26
1245	12/8/2003 11:46:16	M. CDS	300007	No		CODE 147	26
444	8/5/2003 14:01:24	M. CDS	300007	No		CODE 147	26
222	8/5/2003 13:59:21	M. CDS	300007	No		CODE 147	26
255	8/4/2003 09:59:21	M. CDS	300007	No		CODE 145	26
33	7/29/2003 08:49:56	M. CDS	300007	No		CODE 147	26
220666	4/14/2003 14:09:43	5NW-PCU2	302506	Yes		CODE 43	20
183197	4/14/2003 10:01:42	1E-PREOP	303398	Yes		CODE 43	07

Electronic Simulator Viewer

All Electronic Simulator results, both external and internal, are listed in chronological order with the newest result at the top of the screen. To view all simulator results together for each analyzer, click the **Serial Number** column header to sort the analyzers by serial number or use the **Find...** option and sort for one analyzer. To list in chronological order again, click the **Date-Time** header.

Location	Date - Time	Serial Number	Comment	Sent	Operator ID	Result	Uses	Simulator Temperature	Pressure	Battery Voltage	Software	Simulator ID
ED	1/12/2001 8:47:00	25351		No	123456	FAIL L	1255	21.7C	758	8.05V	37C A68	26390
PICU	1/12/2001 8:13:13	300098		No	654987	PASS	977	24.5C	764.1 mm	7.77V	103G-A68	30199
CVOR	1/12/2001 7:44:00	300004		No	123456	PASS	124	23.1C	764.0 mm	8.05V	103G-A68	30201
NICU	1/12/2001 7:41:32	300007		No	456789	PASS	134		764.1 mm	8.05V	103G-A68	30184

To view the actual readings taken during the Electronic Simulator check, click **Record ⇨ View Extended Simulator Report...** Note that the **Simulator ID** and **Probe Delta** columns can be viewed in the screen above by scrolling to the right.

Extended Simulator Report

Simulator ID	Probe Delta	Panel	Pot0P	Pot0N	Pot0Z	Pot1P	Pot1N	Pot1Z	Pot2P	Pot2I
INTERNAL		0F	+349.657	-349.692	+0.475	+349.566	-349.681	+0.207	+349.508	-349.72
30144	-0.01C	0F	+250.032	-250.007	-0.007	+250.035	-250.04	-0.018	+250.022	-250.05
30199	+0.00C	0F	+249.932	-249.928	0.00	+249.935	-249.913	+0.042	+249.94	-249.92
30201	+0.00C	0F	+250.00	-249.987	-0.003	+250.011	-249.998	+0.015	+250.001	-249.99
INTERNAL		0F	+349.975	-349.919	+0.572	+349.655	-349.875	+0.295	+349.709	-349.86

Unsent Records Viewer

This viewer is available only if an external interface installed by i-STAT is enabled in the Central Data Station Customization function. This data viewer displays records that have not been sent from the Central Data Station to an external computer system, such as an LIS. The incorrect information can be corrected using **Edit** and the corrected record resent.

Unsent results can be removed from the viewer by highlighting the record, clicking on **Record ⇨ Mark Selected Records as Sent**, or by pressing the **F8** Key.

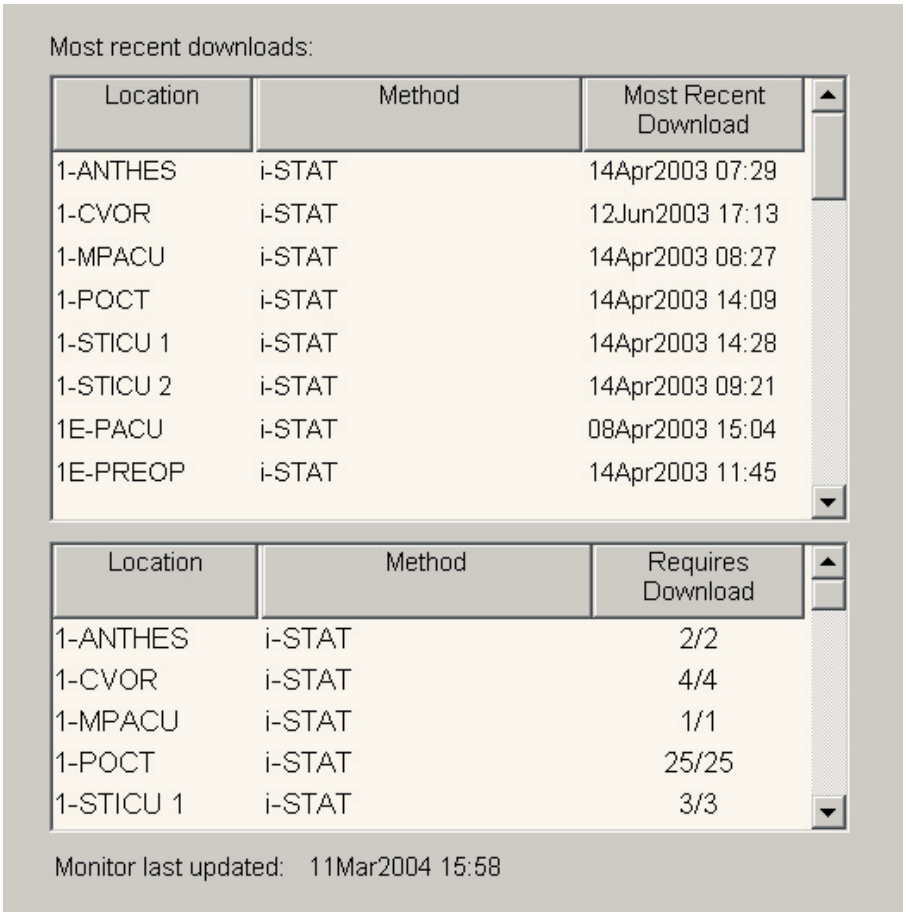
Download Monitor

The download monitor quickly identifies the download status of all locations and any locations that have instruments out of download compliance.

The upper portion of the monitor shows the last time an analyzer from the listed locations was downloaded. These columns can be sorted by clicking the column heading.

The maximum time allowed between downloads from the instrument to the CDS is defined under **Download Criteria** in the Instrument/Location workspace. The download status of each location is recorded in the Download Monitor. The **Requires Download** column indicates how many of the total number of analyzers reporting to a location have exceeded the **Download Criteria**. Clicking the location will open the Instrument and Location workspace where noncompliant analyzers will be highlighted.

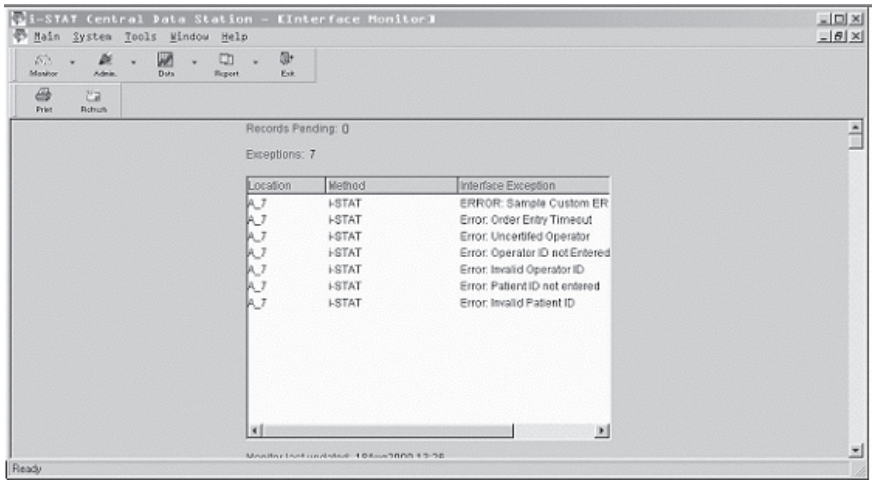
The monitors are updated or refreshed according to the schedule selected during the customization of the CDS. The data can be manually refreshed by clicking the **Refresh** toolbar button or by pressing the **F5** key.



Interface Monitor

The Interface Monitor accessed via the menu bar functions with an interface installed by i-STAT Corporation. To access the the interface monitor for an interface installed by a third party, click on the **Interface Manager** button in the tray at the bottom of the screen.

The Interface Monitor identifies quickly the status of the Interface to an external computer. The number of pending results is shown as well as any exceptions in the last 72 hours. Clicking an exception takes you to the Unsent Results viewer to address the exception.



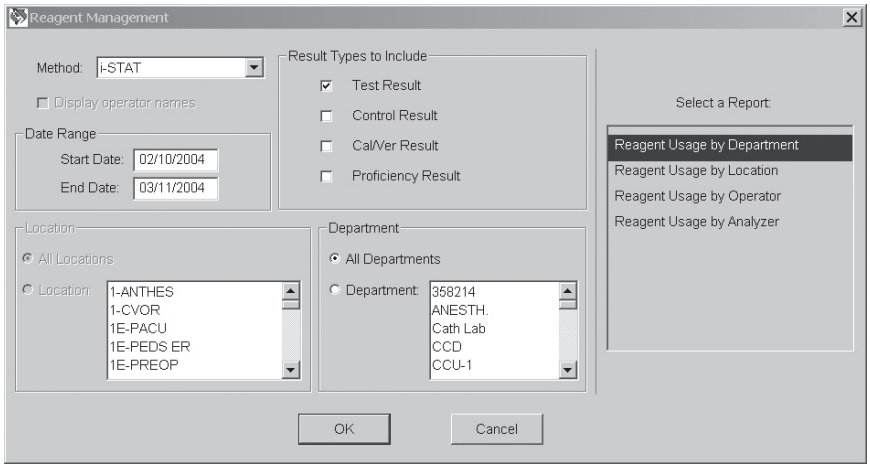
REPORTS

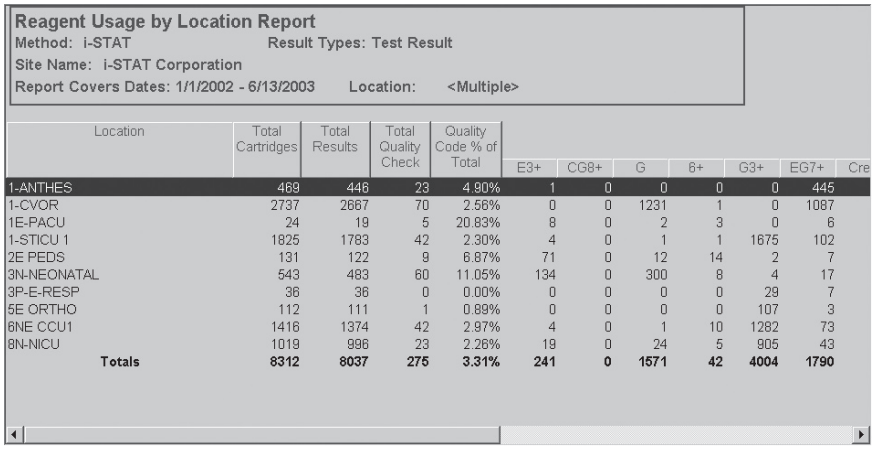
Overview

Reports for managing the point-of-care testing process are available from the CDS program. Three reports can be generated: Reagent Management, Method Competency and Method Compliance. These show information summarized by operator, location, department, or analyzer. Reports can be printed.

Reagent Management

This is a report of cartridge usage by Department or Location. Select a date range for the report. Data in reports, with the exception of "Operator", can be sorted by clicking on the column headers. By Operator data is pre-sorted by department. Select a report by **Reagent Usage by Department**, **Reagent Usage by Location**, **Reagent Usage by Operator**, or **Reagent Usage by Analyzer**, and then select either **All Locations** or **All Departments**, or select one **Location** or one **Department** from the drop down menu. Select the desired result types (Test, Control, Car/Ver, Proficiency) and then click the **OK** button.





Reagent Usage by Location Report

Method: i-STAT **Result Types: Test Result**

Site Name: i-STAT Corporation

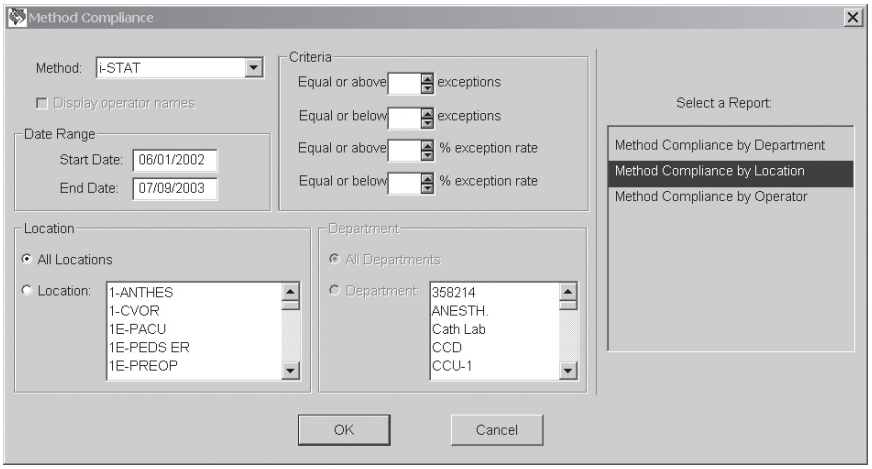
Report Covers Dates: 1/1/2002 - 6/13/2003 **Location: <Multiple>**

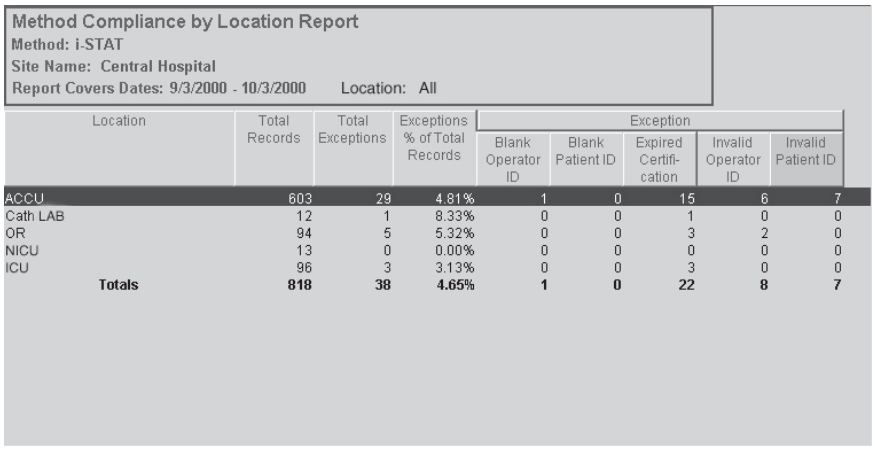
Location	Total Cartridges	Total Results	Total Quality Check	Quality Code % of Total	E3+	CG8+	G	6+	G3+	EG7+	Cre
1-ANTHES	469	446	23	4.90%	1	0	0	0	0	445	
1-CVOR	2737	2667	70	2.56%	0	0	1231	1	0	1087	
1E-PACU	24	19	5	20.83%	8	0	2	3	0	6	
1-STICU 1	1825	1783	42	2.30%	4	0	1	1	1675	102	
2E PEDS	131	122	9	6.87%	71	0	12	14	2	7	
3N-NEONATAL	543	483	60	11.05%	134	0	300	8	4	17	
3P-E-RESP	36	36	0	0.00%	0	0	0	0	29	7	
5E ORTHO	112	111	1	0.89%	0	0	0	0	107	3	
6NE CCU1	1416	1374	42	2.97%	4	0	1	10	1282	73	
8N-NICU	1019	996	23	2.26%	19	0	24	5	905	43	
Totals	**8312**	**8037**	**275**	**3.31%**	**241**	**0**	**1571**	**42**	**4004**	**1790**	

Method Compliance

This is a report of exceptions of policy and procedure for cartridge testing by Department, Location or Operator. This information is available when there is an interface to an external computer.

Select a date range for the report. Select a **Report by Department**, **Location** or **Operator**, then select **All Locations** or **All Departments** or select one **Location** or **Department** from the list. Click on **Display operator names** if desired. When **Method Compliance by Operator** is selected, operators will be listed by department. Select the filtering criteria for the report and then click the **OK** button.





Method Compliance by Location Report
Method: i-STAT
Site Name: Central Hospital
Report Covers Dates: 9/3/2000 - 10/3/2000 Location: All

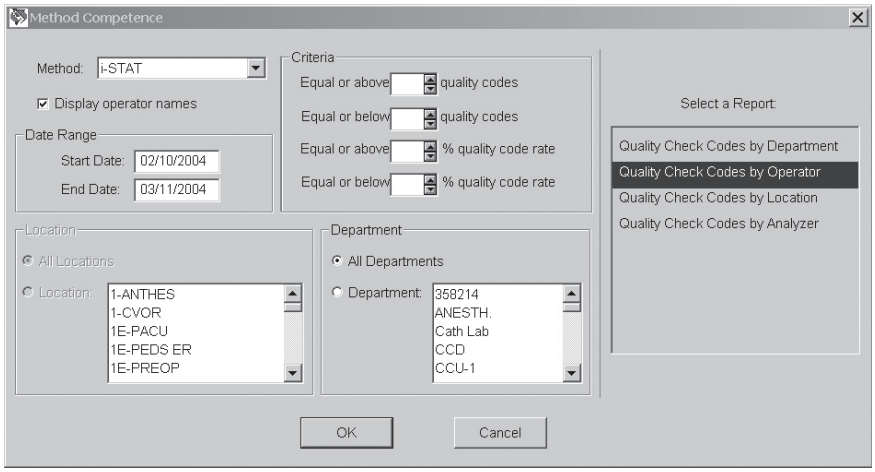
Location	Total Records	Total Exceptions	Exceptions % of Total Records	Exception				
				Blank Operator ID	Blank Patient ID	Expired Certifi-cation	Invalid Operator ID	Invalid Patient ID
ACCU	603	29	4.81%	1	0	15	6	7
Cath LAB	12	1	8.33%	0	0	1	0	0
OR	94	5	5.32%	0	0	3	2	0
NICU	13	0	0.00%	0	0	0	0	0
ICU	96	3	3.13%	0	0	3	0	0
Totals	**818**	**38**	**4.65%**	**1**	**0**	**22**	**8**	**7**

Method Competence

This is a report of Quality Check Code occurrence for cartridges by Department, Operator, Location or Analyzer.

Select a date range for the report. Select a **Report by Department**, **Location**, **Operator**, or **Analyzer** and then select **All Locations** or **All Departments** or select one or more **Locations** or **Departments** from the list. Click on **Display operator names** if desired. Select the filtering criteria for the report. Then click the **OK** button.

When **Quality Check Codes by Department** is selected, operators will be listed by Department.



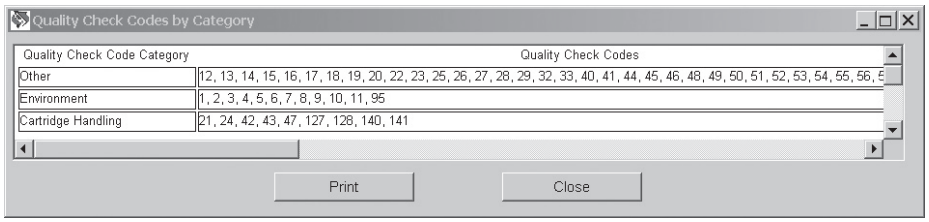
Quality Check Codes by Operator Report
Method: i-STAT
Site Name: i-STAT Corporation
Report Covers Dates: 2/11/2002 - 3/12/2004 **Department:** ANESTH.

					Quality Check Code Count				
Department Name	Operator ID	Total Cartridges	Total Quality Check	Quality Code % of Total	Cartridge Handling	In-sufficient Sample	Overfilled Cartridge	Unable to Position Sample	Under-filled Cartridge
ANESTH.	167895	18	1	5.56%	0	0	0	0	0
	208366	24	2	8.33%	0	0	0	2	0
	234195	8	1	12.50%	0	0	1	0	0
	312265	8	2	25.00%	1	0	1	0	0
	319380	29	2	6.90%	0	0	0	1	0
	347080	30	3	10.00%	1	1	0	0	0
	373046	9	1	11.11%	0	0	0	0	1
ANESTH. Total		**126**	**12**	**9.52%**	**2**	**1**	**2**	**3**	**1**
Totals		**126**	**12**	**9.52%**	**2**	**1**	**2**	**3**	**1**

A legend mapping individual code numbers to their respective quality check code categories is available for viewing. To access this legend:

1. Create the desired Quality Check Code report.

2. With the report still on the screen, click on **Report ⇨ View QC Codes by Category...** The following dialog will appear for viewing or printing.



For details of these Quality Check Codes, see the Technical Bulletin: Analyzer Coded Messages.

SYSTEM

Customization: Central Data Station Settings

Configuration of the CDS can be viewed.

Customization: i-STAT Analyzer Settings

Customization profiles of the i-STAT analyzers can be viewed.

AutoSend

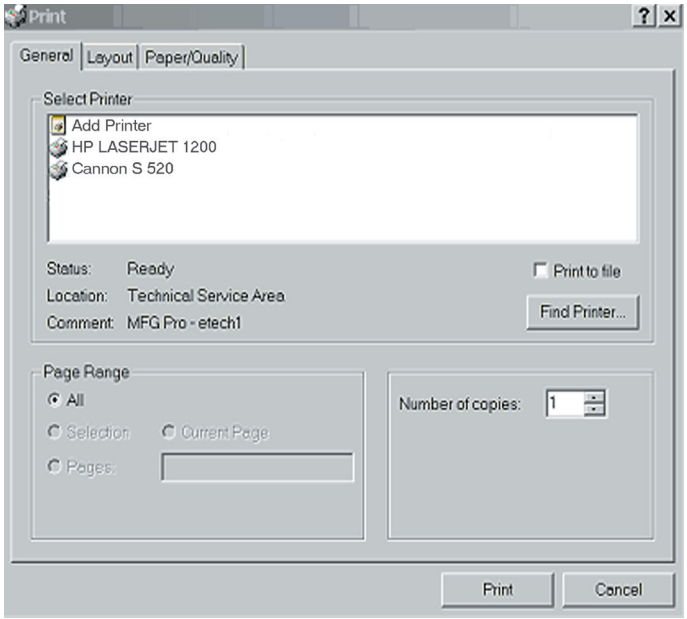
When enabled, data will be transmitted automatically from the CDS to the LIS or other information management system when received by the CDS. If AutoSend is not enabled, results can be sent to the LIS manually. Highlight the records to be sent in the appropriate Data Viewer Results viewer then click **Record ⇨ Send Selected Records**. If AutoSend is enabled, it will be checkmarked under the System option on the menu bar. If an external interface is not enabled, AutoSend will appear in grey typeface.

Print Option

A Printer Dialog box has been added so that when Print is selected from the menu, the user can choose from a list of installed printers. This allows the user the option to utilize their own network printer. To access this feature, you must perform one of the following:

a. Click on **Main ⇨ Print**, or

b. Click on **Records ⇨ Print Selected Records**



HELP

Technical Support Phone number for your Customer Support Representative.

About... Software version of the Central Data Station.

LANGUAGE SUPPORT

For new CDS Version 5 installations only, the CDS screens are now available in English, German, Swedish, Italian, and Spanish languages.

During the initial installation or upgrade of the CDS 5 software, all U.S. customers should choose "English" when the language choice drop down menu appears. Failure to do so will result in the following consequences:

1. If the wrong language was chosen during the initial installation of the Version 5 software, all CDS screens will appear in the language chosen. Contact i-STAT Technical Services if this has occurred.
2. If the wrong language was chosen during an upgrade of the CDS 5 software, the i-STAT installation instructions will appear in the language chosen, but the CDS screens will remain in English.

CUSTOMIZATION 19

Overview

This section describes the parameters that can be customized for site-specific testing requirements and the factory default settings. i-STAT Portable Clinical Analyzers and Philips Blood Analysis Modules can be customized via a Central Data Station Version 4 or Central Data Station Version 5.

Updating Analyzers with Customization Profiles

When the customization function is enabled on a Central Data Station (CDS), the CDS will check the customization profile in the analyzer when the analyzer transmits to the CDS and update the profile in the analyzer if the profile has changed since the last time the analyzer transmitted to the CDS. Only one customization profile can be active on a CDS version 4 while customization profiles can be created and can be active by department on a CDS version 5.

The Blood Analysis Module cannot be automatically updated when in the monitor. It is updated via a local connection to the CDS.

Organization of the Customization Profile

The customization profile is divided into four major tabs: Language, Unit Set, CLEW and Preferences. On CDS version 4, the Preference tab is further divided into Data Entry, Simulator, Reported Values and Computations. On CDS version 5, the Preference tab is further divided into Instrument, ID Entry, Test, QC, Results and Strip Lot tabs. The CDS version 5 tabs are used to group the preferences in the following tables. The default settings for the i-STAT1 (Default0) and Portable Clinical Analyzer (Default1) are in bold face type.

Caution

New analyzers or analyzers that have been repaired and returned or replaced will have the factory default settings as indicated by the DEFAULT1 (Portable Clinical Analyzer) or DEFAULT0 (i-STAT1 Analyzer) on the analyzer status screen and 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. If analyzers in your facility do not use the default customization profile, the appropriate customization profile should be installed before the analyzers are put into use.

Note: In some countries, the analyzers may be customized for language, unit set, decimal separator and Electronic Simulator characteristics before shipment.

After a software update, ensure that the new CLEW is selected in the customization profile before re-enabling the customization function. If the CLEW is not updated before customization is re-enabled, the old CLEW will be sent to the newly updated analyzers and they will display quality check code 13 “Invalid or Expired CLEW”.

Some changes to the customization profile may affect the interface (communication software between Central Data Station and another information system).

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.

ANALYZER CUSTOMIZATION OPTIONS AND DEFAULT SETTINGS

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
LANGUAGE	Language for text	**English**, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, Finnish	**English**, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Russian	Language for the BAM is selected by the monitor.
UNIT SET	Reporting units for results. Select by predefined unit sets or by analyte using unit set 99. See end of this section for a list of predefined unit sets.	All unit sets available. **Unit set 00 is default.**	All unit sets available. **Unit set 00 is default.**	Caution: Take care to note the reporting units for some tests. For example, Unit Set 00 reports BUN in mg/dL, Unit Set 01 reports BUN in mmol/L and Unit Set 03 reports Urea in mg/dL. i-STAT 1 Analyzer - Reference Ranges and Action Ranges in the Preference Tab must be changed when changing units.
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.
PREFERENCES	Options and default settings are listed under six headings: Instrument, ID Entry, Test, QC, Results, Strip Lots.			
USE OPERATOR LIST	4000 operator ID's can be stored in the analyzer along with certification start and end dates for both glucose test strip and cartridge testing.	Not Enabled (no information stored)	N/A	Operator lists are created in the Operator Workspace on the Central Data Station Version 5. This check box cannot be enabled if the Operator List is empty in the Operator Workspace for all Departments (other than the one labeled "Unassigned").

PREFERENCE WINDOW: FOR INSTRUMENT OPTIONS

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
PASSWORD	0-5 digit password to access Set Clock, the Change function in Customization, and Utility under the Administration menu.	**No password**	N/A	Password protection for the Set Clock function can be enabled or disabled. See below
DATE FORMAT	mm/dd/yy or dd/mm/yy	**mm/dd/yy**	N/A	For Clock Set function only.
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**	N/A	
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.	Disabled or **Enabled**	N/A	If Sound is disabled, the analyzer will only beep when a sample is accepted during glucose test strip testing and after a successful barcode entry.
AUTO TRANSMIT	Analyzer transmits results when placed in Downloader or Downloader/Recharger.	Disabled or **Enabled**	N/A	
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).	**Disabled** or Enabled	N/A	Memory Full refers to when the unsent records as recorded on the Analyzer Status screen reaches 5000. Uploading does not erase the data from the analyzer's memory.
BATCH MODE TIMEOUT	Not active at this time.		N/A	
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.	Disabled or **Enabled**	N/A	
ENABLE PCX GLUCOSE	Enables the PCx glucose test strip reader on the i-STAT 1 Analyzer.	**Disabled** or Enabled	N/A	When glucose test strip testing is disabled, the analyzer does not display any options for the PCx Glucose Test Strip.

PREFERENCE WINDOW: FOR INSTRUMENT OPTIONS (CONT.)

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
SYNCHRONIZE CLOCK TO CDS	Will synchronize or update the real time clock in the i-STAT 1 Analyer to the Central Data Station's clock at the time of each download.	Not Enabled	N/A	This eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Savings Time.
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.	Not Enabled	N/A	This option can help a facility comply with patient privacy regulations.
LIMIT NUMBER OF RECORDS IN TRANSMIT ALL	Allows the user to apply a date range limit to the Transmit All function on the i-STAT 1 Analyzer.	Not Enabled	N/A	This will prevent operators from sending older patient records that may have already been deleted from the Central Data Station.
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).	**Off:** no warning or lockout.	N/A	If no upload schedule is specified and the Memory Full warning is ignored and Auto-transmit disabled, data will eventually be overwritten. However, if an analyzer has not been used and the upload interval is exceeded, this analyzer will be inoperable if the lockout option is used.

PREFERENCE WINDOW: FOR OPERATOR AND PATIENT ID OPTIONS

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
OPERATOR ID	Minimum and maximum allowed operator ID length (scanned or manually entered)	**Min = 0 Max = 15**	**Min = 0 Max = 7**	If operator IDs are a fixed length, the min. and max. settings should both be equal to the ID length.
REPEAT ID ENTRY	Operator must enter ID twice. This option can be set for manual and/or scanned ID entry on the i-STAT 1 Analyzer.	**Enabled: repeat required**	**Enabled: repeat required**	Analyzer prompts operator to start again if IDs do not match.
INCLUDE ID ON PRINTOUT	Enables/Disables printing of operator IDs on printouts from the Martel Printer.	**Enabled**	N/A	Disabling the printing of operator IDs can prevent uncertified operators from learning the IDs of certified operators.
BARCODE OPTIONS	The type of barcodes used for Operator ID. See table below.	**All barcode types**	N/A	
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.	**None**	N/A	Check digit algorithms are given in HL7 Specification, Section 2.9.5.3
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).	**Continue without warning**	N/A	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.
PATIENT ID	Minimum and maximum allowed patient ID length (scanned or manually entered)	**Min = 0 Max = 15**	**Min = 0 Max = 12**	If patient ID numbers are a fixed length, the min and max settings should both be equal to the ID length. Not customizable on BAM - factory default any length.
REPEAT ID ENTRY	Operator must enter patient ID twice. Analyzer prompts operator to start again if IDs do not match.	**Enabled: repeat required**	**Enabled: repeat required**	Not customizable on BAM: factory default is repeat required.
PATIENT ID RECALL	Operator can recall last patient ID when analyzer prompts for Patient ID.	**Enabled**	**Enabled on PCA** N/A for BAM	i-STAT1 Analyzer: press the → key. Portable Clinical Analyzer: press the DIS key.
BARCODE OPTIONS	The type of barcodes used for Patient ID. See table below.	**All barcode types**	N/A	
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.	None	N/A	Check digit algorithms are given in HL7 Specification, Section 2.9.5.3

PREFERENCE WINDOW: FOR TEST OPTIONS

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
AUTO-CHART PRESENTATION	If enabled, the Chart page will be displayed automatically. Selected separately for cartridge and glucose test strip tests.	Enabled or **Disabled**	Enabled or **Disabled**	Not customizable on BAM: factory default is Off (disabled)
CARTRIDGE PATIENT TEST	Require information before running cartridge: Operator will be required to enter Operator and Patient IDs before the analyzer will initiate a cartridge test cycle. Enter Lot Number: Adds a Cartridge Lot Number prompt to the cartridge test cycle. If the option above is enabled along with this option, the operator will be required to enter the cartridge lot number before the analyzer will initiate a patient test cycle. Scan Cartridge Barcode: requires the user to scan the cartridge Lot number barcode before entering an operator and patient ID after a cartridge has been inserted into an i-STAT 1 Analyzer. Third Party Result Output and Require Analyzers to be in Downloader: These two options were instituted in preparation for the future release of a new data integration option and SHOULD NOT be activated by users at this time. Misconfigurating your analyzers using these new features can cause testing to be disabled.	Enabled or **Disabled**	N/A	This option is referred to as "Information First" in the Procedure for Cartridge Testing section. When not enabled, the operator can insert a cartridge and the test cycle will initiate. Information is then entered during the test cycle. Cartridge lot numbers are mandatory prompts for tests performed under Quality Tests. The Scan Cartridge Barcode option is required for i-STAT's immunoassays.
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.	**No prompt**	N/A	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.
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.	**1-ART 4-CAP** **2-VEN 5-CORD** **3-MIX 6-OTHR**	N/A	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 Central Data Station.
CHART FIELDS	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.	**All items set to not mandatory**	N/A	
TEST STRIP PROMPT FOR SAMPLE TYPES	Options are: Prompt operator to choose between Art/Cap or Venous sample types or NO PROMPT with either Art/Cap or Venous as the default sample type.	**Prompt**	N/A	

PREFERENCE WINDOW: FOR QUALITY CONTROL OPTIONS – CARTRIDGE

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
EXTERNAL SIMULATOR SCHEDULE	Time interval when a prompt for the operator to use the external simulator should appear. i-STAT 1: The behavior of an analyzer if the schedule is not met can also be specified: Warn or Lockout (testing disabled until simulator used).	Off (no prompt), an interval specified in hours (1 to 65535) or interval specified in tests (up to 99999). **Default is Off.**	Off or an interval of specified hours (1 to 65535 hours). **Default is 24 hours.**	For the quality control of i-STAT analyzers, i-STAT recommends the use of the Electronic Simulator.
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.	**Default is ON every 24 hours with Lockout.**	Patient intervals are not applicable. **Default is OFF.**	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.

PREFERENCE WINDOW: FOR QUALITY CONTROL OPTIONS – TEST STRIP

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
STRIP CONTROL SCHEDULE	Schedule options are: Off, Every (x) hours (1 to 65535 hours), Every (x) Patient Tests (0 to 255 tests), and up to three predetermined times daily The behavior of the analyzer if the schedule is not met can also be specified. Options are: Warn (start-up warning) or Lockout (disable test strip testing until QC run).	**Off**	N/A	
STRIP CONTROL TEST SETTINGS	Prompt or no prompt for Normal/(Mid)Level Control. Comment Code when a value is in-range. Options are: Disabled (no prompt for comment code), Allow no Comment (Comment Code optional), Require Comment. Comment Code when value is out of range. Options are: disabled (no prompt for Comment Code), Allow no Comment (Comment Code optional), Require Comment. A Comment Code of 3 characters is allowed.	**No prompt for Normal/(Mid) Level Control and no prompt for Comment Code.**	N/A	If selected, the prompt for the Normal Level control will come after the prompt for the Low Level control.

PREFERENCE WINDOW: FOR RESULTS REPORTING OPTIONS

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
ANALYTE ENABLED	Tests can be disabled. If disabled, the test will not appear in the Operator Test Selection list or on the results page and test results will not be stored.	**All tests enabled.**	**All tests enabled.**	
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 listed in the Cartridge and Test Information sheets and the Precision PCx and PCx Plus Glucose Test Strip package insert.	N/A	Ranges will be displayed on the Customization screen of the i-STAT 1 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.**
ACTION RANGES	High and low action ranges can be defined for each test (-99999.9 to 99999.9).	**Disabled**	N/A	**Care should be taken to enter Action Ranges within the reportable ranges of the tests.** **Care should be taken to enter the same units as selected in the Unit Set Window.** The action ranges for glucose apply to the cartridge and the test strip.
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.	**Disabled**	N/A	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.
OPERATOR TEST SELECTION	Requires the operator to select tests to be reported from a cartridge test panel.	**Disabled**	**Disabled**	This option facilitates compliance with Medicare/ Medicaid regulations in the USA.
ACT OPTIONS	The user can select between the current 37°C (PREWRM) result calibration and a new "NON-PREWARM" (ambient temperature) result calibration for both Celite ACT and Kaolin ACT cartridges.	**PREWRM** for both cartridge types.	N/A	Please see the Technical Bulletin "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT 1 Analyzer" for full discussion.
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.) For the i-STAT 1 Analyzer CPB options are: Prompt or no prompt for CPB compensation when cartridge includes hematocrit sensor, and if no prompt, automatically Adjust or Do not adjust.	**K3EDTA** **Prompt CPB**	**K3EDTA** CPB options are: Report CPB always: **Off** or On Not customizable on BAM.	See the Theory section of this manual for an explanation of the reference anticoagulant and the CPB compensation.

PREFERENCE WINDOW: FOR RESULTS REPORTING OPTIONS (CONTINUED)

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
DECIMAL SEPARATOR	Select comma (,) or period (.)	**Period**	**Period.** Not customizable on BAM.	
BASE EXCESS CALCULATION	Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb).	**BEecf**	**BEecf**	See Cartridge and Test Information sheet for ***P***CO2 for formulas.

PREFERENCE WINDOW: FOR QUALITY CONTROL OPTIONS – TEST STRIP LOTS

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
TEST STRIP LOT NUMBERS	Up to 5 test strip lot numbers of 14 characters each can be entered. Upper and lower ranges for low, mid and high controls for each test strip lot can be entered.	**Blank**	N/A	Expired test strip lots must be manually deleted on the expiration date. If no control values are entered, the analyzer will use the control values programmed into the test strip lot number. If the Customization program is enabled (active), new lot numbers will be automatically added to the analyzer's memory when it is placed in a Downloader or Downloader/ Recharger.
TEST STRIP LOT NOT ON LIST ACTION	Behavior of analyzer when a scanned/entered test strip lot is not on the test strip lot list. Options are: Disable (allow test to continue without warning); Warn (and prompt to continue); Lockout (disable testing until valid test strip lot number is scanned/entered).	**Disabled**	N/A	

PREFERENCE WINDOW: FOR BARCODES

Option	Description	Choices & Default i-STAT 1	Choices & Default Port.Clin.An. & BAM	Comments
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	All barcode types	N/A	Barcode type Code 128 will support USS 128 and UCC/EAN 128, but not ISBT 128.
I2 OF 5 OPTIONS	No Check Digit USS Check Digit OPCC Check Digit	**USS Check Digit**	N/A	
CODE 39 OPTIONS	Check Digit or No Check Digit Alphanumeric or Full ASCII	**Check Digit, Full ASCII**	N/A	
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.	**No truncation**	N/A	The analyzer will accept up to 15 characters for operator and patient IDs.

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 USSS Check Digit.
- Code 39 Full ASCII with Check Digit.

Unit Sets 17 predefined unit sets are available in the Unit Set Window. There is also a Unit Set 99 that can be used to select the name and unit for each test. The default unit set is 00

RESULT	0	1	2	3	4	5	6	7	8	9	10
Na/K/Cl *	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
BUN	mg/dL										
Urea		mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
Crea	mg/dL	µmol/L	µmol/L	mg/dL	mg/dL	mg/dL	mg/dL	µmol/L	µmol/L	µmol/L	µmol/L
Glu	mg/dL	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH											
PCO2/PO2	mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg	kPa	mmHg	mmHg	kPa
Hct	%		%	%	%	%	%	%			
Hb	g/dL	g/L	g/L	g/dL	g/dL	g/dL	g/dL	mmol/L	g/L	g/dL	g/dL
HCO3/BE	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L	mmol/L
iCa	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
sO2	%	%	%	%	%	%	%	%	%	%	%

RESULT	11	12	13	14	15	16
Na/K/Cl	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
BUN		mg/dL			mg/dL	
Urea	mmol/L		mmol/L	mmol/L		g/L
Crea	µmol/L	mg/dL	µmol/L	µmol/L	mg/dL	µmol/L
Glu	mmol/L	mg/dL	mmol/L	mmol/L	mg/dL	g/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH						
PCO2/PO2	kPa	mmHg	mmHg	mmHg	mmHg	mmHg
Hct		%	%	%	%	%
Hb	g/dL	g/dL	g/dL	mmol/L	g/dL	g/dL
HCO3/BE	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
iCa	mg/dL	mg/dL	mmol/L	mmol/L	mEq/L	mmol/L
sO2	%	%	%	%	%	%

* Also, TCO2 and Anion Gap, except:

03 TCO2 mEq/L

04 TCO2, BE mmol/L

06 Anion Gap, HCO3, BE mEq/L

Note: There are no units for pH or for hematocrit when reported as decimal fraction

Note: See Cartridge and Test Information sheets for ACT, PT/INR, and cTnI units.

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 Portable Clinical Analyzer, the i-STAT 1 Analyzer* and the Philips Medical Systems Blood Analysis Module** for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGES SPECIFICATIONS

Shelf Life: Refrigerated at 2 to 8ºC (35 to 46ºF) until expiration date.

Room temperature at 18 to 30ºC (64 to 86ºF) for two weeks.

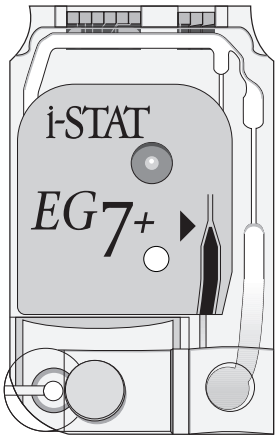
Preparation for Use: Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

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 is NOT a recommended sample type for ACT, cTnI, or CK-MB testing.)

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.



Sample Volume: 17µL, 20µL, 40µL, 65µL, or 95µL 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, both with and without 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, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection

- Sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB. Remix thoroughly before testing.

* The cTnI and CK-MB cartridges can only be used with the i-STAT 1 analyzer bearing the i immuno symbol. The CHEM8+ cartridge can only be used with the i-STAT 1 analyzer.

** Blood Analysis Module supports neither the PT/INR, the CHEM8+, the cTnI, nor the CK-MB cartridge.

Analysis Time:

- ACT cartridge: to detection of end point - up to 1000 seconds (16.7 min.)
- PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- cTnI cartridge: 600 seconds (10 min.)
- CK-MB cartridge: 300 seconds (5 min.)
- Other cartridges: typically 130 to 200 seconds

Cartridges	Collection Options			
	Syringes	**Evacuated Tubes**	**Capillary Tubes**	**Directly from Skin Puncture**
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Without anticoagulant • With balanced heparin anticoagulant	• Not recommended
Cartridges which perform ACT	• 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
Cartridges which perform PT/INR	• 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
Cartridges which perform Troponin I or CKMB	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw.	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended
All other cartridges	• Without anticoagulant • With lithium, sodium, or balanced heparin anticoagulant	• Without anticoagulant • With lithium or sodium heparin anticoagulant	• Without anticoagulant • With balanced heparin anticoagulant • With sodium or lithium heparin if labeled for the measurement of electrolytes	• While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred.

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, i-STAT recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

Measured:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115
pH		6.5 – 8.2	7.35 – 7.45	7.31 – 7.41
***P*CO_2**	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
TCO_2 (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
***P*O_2**	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN **Urea**	mg/dL mmol/L mg/dL	3 – 140 1 – 50 6 – 300	8 – 26 2.9 – 9.4 17 – 56	8 – 26 2.9 – 9.4 17 – 56
Hematocrit/Hct	%PCV Fraction	10 – 75 0.10 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / ^{Celite}ACT	seconds	50 – 1000	74 – 125 (Prewrm) 84 – 139 (Nonwrm)	74 – 125 (Prewrm) 84 – 139 (Nonwrm)
The range from 80 - 1000 seconds has been verified through method comparison studies.				
Kaolin Activated Clotting Time / ^{Kaolin}ACT	seconds	50 – 1000	74 – 137 (Prewrm) 82 – 152 (Nonwrm)	74 – 137 (Prewrm) 82 – 152 (Nonwrm)
The range from 77 - 1000 seconds has been verified through method comparison studies.				

Measured: (cont.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Prothrombin Time / PT	INR	0.9 – 8.0		
Performance characteristics have not been established for INRs above 6.0.				
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03*
Performance characteristics have not been established for cTnI values above 35.00 ng/mL. ** Represents the 0 to 97.5% range of results.*				
Creatine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5**
***Represents the 0 to 95% range of results.*				

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Hemoglobin/Hb	g/dL g/L mmol/L	3.4 – 25.5 34 – 255 2.1 – 15.8	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11
TCO_2 (on all cartridges but the CHEM8+)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	0 – 100	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT EC8+ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2*
HCO_3*
BE*
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT 6+ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT EC4+ (65µL)
Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT E3+ (65µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT G (65µL)
Glucose (Glu)

i-STAT CREA (65µL)
Creatinine (Crea)

i-STAT EG7+ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT EG6+ (95µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT G3+ (95µL)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT CG4+ (95µL)
pH
PCO_2
PO_2
Lactate
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT CG8+ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT Celite ACT (40µL)
Celite® ACT

i-STAT Kaolin ACT (40µL)
Kaolin ACT

i-STAT PT/INR (20µL)
Prothrombin Time

i-STAT cTnI (17 µL)
Troponin I

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

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

i-STAT CHEM8+ (95µL)**
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)

**Calculated*

***(under development)*

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

SODIUM/NA

Sodium is measured by ion-selective electrode potentiometry. In the calculation of results for sodium, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for sodium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of sodium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of sodium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Sodium (Na^+)

Metrological Traceability

The i-STAT System test for sodium measures sodium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Sodium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Sodium/Na	mmol/L (mEq/L)	100–180	138 – 146

*The i-STAT System can be configured with the preferred units.

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	120.0	0.46	0.4
Level 3	160.0	0.53	0.3

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.74	0.52	0.54
Syy	0.53	0.58	0.53
Slope	1.00	0.98	0.95
Int't	-0.11	3.57	5.26
Sy.x	1.17	1.04	1.53
Xmin	126	120	124
Xmax	148	148	148
r	0.865	0.937	0.838

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 130–150 mmol/L range the average difference was 0.750.

Factors Affecting Results*

Sodium heparin may increase sodium results up to 1mmol/L.

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	Effect
β-hydroxybutyrate	16 mmol/L (166 mg/dL) β-hydroxybutyrate will decrease sodium results by 5 mmol/L.
Bromide	37.5 mmol/L bromide will increase sodium results by 5 mmol/L.
Lactate	20 mmol/L lactate will decrease sodium results by 5 mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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4. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline*. NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

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POTASSIUM/K

Potassium is measured by ion-selective electrode potentiometry. In the calculation of results for potassium, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of potassium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of potassium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Potassium (K^+)

Metrological Traceability

The i-STAT System test for potassium measures potassium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Potassium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Potassium/K	mmol/L(mEq/L)	2 – 9	3.5 – 4.9**

*The i-STAT System can be configured with the preferred units.

**The reference range for potassium listed above has been reduced by 0.2mmol/L from the range cited in Reference 3 to account for the difference between serum and plasma results.

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketacidosis (DKA), sepsis and in vitro hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	2.85	0.038	1.3
Level 3	6.30	0.039	0.6

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.060	0.031	0.065
Syy	0.055	0.059	0.055
Slope	0.97	1.06	0.99
Int't	0.02	-0.15	-0.01
Sy.x	0.076	0.060	0.112
Xmin	2.8	3.0	2.8
Xmax	5.7	9.2	5.8
r	0.978	0.993	0.948

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 3.0–5.0 mmol/L range the average difference was 0.049.

Factors Affecting Results*

If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time. Potassium values will increase in iced specimens.

Potassium values from anticoagulated samples are preferred to serum values because 0.1 to 0.7 mmol/L potassium can be released from platelets[1] and red blood cells during the clotting process. Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

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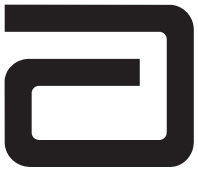

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CHLORIDE/CL

Chloride is measured by ion-selective electrode potentiometry. In the calculation of results for chloride, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels in vivo.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for chloride, as part of the i-STAT System, is intended for use in the in vitro quantification of chloride in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of chloride, a list of reactive ingredients is indicated below:

Reactive Ingredient
Chloride (Cl^-)

Metrological Traceability

The i-STAT System test for chloride measures chloride amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Chloride values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Chloride/CL	mmol/L(mEq/L)	65 – 140	98 – 109

*The i-STAT System can be configured with the preferred units.

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for chloride in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for chloride include prolonged diarrhea, renal tubular disease, hyperparathyroidism and dehydration. Some causes for decreased values for chloride include prolonged vomiting, burns, salt-losing renal disease, overhydration and thiazide therapy.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	76.7	0.54	0.7
Level 3	114.0	0.56	0.5

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	1.27	0.41	0.89
Syy	0.88	0.90	0.88
Slope	0.99	0.88	0.93
Int't	-0.82	14.6	4.3
Sy.x	1.65	1.84	2.33
Xmin	93	63	96
Xmax	114	128	117
r	0.817	0.914	0.752

Factors Affecting Results*

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	Effect
ß-hydroxybutyrate	16 mmol/L (166 mg/dL) b-hydroxybutyrate will increase chloride results by 3 mmol/L.
Bromide	12.5 mmol/L (100 mg/dL) bromide will increase chloride results by 30 mmol/L.
Lactate	11 mmol/L (100 mg/dL) lactate will increase chloride results by 3.5 mmol/L.
Salicylate	4 mmol/L salicylate will increase chloride results by 5 mmol/L
Thiocyanate	Thiocyanate may cause falsely elevated chloride results, or may cause chloride results to be suppressed ("star out").

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

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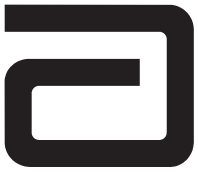

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BUN/UREA

Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.

$$\text{Urea} + H_2O + 2H^+ \xrightarrow{\text{urease}} 2NH^+_4 + CO_2$$

The ammonium ions are measured potentiometrically by an ion-selective electrode. In the calculation of results for urea, concentration is related to potential through the Nernst Equation.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for blood urea nitrogen (BUN/urea), as part of the i-STAT System, is intended for use in the *in vitro* quantification of BUN/urea in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of urea nitrogen, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Urea	N/A
Urease	*Canavalia ensiformis*

Metrological Traceability

The i-STAT System test for blood urea nitrogen/urea measures blood urea nitrogen/urea amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. BUN/urea values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4
Urea	mg/dL	6 – 300	17 - 56

*The i-STAT System can be configured with the preferred units.

To convert a BUN result in mg/dL to a urea result in mmol/L, multiply the BUN result by 0.357. To convert a urea result in mmol/L to a urea result in mg/dL, multiply the mmol/L result by 6.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g. shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	52.8	0.76	1.4
Level 3	5.5	0.45	8.2

Method Comparison (mg/dL)

	Beckman Coulter LX20	Dade Dimension RxL-Xpand	Beckman Coulter CX9
n	39	32	26
Sxx	0.36	0.48	0.39
Syy	0.67	0.34	0.60
Slope	1.03	1.05	1.00
Int't	1.39	-0.28	-0.38
Sy.x	0.99	0.31	0.85
Xmin	5	5	7
Xmax	70	38	66
r	0.997	0.998	0.997

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC8+ cartridges. In the 25–60 mg/dL range the average difference was -1.13. In the 60–140 mg/dL range the average difference was -0.77.

Factors Affecting Results*

Endogenous ammonium ions will not affect results.

Interferent	Effect
Thiocyanate	Thiocyanate can cause falsely decreased BUN/urea results on the i-STAT System. Preliminary studies indicated that 140 mg/dL (24 mmol/L) thiocyanate decreased BUN/urea results from 11.8 to 9.3 mg/dL (4.2 to 3.3 mmol/L), approximately 21%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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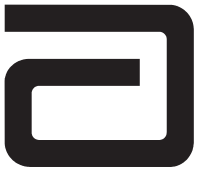

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GLUCOSE/GLU

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the electrode to produce a current which is proportional to the sample glucose concentration.

$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\textit{glucose oxidase}} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of glucose in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of glucose, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Glucose	N/A
Glucose Oxidase	*Aspergillus niger*

Metrological Traceability

The i-STAT System test for glucose measures glucose amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Glucose values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM965. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Glucose/Glu (fasting)	mg/dL	20 – 700	70 – 105
	mmol/L	1.1 – 38.9	3.9 – 5.8
	g/L	0.20 – 7.00	0.70 – 1.05

*The i-STAT System can be configured with the preferred units.

To convert a result from mg/dL to mmol/L, multiply the mg/dL value by 0.055.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g. Cushing's syndrome), drugs (e.g. steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected at multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	41.8	0.68	1.6
Level 3	289	2.4	0.8

Method Comparison (mg/dL)

	Beckman Coulter LX20	Bayer 860	Dade Dimension RxL-Xpand
n	35	40	32
Sxx	2.21	4.71	0.98
Syy	0.69	0.96	0.59
Slope	1.03	0.99	1.01
Int't	-3.39	-1.67	-0.85
Sy.x	0.91	0.70	1.57
Xmin	45	58	48
Xmax	297	167	257
r	0.999	0.993	0.998

Cartridge Comparison

System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 100–200 mg/dL range the average difference was 1.77. In the 200–300 mg/dL range the average difference was 3.7.

Factors Affecting Results*

Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7 mg/dL less than capillary blood glucose as a result of tissue utilization.[6]

Interferent	Effect
Bromide	37.5mmol/L (300mg/dL) bromide will decrease glucose results by 30 mg/dL.
pH	Values below 7.4 at 37°C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH units. Values above 7.4 at 37°C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH units.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of glucose with the i-STAT System. Use an alternative method to measure glucose when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Thiocyanate	Thiocyanate can cause falsely low glucose results on the i-STAT System. Preliminary studies indicated that 24 mmol/L (140 mg/dL) thiocyanate decreased glucose results from 85.6 to 65.8 mg/dL (4.75 to 3.65 mmol/L), approximately 23%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.
PO_2	Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, glucose will be increased by approximately 8 mg/dL (0.44 mmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the glucose level over a range of at least 75 mg/dL (4.2 mmol/L) to 645 mg/dL (35.8 mmol/L).

Ascorbic acid up to 0.63 mmol/L (11 mg/dL), uric acid up to 12 mg/dL, lactate up to 20 mmol/L (182 mg/dL), β-hydroxybutyrate up to 20 mmol/L (208 mg/dL), acetoacetate up to 10 mmol/L (100 mg/dL), acetaminophen up to 1.32 mmol/L (20 mg/dL), maltose up to 13.3 mmol/L (480 mg/dL) and hematocrit levels between 15–75 %PCV were tested and found not to interfere with glucose results.

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HEMATOCRIT/HCT AND CALCULATED HEMOGLOBIN/HB

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution of known conductance that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for hematocrit measures packed red blood cell volume fraction in arterial, venous, or capillary whole blood (expressed as the % packed cell volume) for *in vitro* diagnostic use. Hematocrit values assigned to i-STAT's working calibrators are traceable to the U.S. National Committee for Clinical Laboratory Standards (NCCLS) H7-A3 procedure for determining packed cell volume by the microhematocrit method[2]. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Hematocrit/Hct	%PCV	10 – 75	38 – 51**
	Fraction	0.10 – 0.75	0.38 – 0.51
Hemoglobin/Hb	g/dL	3.4 – 25.5	12 – 17
	g/L	34 – 255	120 – 170
	mmol/L	2.1 – 15.8	7 – 11

* The i-STAT System can be configured with the preferred units.

**The reference ranges for hematocrit and hemoglobin span both female and male populations.

To convert a result from %PCV to fraction packed cell volume, divide the %PCV result by 100. For the measurement of hematocrit, the i-STAT System can be customized to agree with methods calibrated by the microhematocrit reference method using either K_3EDTA or K_2EDTA anticoagulant. Mean cell volumes of K_3EDTA anticoagulated blood are approximately 2-4% less than K_2EDTA anticoagulated blood.[2] While the choice of anticoagulant affects the microhematocrit method to which all hematocrit methods are calibrated, results from routine samples on hematology analyzers are independent of the anticoagulant used. Since most clinical hematology analyzers are calibrated by the microhematocrit method using K_3EDTA anticoagulant, the i-STAT System default customization is K_3EDTA.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Hematocrit is a measurement of the fractional volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. A decreased hematocrit can be due to either overhydration, which increases the plasma volume, or a decrease in the number of red blood cells caused by anemias or blood loss. An increased hematocrit can be due to loss of fluids, such as in dehydration, diuretic therapy, and burns, or an increase in red blood cells, such as in cardiovascular and renal disorders, polycythemia vera, and impaired ventilation.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7-P.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (%PCV)

Whole Blood Control	Mean	SD	%CV
Low	30.0	0.44	1.5
High	49.0	0.50	1.0

Method Comparison (%PCV)

	Coulter® S Plus	Nova STAT Profile® 5	Abbott Cell-Dyn 4000	Sysmex SE9500
n	142	192	29	29
Sxx	0.50	0.46	0.41	0.53
Syy	1.09	1.31	0.77	0.76
Slope	0.98	1.06	1.06	1.11
Int't	1.78	-3.98	-1.42	-4.19
Sy.x	2.03	2.063	1.13	0.98
Xmin	18	21	19	24
Xmax	51	50	46	47
r	0.952	0.932	0.993	0.980

Factors Affecting Results*

Interferent — **Effect**

WBC — Grossly elevated white blood cell counts may increase results.

Total Protein — Hematocrit results are affected by the level of total protein as follows:

Displayed Result	TP < 6.5 g/dL	TP > 8.0 g/dL
HCT < 40 %PCV	Hct decreased by ~1% PCV for each decrease of 1 g/dL TP	Hct increased by ~1% PCV for each increase 1 g/dL TP
HCT > 40 % PCV	Hct decreased by ~0.75 % PCV for each decrease of 1 g/dL TP	Hct increased by ~0.75 %PCV for each increase 1 g/dL TP

Total protein levels may be low in neonatal and burn patient populations, as well as in additional clinical populations listed in Statland[3]. Total protein levels may also be decreased in patients undergoing cardiopulmonary bypass (CPB) or ECMO, and with patients receiving large volumes of saline-based IV fluids. Care should be taken when using hematocrit results from patients with total protein levels below the adult reference range (6.5 to 8 g/dL).

The CPB sample type can be used to correct the hematocrit result for the dilutional affect of the pump prime in cardiovascular surgery. The CPB algorithm assumes that cells and plasma are diluted equally and that the pump priming solution has no added albumin or other colloid or packed red blood cells. Since perfusion practices vary, it is recommended that each practice verify the use of the CPB sample type and the length of time in which the CPB sample type should be used during the recovery period. Note that for hematocrit values above 30 %PCV, the CPB correction is ≤1.5 %PCV; the size of the correction at this level should not impact transfusion decisions.

Lipids — Abnormally high lipids may increase results. Interference from lipids will be about two thirds the size of the interference from protein.

Sodium — The sample electrolyte concentration is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also affect hematocrit.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Sample Collection and Handling

Erroneous hematocrit results can be obtained by improper sample handling.

- Hematocrit results can be affected by the settling of red blood cells in the collection device. The best way to avoid the affect of settling is to test the sample immediately. If there is a delay in testing of a minute or more, the sample must be remixed thoroughly:
  - If the sample is in a collection tube, invert the tube gently 10 times.
  - If the sample is in a syringe, roll the syringe between the palms for five seconds in one direction, then roll in a second direction for five seconds, then gently invert repeatedly for five seconds. Note that it may not be possible to adequately mix a blood sample in a 1 mL syringe. Samples from 1 mL syringes should not be used to determine hematocrit if testing is delayed. Discard one or two drops of blood from a syringe before filling a cartridge.
- Low hematocrit results can be caused by contamination of flush solutions in an arterial or venous line.
  - Back flush a 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.

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT E3+ cartridges. In the 15–30 %PCV range the average difference was 0.462. In the 30–50 %PCV range the average difference was 0.097.

Calculated Result for Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows[7]:

hemoglobin (g/dL) = hematocrit (% PCV) x 0.34

hemoglobin (g/dL) = hematocrit (decimal fraction) x 34

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

References

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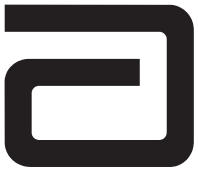

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IONIZED CALCIUM/ICA

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ionized calcium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Calcium (Ca^{2+})

Metrological Traceability

The i-STAT System test for ionized calcium measures ionized calcium (*i.e.* free calcium ion) amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Ionized calcium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

*The i-STAT System can be configured with the preferred units.

To convert a result from mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L multiply the mmol/L value by 2.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7-P.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.60	0.017	1.1
Level 3	0.84	0.012	1.4

Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	47	57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

Factors Affecting 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[6]. Exposing the sample to air will cause an increase in pH due to the loss of CO_2 which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L.[6] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L.[6] Use only unheparinized sample transfer devices when using i-STAT's aqueous control and calibration verification materials.

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Affect of Freezing: Cartridges should be stored between 2 and 8 ºC. Freezing should be avoided. Freezing will cause the ionized calcium in the calibrant fluid to precipitate, which will cause sample results to be falsely elevated. To help avoid freezing, do not store cartridges against the walls of the refrigerator. If freezing is suspected, test a sample of the cartridges using i-STAT controls.

Interferent	Effect
β-hydroxybutyrate	20 mmol/L β-hydroxybutyrate will decrease ionized calcium results by 0.1 mmol/L.
Lactate	20 mmol/L lactate will decrease ionized calcium results by 0.05 mmol/L.
Magnesium	1.0 mmol/L magnesium above normal will increase ionized calcium results by 0.04 mmol/L.
Salicylate	4.34 mmol/L salicylate will decrease ionized calcium results by 0.1 mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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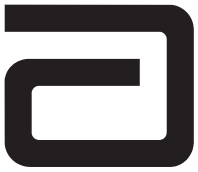

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PO_2 AND CALCULATED OXYGEN SATURATED (sO_2)

PO_2 is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ***P***O_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of oxygen partial pressure in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for oxygen partial pressure measures oxygen partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. ***P***O_2 values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test	Units*	Reportable Range	Reference Range[2]
PO_2	mmHg	5 – 800	80 – 105
	kPa	0.7 – 106.6	10.7 – 14.0
sO_2**	%	not applicable	95 – 98

*The i-STAT System can be configured with the preferred units.

** Calculated

To convert ***P***O_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (eg. patient temperature, ventilation, posture and circulatory status).

Clinical Significance

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of ***P***O_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).

$$sO_2 = 100 \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

$$\text{where } X = \textbf{\textit{P}}O_2 \bullet 10^{(0.48(pH-7.4)-0.0013(HCO_3-25))}$$

sO_2 is calculated from measured ***P***O_2 and pH and from HCO_3 calculated from measured ***P***CO_2 and pH. However, this calculation assumes normal affinity of oxygen for hemoglobin (it does not take into consideration erythrocyte diphosphoglycerate (2,3-DPG) concentrations which affect the oxyhemoglobin dissociation curve) and assumes that normal amounts of disfunctional hemoglobin (carboxy-, met- and sulfhemoglobin) are present. Oxygen saturation is a useful predictor of the amount of oxygen that is available for tissue perfusion. Some causes for decreased values of sO_2 include low ***P***O_2 or impaired ability of hemoglobin to carry oxygen.

Temperature "Correction" Algorithm

PO_2 is a temperature-dependent quantity and is measured at 37°C. The ***P***O_2 reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The ***P***O_2 at the patient's temperature (T_p) is calculated as follows[3]:

$$PO_2(T_p) = PO_2 \times 10^{\frac{5.49\times10^{-11} PO_2^{3.88} + 0.071}{9.72\times10^{-9} PO_2^{3.88} + 2.30}(T_p - 37)}$$

Note: The input of patient temperature on the chart page is only possible when a cartridge contains pH, ***P***CO_2, and ***P***O_2 sensors.

Performance Characteristics

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative method.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[6] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	65.1	3.12	4.79
Level 3	146.5	6.00	4.10

Method Comparison (mmHg)

	Radiometer ABL500	Radiometer ABL700	Bayer 845
n	45	29	30
Sxx	3.70	2.04	3.03
Syy	2.78	2.64	3.28
Slope	1.023	0.962	1.033
Int't	-2.6	1.2	-2.9
Sy.x	2.52	3.53	3.44
Xmin	----	39	31
Xmax	----	163	185
r	0.996	0.990	0.996

Factors Affecting Results*

Exposure of the sample to air will cause an increase in $\boldsymbol{P}O_2$ when values are below 150 mmHg and a decrease in $\boldsymbol{P}O_2$ when values are above 150 mmHg (approximate $\boldsymbol{P}O_2$ of room air).

Standing anaerobically at room temperature will decrease pH at a rate of 0.03 per hour, will increase $\boldsymbol{P}CO_2$ by approximately 4 mmHg per hour and will decrease $\boldsymbol{P}O_2$ at a rate of 2–6 mmHg per hour.[6]

Do not ice samples before testing – $\boldsymbol{P}O_2$ results may be falsely elevated in cold samples. Do not use a cold cartridge – $\boldsymbol{P}O_2$ results may be falsely decreased if the cartridge is cold.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Factors Affecting Calculated Results

sO_2 values calculated from a measured $\boldsymbol{P}O_2$ and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement.[3]

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradel, NJ: Medical Economic Books, 1987).

3. NCCLS. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*. NCCLS document C46-A [ISBN 1-56238-444-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.

4. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, "Blood Gases and pH," in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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Art: 714180-01E Rev. Date: 01/25/05

pH

pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation. Results are reported at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for pH, as part of the i-STAT System, is intended for use in the *in vitro* quantification of pH in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of pH, a list of reactive ingredients is indicated below:

Reactive Ingredient
Hydrogen Ion (H^+)

Metrological Traceability

The i-STAT System test for pH measures the hydrogen ion amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (expressed as the negative logarithm of the relative molal hydrogen ion activity) for *in vitro* diagnostic use. pH values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range	
pH		6.50 – 8.20	7.35 – 7.45[2] (arterial)	7.31 – 7.41* (venous)

* Calculated from Siggaard-Andersen nomogram.

Venous samples normally measure 0.01 – 0.03 pH units lower than arterial samples.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia.[3]

Temperature "Correction" Algorithm

pH is a temperature-dependent quantity that is measured on the i-STAT System at 37°C. The pH reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The pH at the patient's temperature (T_p) is calculated as follows[4]:

$$pH(T_p) = pH - 0.0147(T_p - 37) + 0.0065(7.4 - pH)(T_p - 37)$$

Note: The input of patient temperature on the chart page is only possible when a cartridge contains pH, PCO_2, and PO_2 sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[5]. Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant. All sample were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 mL blood gas syringes and were analyzed in duplicate on the i-STAT-System and the comparative method within 5 minutes of each other.

Deming regression analysis[6] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data

Aqueous Control	Mean	SD	%CV
Level 1	7.165	0.005	0.08
Level 3	7.656	0.003	0.04

Method Comparison

	IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
n	62	47	57	45
Sxx	0.005	0.011	0.006	0.004
Syy	0.009	0.008	0.008	0.008
Slope	0.974	1.065	1.058	1.0265
Int't	0.196	-0.492	-0.436	-0.1857
Sy.x	0.012	0.008	0.010	0.0136
Xmin	7.210	7.050	7.050	
Xmax	7.530	7.570	7.570	
r	0.985	0.990	0.9920	.986

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid. Exposing the sample to air will cause an increase in pH due to the loss of CO_2. pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour.[3]

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

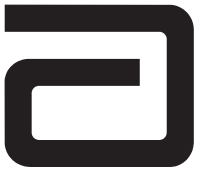
2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

3. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994.

4. NCCLS. *Blood Gas amd pH Analysis and Related Measurements; Approved Guideline*. NCCLS document C46-A [ISBN 1-56238-444-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

5. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

6. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).



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PCO_2 AND CALCULATED VALUES FOR HCO_3, TCO_2, BASE EXCESS AND ANION GAP

PCO_2 is measured by direct potentiometry. In the calculation of results for ***P***CO_2, concentration is related to potential through the Nernst equation. Results are measured at 37°C when using cartridges that require thermal control and corrected to 37°C when using cartridges that do not require thermal control.

Calculated Values

When a cartridge includes sensors for both pH and ***P***CO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) are calculated.[1]

$\log HCO_3 = pH + \log$ ***P***$CO_2 - 7.608$

$TCO_2 = HCO_3 + 0.03$ ***P***CO_2

$BE_{ecf} = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$

$BE_b = (1 - 0.014*Hb) * [\ HCO_3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)\ ]$

When a cartridge includes sensors for sodium, potassium, chloride, pH and ***P***CO_2, anion gap can be calculated.

Anion Gap = $(Na + K) - (Cl + HCO_3)$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ***P***CO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of carbon dioxide partial pressure in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ***P***CO_2, a list of reactive ingredients is indicated below:

Reactive Ingredient
Carbon Dioxide (CO_2)

Metrological Traceability

The i-STAT System test for carbon dioxide partial pressure measures carbon dioxide partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. ***P***CO_2 values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Partial Pressure Carbon Dioxide/PCO_2	mmHg	5 – 130	35 – 45[3]	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
Bicarbonate/HCO_3	mmol/L	1.0 – 85.0	22 – 26**	23 – 28**
Total Carbon Dioxide/TCO_2	mmol/L	5 – 50	23 – 27**	24 – 29**
Base Excess/BE	mmol/L	(-30) – (+30)	(-2) – (+3)[3]	(-2) – (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) – (+99)	10 – 20[3]	10 – 20[3]

*The i-STAT System can be configured with the preferred units.
**Calculated from Siggaard-Andersen nomogram.[4]

For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and PCO_2 due to loss of CO_2 during non-anaerobic handling.[5] Up to 6mmol/L CO_2 can be lost per hour by exposure of the sample to air.[6]

To convert PCO_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

PCO_2 along with pH is used to assess acid-base balance. PCO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

TCO_2 (total carbon dioxide) is either measured on plasma by automated chemistry analyzers or is calculated from pH and PCO_2 measured on whole blood gas analyzers. TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, HCO_3 or CO_3 ions, and carbonic acid (H_2CO_3). Bicarbonate ions make up all but approximately 2 mmol/L of the total carbon dioxide of plasma. Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at PCO_2 of 40 mmHg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Temperature "Correction" Algorithm

PCO_2 is a temperature-dependent quantity and is measured at 37°C. The ***PC***O_2 reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The ***PC***O_2 at the patient's temperature (T_p) is calculated as follows[1]:

$$PCO_2(T_p) = PCO_2 \times 10^{0.019(T_p - 37)}$$

Note: The input of patient temperature on the chart page is only possible when a cartridge contains pH, ***PC***O_2, and ***P***O_2 sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[7]. Venous blood samples were collected in blood gas syringes. To measure TCO_2, the sample was centrifuged to obtain plasma. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[8] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.8	1.57	2.5
Level 3	19.6	0.40	2.0

Method Comparison (mmHg)

	PCO_2 IL BGE	TCO_2 IL BGE	TCO_2 Beckman CX®3	***P***CO_2 Radiometer ABL500
n	62	62	51	29
Sxx	0.69	0.40	0.55	0.74
Syy	1.24	0.84	0.55	0.53
Slope	1.003	1.136	1.155	1.016
Int't	-0.8	-4.1	-2.6	1.1
Sy.x	1.65	1.38	1.56	0.32
Xmin	30.4	19.3	18.3	28
Xmax	99.0	43.9	36.1	91
r	0.989	0.965	0.935	0.999

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes ***P***CO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated. The use of partial-draw 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) is not recommended for use with the i-STAT System because of the potential for decreased measured ***P***CO_2 results and calculated HCO_3 and TCO_2 values. Under-filling blood collection tubes may also cause decreased ***P***CO_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.

Allowing blood to stand (without exposure to air) before testing allows ***P***CO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

For patients administered propofol (Diprivan®) or thiopental sodium (syn. thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[9]), i-STAT recommends the use of G3+, CG4+, CG8+, EG6+ and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol (Diprivan®) or thiopental sodium.

* It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. NCCLS. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*. NCCLS document C46-A [ISBN 1-56238-444-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

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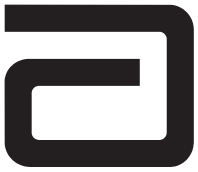

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CREATININE/CREA

Creatinine is measured amperometrically. Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

INTENDED USE

The test for creatinine, as part of the i-STAT System, is intended for use in the *in vitro* quantification of creatinine in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of creatinine, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Creatinine	N/A
Creatine Amidinohydrolase	*Actinobacillus sp.*
Creatinine Amidohydrolase	Microbial
Sarcosine Oxidase	Microbial

Metrological Traceability

The i-STAT System test for creatinine measures creatinine amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension µmol L^{-1}) for *in vitro* diagnostic use. Creatinine values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3[2]
	µmol/L	18 – 1768	53 – 115

To convert a creatinine result from mg/dL to µmol/L, multiply the mg/dL value by 88.4.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed. The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by professionals trained in the use of the i-STAT System and comparative methods. Clinical settings vary and some may require different performance characteristics to assess renal function status than others (e.g., medication dosing, intravenous contrast use, and outpatient clinic). If deemed necessary by a health care facility, performance data should be obtained in specific clinical settings to assure patients' needs are met.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	4.7	0.08	1.7
Level 3	0.76	0.05	6.3

Method Comparison (mg/dL)

	Hitachi 917	J&J Vitros
n	67	48
Sxx	0.045	0.035
Syy	0.087	0.109
Slope	1.002	1.005
Int't	0.030	-0.109
Sy.x	0.110	0.229
Xmin	0.3	0.5
Xmax	11.2	12.6
r	0.9987	0.9931

Factors Affecting Results*

Interferent	**Effect**
Acetaminophen	Creatinine results will increase by approximately 0.25 mg/dL per every 1 mmol/L of acetaminophen.
Ascorbate	0.227 mmol/L ascorbate will cause a 0.7 mg/dL increase in creatinine.
Bromide	100 mg/dL (12.5 mmol/L) bromide will increase creatinine by 0.8 mg/dL (71 µmol/L) from an initial creatinine concentration of 1.0 mg/dL (88 µmol/L).
CO_2	For Crea values below 2 mg/dL: For $\boldsymbol{P}CO_2$ values above 40 mmHg, the values are increased by 6.9% for every 10 mmHg For $\boldsymbol{P}CO_2$ values below 40 mmHg, the values are decreased by 6.9% for every 10 mmHg $[Cr]actual = [Cr]istat \times \{ 1 - (0.069 \times [(\boldsymbol{P}CO_2 - 40)/10]) \}$ For Crea values above 2 mg/dL: For $\boldsymbol{P}CO_2$ values above 40, the values are decreased by 3.7% for every 10 mmHg For $\boldsymbol{P}CO_2$ values below 40, the values are increased by 3.7% for every 10 mmHg $Cr]actual = [Cr]istat \times \{ 1 - (0.037 \times [(40 - \boldsymbol{P}CO_2)/10]) \}$
Creatine	5 mg/dL creatine will cause a 0.20 mg/dL increase in Creatinine. For clinical situations in which creatine may be elevated, see note (1) below.
N-acetylcysteine	16.6 mmol/L N-acetylcysteine will cause a 0.4 mg/dL increase in creatinine.

Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of creatinine with the i-STAT System. Use an alternative method to measure creatinine when patients have been administered hydroxyurea. See note (2) below for typical uses of this drug and note (3) below for details of the interference.

Notes:

(1) The normal range of creatine concentration in plasma is 0.17 – 0.70 mg/dL (13 – 53 µmol/L) in males and 0.35 – 0.93 mg/dL (27 – 71 µmol/L) in females[7]. Creatine may be elevated in patients using creatine supplements, experiencing muscle trauma or other primary or secondary myopathies, taking statins for hyperlipidemia control, or in patients with hyperthyroidism or a rare genetic defect of the creatine transporter protein.

(2) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

(3) For every 100 µmol/L hydroxyurea in the whole blood sample, creatinine will be increased by approximately 1.85 mg/dL (164 µmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the creatinine level over a range of at least 1.0 mg/dL (88 µmol/L) to 12.4 mg/dL (1096 µmol/L).

Bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL (342 µmol/L), calcium up to 5.0 mg/dL (1.25 mmol/L), dopamine up to 13 mg/dL (0.85 mmol/L), methyldopa up to 2.5 mg/dL (118.4 µmol/L), salicylate up to 77.5 mg/dL (4.34 mmol/L), sarcosine up to 1.0 mmol/L, and uric acid up to 20 mg/dL (1190 µmol/L) were tested and found not to interfere with creatinine results.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

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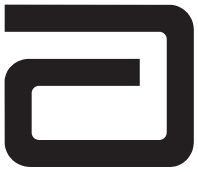

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LACTATE/LAC

Lactate is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at a platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$\text{L-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of lactate, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Lactate	N/A
Lactate Oxidase	*Aerococcus viridans*

Metrological Traceability

The i-STAT System test for lactate measures L-lactate amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Presently, no international conventional reference measurement procedure or international conventional calibrator for lactate is available. Lactate values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from sodium L-lactate (Sigma-Aldrich Fluka, >99 % purity). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference[2] Range	
			(arterial)	(venous)
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3

To convert a lactate result from mmol/L to mg/dL, multiply the mmol/L value by 9.01.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolumia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.[2]

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected using NCCLS guideline EP5-A[3]. Duplicates of each level of control were tested on three lots of cartridges over 20 days for a total of 120 replicates.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples, collected in sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. In the plasma study, a portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)	Aqueous Control	n	Mean	SD	%CV
	Level 1	120	6.35	0.08	1.21
	Level 3	120	0.81	0.03	3.27

Method Comparison (mmol/L)	Radiometer ABL 725 **(whole blood vs. whole blood)**	Hitachi 917 **(i-STAT whole blood vs. Hitachi plasma)**
n	47	47
Sxx	0.123	0.084
Syy	0.136	0.079
Slope	1.02	1.06
Int't	0.12	-0.32
Sy.x	0.18	0.17
Xmin	0.80	1.77
Xmax	14.20	14.24
r	0.998	0.997

Factors Affecting Results*

Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.

Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 ºC as a result of glycolysis.[2]

Interferent	Effect
Bromide	25 mmol/L (200 mg/dL) bromide will decrease lactate results by 40%.
Cysteine	6.4 mmol/L (101 mg/dL) cysteine will decrease lactate results by 11%.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of lactate with the i-STAT System. Consider using an alternative method to measure lactate when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Glycolic Acid:	Glycolic acid can cause falsely increased lactate results on the i-STAT System. Preliminary studies indicated that 10 mmol/L glycolic acid increased lactate from 1.45 mmol/L to 3.41 mmol/L. See note (3) for details.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, lactate will be increased by approximately 0.16 mmol/L, up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the lactate level over a range of at least 2.8 mmol/L to 16.0 mmol/L.

3) Glycolic acid is a product of ethylene glycol metabolism. Unexpected increased lactate concentrations caused by glycolic acid may be a clue to the possibility of ethylene glycol ingestion as the cause of an otherwise unknown high anion gap metabolic acidosis. [7, 8] In a study of 35 patients who had ingested ethylene glycol, initial glycolic acid concentrations of 0 to 38 mmol/L corresponded to ethylene glycol levels of 0.97 - 130.6 mmol/L. [7]

Acetaldehyde up to 0.6 mg/dL (0.14 mM), acetominophen up to 20 mg/dL (1.3 mM), acetylsalicylic acid up to 50 mg/dL (2.8 mM), ascorbic acid up to 3 mg/dL (0.17 mM), ß-hydroxybutyric acid up to 202 mg/dL (16 mM), dopamine up to 13 mg/dL (0.85 mM), formaldehyde up to 1.2 mg/dL (0.40 mM), glycine up to 98 mg/dL (13 mM), pyruvic acid up to 2.6 mg/dL (0.24 mM), and uric acid up to 25 mg/dL (1.5 mM) were tested and found not to interfere with lactate results. Hematocrit levels between 25 and 67% were tested and found not to interfere with lactate results.

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CELITE ACTIVATED CLOTTING TIME/ (CELITEACT)

The i-STAT® Celite® Activated Clotting Time test, CeliteACT, is a measure of the time required for complete activation of the coagulation cascade.[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT CeliteACT test is similar to traditional ACT tests except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3 . The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) as a whole blood time (WBT) in seconds.

The i-STAT CeliteACT test is calibrated to match the Hemochron Celite FTCA510 using prewarmed tubes. However, users of the i-STAT®1 analyzer may choose to customize their individual i-STAT locations to report ACT results as calibrated against the Hemochron Celite ACT using non-prewarmed (ambient) temperature tubes. This customization affects the Patient path only, and will not be applied to the Control or the Proficiency Testing pathway.

The customization in effect (prewarm or non-prewarm calibration mode) is identified on the analyzer screen as PREWRM or NONWRM, respectively. Please note that different locations within a given hospital may utilize different customization profiles. Prior to patient sample testing, ensure the appropriate calibration mode is employed. For a comprehensive discussion of this customization feature, please see the Technical Bulletin entitled "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer".

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Celite Activated Clotting Time (CeliteACT) test cartridge, as part of the i-STAT System, is an *in vitro* diagnostic test used to monitor moderate- and high-level heparin therapy through analysis of arterial and venous whole blood samples.

Contents

Each i-STAT CeliteACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint, and dry reagents necessary to initiate and allow coagulation. Stabilizers and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient
Diatomaceous Earth
Thrombin Substrate

Metrological Traceability

The i-STAT System test for Celite Activated Clotting Time measures the time interval required for complete activation, by Celite®, of the coagulation cascade in arterial or venous whole blood (dimension seconds) for *in vitro* monitoring of moderate- and high-level heparin therapy. Presently, no international conventional reference measurement procedure or international conventional calibrator for CeliteACT is available. CeliteACT values assigned to i-STAT's controls are traceable to i-STAT's selected reference measurement procedure, which employs diatomaceous earth (Celite) activated glass reagent tubes, an automated timer and traditional viscometric clot detection and is run under specified temperature and sample conditions. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (PREWRM)	Reference Range (NONWRM)
Activated Clotting Time/ACT	seconds	50 - 1000*	74 - 125	84 - 139

* The range from 80 - 1000 seconds has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods. All data uses the PREWRM calibration, unless otherwise noted.

Precision data were collected at i-STAT and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	329	221 seconds	18 seconds	8.1
Level 2	438	456 seconds	22 seconds	4.8

Method comparison data were collected using a modification of the NCCLS guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used. This includes baseline, heparin-treated, and heparin-reversed samples from from patients undergoing cardiac catheterization and cardiac bypass.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

Cath Lab	Medtronic HR-ACT	Hemochron CA510/FT CA510
n	270	418
Sxx	10.1	19.7
Syy	10.7	13.5
Slope	1.15	0.86
Int't	-30	-3
Sy.x	32.5	22.5
Xmin	73	63
Xmax	523	763
r	0.848	0.903

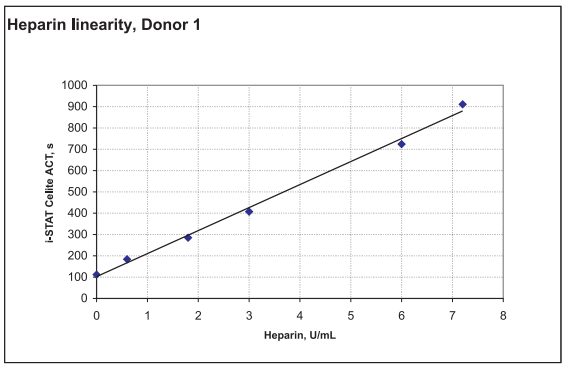
	Hemchron CA510/FT CA510		
CVOR	Site 1	Site 2	Site 3
n	35	30	24
Sxx	15.8	34.2	24.4
Syy	13.0	11.5	20.8
Slope	0.85	1.10	1.19
Int't	4	-52	-73
Sy.x	43.8	17.4	62.1
Xmin	118	94	125
Xmax	671	735	767
r	0.912	0.952	0.891

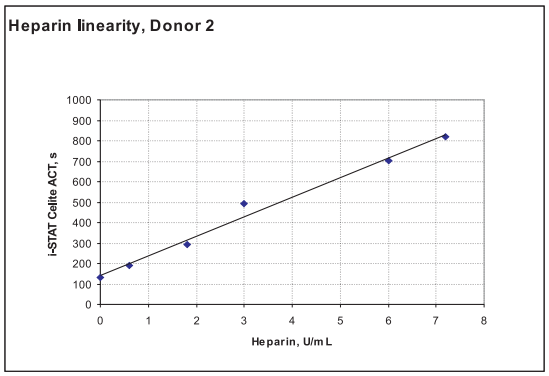
Factors Affecting Results*

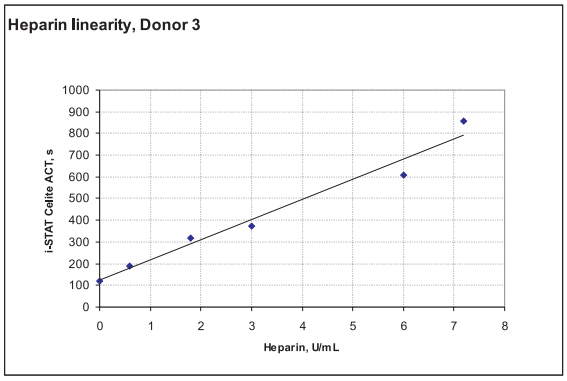
*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

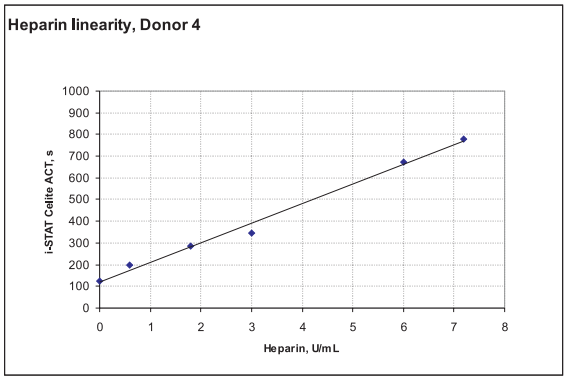
Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

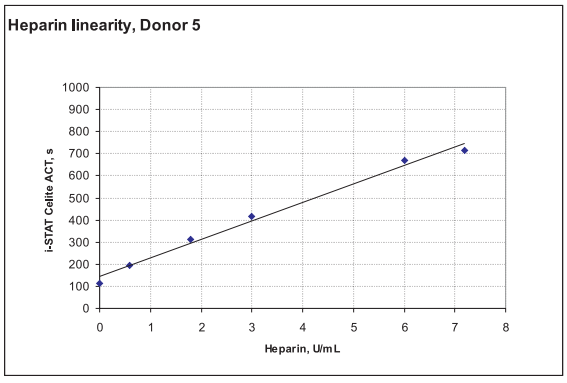
The five graphs below each indicate the response of a different donor with respect to heparin concentration:



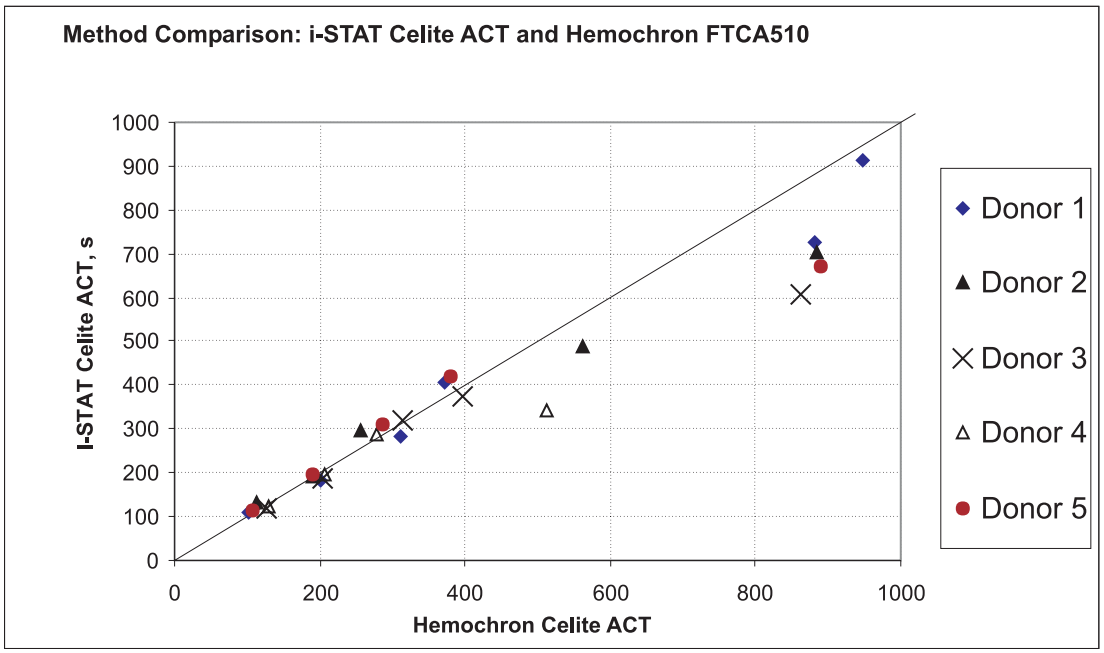


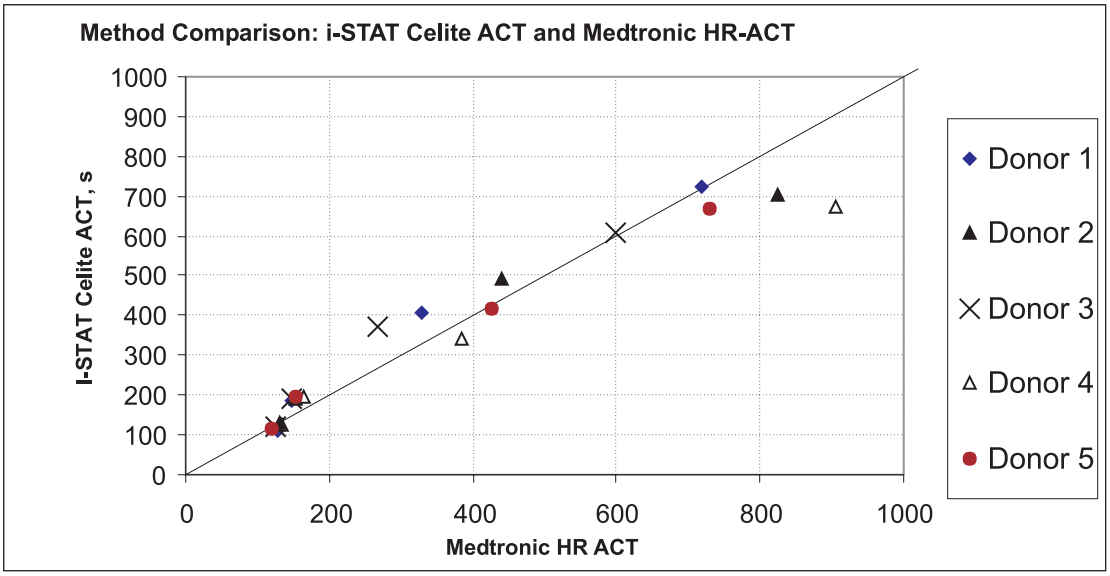




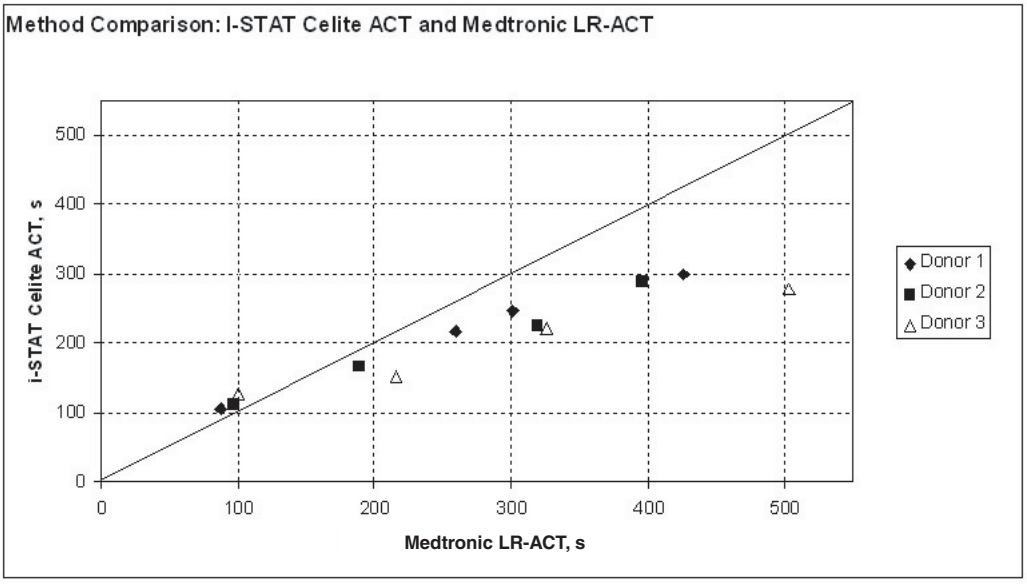


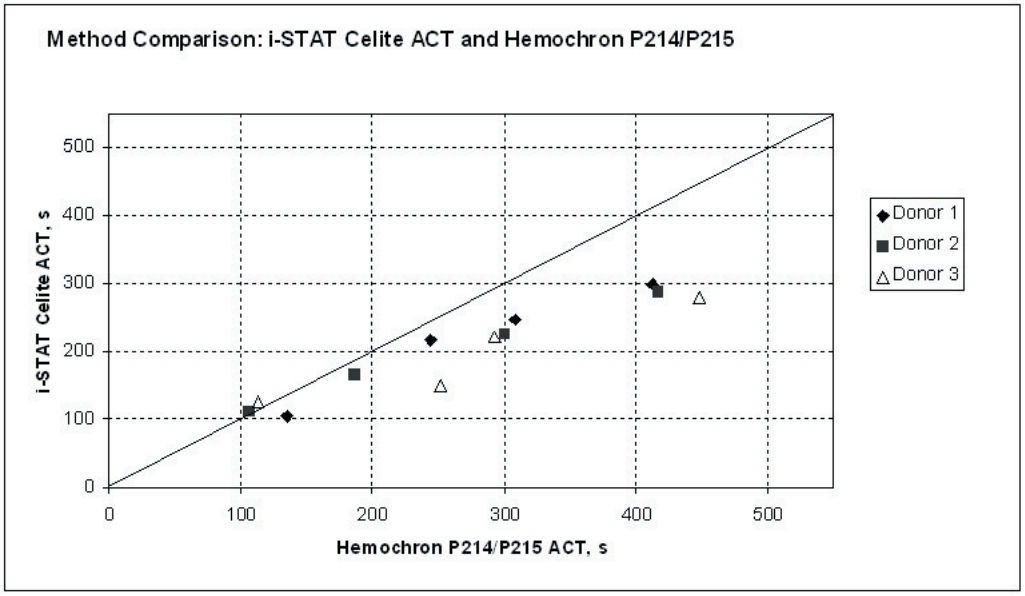
The graphs below indicate the response of the same five donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Celite FTCA 510.





Performance of the i-STAT Celite ACT at lower levels of heparin is shown below with two "Low Range" ACT methods included for comparison:





Test Limitations

The i-STAT CeliteACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The i-STAT ACT test uses Celite brand diatomaceous earth as the activator of the intrinsic pathway. The result may, therefore, be prolonged in the presence of aprotinin.[4] **The test is not recommended for use with patients receiving aprotinin.**

The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%.

Hemodilution may affect test results.

Platelet dysfunction, factor deficiencies, dysprothrombinemias, pharmacological compounds, and other coagulopathies may affect the results of this test.

The i-STAT ACT test is not affected by hematocrit in the range of 20 - 70%, fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37ºC.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperature was satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT ACT Controls using any verified Analyzer. Instructions for the use of these controls are found in the i-STAT System Manual.

For additional information on Quality Control of the i-STAT System, refer to the Quality Control section in the i-STAT System Manual.

Specimen Collection and Preparation

The i-STAT Celite ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[5]

In-dwelling line

- Fluid drip through the line must be discontinued.
- Withdraw 2 mL of blood into a syringe and discard it.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

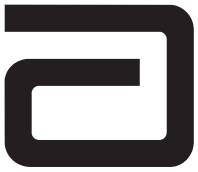
1. Hattersly, P. Activated coagulation time of whole blood. Journal of the American Medical Association 136:436-440, 1966.

2. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.

3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Wang, JS; Lin, CY; Hung, WT; Thisted, RA; Carp, RB. In vitro effects of aprotinin on activated clotting time measured with different activators. Journal of Thoracic Cardiovascular Surgery 104(4):1135-40, 1992.

5. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.



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Art: 714185-01D Rev. Date: 04/16/04

KAOLIN ACTIVATED CLOTTING TIME/ (^{KAOLIN}ACT)

The i-STAT® Kaolin Activated Clotting Time test, ^{Kaolin}ACT, is a measure of the time required for complete activation of the coagulation cascade.[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT ^{Kaolin}ACT test is similar to traditional ACT tests except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3. The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) in seconds.

The i-STAT ^{Kaolin}ACT test is calibrated to match the Hemochron Celite FTCA510 using prewarmed reagent tubes. However, users of the i-STAT®1 analyzer may choose to customize their individual i-STAT locations to report ACT results as calibrated against the Hemochron Celite ACT using non-prewarmed (ambient temperature) tubes. This customization affects the Patient path only, and will not be applied to the Control or the Proficiency Testing pathway.

The customization in effect (prewarm or non-prewarm calibration mode) is identified on the analyzer screen as PREWRM or NONWRM, respectively. Please note that different locations within a given hospital may utilize different customization profiles. Prior to patient sample testing, ensure the appropriate calibration mode is employed. For a comprehensive discussion of this customization feature, please see the Technical Bulletin entitled "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer".

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Kaolin Activated Clotting Time (^{Kaolin}ACT) test is an *in vitro* diagnostic test that uses fresh whole blood to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

The test is to be used with the i-STAT Portable Clinical Analyzer and the i-STAT 1 Analyzer, but not the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM).

Contents

Each i-STAT ^{Kaolin}ACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint, and dry reagents necessary to initiate and allow coagulation. Stabilizers and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient
Kaolin
Thrombin Substrate

Metrological Traceability

The i-STAT System test for Kaolin Activated Clotting Time measures the time interval required for complete activation, by kaolin, of the coagulation cascade in arterial or venous whole blood (dimension seconds) for *in vitro* monitoring of high-level heparin therapy. Presently, no international conventional reference measurement procedure or international conventional calibrator for ^{Kaolin}ACT is available. ^{Kaolin}ACT values assigned to i-STAT's controls are traceable to i-STAT's selected reference measurement procedure, which employs Celite activated glass reagent tubes, an automated timer and traditional viscometric clot detection and is run under specified temperature and sample conditions. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (PREWRM)	Reference Range (NONWRM)
Activated Clotting Time/ACT	seconds	50 - 1000*	74 - 137	82- 152

* The range from 77 - 1000 seconds (PREWRM mode) has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods. All data uses the PREWRM calibration, unless otherwise noted.

Precision data were collected at i-STAT and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	119	169 seconds	4 seconds	2.0
Level 2	113	409 seconds	21 seconds	5.2

Method comparison data were collected using a modification of the NCCLS guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used and included both aprotinin and non-aprotinin receiving patients. All were undergoing cardiac surgery. Sample types included baseline, heparin-treated, and heparin-reversed samples.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

	Hemochron FTK-ACT		
CVOR	**Site 1**	**Site 2**	**Site 3**
n	104	118	106
Sxx	9.1%	6.8%	7.6%
Syy	3.6%	4.0%	3.6%
Slope	0.96	1.05	0.96
Intercept	-12	-38	-39
Xmin	68	111	81
Xmax	1286	1310	1102
r	0.906	0.940	0.971

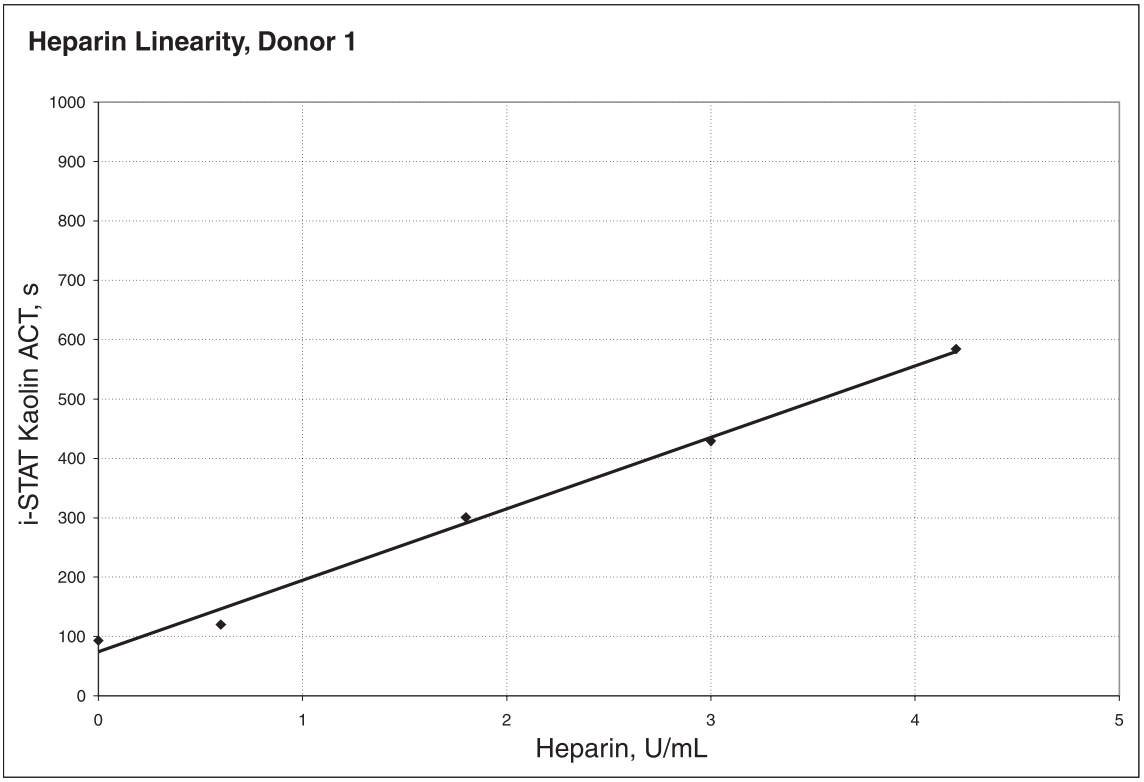
Factors Affecting Results*

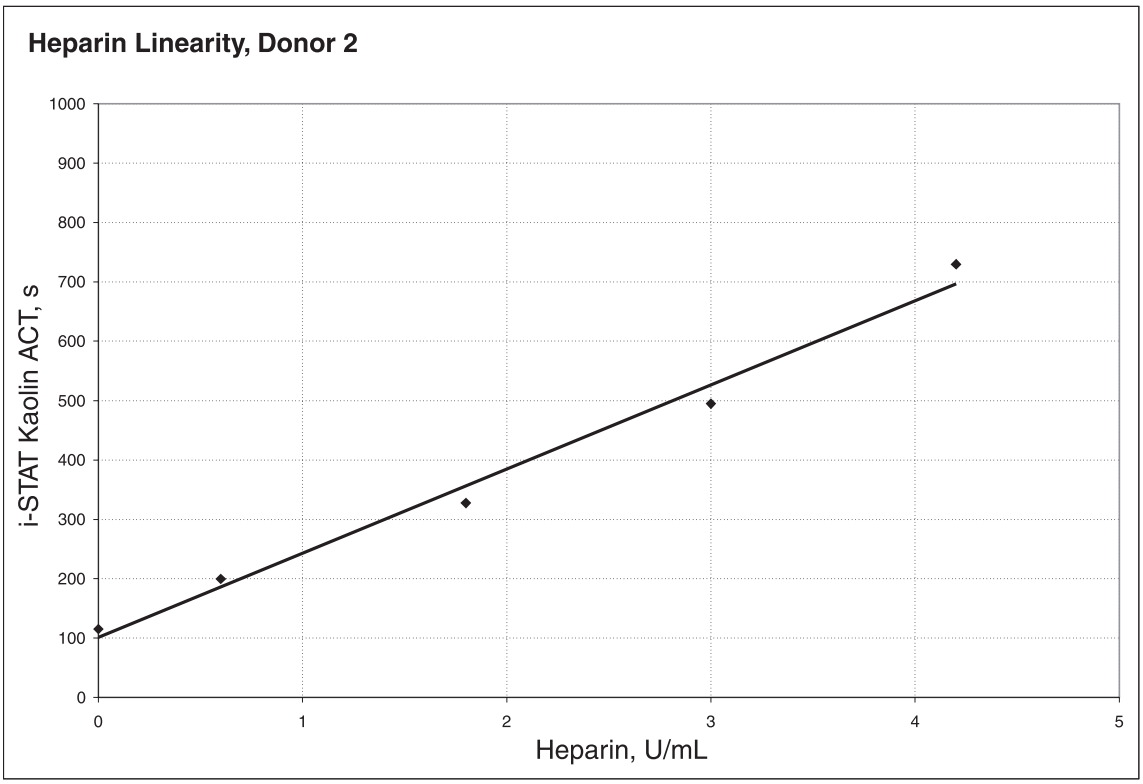
The i-STAT ^{Kaolin}ACT test is not significantly prolonged in the presence of aprotinin (Trasylol).

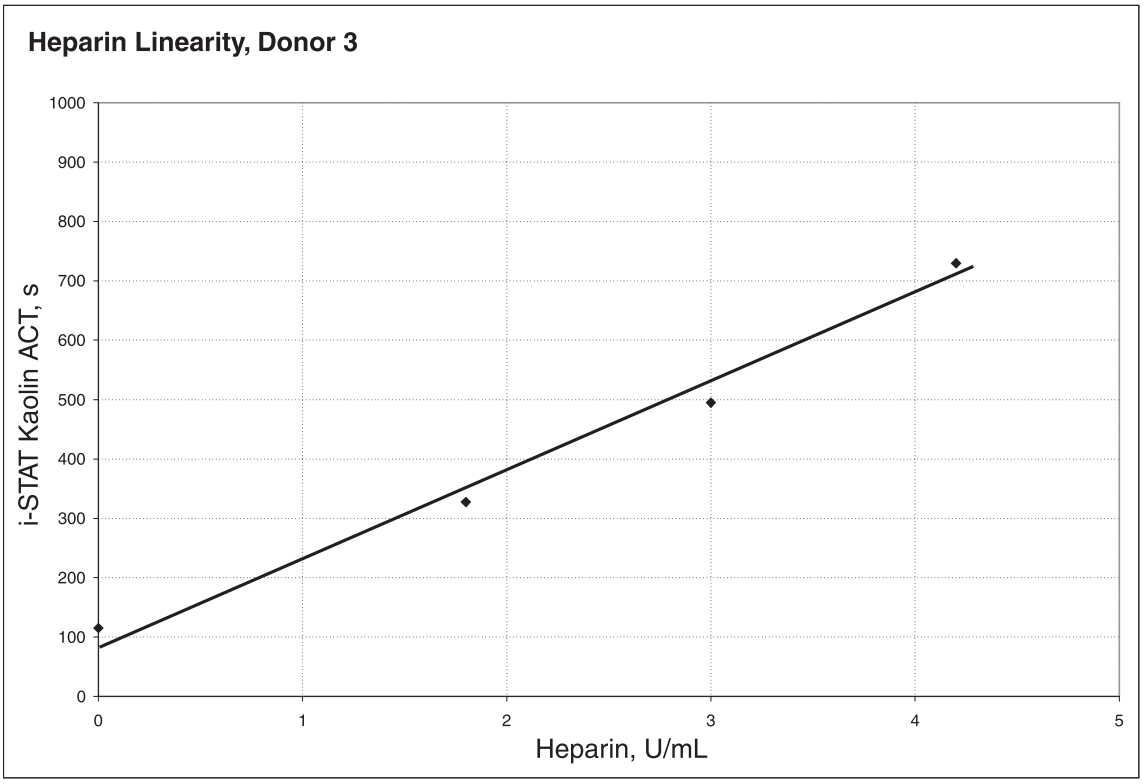
*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

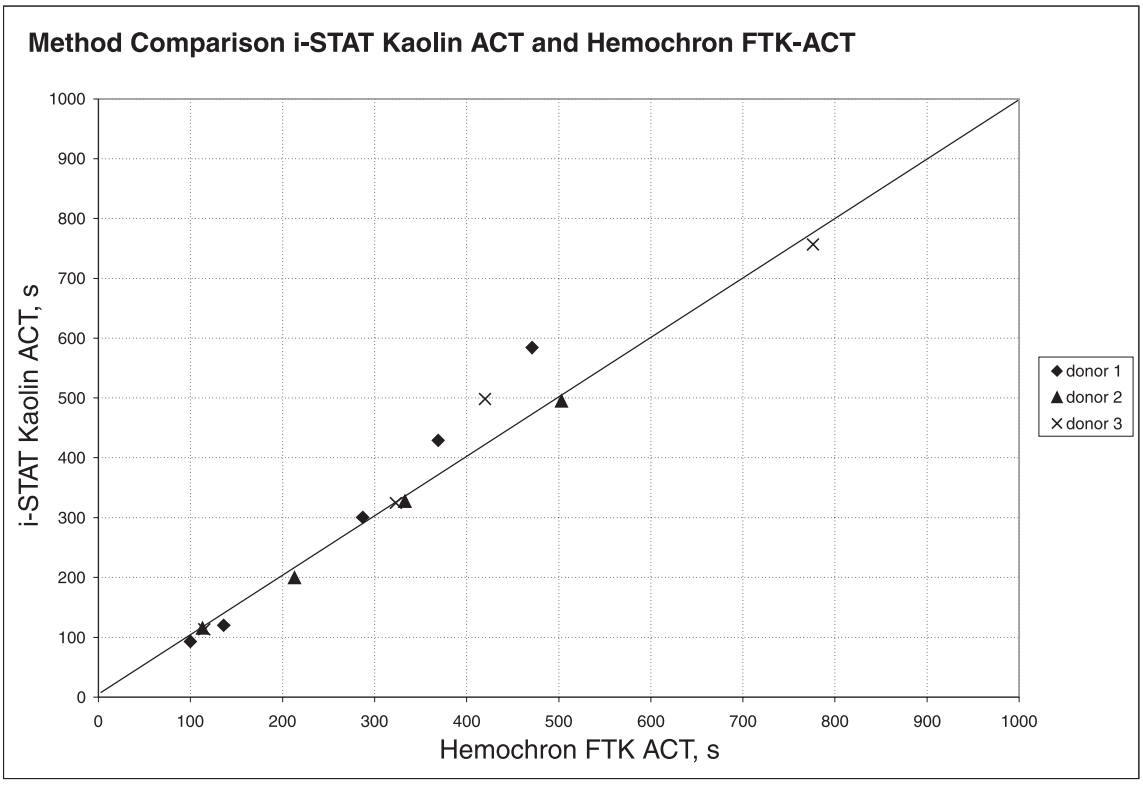
The following three graphs below each indicate the response of a different donor with respect to heparin concentration:

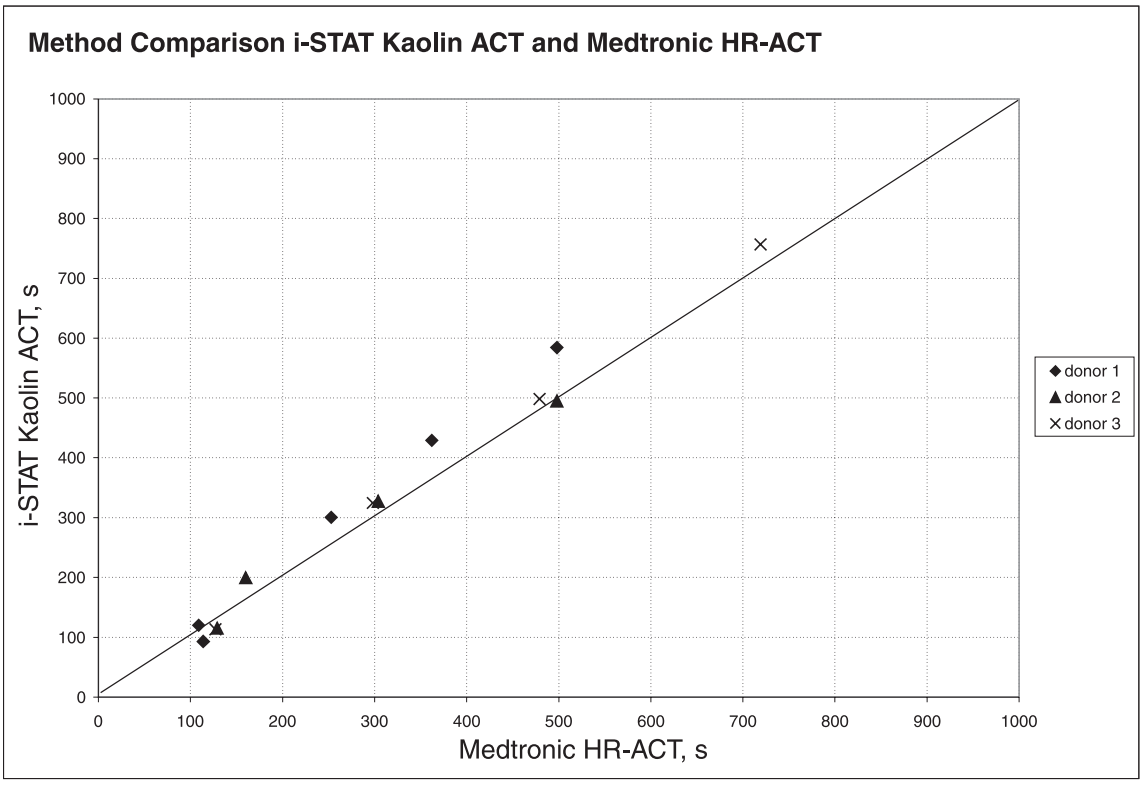



Heparin Linearity, Donor 2
i-STAT Kaolin ACT, s
1000
900
800
700
600
500
400
300
200
100
0
0
1
2
3
4
5
Heparin, U/mL


Heparin Linearity, Donor 3
i-STAT Kaolin ACT, s
1000
900
800
700
600
500
400
300
200
100
0
0
1
2
3
4
5
Heparin, U/mL

The following two graphs indicate the response of the same three donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Kaolin FTK-ACT.





Test Limitations

The i-STAT ^{Kaolin}ACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%.

Hemodilution may affect test results.

Platelet dysfunction, factor deficiencies, dysprothrombinemias, pharmacological compounds, and other coagulopathies may affect the results of this test.

The i-STAT ACT test is not affected by fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37ºC.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On each day the analyzers are in use, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperature was satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT ACT Controls using any verified Analyzer. Instructions for the use of these controls are found in the i-STAT System Manual.

For additional information on Quality Control of the i-STAT System, refer to the Quality Control section in the i-STAT System Manual.

Specimen Collection and Preparation

The i-STAT ^{Kaolin}ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[4]

In-dwelling line

- Fluid drip through the line must be discontinued.
- Withdraw 2 mL of blood into a syringe and discard it.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

1. Hattersly, P. Activated coagulation time of whole blood. Journal of the American Medical Association 136:436-440, 1966.

2. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.

3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

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Art: 715878-01C Rev. Date: 07/12/04

PROTHROMBIN TIME/ (PT/INR)

The i-STAT® PT/INR test is a whole blood determination of the prothrombin time used for monitoring oral anticoagulant (warfarin) therapy. The test determines the time required for complete activation of the extrinsic pathway of the coagulation cascade when initiated (activated) with a thromboplastin.

In a prothrombin time test, coagulation is initiated by mixing the sample with tissue thromboplastin. In traditional prothrombin time tests, complete activation is indicated when activated thrombin converts fibrinogen to fibrin and extensive or localized clots are detected mechanically or optically. The i-STAT PT/INR test is similar except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen. An electrochemical sensor is used to detect this conversion.

The added thrombin substrate is H-D-phenylalanyl-pipecolyl-arginine-p-amino-p methoxydiphenylamine, which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3. A formation of the electroactive compound is detected amperometrically and the time of detection is measured.

The PT/INR test result is reported as an International Normalized Ratio (INR) and, optionally, in seconds. The INR is the recommended method of result reporting for monitoring of oral anticoagulant therapy[1]. A Mean Normal i-STAT prothrombin time (sec) and an ISI are determined following the WHO recommendations at a CAP-accredited facility. INR results are calculated using the following equation:

$$\text{INR} = \left\lceil \frac{\text{Patient i-STAT prothrombin time (sec)}}{\text{Mean Normal i-STAT prothrombin time (sec)}} \right\rceil^{\text{ISI}}$$

The optionally displayed units of seconds reflect traditional plasma PT times. The reported time is derived from the PT/INR result and the equation below using an ISI of 1.05 and a typical Mean Normal Plasma PT time of 12.0 seconds.

$$\text{INR} = \left\lceil \frac{\text{Patient Plasma prothrombin time (sec)}}{\text{Mean Normal Plasma prothrombin time (sec)}} \right\rceil^{\text{ISI}}$$

If results appear inconsistent with the clinical assessment, the patient sample should be recollected and retested using another cartridge.

Intended Use

The i-STAT PT/INR is an *in vitro* diagnostic test intended for quantitative prothrombin time testing for the monitoring of oral anticoagulation therapy using fresh capillary or venous whole blood samples. The i-STAT PT/INR test is not intended for evaluating individual factor deficiencies. The PT/INR is to be used with the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer, but will not run on the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM). As part of the i-STAT System, the

PT/INR test is to be used by trained and certified health care professionals in accordance with a facility's policies and procedures.

Contents

Each i-STAT PT/INR cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint and dry reagents necessary to initiate and allow coagulation. Inert matrix components and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient	Biological Source
Recombinant Tissue Thromboplastin	Human
Heparinase I	*Flavobacterium heparinum*
Thrombin Substrate	N/A

Metrological Traceability

The i-STAT System test for Prothrombin Time (PT/INR) measures the International Normalized Ratio (dimensionless) expressing the relative time interval required for complete activation, by thromboplastin, of the coagulation cascade in capillary or venous whole blood for *in vitro* monitoring of oral anticoagulant (warfarin) therapy. PT/INR values assigned to i-STAT's controls are traceable to the World Health Organization (WHO) international reference measurement procedures and the WHO human recombinant thromboplastin International Reference Preparation[2]. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units	Verified Clinical Range
Prothrombin Time/ (PT/INR)	INR	0.9 - 6.0*

*The performance characteristics of the i-STAT PT/INR measurement have not been established at INRs above 6.0.

Performance Characteristics

The typical performance data summarized below were collected in healthcare facilities by healthcare professionals trained in the use of the i-STAT System and comparative methods.

Imprecision

Typical imprecision data for venous whole blood samples are presented in the table below for sample duplicates collected at two clinical sites. Typical imprecision data for capillary whole blood samples are presented for sample duplicates collected at one clinical site using a single capillary stick.

Statistic	Site 1 (venous)	Site 2 (venous)	Site 3 (capillary)
n	181	102	33
Mean (INR)	2.6	2.4	2.5
%CV	4.7%	4.0%	4.6%

Typical imprecision data for lyophilized plasma material are presented below for studies performed at an i-STAT Corporation facility and during clinical trials.

Plasma Control	Mean	SD	%CV
Level 1	1.1 (INR)	0.05	4.5%
Level 2	2.5 (INR)	0.17	6.9%

Reference Interval

In a study to determine a reference interval for PT/INR, venous samples from healthy volunteers were collected in plastic tubes, and whole blood was analyzed with one lot of cartridges on the i-STAT System. Capillary samples were obtained from the same volunteers using Softclick Pro (setting of 3) and analyzed on the same cartridge lot. Reference intervals for INR in venous and capillary samples were determined according to the NCCLS Guideline C28-A2.[3] The data are summarized in the table below:

Statistic	Venous whole blood	Capillary whole blood
n	120	119
Mean (INR)	1.0	1.0
SD	0.1	0.1
Reference Range (INR)	0.8 - 1.2	0.8 - 1.2

Due to the many variables that may affect PT/INR results, each laboratory should establish its own reference interval.

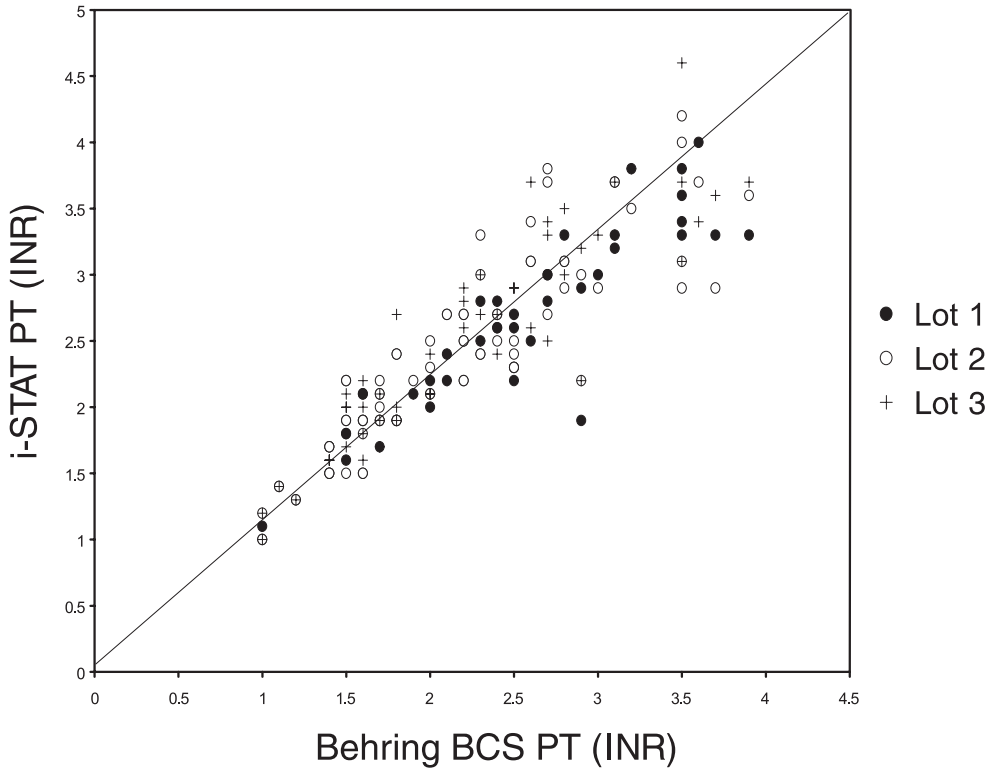
Method Comparison

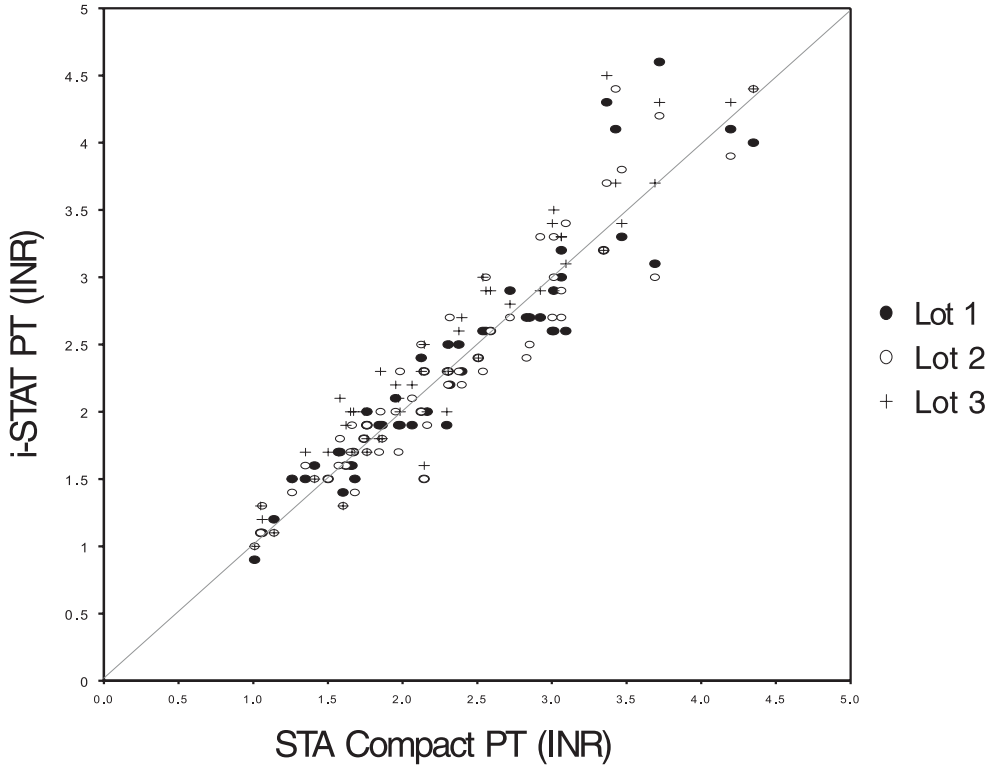
Method comparison data were collected at three clinical sites using a protocol in accordance with the NCCLS Guideline EP9-A.[4] Venous samples from outpatients undergoing routine oral anticoagulation therapy were collected in plastic tubes and analyzed in duplicate on 3 lots of cartridges on the i-STAT System; plasma from tubes containing a citrate anticoagulant were analyzed in duplicate on the comparative instruments using Dade® Innovin® reagent.

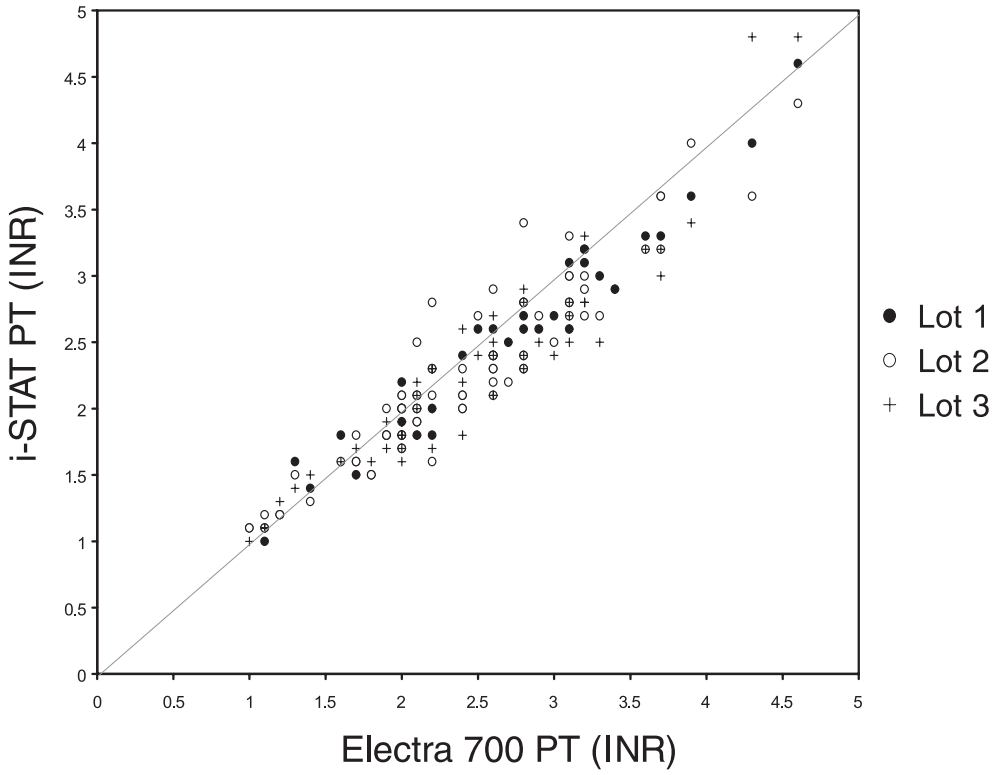
Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table below, *n* is the number of specimens in the data set, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables. A correlation study should be performed to establish the differences between the i-STAT PT/INR measurement and other methods used.

Statistic	i-STAT vs. Behring BCS® and Dade® Innovin® reagent	i-STAT vs. STA Compact® and Dade® Innovin® reagent	i-STAT vs. Electra® 700 and Dade® Innovin® reagent
n	183	180	177
Mean (INR)	2.3	2.3	2.5
Range (INR)	1.0 – 3.9	1.0 – 4.3	1.0 – 4.6
Sx (INR)	0.729	0.777	0.779
Slope	0.922	1.013	0.914
Intercept (INR)	0.402	0.012	0.054
r	0.898	0.943	0.948
Sy.x	0.322	0.272	0.191

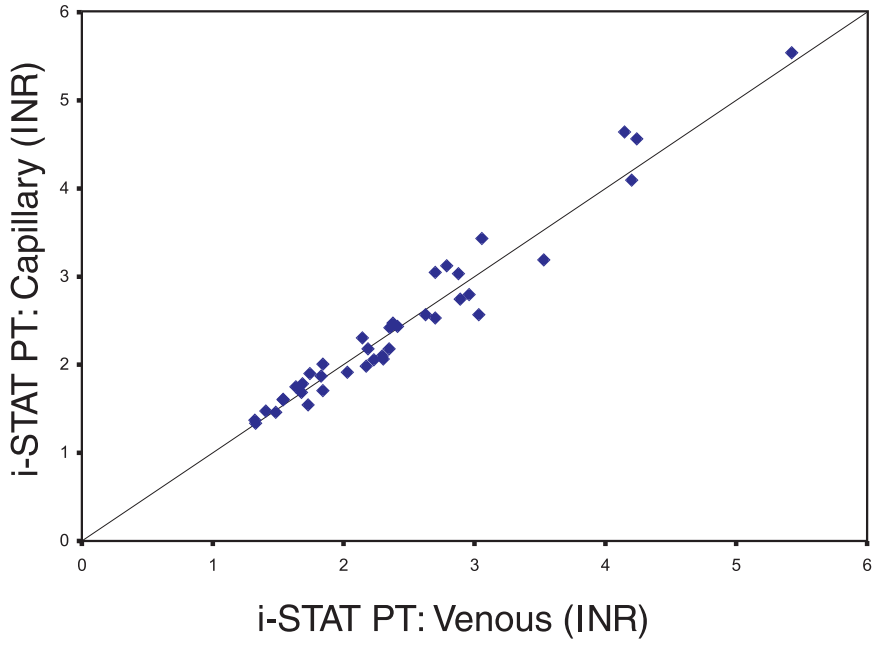

i-STAT PT (INR)
Behring BCS PT (INR)
Lot 1
Lot 2
Lot 3


i-STAT PT (INR)
STA Compact PT (INR)
Lot 1
Lot 2
Lot 3



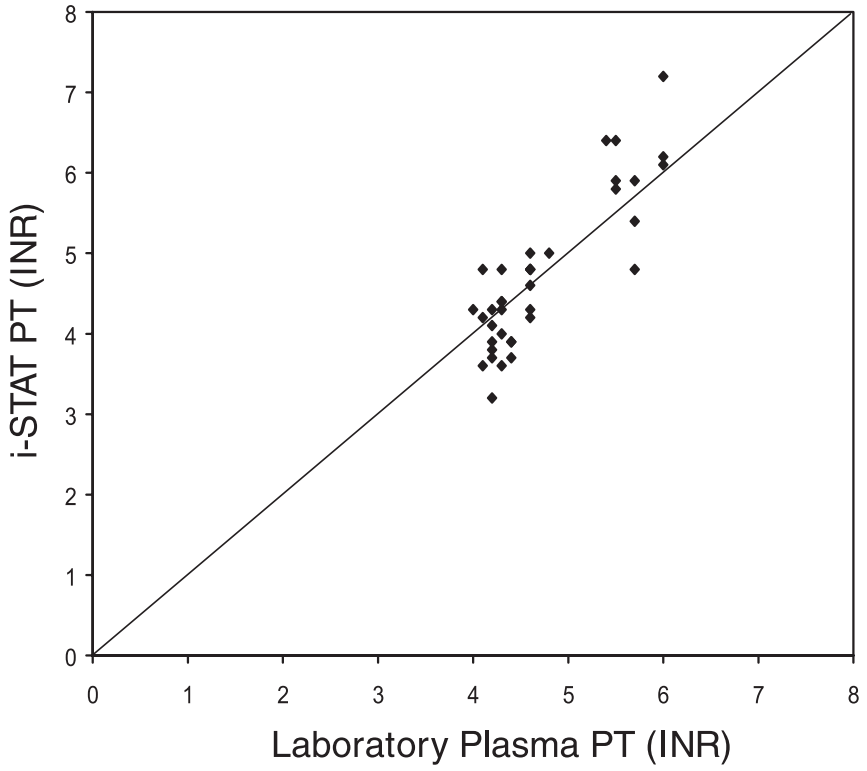
Data is presented below from one clinical site comparing data from capillary samples to data from venous samples analyzed on the i-STAT System.

Statistic	Capillary vs. Venous
n	39
Mean (INR)	2.4
Range (INR)	1.3 – 5.4
Sx (INR)	0.960
Slope	1.049
Intercept (INR)	-0.098
Sy.x	0.128
r	0.978



Performance Above the Therapeutic Range

Data are presented from multiple sites to demonstrate the performance at PT/INR levels above the therapeutic range (greater than an INR of 4.0 on the comparative instrument). Results from these sites are presented in the correlation graph below. The comparative method at all sites used a high-sensitivity (ISI approximately 1.0) recombinant (Dade® Innovin®) reagent.



Factors Affecting Results

- The presence of exogenously added heparin, citrate, oxalate, or EDTA from blood collection devices will interfere with test results.
- Poor technique in sample collection may compromise the results. (See Specimen Collection and Preparation below.)
- Glass syringes or tubes may prematurely activate coagulation, resulting in accelerated clotting times and lower INRs.
- The i-STAT PT/INR test is insensitive to fibrinogen concentration between 70 and 541 mg/dL.
- The i-STAT PT/INR test is insensitive to heparin up to 1.0 U/mL.
- Hematocrits in the range of 24 – 54% PCV have been demonstrated not to affect results.
- PT/INR results may be affected by commonly administered drugs.

Test Limitations

- The analyzer must remain on a level, vibration free surface with the display facing up during testing.
- Venous samples must be collected into plastic syringes or tubes.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 24 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On a daily basis, the performance of all analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT PT/INR Controls using any verified analyzer. These controls should also be used to verify cartridge performance when storage conditions are in question. Instructions for the use of these controls is available with the i-STAT System Manual.

For additional information on Quality Control of the i-STAT System, refer to the "Quality Control" section in the i-STAT and i-STAT 1 System Manuals.

Specimen Collection and Preparation

Caution: The i-STAT PT/INR cartridge is designed to accept a sample between 20 and 45 microliters. A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled from the cartridge.

The i-STAT PT/INR test can be performed using capillary or venous samples.

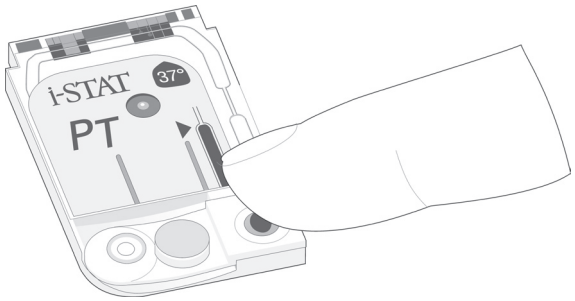
Skin Punctures

1. Remove cartridge 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. Allow finger to dry thoroughly before sampling.
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.

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



Venipunctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device **cannot contain clot activators or serum separators.**
- The sample should be immediately dispensed into the sample well of a cartridge. A drop of blood should be touched against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
- If a second measurement is required, a fresh sample should be obtained.

Note: Some experts recommend drawing and discarding a (venous) sample of at least 1.0 mL prior to drawing sample for coagulation testing.[6]

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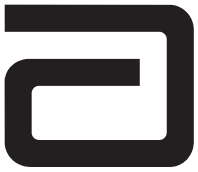
4. NCCLS. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.
5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).
6. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.
7. NCCLS. Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard—Fourth Edition. NCCLS document H4-A4 [ISBN 1-56238-382-5]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 1999.



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i-STAT

TECHNICAL BULLETIN

ANALYZER CODED MESSAGES

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.

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".

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.

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 are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-14 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.

Code Number	Cause/Action Message on Display	Explanation
3	New Software Installed / Use Electronic Simulator	This message appears on the Portable Clinical Analyzer after new software has been installed or, in some cases, when a new customization profile is received.
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.
5, 6, 9	**Analyzer Interrupted** / Ready for Use	The Portable Clinical Analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down. Check that batteries are inserted properly and seated well in the analyzer. Batteries that are too short will not make proper contact. Check the battery voltage on the Status Page.
7	**Batteries Changed** / Ready for Use	This is a normal response on the Portable Clinical Analyzer when the batteries are changed after a code 1 has occurred.
10	**Temperature In Range** / Ready for Use	Temperature is back in range following a code 2 on the Portable Clinical Analyzer.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Invalid or Expired CLEW** / See Manual	The CLEW standardization has expired. Download a valid CLEW. The date on the real time clock exceeds the expiration date of the CLEW software. Check the date on the real time clock.
13	**Invalid or Expired CLEW** / See Manual	The CLEW is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Retransmit the customization profile. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
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.

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
19	**No Clot Detetced** / See Manual	During the PT/INR cycle, no clot was detected. Run another cartridge. If code 19 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.
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, and 41 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin.
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.

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.
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.

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. 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.
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.

Code Number	Cause/Action Message on Display	Explanation
23, 53, 63, 65-68, 70, 72-74, 82, 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. Code 23 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. Code 70 can occur on the Portable Clinical Analyzer if the user presses the DIS key before the Electronic Simulator is run after a software update. If this happens, reseat the batteries to reset the analyzer, and then run the Electronic Simulator. 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. 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.
69	**Cartridge Type Not Recognized** / Use Another Cartridge	This code could be due to use of a cartridge type that is not compatible with the version of software in the analyzer, or the use of expired cartridges. Check the cartridge expiration date on the cartridge box or pouch. If the cartridges have not expired, and if a new cartridge type is being run, contact i-STAT Technical Services or your local support organization for a software update. When running coagulation cartridges, Code 69 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. During immunoassay cartridge runs, this code will be displayed if incorrect information is entered in response to the prompt “Enter or Scan Cartridge Lot Number”. The instrument expects the barcode on the back of the individual cartridge portion pack to be scanned. The correct barcode looks like this:  For immunoassay cartridges, the instrument will not accept keypad entries of the cartridge lot number nor a scan of the barcode on the cartridge box. This condition may be due to an aberrant cartridge. However, if the condition occurs repeatedly on one analyzer, the analyzer may need repair. Contact i-STAT Technical Services or your local support organization for further assistance.

Codes 100-111 indicate a condtion with the PCx Glucose Test Strip on the I-STAT 1 Analyzer

Code Number	Cause/Action Message on Display	Explanation
100	**Strip Error** / Use Another Strip	The user tried to run a wet strip. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
101	**Strip Error** / Use Another Strip	The test strip was removed from the strip port during testing. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
103, 105, 106, 107, 111	**Strip Error** / Use Another Strip	Test unsuccessful. An error was detected during the analysis sequence. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test. If the problem persists, record the three digit error code and contact MediSense support services or your local support organization.
102, 104	**Strip Error** / Use Another Strip	The test strip malfunctioned or the blood glucose level in the sample is beyond the measuring capability of the test strip and strip reader. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test with a new test strip. If the error occurs again, confirm the result by performing the test on a different method. Contact MediSense support services or your local support organization.
108, 109	**Temperature Out of Range** / Check Status Page	During the test, room temperature became unstable or moved outside the limits within which the test strip reader can perform a test. Ensure that the room temperature is within the specified limits. Allow the analyzer to stabilize to a room temperature of 15-40ºC or 59-104ºF. Press the Menu key until the Administration Menu is displayed. Press 1 for Analyzer Status where the room temperature reading is displayed. If the temperature reading on the Status Page is within the limits described above, yet these codes persist, there may be a problem with one of the thermistors in the analyzer. Contact i-STAT Technical Services or your local support organization for further assistance.
110	**Strip Error** / Use Another Strip	At the start of the test strip cycle, the analyzer prompts the user to apply blood to the strip and waits for 20 minutes for the user to do so. This error occurs when the 20 minutes have elapsed and the analyzer didn't detect blood. The most likely cause of this error is lack of user interaction.

Codes in the range of 120 to 137 and 140 to 148 indicate a failure during an immuno cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used. Only the i-STAT 1 Analyzer produces these codes, as the Portable Clinical Analyzer does not support immuno cycles.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144	**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.

Code Number	Cause/Action Message on Display	Explanation
126	Cartridge Error / Use Another Cartridge	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. 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.
128, 131, 132, 134, 135 - 137	**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** one drop *(only)* to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of RED FILL LINE diagram. 5. **Close** slide cover from left to right. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge closure between your first finger and thumb. There is a recess for your thumb in the closure. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error** / Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error** / Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.
140	**Lot Expired**	The analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
141	**Test Canceled by Operator**	This code will be displayed if the cartridge barcode is not scanned within 60 seconds of cartridge insertion. The correct barcode to scan is the barcode on the cartridge portion pack, not the one on the cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above.
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): • cartridge leak, • failure to close the cartridge completely. Ensure that the slide cover 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 to” mark, and then close the cartridge.

Code Number	Cause/Action Message on Display	Explanation
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  symbol and • be customized for a) Cartridge Barcode Required, or b) Cartridge Information First Required and Cartridge Lot Number Required. If either of these two conditions above are not met, the analyzer will display this code.

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.	Allow analyzer to equilibrate in new environment for 30 minutes and repeat test. If code reoccurs, return anlayzer.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Reinsert the simulator straight. If code reoccurs, return analyzer.
R, r	Resistance reading on conductometric channel out of limits.	Return analyzer.
t	Thermal probe failure.	Return analyzer.
B	Potentiometric channel out of limits.	Return analyzer.

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.	

i-STAT

TECHNICAL BULLETIN

Installation Guide for the Central Data Station to Receive Data from a Philips Clinical Data Server*

The i-STAT Central Data Station (CDS) application can be configured to receive results from cartridges analyzed on a Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM) for the CMS and 24/26 Patient Monitors. This data is sent to the CDS by the Philips Clinical Data Server (Philips). This document describes how to set up the i-STAT CDS application to receive data from the Philips Clinical Data Server. It is independent of the computer hardware platform being used.

Configuration Instructions

This guide assumes that the Philips Clinical Data Server connectivity to the location of the CDS computer is completed, and that the Philips Clinical Data Server data is available via one of these two protocols:

- A direct RS-232 serial connection
- An Ethernet connection to a ETS 8 Terminal Server (CDS 4.x) or a Network Interface Card (CDS5.x)

To configure the CDS 5.x:

Step	Action
1	Run the CDS application (wcds32.exe) with the “config” command line parameter.

The remainder of the configuration is dependent on the connection of the Philips Clinical Data Server to the CDS.

For Philips Clinical Data Server data received via a direct RS-232 connection:

2	Determine which COM Port of the CDS computer is to be used for the Philips Clinical Data Server data.
3	At the Serial Ports tab page, select *“Enable Serial Communications”*. Add the COM Port to be used for the Philips Clinical Data Server to the *“Configured Ports”* list, select Agilent Connect as instrument type, and click *“Accept”*.
4	Connect the cable to the appropriate COM Port on the CDS computer.
5	Verify that the Philips Clinical Data Server data is being received.

For Philips Clinical Data Server data received via a Network Interface Card:

2	At the Network tab page, select *“Enable Network Communications”*. Note the default of 6002 for Agilent Connect TCP port, change if neccessary. Click *“Accept”*.
3	Verify that the Philips Clinical Data Server is configured to transmit to the specific port noted in step 2 at the CDS IP network address.
4	Verify that the Philips Clinical Data Server data is being received.

* This product has formerly been known as HP Patient Data Server and Agilent Connect.

To configure the CDS 4.x:

Step	Action
1	Determine which COM Port of the CDS computer is to be used for the Philips Clinical Data Server data.
2	Using the Configuration Utility of the CDS, change the data source of this COM Port to the “CDS” option.
3	Exit the Configuration Utility.

The remainder of the configuration is dependent on the form of the Philips Clinical Data Server data.

For Philips Clinical Data Server data received via a direct RS-232 connection:

4	Determine the communication speed of the Philips Clinical Data Server. Ideally, it should be set at 19200 baud.
5	• If set to 19200, use any text editor to edit the file C:\istatcds\istatcfg.txt. Add the following line to the section with the heading of **[Options]:** **FastCdsSend=YES** Save the file and exit the Text Editor. • If set to 4800, no changes are needed
6	Connect the cable to the appropriate COM Port on the CDS computer.
7	Verify that the Philips Clinical Data Server data is being received.

For Philips Clinical Data Server data received via an ETS 8 Terminal Server:

4	Determine which serial port on the ETS 8 will be used for the Philips Clinical Data Server transmission.
5	Verify that the Philips Clinical Data Server is configured to transmit to that specific port at the ETS 8 Ethernet address
6	Verify that the port of the ETS 8 is configured for 19200 baud.
7	Using any text editor, edit the file C:\istatcds\istatcfg.txt. Add the following to the section with the heading of **[Options]:** **FastCdsSend=YES** Save the file and exit the Text Editor.
8	Connect the cable from the selected ETS 8 serial port to the selected COM port on the on the CDS computer.
9	Verify that the Philips Clinical Data Server data is being received.

i-STAT

TECHNICAL BULLETIN

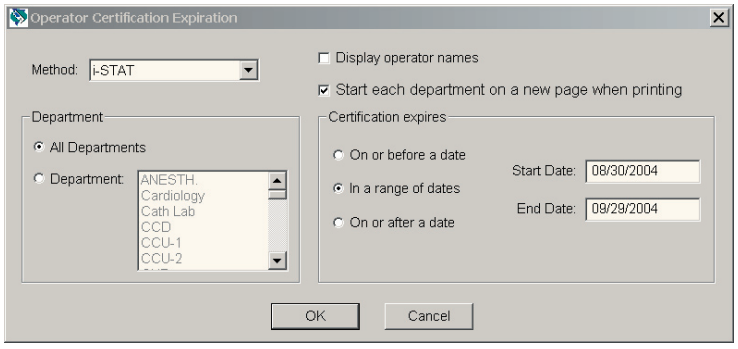
October 2004 Update to the i-STAT Central Data Station Version 5

CENTRAL DATA STATION LOGON

Previously open windows will now be restored when a user logs on to the CDS application again.

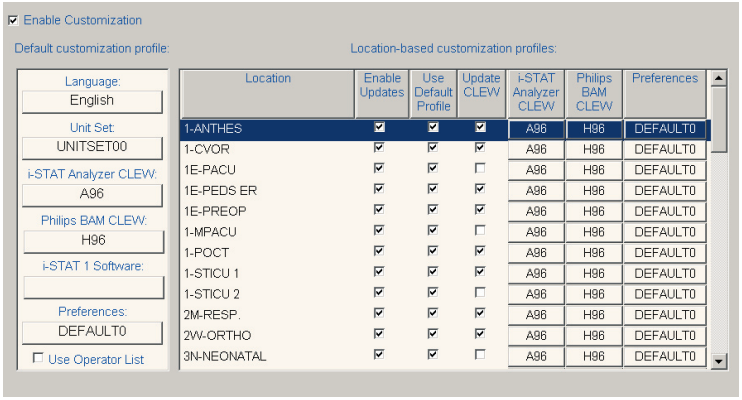
OPERATOR WORKSPACE

An option has been added to have page breaks between the departments listed in the Operator Certification Expiration report.



CUSTOMIZATION WORKSPACE

In the "Default customization profile:" column, a new "i-STAT 1 Software" selection box has been added in preparation for a new February 2005 feature allowing users to remotely request a JAMS update from the CDS.



USER ADMINISTRATION WORKSPACE

A User Log tab has been added to the User Administration Workspace. The activities tracked by this log include:

a. CDS Startup

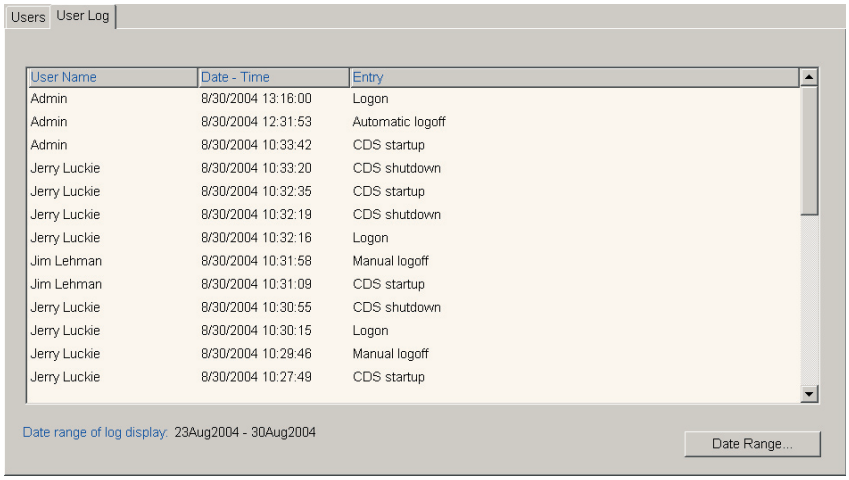
b. CDS Shutdown

c. User Logon

d. Manual User Logoff

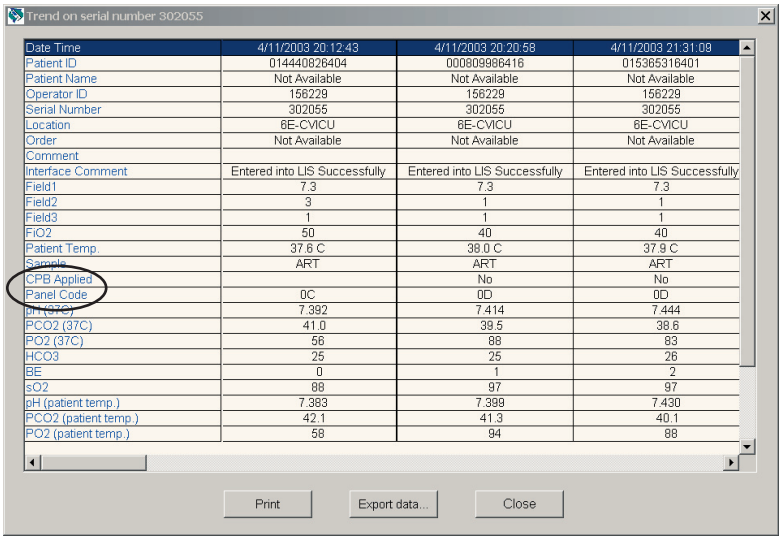
e. Automatic User Logoff, and

f. Disabling of the Security Feature via the Configuration Screen



TRENDING

"CPB Applied" and "Panel Code" have both been added as new rows in the Trend display and printout.



DATA EXPORT

A data export option is now available in the following areas of the Central Data Station application:

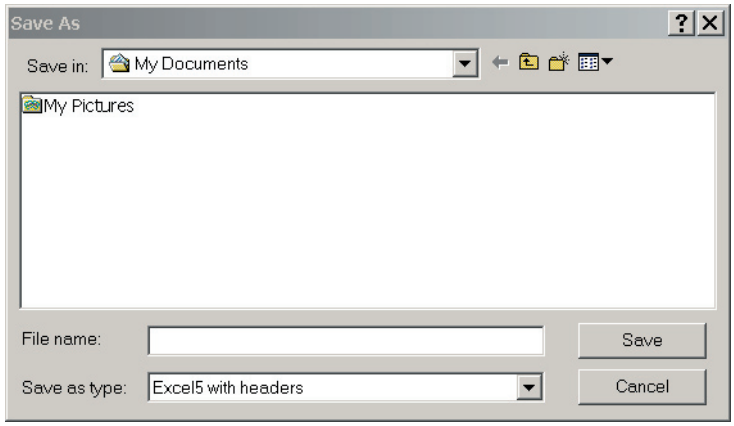
a. Data Viewers

b. Reports

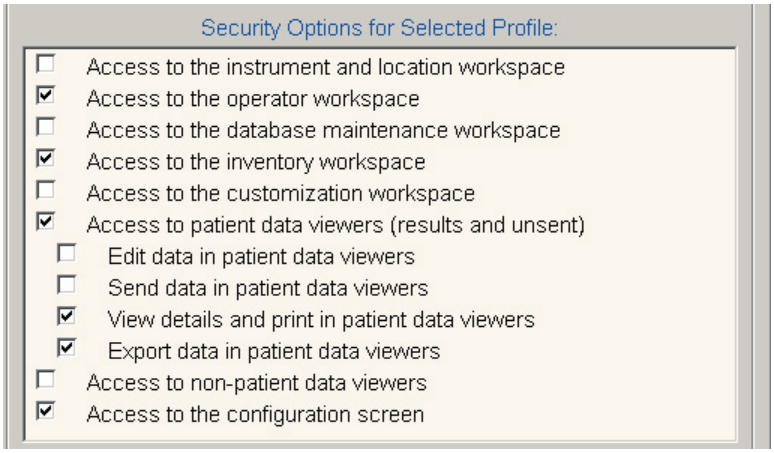
c. Trend report, and

d. the Extended Simulator report screen

To access this option from any of the Data Viewers or Reports, click on **Window ⇨ Export**. From a Trend report or the Extended Simulator report screen, click on the **Export data...** button at the bottom of the report. A dialog box will then appear on the screen. Choose the file destination location and the type of file you want the exported data saved as from the drop-down menus, then type in the File Name and click on Save.



Note: Users can be blocked from or allowed access to this data export feature through the User Administration Workspace by using the check box **"Export data in patient data viewers"** under the **Security Options for Selected Profile** section.



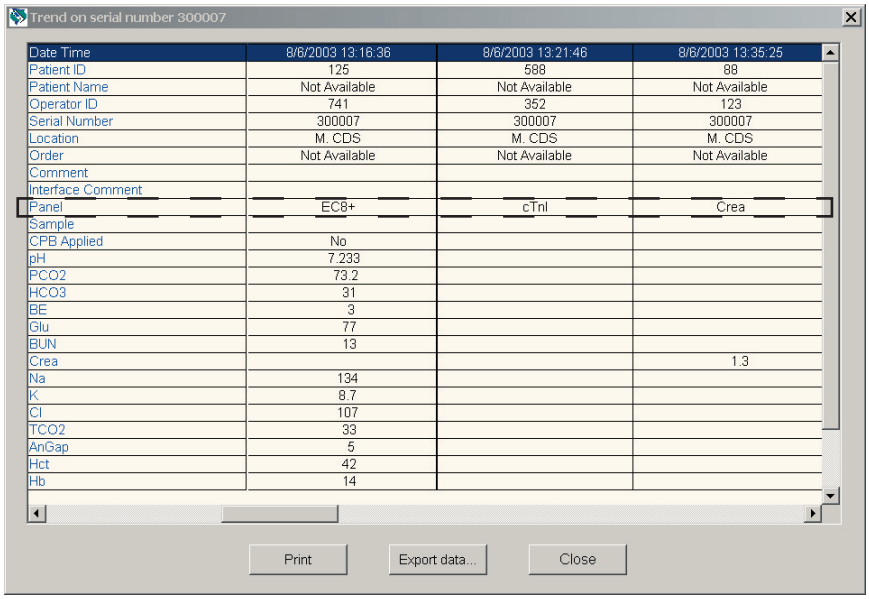
i-STAT

TECHNICAL BULLETIN

APRIL 2005 UPDATE TO THE i-STAT CENTRAL DATA STATION VERSION 5

TRENDING

The "Panel Code" row has been renamed as "Panel" and now lists the name of the cartridge type run for each individual record in the Trend display and printout.



Date Time	8/6/2003 13:16:36	8/6/2003 13:21:46	8/6/2003 13:35:25
Patient ID	125	588	88
Patient Name	Not Available	Not Available	Not Available
Operator ID	741	352	123
Serial Number	300007	300007	300007
Location	M. CDS	M. CDS	M. CDS
Order	Not Available	Not Available	Not Available
Comment			
Interface Comment			
Panel	EC8+	cTnI	Crea
Sample			
CPB Applied	No		
pH	7.233		
PCO2	73.2		
HCO3	31		
BE	3		
Glu	77		
BUN	13		
Crea			1.3
Na	134		
K	8.7		
Cl	107		
TCO2	33		
AnGap	5		
Hct	42		
Hb	14		

CUSTOMIZATION WORKSPACE

A new feature allows users to remotely request both a JAMS and a CLEW update for an i-STAT 1 Analyzer from the CDS.

Notes:

- This new feature does not apply to the Portable Clinical Analyzer or to the Philips Blood Analysis module.
- The procedure for uploading a new CLEW version into the i-STAT 1 Analyzer remains the same. To upload just a CLEW version, users transfer the new CLEW files to the CDS, select the new CLEW version in the Customization Workspace, and then transmit the i-STAT 1 Analyzers to the CDS.
- If the CDS is on version 5.18a or higher, users no longer need to disable Customization prior to uploading analyzer software using the Jammlite utility.

After installing CDS version 5.18a, to perform a JAMS and CLEW update on an i-STAT 1 Analyzer using this new Customization feature:

1. ***Transfer the Files***
   - Place the JAMS diskette into the A: drive.
   - Click **Start ⇨ Run…**
   - Type: **a:transfer** and press the **Enter** key.

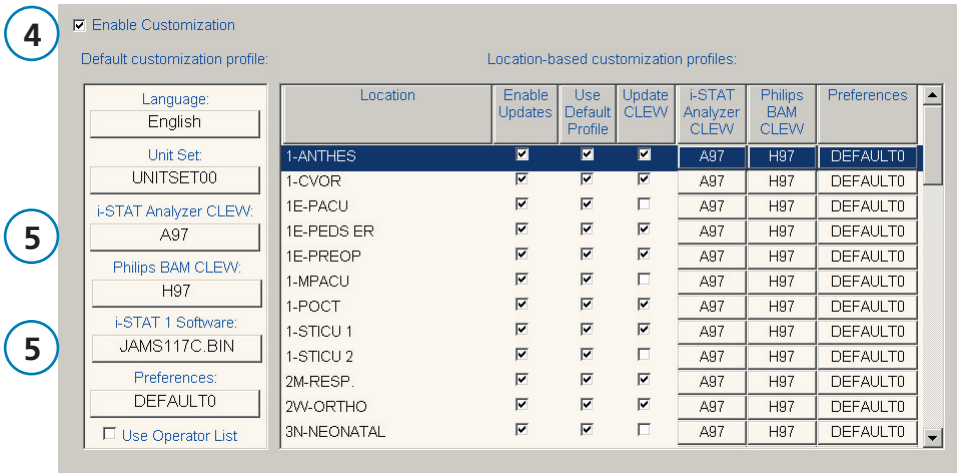
Note: If you do not have access to the **Run…** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

2. ***Start the Central Data Station Application (if not already open)***
   - Click on the Central Data Station icon.

3. ***Access the Customization Workspace***
   - Click on **Main ⇨ Open Administration Function ⇨ Customization**
   - Type in the Password. The default password is **istat**.

4. ***Enable Customization***
   - If the Enable Customization box is not already checked, click the box next to this listing.
   - Under the "Location-based customization profile:" section, make sure Enable Updates is checked for every location from which you wish to perform software updates on your i-STAT 1 Analyzers.

5. ***Select the Desired Analyzer CLEW and i-STAT 1 Software***
   - Under the "Default customization profile:" column, click on the i-STAT Analyzer CLEW button. Click the new version of CLEW and click OK.
   - Under the "Default Customization profile:" column, click on the i-STAT 1 Software button. Click the new i-STAT 1 software file and click OK.



6. ***Update the Software in the i-STAT 1 Analyzer***

   - Go to the location where the i-STAT 1 Analyzers you wish to update are located.
   - Press the On/Off button on the analyzer to turn the display on.
   - Press the Menu key to bring up the Administration Menu.
   - Press 7 for Utility. The Utility menu may be password protected. Enter the password or press the Enter key if no password has been specified.
   - From the Utility Menu, select **3-Receive Software**. The "Waiting to Send" message will appear on the analyzer display.
   - Place the analyzer in the downloader or downloader/recharger. A Communication in Progress message will appear on the screen. After this message disappears, the analyzer display will stay blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the procedure.
   - A scrolling bar will then appear on the analyzer display. This bar indicates that the software is uploading into the analyzer. Do not move the analyzer while the scrolling bar appears on the display screen. When the upload process is complete, the scrolling bar will disappear and the analyzer display will again go blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the process.
   - A Waiting to Send message followed by a Communication in Progress message will then appear on the analyzer display. After these messages disappear, the analyzer display will go blank, and the update process is complete.

7. ***Verify the Update***

   - Run an external Electronic Simulator on updated Analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

i-STAT

TECHNICAL BULLETIN

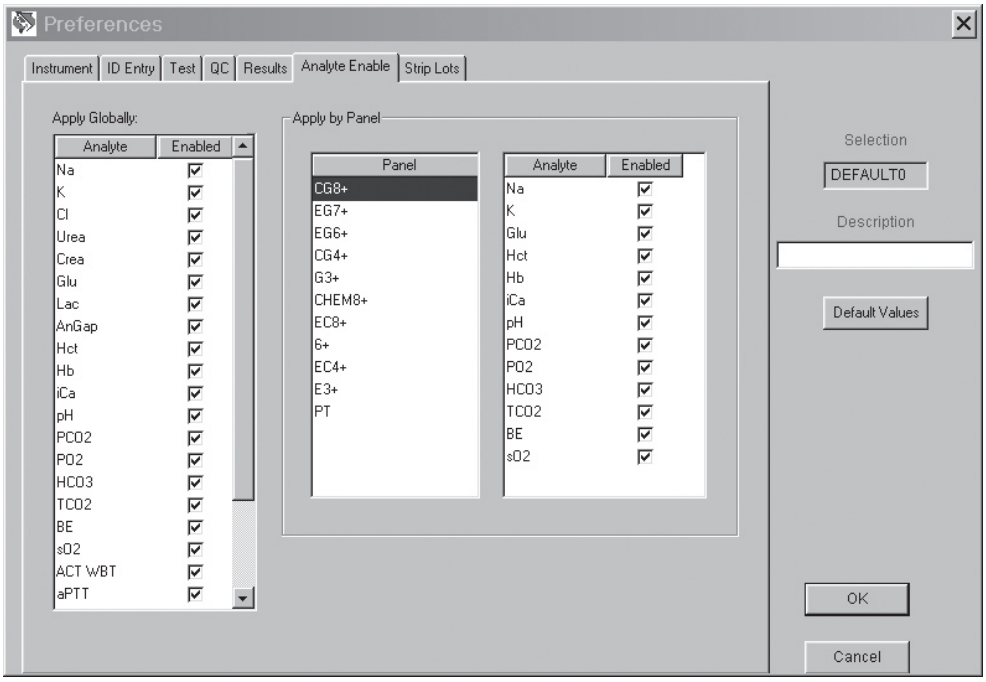
OCTOBER 2005 UPDATE TO THE i-STAT CENTRAL DATA STATION VERSION 5

CUSTOMIZATION WORKSPACE

1. ANALYTE ENABLE/DISABLE

A new feature allowing users the option to enable/disable analyte functionality by cartridge type has been added.

The current analyte enable/disable check boxes have been removed from the Results tab of the Customization Workspace and placed in a new tab titled "Analyte Enable". This new tab contains the original check box list (under the "Apply Globally" section) and a new "Apply by Panel" section, allowing the user to narrow the global selection further by cartridge type.



To enable/disable a particular analyte on all cartridge types, simply check/uncheck the box next to the analyte in the Apply Globally section.

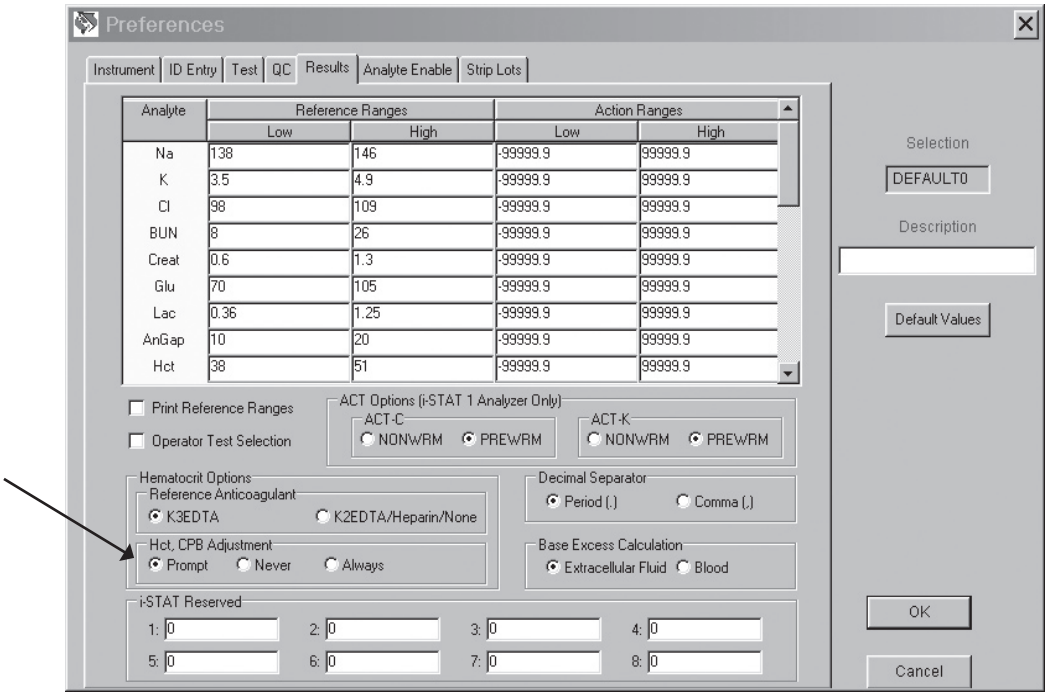
If you wish to enable/disable a particular analyte only on a specific cartridge type, make sure that the analyte is first checked under the Apply Globally section. Then click on the cartridge type under the Apply by Panel section, and then check/uncheck the box next to the analyte name.

Please note that the global selection takes precedence over the cartridge type selection. The default setting is to have all analytes for all cartridge types enabled.

2. CPB CHOICES

The presentation of the CPB customization item in the Results tab has been changed. The new presentation will now have 3 choices:

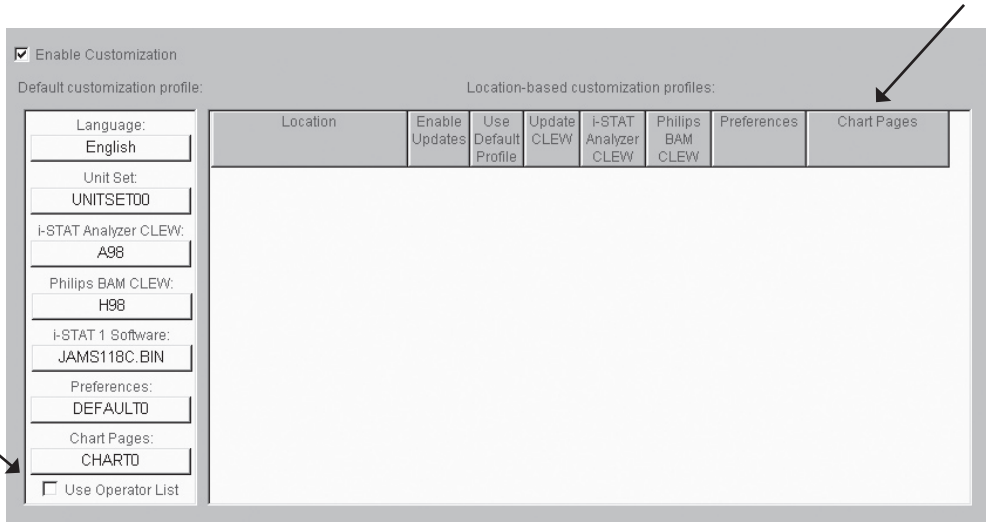
1. Prompt: asks user whether to apply the CPB correction when running a cartridge containing a hematocrit sensor
2. Always: applies CPB correction every time it runs a cartridge with a hematocrit sensor
3. Never: CPB correction is never applied when running a cartridge with a hematocrit sensor.



Note: The change in presentation **does not** affect the settings previously made for CPB adjustment.

DEFAULT CUSTOMIZATION PROFILE AND CUSTOMIZATION MENU LISTS

In the “Default customization profile:” column, a new “Chart Pages:” selection box has been added in preparation for an upcoming feature allowing users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings.



Also in preparation for the upcoming chart page customization feature, a new “Chart Pages” column has also been added to the “Location-based customization profiles:” section, along with three new menu items

1. “Manage Chart Pages…” has been added to the Tools menu,
2. “Chart Pages…” has been added to the “Change Default” submenu of the “Profile” menu, and
3. “Chart Pages…” has been added to the “Change Location-based” submenu of the “Profile” menu.

i-STAT

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 NCCLS 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).

i-STAT has verified with the manufacturers of the Advia®, Cell-Dyn®, Coulter® and Sysmex® hematology analyzers that hematocrit results on these analyzers are calibrated to MH-K_3EDTA. Because these hematology analyzers report hematocrit results calibrated to MH-K_3EDTA and are representative of the hematology market, "K_3EDTA" was chosen as the factory default customization setting for the i-STAT System.

When 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.

Note: The original agreement criteria recommended by i-STAT for the calibration verification procedure (using the microhematocrit method) was 3 %PCV across the entire measurement range. i-STAT believes that these new criteria are more clinically relevant and should be applied to method comparisons and the calibration verification procedure.

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i-STAT

TECHNICAL BULLETIN

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Abbott Point of Care and its distributors are committed to helping you resolve any problems with the i-STAT System: Portable Clinical Analyzer, i-STAT 1 Analyzer, cartridges, accessories and Central Data Station software. For technical assistance within the United States, please call Technical Services at 800-366-8020 toll free. Outside the U.S., please contact your local i-STAT distributor.

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