i-STAT 1

Important!

i-STAT 1 System Manual Update

As of November 2022, the current i-STAT 1 System Manual has been updated. Please **ADD** and **DELETE** the sheets as listed below. Once the updates have been completed these instructions may be discarded. If you have any questions about these instructions, please contact your i-STAT Support Services provider.

A ▶ ADD SHEET   ◀ D DESTROY SHEET

	Item	**Art#**
A▶	i-STAT 1 System Manual Configuration Sheet	714419-00BK
◀D	i-STAT 1 System Manual Configuration Sheet	714419-00BJ (or lower)
	System Components Tab	
A▶	i-STAT 1 System Manual Section 1: Introduction	714363-00AE
◀D	i-STAT 1 System Manual Section 1: Introduction	714363-00AD (or lower)
A▶	i-STAT 1 System Manual Section 2: i-STAT 1 Analyzer	714364-00X
◀D	i-STAT 1 System Manual Section 2: i-STAT 1 Analyzer	714364-00W (or lower)
	Care and Software Updates Tab	
A▶	Technical Bulletin: Network Options for Updating the i-STAT 1 Analyzer Using www.globalpointofcare.abbott	731336-00J
◀D	Technical Bulletin: Network Options for Updating the i-STAT 1 Analyzer Using www.globalpointofcare.abbott	731336-00I (or lower)
	Technical Bulletins Tab	
◀D	New Ultralife 9-Volt Lithium Battery For Use With the i-STAT System	730271-00B (or lower)
A▶	Technical Bulletin: Support Services	716144-00AM
◀D	Technical Bulletin: Support Services	716144-00AL (or lower)

END

Abbott

i-STAT 1 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 November 2022, your i-STAT 1 System Manual should be configured with the contents as listed below and in the order shown.

ITEM	Art #
Cover Sheet	714336-00R
Configuration Sheet	714419-00BK
Table of Contents	714362-00AH
Section 1	714363-00AE
Section 2	714364-00X
Section 3	714365-00J
Section 4	714366-00D
Section 5	714367-00I
Section 6	714368-00N
Section 7	714369-00O
Section 8	714370-00G
Section 9	714371-00J
Section 10	714372-00R
Section 11	714373-00K
Section 12	714374-00P
Technical Bulletin: Sample Type Customization on the i-STAT 1 Analyzer	765893-00B
Section 13	714375-00G
Section 14	714376-00Z
Section 15	714377-00U
Section 16	714378-00J
Section 17	714379-00K
Section 18	714380-00R
Technical Bulletin: Instructions for Updating i-STAT 1 Analyzer Software Using www.globalpointofcare.abbott	731335-00I
Technical Bulletin: Network Options for Updating the i-STAT 1 Analyzer Using www.globalpointofcare.abbott	731336-00J
Section 19	714381-00L
Technical Bulletin: Analyzer Coded Messages	714260-00Z
Section 20	714382-00F

CTI Sheets

Technical Bulletins

INTRODUCTION   **1**

This Manual

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

Note: Not all products are available in all regions.

Intended Use

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

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

FDA Test Categorization

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

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

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

Overview of the i-STAT System

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

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

The Data Manager provides system management tools including real-time monitoring of testing and operator competency.
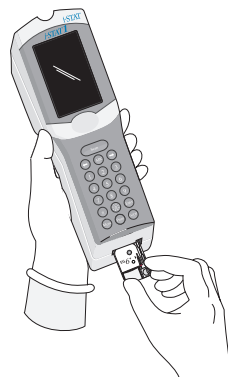
Components   The i-STAT System consists of:

◇ i-STAT Cartridges

◇ i-STAT 1 Analyzer

◇ Portable Printer

◇ Quality Assurance Materials

- Electronic Simulator
- Control Solutions
- Calibration Verification Set (for cartridges)

◇ Data Management System

- i-STAT 1 Downloader
- i-STAT 1 Downloader/Recharger
- Data Manager

◇ LIS/HIS Interface Software

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

◇ Types of tests to be performed

◇ Number of testing sites

◇ Number of tests per site

◇ System administration requirements

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

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Data Management Test records can be transmitted to the Data Manager where they can be printed and/or transmitted to the Laboratory Information System or Hospital Information System. An optional portable printer enables the operator to print results at the point of care.
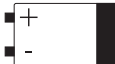
Interfacing The Data Manager can be interfaced to a Laboratory Information System (LIS) or Hospital Information System (HIS) to automate billing and patient record keeping.

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

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 or #	Model number. The model number will appear adjacent to this symbol.
	Date of manufacture.
	Manufacturer.
IVD	*In vitro* diagnostic medical device.
Rx ONLY	For prescription use only.
EC REP	Authorized Representative for Regulatory Affairs in the European Community.
	Importer in the European Community.
CE	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) with respect to safety, health, environment and consumer protection.
Σ	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.
ETL c/us LISTED Intertek	Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010-1: 3rd Ed.; Am. 1 CAN/CSA C22.2 No. 61010-1-12 3rd Ed. (R2017) +U1;U2
i immuno	i/immuno: Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.

Symbol	Definition
	Battery: i-STAT 1 Analyzer low battery icon (flashes on lower left side of display screen).
	Note concerning batteries: The following information is applicable to EEA (European Economic Area) countries: The directive 2006/66/EC requires separate collection of spent batteries. You are requested to dispose those batteries referred to on page 2-3 in accordance with local regulations. This product also contains a separate internal lithium battery that is not intended to be replaced by the user. See page 2-4 under "Additional Power" for more information.
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
BODYYYY-MM-DD	Born On Date: the label BODYYYY-MM-DD defines year, month and day of manufacture.
	Do not reuse.
	This symbol is used for compliance with the China RoHS regulation (s). It indicates in years the Environmentally Friendly Use Period (EFUP) for the labeled electronic medical device product.
<< >>	As the Martel Printer is incapable of printing the ↑ or ↓ symbols, this symbol appears on the Martel printout next to results which are outside the action range limits.
	14 days room temperature storage at 18-30 °C
	2 months room temperature storage at 18-30 °C
	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.
	The near-patient testing symbol illustrates that a device can only be used in a near-patient setting by a health care worker, professional or trainee.

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

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

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

Symbol	TEST
Na	Sodium
K	Potassium
Cl	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
pH	pH
PCO_2	Partial pressure of carbon dioxide
PO_2	Partial pressure of oxygen
iCa	Ionized Calcium
BUN/UREA	Urea nitrogen/Urea
Hct	Hematocrit
ACTc Celite ACT	Activated Clotting Time with Celite® activator

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Symbol	TEST
ACTk **Kaolin ACT**	Activated Clotting Time with Kaolin activator
PT/INR	Prothrombin Time / International Normalized Ratio
Hb	Hemoglobin
TCO_2	Total carbon dioxide concentration
HCO_3	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extra cellular fluid)
AnGap	Anion Gap
sO_2	Oxygen saturation
cTnI	Cardiac Troponin I
CK-MB	Creatine Kinase MB Isoenzyme
BNP	B-type Natriuretic Peptide
Total ß-hCG	Total Beta-Human Chorionic Gonadotropin

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

The warranty for the 9V rechargeable battery remains in effect for one year following the Born on Date (BODYYYY-MM-DD) noted on the battery's label (pictured below).

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

Limitations of Warranty

The foregoing warranty shall not apply to defects resulting from:

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

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

INTRODUCTION

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

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

BEFORE YOU USE THE ANALYZER

Install Batteries

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

Check Date and Time

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

Check Software

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have standard CLEW and application software. If a different CLEW and/or application software is in use in your facility, it must be installed in new, repaired or replaced analyzers before they are put into use. Check the Analyzer Status page for the installed CLEW and application software. For steps to verify the software, see *Procedures for Customization using the Analyzer Keypad* in Section 9 of this manual. See under "Standardization and Calibration" in section 3 of this manual for an explanation of CLEW.

Customization

Analyzers can be customized for many site-specific testing requirements. See Section 9 in this manual for a list of customizable parameters and their default values. To change the customization profile via the analyzer keypad see "Customization" under "Administration" in this section of the manual. To change the customization profile via i-STAT/DE, see the "i-STAT/DE User Guide" located at www.globalpointofcare.abbott.

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

Perform Quality Check

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

DESCRIPTION

Specifications

DIMENSIONS	Width 7.68 cm (3.035 in.)
	Length 23.48 cm (9.245 in.)
	Depth 7.24 cm (2.85 in.)
WEIGHT	With rechargeable battery 650 grams (22.9 oz.)
	With disposable battery 635 grams (22.4 oz.)
POWER	Two 9-volt lithium batteries, or rechargeable battery.
CALIBRATION	Factory: electronic, mechanical, thermal, pressure
MEMORY/CLOCK BACKUP POWER	Lithium Battery
DISPLAY	Dot matrix supertwist liquid crystal
COMMUNICATION LINK	Infrared light-emitting diode (LED)
OPERATING TEMPERATURE	16-30°C (61-86°F) for i-STAT cartridge testing
TRANSPORT TEMPERATURE	-10-46°C (14-115°F)
RELATIVE HUMIDITY	10-90% non-condensing
BAROMETRIC PRESSURE	300-850 mmHg
LASER SCANNER	Complies with U.S. 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No. 50, dated June 24, 2007.
	EN 60825-1:2014
	IEC 60825-1:2014

Software

All analyzer functions are controlled by application software that can be updated as additional tests and features are developed. Coefficients used to maintain the accuracy of cartridge results over time are programmed into the analyzer via CLEW software updates every six months. See under "Standardization and Calibration" in Section 3 of this manual for an explanation of CLEW.

Power

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

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

Battery Compartment

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

Disposable Batteries

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

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

Rechargeable Battery

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

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

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

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

Low Battery Warning

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

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

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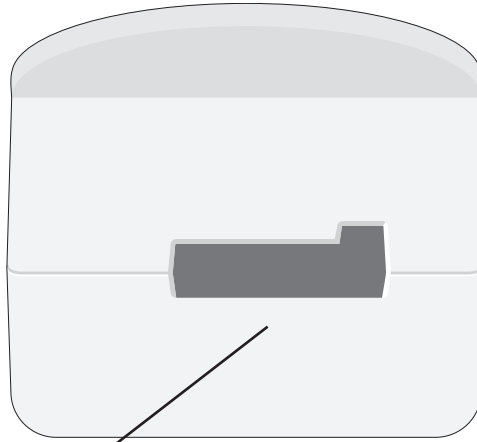
i-STAT Cartridge Port

Infrared Communication Window

Battery Compartment   Laser Barcode Scanner Window
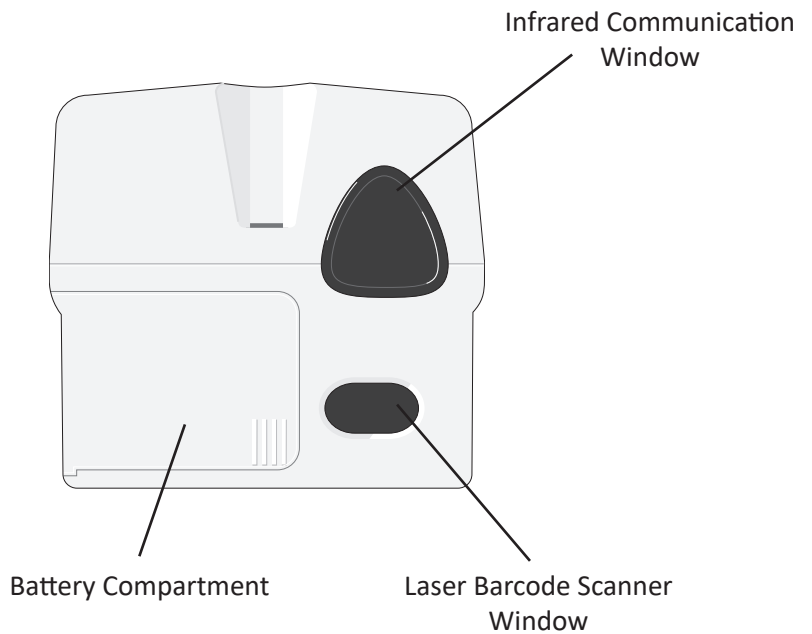
Infrared Communication Window	The Infrared Communication Window provides the analyzer with two-way communication to the Central Data Station via a Downloader, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.
Thermal Control	The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and fluids that come into contact with the sensors to 37°C. This subsystem is activated automatically when a cartridge containing tests which require thermal control at 37°C is inserted into the analyzer.
Barometric Pressure Sensor	The analyzer contains a solid-state barometric pressure sensor, which determines the ambient atmospheric pressure used for the PO_2 sensor calibration.
Cartridge Test Cycle	An operator starts a cartridge test cycle either by selecting i-STAT Cartridge from the Test Menu or Quality Tests from the Administration Menu.

The analyzer:

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

Data Entry

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

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

```
        Pt:145
────────────────────────
Scan or Enter Data
Sample Type
Field 1 _ _ _ _ _ _ _ _ _
Field 2 _ _ _ _ _ _ _ _ _
Field 3 _ _ _ _ _ _ _ _ _
PtTemp  _ _ _ _ _
FIO2    _ _ _
CPB              No

 1-ART      4-CAP

 2-VEN      5-CORD

 3-MIX      6-OTHR
      ➡ Page
  Results Ready
```

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

Storage of Results

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

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

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

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

LCD Display and Backlight

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

Audible Indicator

The analyzer will beep to indicate:

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

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

```
      Code # 31
    17:42 30JUN00

     UNABLE TO
      POSITION
       SAMPLE

    USE ANOTHER
     CARTRIDGE


   1- Test Options
```
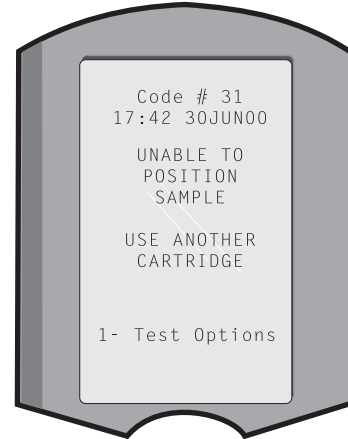
Time Out

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

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

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

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

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

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

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

Keypad

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

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

i-STAT 1 Menu Tree

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

Test Menu

1- Last Result

2- i-STAT Cartridge

Administration Menu

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

TEST MENU

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

The options are:

    1 - Last Result

    2 - i-STAT Cartridge

Option 2 is used for testing patient samples.

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

```
     15:26 30JUN00
       Test Menu

 1- Last Result
 2- i-STAT Cartridge
```

```
     15:44 30JUN00
       Test Menu

 1- Last Result
  - i-STAT Cartridge


     Upload Required
     Testing Disabled
```
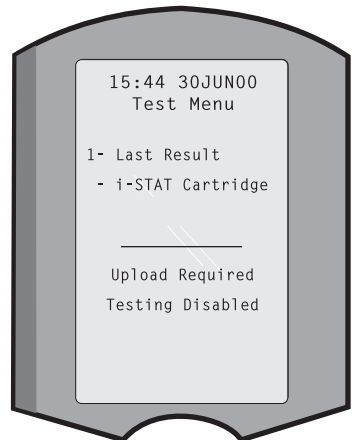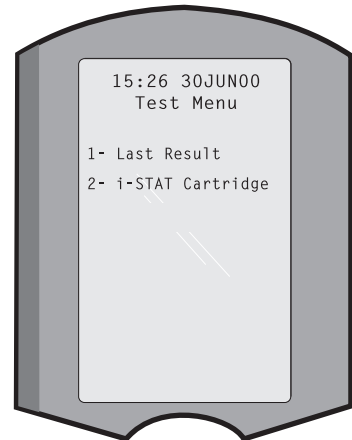
ADMINISTRATION MENU

Overview

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

    1 - Analyzer Status

    2 - Data Review

    3 - Quality Tests

    4 - Customization

    5 - Set Clock

    6 - Transmit Data

    7 - Utility

```
      13:22 21JUN00
 Administration Menu

 1- Analyzer Status
 2- Data Review
 3- Quality Tests
 4- Customization
 5- Set Clock
 6- Transmit Data
 7- Utility
```
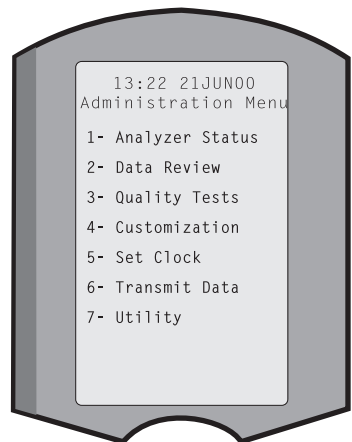
Analyzer Status   The Analyzer Status screen contains information about the condition or "status" of the analyzer. Fresh readings are made whenever this option is selected.

Temp	Room temperature.
Pressure	Barometric pressure.
Battery	Battery voltage.
Uses	Total number of cartridge and simulator test cycles, whether or not results reported.
Serial	Serial number of the analyzer.
CLEW	Version of standardization data installed in the analyzer.
Version	Version of application software installed in the analyzer.
Custom	Customization profile name.
Stored Records	Total: The number of test records in the analyzer's memory. The maximum storage capacity is 1,000 test records, which include records with results and Quality Check Codes for patients and controls both liquid and electronic. Unsent: The number of test records that have not been transmitted to i-STAT/DE.

```
  Analyzer Status
Temp: 23.9C
Pressure: 760mmHg
Battery:  8.20V
Uses: 118
Serial: 300102-A
CLEW: A82
Custom: Default1
Version: JAMS108

  Stored Records
Total: 116
Unsent: 22
```

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

1 - Patient	The records for a patient are recalled by scanning or entering via the keypad the Patient ID. If no Patient ID is entered, all patient tests are recalled.
2 - Control	
3 - Proficiency	
4 - Cal Ver	
5 - Simulator	All external and internal Electronic Simulator records.
6 - All	All test records in the analyzer's memory.

```
   Data Review

  1- Patient
  2- Control
  3- Proficiency
  4- Cal Ver
  5- Simulator
  6- All
  7- List
```
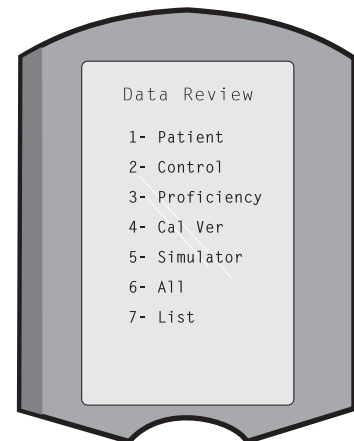
7 - List   Records are listed with
              Cartridge type, date and time
              of test, patient ID, control lot,
              proficiency ID, or Cal Ver lot
              and test level as applicable.
              Any number of test records
              can be selected for viewing
              or printing using the number
              keys. Pressing the number
              key corresponding to a record
              selects a record; pressing the
              number key a second time
              deselects the record.
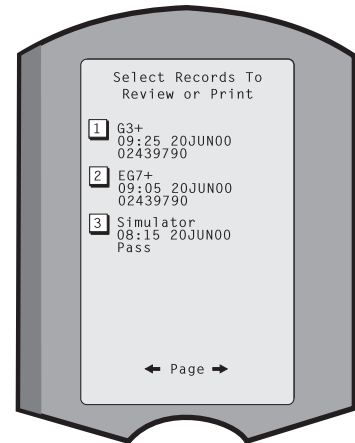
To view one or more records,
select the records and press
the Enter key. To print records, select the records and
press the Print key.

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

1 - Control

2 - Proficiency   (external quality control)

3 - Cal Ver   (Calibration Verification for
                    cartridges)

4 - Simulator   (cartridge-reading function
                    only)

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

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

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

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

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

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

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

Viewing the Customization Profile

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

<div style="text-align:center">

1 - Analyzer

2 - ID Entry

3 - Patient Tests

4 - QC Tests

5 - Results

</div>

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

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

Note:

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

1 - Analyzer

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

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

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

2 - ID Entry

1 – Operator ID

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

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

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

Fourth page
Warn User
Print ID

2 – Patient ID

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

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

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

Fourth page
Lockout Override
Confirmation Method
Print ID

3 - Patient Tests

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

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

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

    2 – Cartridge QC
        <u>First page</u>
        Pass/Fail Method
        Comment Code In Range
        Comment Code Out of Range
        Result Format
        APOC fluid Lot Scan Only
        <u>Second page</u>
        eVAS Name
5 - Results
        1 – ACT/Ref Ranges
        2 – Display Ranges
        3 – Units
        4 – Options
        <u>First page</u>
        Decimal Separator
        Test Selection
        Hematocrit
        Base Excess
        ACT-C

        <u>Second page</u>
        ACT-K
        Print Ref. Ranges

Changing the Profile

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

Note:

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

1 - Analyzer
        <u>First page</u>
        Language
        Date Format
        Sound
        Auto-transmit
        Memory Full

        <u>Second page</u>
        Batch Mode Timeout
        Inactivity Timeout
        Upload Schedule
        Clock Password
        Sync Clock

        <u>Third page</u>
        Wireless (available with the i-STAT 1 wireless)

2 - ID Entry

  1 – Operator ID

     <u>First page</u>
     Minimum Length
     Maximum Length
     Repeat ID
     Manual Entry
     Code I2of5

     <u>Second page</u>
     Code 128
     EAN-8, EAN-13
     Codabar
     Code 93
     Code 39
     <u>Third page</u>
     Code 39, Check Digit
     Truncate First
     Truncate Last
     Print ID

  2 – Patient ID

     <u>First page</u>
     Minimum Length
     Maximum Length
     Repeat ID
     ID Recall
     Manual Entry

     <u>Second page</u>
     Code I2of5
     Code 128
     EAN-8, EAN-13
     Codabar
     Code 93

     <u>Third page</u>
     Code 39
     Code 39 Check Digit
     Truncate First
     Truncate Last

3 - Patient Tests

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

     <u>Second page</u>
     Comment Code, Out of Range
     Cart Sample Type
     Result Output
     Downloader Lockout

4 - QC Tests

  1 – Simulator

     Ext Simulator
     Int Simulator
     Int Simulator Schedule Option

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

5 - Results
   1 – Units and Ranges
   2 – Options
      <u>First page</u>
      Decimal Separator
      Test Selection
      Hematocrit
      Base Excess
      ACT-C
      <u>Second page</u>
      ACT-K
      Print Ref. Ranges

6 - Password

7 - Restore Factory Settings

Note: For additional procedures related to customization using the analyzer keypad, refer to *Procedures for Customization using the Analyzer Keypad* in Section 9 of this manual.

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

```
Enter Current
Time And Date

   13:40
  06/21/00
  mm/dd/yy


ENTER-Set And Exit
MENU-Cancel
```

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

The analyzer can be customized using i-STAT/DE to synchronize or update the real time clock to the i-STAT/DE's clock at the time of each download. This option eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Saving Time. Otherwise, the clock must be manually changed for Daylight Savings Time changes.
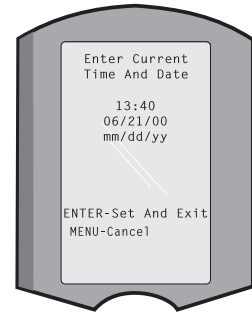
Transmit Data   Unsent test records are automatically transmitted to i-STAT/DE when an analyzer is placed in a Downloader/Downloader/Recharger. In some cases it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:

    1 – Most Recent

    2 – This Month

    3 – Last Month

    4 – All

    5 – Unsent

```
Transmit Data

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

Most Recent is the result from the last cartridge tested.

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

Auto-transmit is temporarily disabled when the Transmit Data option is selected to allow the user to control transmission of data.
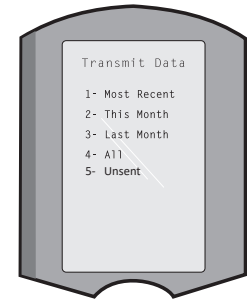
Utility   The Utility menu can be password protected using the Customization function on the analyzer or in i-STAT/DE.

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

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

```
     Utility
  Clear Memory

1- Previous To
   01Jun00
2- Previous To
   01May00

3- All
4- Cancel
```

        1 – Previous to 01MMMYY (where MMMYY is current month and year, such as 01JUN00)

        2 – Previous to 01mmmyy (where mmmyy is previous month and year, such as 01May00)

        3 – All

        4 – Cancel

    3 – Receive Software: Allows users to remotely request a JAMS and CLEW update for the analyzer from i-STAT/DE. See section 18 (Updating Software) for full details.

LASER BARCODE SCANNER

Laser Barcode Scanner

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

Laser Specifications

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

Warning Labels

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

Laser Barcode Scanner Window

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

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

Class 2 laser scanners use a low power, visible light diode. As with any bright light source, such as the sun, the user should avoid staring directly into the laser beam. Momentary exposure to a Class 2 laser is not known to be harmful. |
Barcode Label Quality	To ensure that printed barcode labels are reliably read by i-STAT handhelds, the best available printing methods and settings should be used. However, as specified in the *Health Industry Bar Code (HIBC) Provider Applications Standard* (ANSI/HIBC 1.3-2010), the quality of printed labels should meet the minimum grade level of 1.5.
Ambient Lighting from LED Light Sources	The analyzer's barcode scanning functionality may experience interference when scanning barcodes under ambient light from an LED light source. This interference results in the analyzer being unable to scan a barcode at all (no beep acknowledgement). When scanning barcodes under ambient light from an LED light source, it is recommended that the barcode be shielded from the ambient light when attempting to scan the barcode.
Procedure	Before scanning, check to see what information is required by the displayed prompt. Hold the analyzer 3-9 inches (8 – 23 cm) from the barcode to be scanned. An angle of about 10 degrees from perpendicular is best. Hold the analyzer and place the object to be scanned on a flat surface or, place the analyzer on a flat surface and hold the object in front of the analyzer. Avoid accidentally scanning other nearby items. Avoid pointing the beam into anyone's eyes.

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

PROMPTS AND MESSAGES

Prompts

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

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

Startup Messages

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

Quality Check Messages

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

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

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

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

i-STAT 1 SYSTEM
TECHNICAL BULLETIN

NETWORK OPTIONS FOR UPDATING THE i-STAT 1 ANALYZER USING www.globalpointofcare.abbott

OVERVIEW

This Technical Bulletin has been created specifically to guide you through the process of updating the software on the i-STAT 1 Analyzer(s) using one of three network options:

1. Using a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process with TCP/IP

2. Using a Serial Downloader or a serially connected DRC-300 and the JammLite process for accounts with RALS-Plus and i-STAT/DE

3. Using the i-STAT/DE Customization Workspace and a Network Downloader, Downloader/ Recharger, or DRC-300

Before beginning, check the Analyzer Status page and verify that the i-STAT 1 Analyzer has enough battery power (7.5 volts or higher).

WHY DO i-STAT ANALYZERS NEED SOFTWARE UPDATES?

The i-STAT System is designed to eliminate operator influence on delivered results.

Due to continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer.

New CLEW software -- delivered twice a year -- re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the i-STAT Analyzer to recognize any newly launched cartridge types and to perform any newly launched features.

i-STAT is for *in vitro* diagnostic use.

1. UPDATE PROCEDURE USING A NETWORK DOWNLOADER AND THE JammLite PROCESS WITH TCP/IP

1.1: **Before starting the process, make sure all the required equipment / information is available.**

- **Computer with:**

    o   Windows 2000, XP, or Windows 7

    o   Access to www.globalpointofcare.abbott

- **i-STAT System Equipment**

    (1)   Network Downloader, Downloader / Recharger, or DRC-300

    Note: These instructions assume that the Network Downloader types used for the update process are already installed and in use on the customer's network.

    (2)   i-STAT 1 Analyzer

    (3)   Electronic Simulator

- **List of the IP Address(es) for the network downloader(s) to be used for the software update process**

1.2: **Close all open programs on the computer.**

1.3: Navigate to www.globalpointofcare.abbott > Support > i-STAT 1 and i-STAT Alinity Support > i-STAT 1 Resources Login > Product Software > i-STAT System Software Updates and Access Software.

1.4: Scroll to "Step 2: Download Software Update File".

No Data Management
Click on "DOWNLOAD **SUXXXXXX.ZIP**" and save the file to the Desktop.
Close the "Download Complete" window.

Data managment with i-STAT/DE version ≥2.8.0.1
Click on "DOWNLOAD **SUXXXXXX.ZIP**" and save the file to the Desktop.Close the "Download Complete" window.

Note: i-STAT/DE versions less than 2.8.0.1 are no longer supported. Use a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process to perform the software update via its IP Address (TCP/IP) or Port (COM Port) for serially connected downloaders.

1.5: Navigate to saved zip file location. Right click on the zip file and select Extract All and Extract to the Desktop.

- Navigate to the Desktop and click on the folder SUXXXXXX to open.

Art: 731336-00J   Rev. Date: 17-SEP-2022

1.6: Double click the software file "SUXXXXXX.exe" to run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes. From among the icons that appear, double click ![JAMMLITE.EXE] to launch the JammLite Utility.

- If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to launch the JammLite Utility.
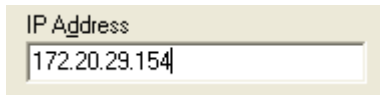
1.7: In the JammLite utility, select the **i-STAT 300 Analyzer** within the Instrument dropdown menu.
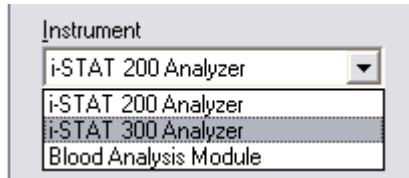
1.8: Select **TCP/IP** within the Port dropdown menu.
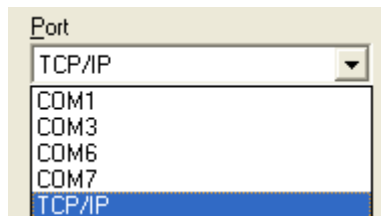
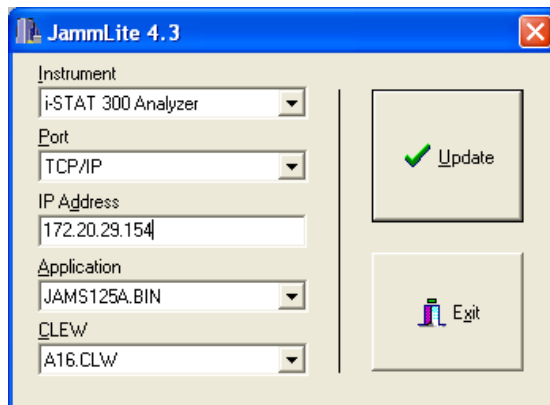**1.9:** Type the IP Address of the Network Downloader being used for the software update in the **IP Address** box.
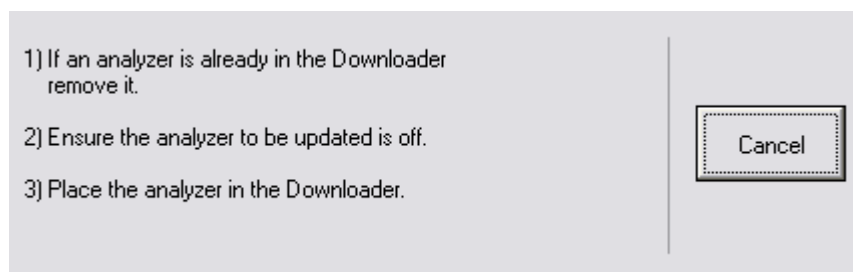
   Note: the address used is for example only.

1.10: Check that the **Application** and **CLEW** listings match those in the Product Update. Click the **Update** button.
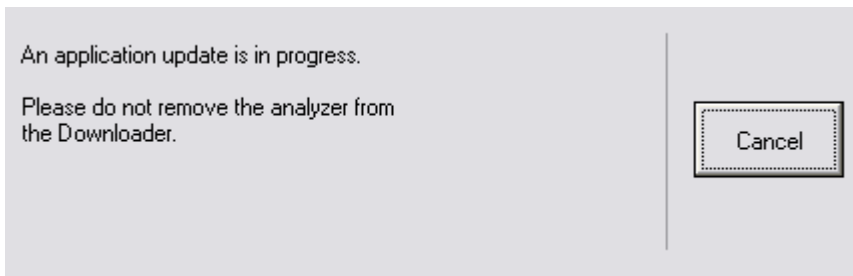
   Note: Application and CLEW numbers are for example only.

**1.11:** Follow the onscreen instructions.

1.12: When the update is in progress, the following screen will appear:

> An application update is in progress.
>
> Please do not remove the analyzer from the Downloader.
>
> [Cancel]

The analyzer will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the analyzer until the success screen is displayed.

> The application update was successful.
>
> The CLEW update was successful.
>
> [Close]
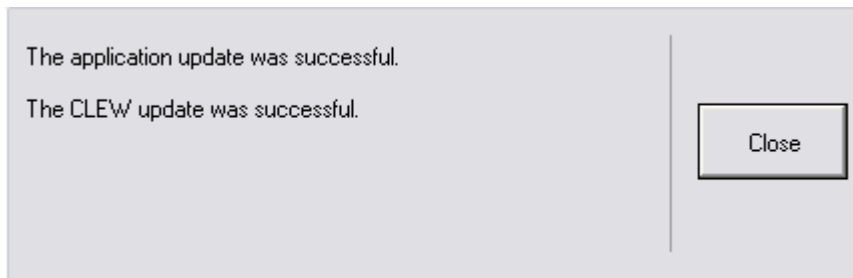
1.13: Run the Electronic Simulator in the analyzer. When the simulator finishes, PASS should be displayed.

> **Note:** If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the Electronic Simulator, see Section 14 of the i-STAT 1 System Manual.

Congratulations. **The process for updating the first i-STAT 1 Analyzer is complete.**

Review the options below for additional instructions.

If there are no additional analyzers to update, the process is complete.

- Click the button in the upper right corner of the software screen.
- Close all other open boxes.
- Confirm all messages.

If there are additional analyzers to update via the same Network Downloader address:

- Click **Close**.
- Repeat steps **1.10** through **1.13**

If there are additional analyzers to update via a different Network Downloader address:

- Click **Close**.
- Repeat steps **1.9** through **1.13**

2. **UPDATING THE i-STAT 1 ANALYZER USING A SERIAL DOWNLOADER OR SERIALLY CONNECTED DRC-300 AND THE JammLite PROCESS FOR ACCOUNTS WITH RALS-Plus AND i-STAT/DE**

2.1: Before starting the process, make sure all the necessary required equipment is available.

- Computer with:
  - o RALS-Plus IMS
  - o Applicable ports, depending on the type of downloader being used
  - o Access to www.globalpointofcare.abbott

- i-STAT System Equipment
  - (1) i-STAT 1 Analyzer
  - (2) Serial Downloader, Downloader / Recharger, or DRC-300

    Note: These instructions assume that the Serial Downloader types being used for the update process are already installed and in use at the customer's facility.
  - (3) All supplied downloader cables
  - (4) Electronic Simulator

2.2: Using the supplied downloader cables, connect the i-STAT 1 serial Downloader, Downloader/ Recharger, or DRC-300 to an accessible port on the back of the computer, and connect the power supply to a wall outlet or power strip.

2.3: Close all open programs on the computer.

2.4: Disable the RALS remote connections.

- Right click on the red RRC dot in the lower right corner of the display next to the clock and go to "Administrator Settings."

- Enter the RRC Password of the Day. Call 877-627-7257 to obtain the password, or go to https://www.rals.com/us/home/rals-system/software/rals-password.html and type "richmond" as the key code. Note: Abbott Point of Care Inc. recommends changing the default password.

- Double click on "**COM1.**"
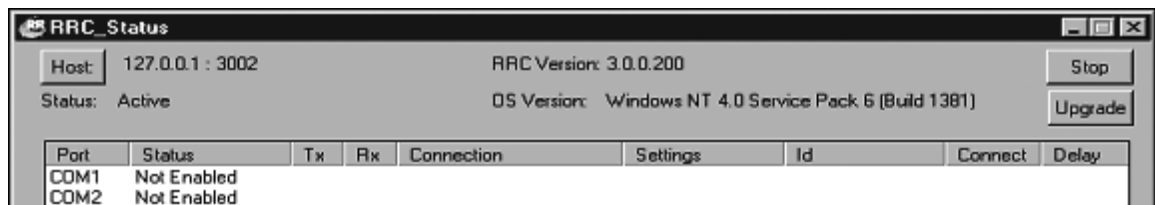
- Record "**Host**" and "**ID**" entry.

- Uncheck the "**Enabled**" box. Click **OK**.
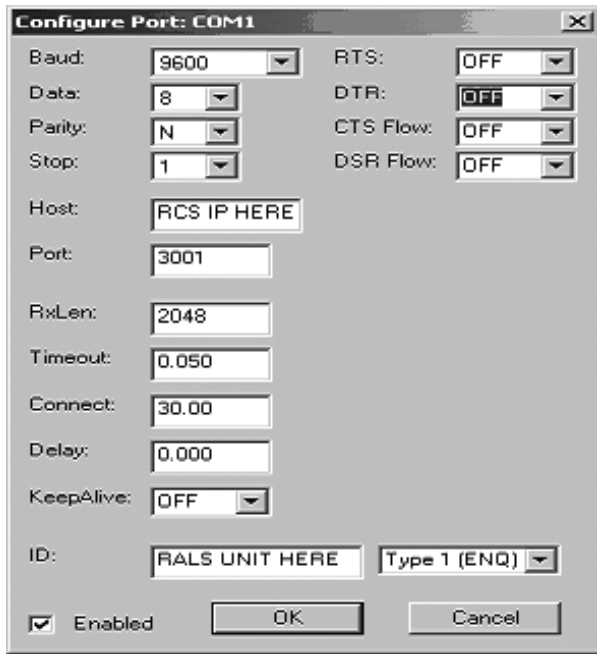
- If not enabled, minimize the window and proceed to the next step.

2.5: Navigate to www.globalpointofcare.abbott > Support > i-STAT 1 and i-STAT Alinity Support > i-STAT 1 Resources Login > Product Software > i-STAT System Software Updates and Access Software.

Scroll to "Step 2: Download Software Update File"

Data management with i-STAT/DE version ≥2.8.0.1
Click on "**DOWNLOAD SUXXXXXX.ZIP**" and save the file to the Desktop.Close the "Download Complete" window.

Note: i-STAT/DE versions less than 2.8.0.1 are no longer supported. Use a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process to perform the software update via its IP Address (TCP/IP) or Port (COM Port) for serially connected downloaders.

2.6: Navigate to saved zip file location. Right click on the zip file and select Extract All and Extract to the Desktop.

- Navigate to the Desktop and click on the folder SUXXXXXX.exe to open.

- Click Run. Double click the software file "SUXXXXXX.exe" to run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes.

- Double click to launch the JammLite Utility.

  Note: If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to complete step **2.6** of this document.

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2.7: In the JammLite utility, select the i-STAT 300 Analyzer within the Instrument dropdown menu.
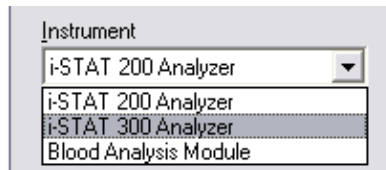
2.8: Make sure there is at least one port number listed under the Port Drop-Down **List.**
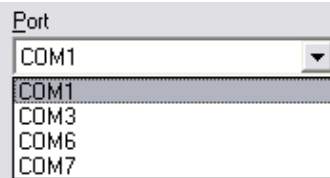
> **Note:** If the Port drop-down list says "None." make certain the connection from the Serial Downloader to the computer is tight. Then reboot the computer and return to step **2.3.**

2.9: Check that the Application and CLEW listings match those in the Product Update for the current software release.

2.10: Click on the "Update" button.
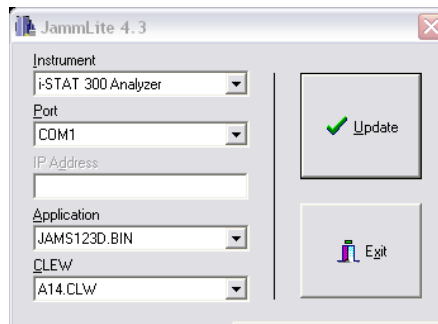
Note: Application and CLEW numbers are for example only.

2.11: Follow the onscreen instructions.
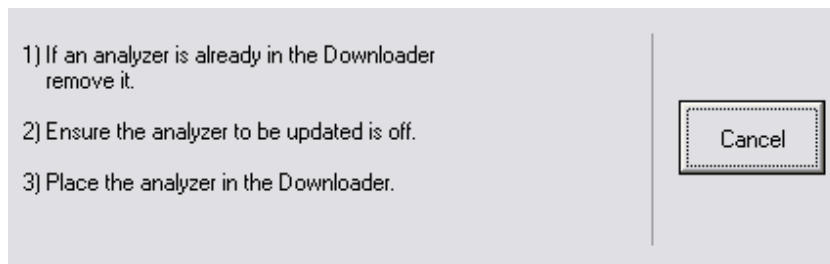
2.12: When the update is in progress, the following screen will appear:

The analyzer will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the analyzer until the success screen is displayed.

The application update was successful.

The CLEW update was successful.

Close

2.13: Run the Electronic Simulator in the analyzer. When the simulator finishes, **PASS** should be displayed.
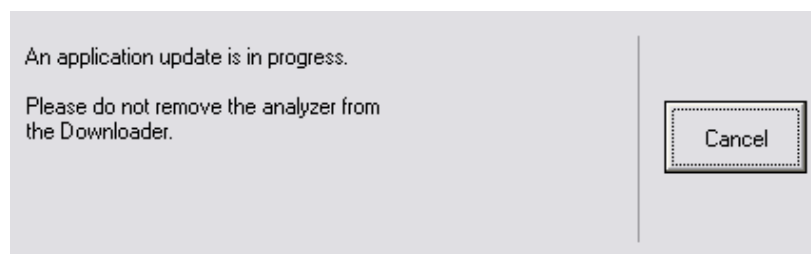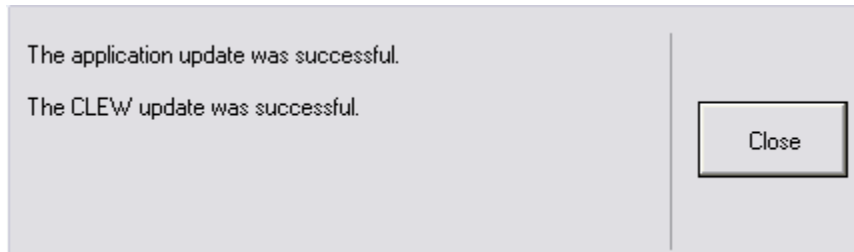
> **Note:** If **PASS** is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the Electronic Simulator, see Section 14 of the i-STAT 1 System Manual.

Congratulations. **The process for updating the first i-STAT 1 Analyzer is complete.**

If there are additional analyzers to be updated via JammLite:

- Click **Close.**
- Repeat steps **2.10 through 2.13**.

If there are no additional analyzers to update, the process is complete.

- Click the [X] button in the upper right corner of the software screen.
- Proceed to step **2.14** to restart the RRC if it was disabled in Step **2.4.**
- Proceed to step **2.14** to update the RALS-Plus i-STAT/DE with the latest CLEW and JAMS software files.

2.14: Restart the RALS remote connection.

- Maximize the RRC Status window.
- Double click on Com1.
- Check the "Enabled" box.
- Enter the recorded "Host" and "ID" entry from step **2.4.**
- Click "OK."

2.15: Update the CLEW version in the Customization Workspace.

- Transfer the files.

    o Access the main Customization Workspace page.

    o Click **Update i-STAT/DE → Upload Update File.**

    o Browse to desktop, click on XXX.CLW and click **Upload**.

    (Note: the XXX is the CLEW version that you are updating.)

    o Click **Update i-STAT/DE → Upload Update File.**

    o Browse to Desktop, click on JAMSXXXX.BIN and click **Upload.**

    (Note: the XXXX is the JAMS version that you are updating.)

- In the Customization Workspace, under the "Default customization profile:" column, click on the **"i-STAT Analyzer CLEW"** button.

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Note: Customization screens may vary depending upon the i-STAT/DE version in use.

- Check the box next to the new version of **CLEW** and click **OK**.

Answer OK to the question that appears.

- If "Uses Default" is not checked beside any Location-based customization profile, click the box under the "**i-STAT Analyzer CLEW**" column.

- Click the new version of **CLEW**, and then click **OK**.

Answer OK to the question that appears.

- Under the "Default Customization profile:" column, click on the **i-STAT 1 Software** drop-down list. Select the JAMS version that matches the Product Update and click **OK**.

3. UPDATING THE i-STAT 1 ANALYZER USING THE i-STAT/DE CUSTOMIZATION WORKSPACE AND A NETWORK DOWNLOADER, DOWNLOADER/RECHARGER, or DRC-300

3.1: Before starting the process, make sure all the required equipment / information is available.

- Computer which can access the Customization Workspace

- Access to www.globalpointofcare.abbott

- i-STAT System Equipment

  (1) i-STAT 1 Analyzer

  (2) Network Downloader, Downloader/Recharger, or DRC-300

  Note: These instructions assume that the Network Downloader types being used for the update process are already installed and in use on the customer's network.

  (3) Electronic Simulator

3.2: Update the CLEW and JAMS versions in the Customization Workspace.

  a) Navigate to: www.globalpointofcare.abbott > Support > i-STAT 1 and i-STAT Alinity Support > i-STAT 1 Resources Login > Product Software > i-STAT System Software Updates and Access Software.

  b) Scroll to "Step 2: Download Software Update File"

Data management with i-STAT/DE version ≥2.8.0.1
Click on "**DOWNLOAD SUXXXXXX.ZIP**" and save the file to the Desktop.Close the "Download Complete" window.

Note: i-STAT/DE versions less than 2.8.0.1 are no longer supported. Use a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process to perform the software update via its IP Address (TCP/IP) or Port (COM Port) for serially connected downloaders.

c. Navigate to saved zip file location. Right click on the zip file and select Extract All and Extract to the Desktop.

d. Access the main Customization Workspace page.

e. Click **Update i-STAT/DE → Upload Update File**

f. Browse to the Desktop, click on the SUXXXXXX folder to open. Select SUXXXXXX.exe and click upload.

> (Note: the XXXXXX is the JAMS and CLEW version that <u>you are updating</u>.) Immediately after uploading the CLEW/JAMS to the i-STAT/DE server, i-STAT/DE will unpack the files and make them available for use in the analyzer's Customization Workspace.

3.3: Close Windows Explorer by clicking on the in the upper right corner.

3.4: Access the Customization Workspace**.**

- RALS-Plus Users:
  - o From the RALS-Plus Application, pick i-STAT from the drop-down menu.
  - o Click on **Device Customization.**

- PrecisionWeb Users:
  - o Double click on the desktop shortcut or Internet Explorer Favorites for **i-STAT Customization**.

3.5: Update the CLEW and JAMS versions in the Customization Workspace.

- Under the "Default customization profile:" column, click on the "**i-STAT Analyzer CLEW**" button.

  Note: Customization screens may vary depending upon i-STAT/DE version in use.
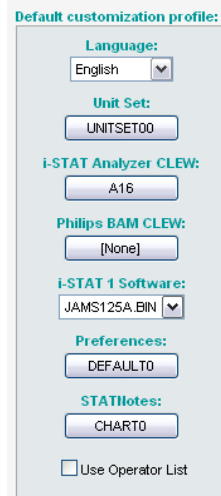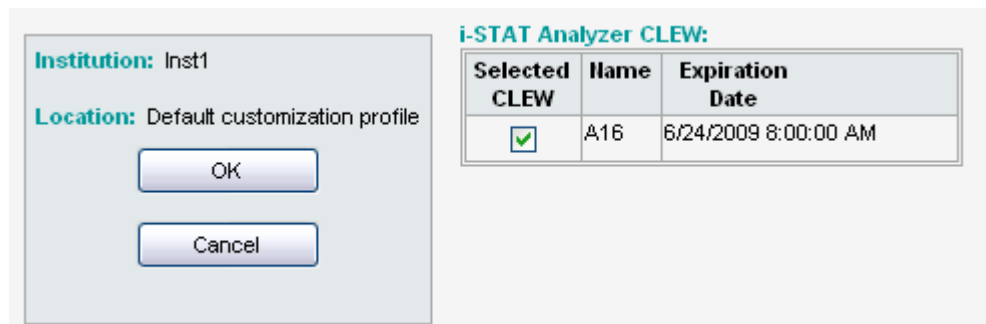
- Check the box next to the new version of **CLEW** and click **OK**.

Answer **OK** to the question that appears.

- If "Uses Default" is not checked beside any Location-based customization profile, click the box under the "**i-STAT Analyzer CLEW**" column.

Location	Enabled	Uses Default	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	STATNotes	
ER	☐	☑	☑	A16	[None]	DEFAULT0	CHART0	☐
ICU	☐	☐	☑	A16	[None]	DEFAULT0	CHART0	☐
Lab	☐	☑	☑	A16	[None]	DEFAULT0	CHART0	☐
OR	☐	☐	☑	A16	[None]	DEFAULT0	CHART0	☐

Location-based customization profiles:

- Click the new version of **CLEW**, and then click **OK**.

Institution: Inst1

Location: Default customization profile

OK

Cancel

i-STAT Analyzer CLEW:

Selected CLEW	Name	Expiration Date
☑	A16	6/24/2009 8:00:00 AM

Answer OK to the question that appears.

- Under the "Default Customization profile:" column, click on the **i-STAT 1 Software** drop-down list. Select the JAMS version that matches the Product Update and click **OK**.

Default customization profile:

Language:
English

Unit Set:
UNITSET00

i-STAT Analyzer CLEW:
A16

Philips BAM CLEW:
[None]

i-STAT 1 Software:
JAMS125A.BIN

Preferences:
DEFAULT0

STATNotes:
CHART0

☐ Use Operator List

3.6: 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 **Enabled** is checked for every location from which you wish to perform software updates on your i-STAT 1 Analyzers.

3.7: Update the software in the i-STAT 1 Analyzer.

- Go to the location where the i-STAT 1 Analyzer(s) you wish to update are located or contact someone at that location who can assist in updating the analyzer(s).

- Press the **On/Off** button on the analyzer.

- Press the **Menu** key to bring up the Administration Menu.

- Press **7 – Utility**. When prompted for a password, press **ENT**. If that did not work, a password is needed. Enter the password defined by your facility and press **ENT**. Note: Abbott Point of Care Inc. recommends changing the default password.

- From the Utility menu, press **3 – Receive Software**. A "Waiting to Send" message will appear on the analyzer display.

- Place the analyzer in the downloader or downloader / recharger. **Do NOT move the analyzer until step 3.8.** A **Communication in Progress** message will appear on the screen. After this disappears, the analyzer display will stay blank for approximately 5-10 seconds.

- The analyzer will then display 1's and 0's streaming across the screen signifying that it is receiving the software. Once the 1's and 0's disappear, the analyzer display will again go blank for approximately 5-10 seconds.

- A **Waiting to Send** message following 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.

3.8: Run the Electronic Simulator in the analyzer. When the simulator finishes, **PASS** should be displayed.

> **Note:** If **PASS** is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the Electronic Simulator, see Section 14 of the i-STAT 1 System Manual.

<div align="center">

Congratulations. **The process for updating the first
i-STAT 1 Analyzer is complete.**

</div>

Review the options below for additional instructions.

- If there are no additional analyzers to update, the process is complete.

- If there are additional analyzers to update, return to step **3.7**.

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i-STAT 1 SYSTEM TECHNICAL BULLETIN

Support Services

Abbott Point of Care and its distributors are committed to helping you resolve any problems with the i-STAT System: i-STAT 1 Handheld, cartridges, accessories and data management 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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