

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 and with the MediSense Precision PCx and PCx Plus Glucose Test Strips for the quantitative measurement of glucose in whole blood.

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

BEFORE YOU USE THE ANALYZER

Install Batteries Two disposable lithium batteries are supplied with the analyzer. 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. 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 the Customization section 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 the Central Data Station, see the “Customization Workspace” in the Central Data section of this manual.

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.

The i-STAT 1 Analyzer is shipped with the glucose test strip functionality disabled. The glucose test strip functionality can be enabled through the Customization function on the Central Data Station or analyzer.

Older i-STAT 1 analyzers may have the test strip port blocked. The test strip port can be unlocked as follows. A small flat-head screwdriver is needed to remove the plug.

- 1 Hold the analyzer with the test strip port facing you and the display facing up.
- 2 Hold the screwdriver with the blade horizontal. Carefully insert the blade into the horizontal gap under the plug.
- 3 Pry up gently until the plug pops free. Take care not to force the screwdriver into the port.
- 4 Remove the screwdriver and then remove the plug. The plug can be replaced if necessary.

Perform Quality Check

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

Use QC protocols to verify the test strip-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	15-40°C (59-104°F) for Medisense strip testing 16-30°C (61-86°F) for i-STAT cartridge testing
TRANSPORT TEMPERATURE	-10-46°C (14-115°F)
RELATIVE HUMIDITY	90% (maximum) non-condensing
BAROMETRIC PRESSURE	300-1000 mmHg
LASER SCANNER	Complies with U.S. 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No. 50, dated July 26, 2001. EN 60825-1:1994 + A1:2002 + A2:2001 IEC 60825-1:1993 + A1:1997 + A2:2001

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.

Note: Calibration information for the glucose test strips is included in the barcode on the foil packet in which each test strip is packaged. The analyzer requires that this information be scanned or entered via the keypad before the test strip can be inserted into the analyzer.

Power

There are two power options for the analyzer: disposable and rechargeable. The analyzer is shipped with two disposable 9-volt lithium batteries and a battery carrier. Lithium batteries may be ordered from i-STAT or obtained locally. ULTRALIFE® lithium batteries (ULTRALIFE Batteries, Inc., Newark, NY, USA) are recommended. Only i-STAT rechargeable batteries may be used.

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, 50 immunoassay cartridges, or about 1,000 glucose test strips can be expected before replacement is necessary. Backlighting, if used continuously, may reduce battery life up to 50%. Extensive laser scanning will affect battery life slightly.

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

Rechargeable Battery

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

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

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

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

Low Battery Warning

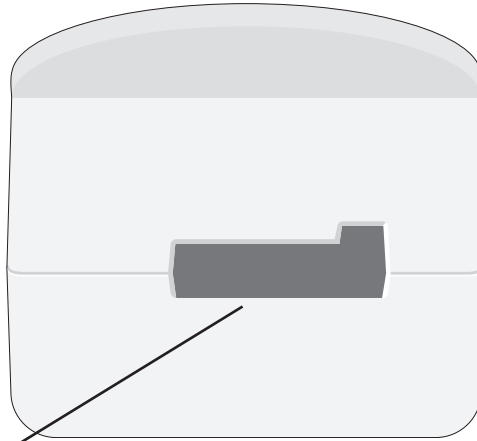
The analyzer will display “Low Battery” when the On/Off key is pressed. Additionally, a flashing battery icon will display on the results screens, as well as the Test Menu and Administration Menu screens when battery replacement is needed. Data is not lost when batteries are fully discharged.

Additional Power

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

Cartridge Port

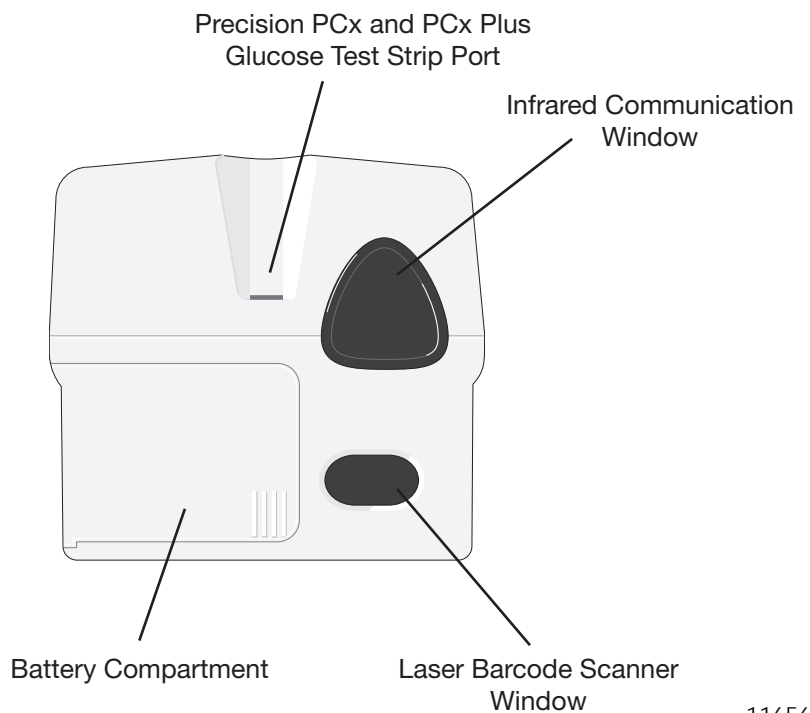
Cartridges and the Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer. Unless the analyzer is customized to require information input before a test, inserting a cartridge or Electronic Simulator initiates the test cycle (i.e., the analyzer does not need to be turned on first). The cartridge and test strip ports cannot be used simultaneously.



i-STAT Cartridge Port

Test Strip Port

Precision PCx and PCx Plus Blood Glucose Test Strips are inserted into the analyzer through the test strip port on the display end of the analyzer when prompted by the analyzer.



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 inserting a cartridge into the analyzer or by selecting the i-STAT Cartridge option from the Test or Quality Tests 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

Strip Test Cycle

An operator starts a test strip test cycle by selecting the PCx Glucose Strip option from the Test or Quality Tests Menu.

The analyzer:

- accepts test strip lot data
- prompts the operator to insert the test strip
- prompts the operator to apply the sample
- measures electrical signals generated by the glucose sensor and sample
- accepts the operator and patient IDs scanned or entered by the operator
- accepts chart page information entered by the operator
- calculates and displays results
- stores results