

iSTAT1: Appendix D - Analyzer Information



Use with i-STAT cartridges for quantitative determination of specific analytes in whole blood.

Calibration:	Factory: electronic, mechanical, thermal, pressure
Operating Temp	16-30°C (61-86°F)
Transport Temp:	-10-46°C (14-115°F)
Relative Humidity	90% (maximum) non-condensing

Software

- Analyzer functions are updated as additional tests and features are developed.
- Manufacturer updates are sent every 6 months.
- i-STAT1 analyzer will alert the operator of pending software expiry.
- Point of Care Testing Technologist function.
- Quality Checks are performed with each software update.

Power

- Disposable and rechargeable batteries available.
- Use disposable batteries - ITT, Oncology Clinic and the MMU.
- Two 9 volt ULTRALIFE Lithium batteries – ordered from Abbott. Contact POCT Technologist email POCTLab@cw.bc.ca local 7521 or after hours contact local 7850.
- Battery Level is > 8.0 volts for analyzer use.
- Approximately 400 thermally controlled 50 immunoassay cartridges.
- cartridges that require thermal control consume power at a faster rate
- Backlighting and extensive laser scanning will affect battery life slightly.
- Analyzer will indicate when battery replacement is needed with a message on the display screen.
- Battery compartment is on the underside of the analyzer.
- Backup Power - Lithium battery for Clock/calendar and stored results – good for 7 years.

Cartridge Port

- The cartridge with sample is inserted into the analyzer cartridge port.
- When properly inserted the cartridge activates the analyzer.

Communication Link

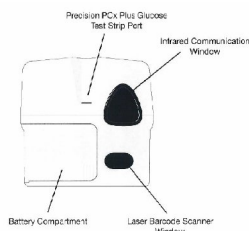
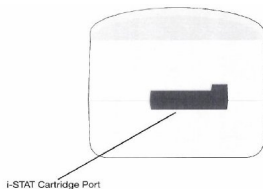
- The infrared light-emitting diode (LED)
- Transmits test records from the analyzer to a receiver on an IR Link
- Can be connected to a portable printer and/or the Central Data Station

Thermal Control Sensor Subsystem

- Handheld analyzer has a thermal control subsystem with thermistors and heating contact wires.
- Controls the temperature of the zone in the cartridge containing the silicon chips, sensors and fluids that come into contact with the sensors to 37oC.
- This function is activated automatically with thermal control cartridges.

Barometric Pressure Sensor Subsystem

- 300-850 mmHg
- Analyzer contains a solid state barometric pressure sensor which determines ambient atmospheric pressure used for the PO2 sensor calibration.



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Test Cycle	<p>The test cycle is initiated by selecting the i-STAT Cartridge option from the Test or Quality Tests Menu:</p> <ul style="list-style-type: none"> • Electrical contact is made with the cartridge. • Identifies the cartridge type • Calibration fluid is released to the sensors. • Mixes sample and reagent • Barometric pressure is measured (when thermal control is required). • Sensors are heated to 37oC (when thermal control is required). • Electrical signals generated at the sensors are measured. • Calibrant solution is displaced with sample. • Electrical signals generated at the sensors are measured. • Operator and patient ID numbers are accepted. • Cartridge Lot number • Control Lot Number • Calibration or Proficiency ID numbers are accepted • Blood gas and patient parameters are accepted. • Results are calculated and displayed. • Results are stored.
Storage of Results	<ul style="list-style-type: none"> • Stores up to 1,000 test records. • To access – Menu Page – [2-Data Review] • a set of results • date and time test performed • cartridge type • all information entered by barcode scanner or keypad including: operator & patient IDs, Lot numbers for controls, cartridges and test strips, Chart page data • serial # of the analyzer • # of times the analyzer has been used • the software version • Quality check codes that may appear during a test cycle
Keypad	<ul style="list-style-type: none"> • 19 labelled keys and 2 smaller unlabelled keys (soft keys) just below the display screen: • SCAN – activates the barcode scanner. • Arrow keys – move the cursor. • ABC – enter alpha characters – arrow keys used to scroll the alphabet • 0-9 – enter digits • [.] – enter decimal point • [0] – turn the screen backlight on and off. • ENT – used to respond to a prompt to complete an action • MENU – to return to previous menu; switch between TEST and ADMIN Menus • PRINT – used to print directly to the portable printer • ON/OFF – when analyzer is on – must be pressed for one second to turn analyzer off.
Test Menu	<ul style="list-style-type: none"> • 1- Last Result • 2- i-STAT Cartridge

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Administration Menu	1 - Analyzer Status <ul style="list-style-type: none"> • Temp • Pressure • Battery • Uses • Serial • CLEW • Version • Custom Stored Records
	2 – Data Review <ul style="list-style-type: none"> • 1-Patient • 2-Control • 3-Proficiency • 4-Cal Ver • 5-Simulator • 6-All • 7-List
	3 – Quality Tests <ul style="list-style-type: none"> • 1-Control • 2-Proficiency • 3-Cal Ver • 4-Simulator
	4 – Customization <ul style="list-style-type: none"> • 1-View • 2-Change
	5 – Set Clock
	6 – Transmit Data <ul style="list-style-type: none"> • 1-Most Recent • 2-This Month • 3-Last Month • 4-All
	7 – Utility <ul style="list-style-type: none"> • 1-Send Software • 2-Clear Memory

REFERENCES

i-STAT1 System Manual. Abbott Point of Care Inc. Abbott Park, IL 60064 USA 20 JAN 2012

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	25 Nov 2013	Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	22 Dec 2016		Dr. Benjamin Jung
1.2	Minor	Updated Contact information	June 23, 2019	Calvin Lee	

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