

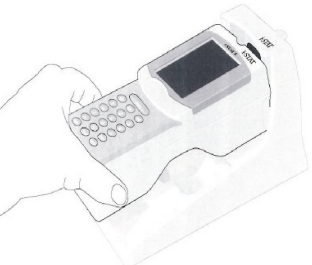



iSTAT1: Appendix B - System Overview

<p>A. Cartridges</p> 	<ul style="list-style-type: none"> - Cartridge is a single-use, self-contained, disposable unit that contains microfabricated thin film electrodes or sensors, a calibrant solution, a fluidics system, and a waste chamber. - Heating elements in cartridges requiring thermal control at 37°C. - Sensors for analysis of blood gases, electrolytes, chemistries and hematocrit are available in different panel configurations. - Calculated values include TCO₂, HCO₃⁻, and sO₂. - Cartridge available for use in PHSA are the EG7+ (blood gases and electrolytes) CHEM 8+ (electrolytes and chemistry); CG4+ (blood gases and lactate); cTnl – (Troponin). - Whole blood sample is used – varies with cartridge. Approximately (95 µL), or 2 to 4 drops is dispensed into the cartridge sample well. - Results are available within 2 minutes. <p style="color: red;">Caution: Sample entry well gasket and tab contain latex rubber.</p>
<p>B. Analyzer</p> 	<ul style="list-style-type: none"> - The Analyzer is a handheld i-STAT Portable Clinical Analyzer with Thermal Control measuring capability at 37°C. - Disposable battery or rechargeable battery power source. (Disposable batteries are used at PHSA). - When a sample-filled cartridge is inserted into the Analyzer for analysis, the Analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. - During a testing cycle, operator, patient identification numbers, cartridge lot #'s, Aqueous Quality Control numbers and Electronic Simulator numbers are entered with an InfraRed scanner or manual entry. - When the testing cycle is completed, results are displayed and the test record is stored in the handheld unit. - Test records are sent via Infrared Link to the Central Data Station.
<p>C.</p> 	<ul style="list-style-type: none"> - The IR Link transmits information bidirectionally between analyzer and the Central Data Station with the downloader/charger unit. - The cradle ensures proper alignment during transmission. - The status light indicates the computer status: Green: Ready to receive transmission. Red: Not ready to receive transmission. Blue: Transmission in progress. - Message will confirm that the transmission is successful or not successful.
<p>D. Central Data Station</p> 	<ul style="list-style-type: none"> - The i-STAT Central Data Station (CDS) is located at the Point of Care testing Chemistry Lab, POCT Technologist email POCTLab@cw.bc.ca local 7521. - The CDS stores patient, Quality Control records, Electronic Simulator, Error Records, Operator Lists, Reagent Management records.

REFERENCES

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

Medical Approval: Dr Benjamin Jung

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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	POCT Contact updated	June 23, 2019	Calvin Lee	

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