

<b>iSTAT1: Appendix C - Cartridge Information</b>					
Department	Infant Transport Oncology	Medical Mobile Unit			Expected Values
i-STAT Cartridges	EG7+ 06F01-01	CHEM8+ 03M88-01	CG4+ 07G02-01	cTnl 06F15-03	Reportable Range
Volume	95 uL	95 uL	95 uL	17 uL	
RT 18-30oC Expiry	2 months	2 months	14 days	14 days	
<b>Chemistry/Electrolytes</b>					
Sodium	X	X			100-180 mmol/L
Potassium	X	X			2.0-9.0 mmol/L
Chloride		X			65-140 mmol/L
TCO2		X			5-50 mmol/L
Anion Gap		X			(-10)-(+99) mmol/L
Ionized Calcium	X	X			0.25-2.50 mmol/L
Glucose		X			1.11-38.85 mmol/L
Urea Nitrogen		X			1.07-50.0 mmol/L
Creatinine		X			15.3-1525 umol/L
Lactate			X		0.30-20.0 mmol/L
<b>Hematology **</b>					
Hematocrit	X	X			<b>** Hematology test parameters not reported.</b>
Hemoglobin	X	X			
<b>Blood Gases</b>					
pH	X		X		6.5-8.2
PCO2	X		X		5-130 mmHg
pO2	X		X		5-800 mHg
TCO2	X		X		5-50 mmol/L
HCO3	X		X		1.0-85.0 mmol/L
Base Excess	X		X		(-30)-(+30) mmol/L
sO2			X		<b>** not reported</b>
<b>Cardiac Markers</b>					
cTnl – Troponin I				X	0.00-50.00 ug/L
<b>Principles of Measurement</b>					
<b>Sodium, Potassium, Ionized Calcium, pH, pCO<sub>2</sub> Urea Nitrogen</b>	<ul style="list-style-type: none"> <li>Measured by direct or by ion-selective electrode potentiometry.</li> <li>Concentrations are calculated from the measured potential through the Nernst equation.</li> </ul> <p>Note: Calculated values TCO<sub>2</sub> and HCO<sub>3</sub> are reported.</p>				
<b>pO<sub>2</sub>, Glucose, Creatinine, Lactate, cTnl-Troponin I</b>	<ul style="list-style-type: none"> <li>Measured amperometrically.</li> <li>Oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution and is reduced at the cathode.</li> <li>Oxygen reduction current is proportional to the dissolved oxygen concentration in solution.</li> </ul> <p>Note: Calculated value SO<sub>2</sub> from the measured pO<sub>2</sub> is not reported.                      (No comparison data to date to support the reporting of this parameter).</p>				

Medical Approval: Dr Benjamin Jung


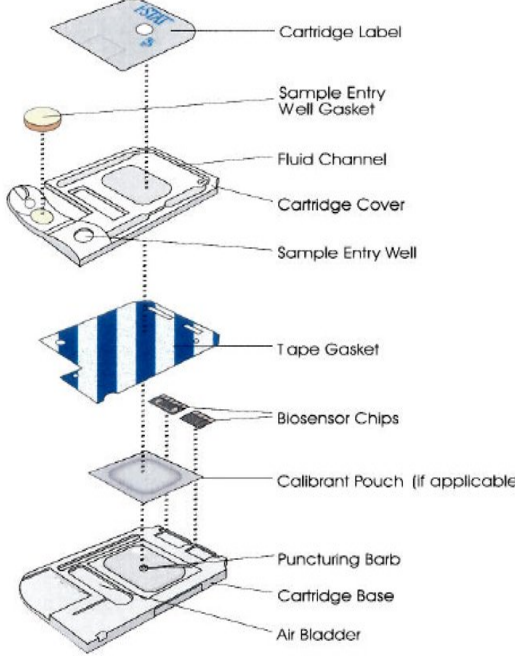
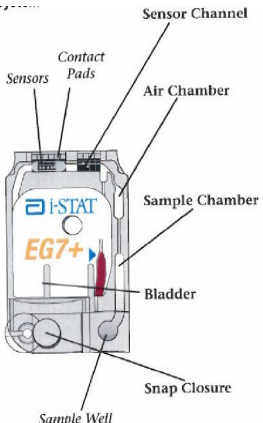
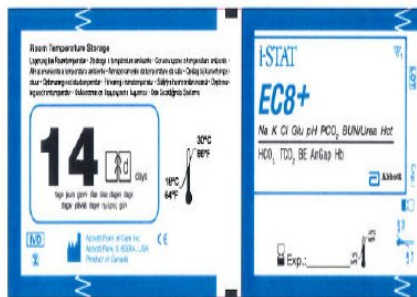

Version: 1.2

Folder Name: CW\Point of Care\Blood Gas Electrolytes - iSTAT

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Cartridge Components	Cartridge Packaging
  	 
<b>Sensor Channel:</b>	<ul style="list-style-type: none"> <li>- Directs the sample from sample well, to sample chamber to the sensors.</li> <li>- An extension of the sensor channel receives calibrating solution as it is displaced by the sample.</li> </ul>
<b>Air Chamber:</b>	<ul style="list-style-type: none"> <li>- Creates an air segment between calibrant and sample.</li> <li>- Monitored by the instrument.</li> </ul>
<b>Bladder:</b>	<ul style="list-style-type: none"> <li>- Analyzer presses on the bladder to displace calibrant from the sensors and moves the sample from the sample chamber to the sensors.</li> <li>- (Located below the label).</li> </ul>
<b>Snap Closure:</b>	<ul style="list-style-type: none"> <li>- Snaps over the sample well to create an airtight seal required for the testing cycle and subsequent cartridge disposal.</li> </ul> <p><b>Caution:</b> "sample entry well gasket" contains natural rubber latex.</p>
<b>Air Vent:</b>	<ul style="list-style-type: none"> <li>- Allows the calibrant and the sample to flow forward within the cartridge.</li> <li>- (Located on the underside of the cartridge).</li> </ul>
<b>Waste Chamber:</b>	<ul style="list-style-type: none"> <li>- To hold calibrating fluid once used in testing.</li> <li>- (Beneath the cartridge label).</li> </ul>
<b>Sensors:</b>	<ul style="list-style-type: none"> <li>- Are electrodes microfabricated on silicon chips.</li> <li>- Each sensor contains coatings of chemically specific sensitive films of ion-selective membranes and enzyme layers.</li> <li>- Each sensor is connected to a contact pad by a signal line.</li> <li>- Each sensor responds to the calibrant or sample producing measurable signals which are then related to analyte concentration.</li> </ul>
<b>Contact Pads:</b>	<ul style="list-style-type: none"> <li>- Via the internal connector conducts the signals generated by the sensors to the analyzer.</li> </ul>

<b>Cartridge Procedure:</b>	
Ready the Cartridge	<ul style="list-style-type: none"> <li>• Room temperature for a minimum of 5 minutes.</li> <li>• Cartridge is used immediately after opening pouch.</li> <li>• Can be left out of pouch for up to 5 minutes.</li> </ul>
Cartridge Handling	<ul style="list-style-type: none"> <li>• Do not touch the contact pads.</li> <li>• Do not exert pressure on the calibrant pack in the center of the cartridge.</li> <li>• Cartridge is on a flat surface or horizontal for sample use.</li> </ul>
Cartridge Fill	<ul style="list-style-type: none"> <li>• Dispense sample slowly and steadily until it reaches fill mark on the cartridge. Leave some sample in the sample well.</li> <li>• If sample goes slightly beyond the fill mark, "SAMPLE POSITIONED BEYOND FILL MARK" may appear.</li> <li>• If air bubbles are trapped in the sample chamber, "INSUFFICIENT SAMPLE" will appear. Use another cartridge.</li> <li>• If the sample reaches the fill mark, but the sample well is left completely empty, an "INSUFFICIENT SAMPLE" condition may be detected. Use another cartridge.</li> <li>• If sample well fills but rest of sample chamber does not, ensure that the air vent is not blocked.</li> <li>• Tilting the cartridge will aid the flow due to gravity.</li> <li>• When the sample begins to flow, return to a horizontal position.</li> <li>• If sample well is so full that sample is seen above the sample well do not wipe with tissue or gauze. Take the syringe and remove some sample.</li> </ul>
Cartridge Seal	<ul style="list-style-type: none"> <li>• Fold the snap closure over the sample well. Press the rounded end of the closure until it snaps into place.</li> <li>• Avoid exerting excessive pressure on the closure directly over the sample well. Excessive pressure can push the sample beyond the fill mark. "SAMPLE POSITIONED BEYOND FILL MARK".</li> <li>• Use another cartridge.</li> <li>• Closing the cartridge before the sample chamber has filled will stop the flow of the sample. "SAMPLE POSITIONED SHORT OF FILL MARK".</li> <li>• Use another cartridge.</li> <li>• If the sample spreads over the outside of the sample well, an airtight seal may not form.</li> <li>• Failure to close the cartridge before inserting it into the Analyzer will prevent sample movement and can cause the sample to flow backward and out of the sample well. "UNABLE TO POSITION SAMPLE."</li> <li>• Use another cartridge.</li> </ul>

### Calibration

- Calibration is automatically performed as part of the test cycle on each cartridge
- Cartridges are self-calibrating.
- Each cartridge includes a sealed foil pack which contains a calibrant solution with a known concentration of each analyte.
- The first part of the testing cycle, calibrant solution is forced over the sensors, corresponding signals are stored. The next phase of testing moves the sample over the sensors.
- Sample signal response is compared to the calibrant signal response and the concentration of each analyte in the sample is calculated.
- Quality check codes and messages are included in the troubleshooting section if the calibration or testing cycle fails.

### Storage

Main Storage 2-8oC	Refrigerated at 2 to 8 <sup>o</sup> C. Expiration date on box. Laboratory walk-in fridge. Rm. 2F40
Infant Transport	Refrigerated at 2 to 8 <sup>o</sup> C. Expiration date on box.
Oncology Clinic	Room Temperature expiry (18 to 30 <sup>o</sup> C) as per cartridge – see Table page 1. Label cartridge with room temperature (RT) expiration date. Use a felt tip pen.
Medical Mobile	<b>Do not exert pressure when writing the RT expiry on the cartridge pouch.</b> <b>Do not return to the fridge once they have been at room temperature.</b> <b>Do not use cartridge if pouch/portion pack has been punctured.</b>

Contact Point of Care Technologist for help with troubleshooting and supplies:  
 POCT Technologist email [POCTLab@cw.bc.ca](mailto:POCTLab@cw.bc.ca) local 7521 or after hours contact local 7850.  
 Loaner iSTAT can be obtained from Chemistry lab Rm 2J17

### REFERENCES

**i-STAT Abbott Point of Care Inc. Abbot Park, IL 60064 USA**

**20 JAN 2012**

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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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