iSTAT1: Electronic Simulator Quality Check Procedure

Purpose: i-STAT1 is tested with Electronic Quality Checks using an Electronic Simulator to confirm analyzer performance.

Electronic Simulator Quality Control Regimen.

- Once every 24 hours when instrument not in use.
- Checked prior to use with each patient
- Every 8 hours when instrument is in use.

Note: Each i-STAT1 analyzer has a designated Electronic Simulator Quality Control device (EQC). Use the appropriate EQC with each of the analyzers.

ELECTRONIC SIMULATOR - Analyzer Performance Verification

1. Obtain Electronic Simulator from i-STAT storage box for the i-STAT1 analyzer.
2. Press [ON].
3. Press [MENU];
4. Press [3-Quality Tests];
5. Press [4-Simulator].
6. Scan or Enter Operator ID. Repeat.
7. Scan or Enter Simulator ID.
8. Insert Electronic Simulator tab into the handheld analyzer. The [i] is face up.
   “Contacting Simulator” and “Simulator Locked” message appears on the screen.
   Electronic Simulator time is 120 seconds.
9. Read screen to confirm Electronic Simulator PASS / FAIL display message.

<table>
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<tr>
<th>If</th>
<th>Then</th>
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| PASS is displayed on the Analyzer screen (after using the external Electronic Simulator), | • Remove the Electronic Simulator after the LCK message disappears from the display screen.  
  | | • Use the Analyzer as required.                           |
| FAIL is displayed on the analyzer screen, | • Repeat the procedure with the same Electronic Simulator.  
  | | • If FAIL is displayed a second time, repeat the procedure with a different external Electronic Simulator.  
  | | • If FAIL is displayed a third time, do not use the i-STAT1 analyzer.  
  | | • Contact area supervisor or POCT Technologist email POCTLab@cw.bc.ca local 7521.          |
10. Replace Electronic Simulator in appropriate storage box.

REFERENCES:
i-STAT1 System Manual. Abbott Point of Care Inc. Abbott Park, IL 60064 USA 20 JAN 2012
REVISION & APPROVAL LOG

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Type</th>
<th>Description of Change</th>
<th>Revision Date</th>
<th>Technical Approval</th>
<th>Medical Approval</th>
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<tbody>
<tr>
<td>1.0</td>
<td></td>
<td>New document</td>
<td>25 Nov 2013</td>
<td>Elvira Kozak</td>
<td>Dr. Cathy Halstead</td>
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<td>1.1</td>
<td>Minor</td>
<td>Document title and number change. Upload to QMS document control</td>
<td>22 Dec 2016</td>
<td></td>
<td>Dr. Benjamin Jung</td>
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<td>1.2</td>
<td>Minor</td>
<td>Reformatted, updated POCT contact</td>
<td>June 21, 2019</td>
<td>Calvin Lee</td>
<td>Dr H. Vallance</td>
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