

# STANTON TERRITORIAL HEALTH AUTHORITY

## Yellowknife, Northwest Territories

<b>TITLE:</b> Nova Biomedical Glucometer Quality Control Test	<b>Revision Date:</b> 07-July-2016	<b>Issue Date:</b> 07-July-2014
<b>Document Number:</b> POC20101	<b>Status:</b> <b>Approved</b>	
<b>Distribution:</b> Point of Care Testing Manual	<b>Page:</b> 1 of 6	
<b>Approved by:</b> C. Case, Manager Diagnostic Services	<b>Signed by:</b> <i>Cheryl Case</i>	

### PURPOSE:

The quality control test is performed to ensure that the Nova Biomedical StatStrip® Glucose Hospital Meter and the StatStrip® Test Strips are functioning properly.

### POLICY:

See Hospital Wide Policy L-1040 Point of Care Testing (Laboratory Testing).

### REAGENTS and/or MEDIA:

- Nova Biomedical StatStrip® GLU Test Strips
- Nova Biomedical StatStrip® GLU KET Control Solutions 1 & 3

### SUPPLIES:

- Nova Biomedical StatStrip® Glucose Hospital Meter

### SPECIAL SAFETY PRECAUTIONS:

- Handle all patient samples and testing sera using "Routine Practices".
- Please refer to the Northwest Territories Infection Prevention and Control Manual, March 2012.
- Gently shake each vial of control solution before use.
- Do not use a control solution after the expiration date printed on the vial label.
- Discard any unused portion 3 months after opening. Write the discard date on the vial when you first open it.

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- Store the control solution(s) at room temperature, below 30°C. Do not refrigerate or freeze.
- The control solutions contain dye that stains clothing.
- The control solutions are not for human consumption.

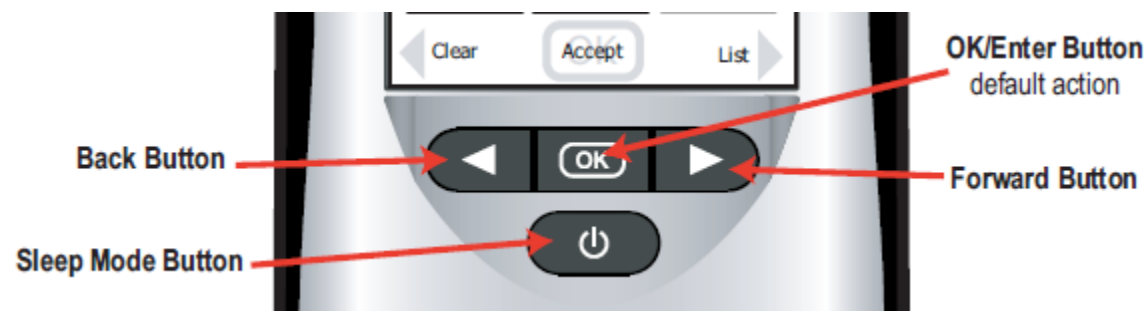
### QUALITY CONTROL:

When to Perform a Quality Control Test:

- Minimum of once every 24 hours.
- When you open a new bottle of test strips.
- If a patient test has been repeated and the blood glucose results are still lower or higher than expected.
- After cleaning the meter.
- If there are other indications that the system is not working properly.
- Whenever problems are identified or any time the accuracy of the meter may have been affected by rough handling (such as dropping the meter).

### PROCEDURE INSTRUCTIONS:

Follow the steps in the table below to perform a quality control test.

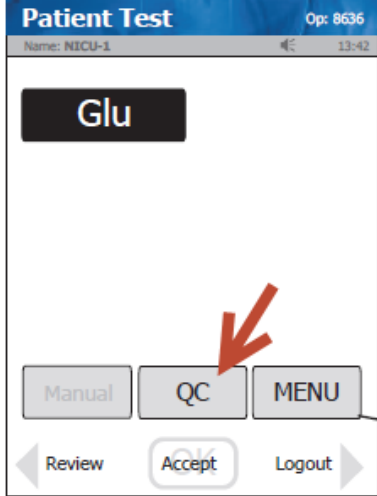
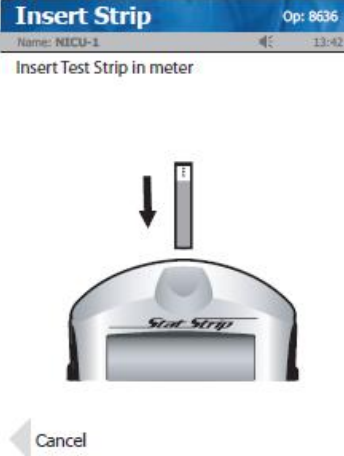
Step	Action
1	Turn on by pressing the <b>Sleep Mode</b> button. 
2	Press the <b>OK/Enter</b> button to begin testing.

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3	Enter your Operator ID number manually or scan your barcode.
4	Press the <b>OK/Enter</b> button to accept your Operator ID number.
5	<p>Touch the <b>QC</b> soft key on the instrument screen.</p>  <p>The screenshot shows a mobile application interface titled "Patient Test" with the operator ID "Op: 8636" and patient name "Name: NICU-1". The main display area shows "Glu". At the bottom, there are three buttons: "Manual", "QC", and "MENU". Below these are "Review", "Accept", and "Logout" options. A red arrow points to the "QC" button.</p>
6	Scan the barcode on the side of the vial for the lot number of the test strips you are using. Press <b>OK/Enter</b> .
7	Scan the lot number of the control solution you will be testing pressing while holding the <b>OK/Enter</b> button and passing the scanner over the barcode on the side of the dropper bottle.
8	Press the <b>OK/Enter</b> button to accept the lot number of the control solution.
9	<p>Insert a test strip into the top of the testing meter as shown on the screen.</p>  <p>The screenshot shows a mobile application interface titled "Insert Strip" with the operator ID "Op: 8636" and patient name "Name: NICU-1". The main display area shows "Insert Test Strip in meter". Below the screenshot is a diagram of the testing meter with a test strip being inserted into the top slot. A "Cancel" button is visible at the bottom left.</p>

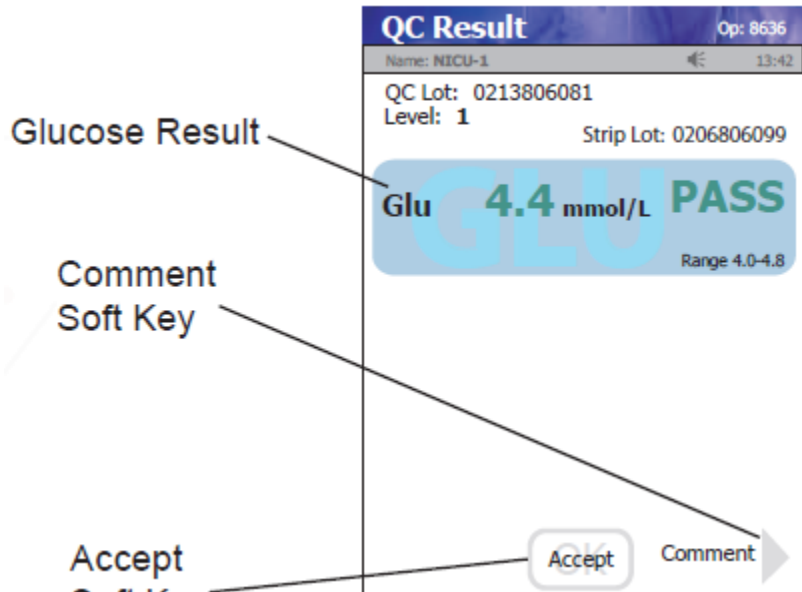
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<b>10</b>	<p>With the test strip correctly inserted, the Apply Sample screen will display.</p> <div style="text-align: center;">  </div>
<b>11</b>	Gently mix the StatStrip® Glucose Control Solution before each use.
<b>12</b>	Discard the first drop of control solution from the bottle to avoid contamination.
<b>13</b>	With the meter placed on a flat level surface, place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When enough blood has been drawn into the strip, an audible beep is sounded by the meter.
<b>14</b>	Recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.

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15	<p>When the meter completes the test, the QC Result screen displays with the results in mmol/L.</p>  <p>The screenshot shows a 'QC Result' screen with the following information: Name: NICU-1, QC Lot: 0213806081, Level: 1, Strip Lot: 0206806099. The main display shows 'Glu 4.4 mmol/L PASS' with a range of 4.0-4.8. At the bottom, there are 'Accept' and 'Comment' soft keys. Arrows point from the text labels 'Glucose Result', 'Comment Soft Key', and 'Accept Soft Key' to their respective elements on the screen.</p>	
	If	Then
	<p>The results are <b>PASS</b></p> <p>The results are <b>FAIL</b></p>	<p>You may accept the results by pressing the <b>Accept</b> soft key.</p> <ol style="list-style-type: none"> <li>i. Verify that the test strips and control solutions are not past their expiration dates</li> <li>ii. Repeat the Quality Control check using a new test strip</li> <li>iii. If the second test fails, inspect and clean the meter</li> <li>iv. If the third test fails, contact Nova Biomedical Technical Support toll free at 1-800-345-NOVA.</li> </ol>
16	Repeat steps 7 to 15 for the other level of control solution.	

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**RELATED DOCUMENTS:**

- POC20201 Nova Biomedical Glucometer Patient Testing
- POC20401 Nova Biomedical Glucometer Basic Maintenance

**REFERENCES:**

Nova Biomedical, StatStrip® Glucose Hospital Meter, Instructions for Use Manual, Nova Biomedical Corporation, Waltham, MA, 2011

Nova Biomedical, StatStrip™ Glucose and β-Ketone Control Solution Package Insert, Nova Biomedical UK, Cheshire, UK, 2011

**REVISION HISTORY:**

REVISION	DATE	Description of Change	REQUESTED BY
1.0	03 Apr 13	Initial Release (Replaces POC2010 to reflect new glucometer instrumentation)	JGD Bernier
2.0	15 May 14	Updated to include reference to: NWT Infection Prevention & Control Manual	JGD Bernier

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