Shared health
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Manitoba

Document History:

Title: StatStrip Glucometer Operator's Manual

Site(s): Shared Health

Document #:	**110-130-10**	**Version #:**	**01**
Section:	**Clinical Biochemistry**	**Subsection:**	**Point of Care**

Approved by: **Signature:**	Hayden Malvern Hayden Malvern	**Date:**	06-June-2018
		Effective Date:	06-July-2018

Details of Recent Revision

1. New document.

Hayden Malvern 06-June 2018

Purpose	To provide direction on safe use of Blood Glucose Meters (Nova StatStrip), and associated infection control and quality assurance requirements for laboratory staff.
Introduction	Glucose is the major carbohydrate present in the peripheral blood. Oxidation of glucose is the major source of cellular energy in the body. Glucose derived from dietary sources is converted to glycogen for storage in the liver or to fatty acids for storage in adipose tissue. The concentration of glucose in blood is controlled within narrow limits by many hormones, the most important of which are produced by the pancreas. The most frequent cause of hyperglycemia is diabetes mellitus resulting from a deficiency in insulin secretion or action. A number of secondary factors also contribute to elevated blood glucose levels. These include pancreatitis, thyroid dysfunction, renal failure and liver disease.
Principle	The glucose measurement is based on the following methodology: Glucose + Enzymes(oxidized form) → Gluconic Acid + Enzymes(reduced form) Enzymes(reduced form) + Ferricyanide → Enzymes(oxidized form) + Ferrocyanide Ferrocyanide $\xrightarrow[\text{Eectrode}]{-e^-}$ Ferricyanide The current generated at the electrode is proportional to the glucose concentration of the sample.
Definitions	**Blood Glucose Meter** – A portable electronic device used to measure the capillary blood glucose level. **Capillary Blood Glucose** – The amount of glucose in blood is measured on a sample obtained by lancing the skin (usually the fingertip or alternate site, e.g. the palmar area of the thumb).
Device Training	Staff using meter must receive training in proper use of the StatStrip Blood Glucose Meter, and associated quality assurance processes. Assign MediaLab TACA, 230-10-57.
Contraindications	Capillary Blood Glucose testing may not be clinically appropriate when peripheral blood flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in the peripheral blood.
Use & Reporting	Laboratory staff use the StatStrip Blood Glucose Meter to check the patient's blood glucose concentration in order to determine if the result meets the criterion for safety for administering the glucose drink, required for performing the Oral Glucose Tolerance Test (OGTT).

<table>
<tr><td>Storage & Handling</td><td>Blood Glucose Meters, test strips and quality control solutions must be stored according to manufacturer's instructions.</td></tr>
<tr><td>Materials</td><td>
<table>
<tr><td></td><td>Vendor code</td><td>SAP</td></tr>
<tr><td>StatStrip Glucose Meter</td><td>53400</td><td>205978</td></tr>
<tr><td>Glucose test strip</td><td>42214</td><td>203423</td></tr>
<tr><td>Alcohol swabs</td><td></td><td></td></tr>
<tr><td>Lancets</td><td></td><td></td></tr>
<tr><td>Control Solutions L1/ L3</td><td>41741, 41743</td><td>205980, 205979</td></tr>
<tr><td>StatStrip Glucose Linearity Kit</td><td>42173</td><td>302261</td></tr>
</table>
</td></tr>
<tr><td>Safety</td><td>Follow Routine Laboratory practice</td></tr>
<tr><td>Sample Requirement</td><td>Whole Blood (Fresh, Sodium heparin, Lithium heparin): Arterial, Venous, Capillary</td></tr>
<tr><td>Quality Control</td><td>Level 1and Level 3 of Nova StatStrip Glucose control solutions are run and evaluated once every 24 hours or before patient or EPT testing whichever is less frequent; and if a problem is suspected with the meter.

EPT – Subscribe to CAP- Quality Cross Check -Whole Blood Glucose (WBGQ) program</td></tr>
<tr><td>Linearity Check</td><td>HSC & SBH Labs Only – Run the linearity check solutions every 6 months. Evaluate against acceptance criteria and document.</td></tr>
<tr><td>Running Samples</td><td>Follow the procedure below to run and evaluate the quality control solutions</td></tr>
<tr><td></td><td>
<table>
<tr><td>Step</td><td></td></tr>
<tr><td>1</td><td>From the Patient Test screen
<table>
<tr><td>If</td><td>Then</td></tr>
<tr><td>QC</td><td>press the QC</td></tr>
<tr><td>Patient sample</td><td>press the Accept</td></tr>
</table>
</td></tr>
<tr><td>2</td><td>The Enter Strip Lot screen is displayed. Enter the Strip Lot Number or scan the barcode. Press the Accept, if the lot number is correct.</td></tr>
<tr><td>3</td><td>
<table>
<tr><td>If</td><td>Then</td></tr>
<tr><td>QC</td><td>The Enter QC Lot screen is displayed. Enter the QC lot number or scan the barcode. Press the Accept, if the lot number is correct.</td></tr>
<tr><td>Patient sample</td><td>From the Enter Patient ID screen, enter or scan the Patient ID. Once the Patient's ID/Accession Number has been entered, press the Accept.</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>The Insert Strip screen is displayed. Insert a Test Strip</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>5</td><td>With the test strip correctly inserted, the Apply Sample screen is displayed.</td></tr>
<tr><td></td><td>6</td><td>
<table>
<tr><td>If</td><td>Then</td></tr>
<tr><td>QC</td><td>-Gently mix the StatStrip Glucose Control Solution.
-Discard the first drop of control solution from the bottle to avoid contamination.
-Place a drop of control solution from the bottle at the end of the test strip until the well of the test strip is full and the meter beeps
-Recap the control solution.</td></tr>
<tr><td>Patient sample</td><td>Following SOP 100-10-79 "Phlebotomy Collection Manual", collect a skin puncture sample. Wipe away the first drop of a skin puncture sample.
Touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.</td></tr>
</table>

CAUTION: If the test strip does not fill completely, DO NOT touch the test strip to the blood a second time. Discard the strip and start over with a new strip.</td></tr>
<tr><td></td><td>7</td><td>The Testing Sample screen is displayed. In six seconds, the test results are displayed in mmol/L.</td></tr>
<tr><td></td><td>8</td><td>Use the ejector button on the back of the meter to eject the strip directly into a biohazard container.</td></tr>
<tr><td></td><td>9</td><td>To accept the result, press Accept.</td></tr>
<tr><td></td><td>10</td><td>Evaluate and document results

<table>
<tr><td>If</td><td>Then</td></tr>
<tr><td>QC results</td><td>Evaluate and document in QC log</td></tr>
<tr><td>Patient results</td><td>Slot enter the result in Delphic LIS</td></tr>
<tr><td></td><td></td></tr>
</table></td></tr>
<tr><td></td><td>11</td><td>When the meter is not in use, place it into the Docking/Charging Station.</td></tr>
<tr><td>Reporting</td><td></td><td>Slot enter results into the LIS</td></tr>
<tr><td>Reference Range</td><td></td><td>3.3 – 6.0 mmol/L</td></tr>
<tr><td>Reportable Range</td><td></td><td>0.6 - 33.3 mmol/L</td></tr>
</table>

<table>
<tr><td>Clinical Limits</td><td>
<table>
<tr><td>WRHA</td><td>Critical Low</td><td>Normal Low</td><td>Normal High</td><td>Critical High</td></tr>
<tr><td>Adult</td><td>2.5</td><td>3.6</td><td>6.0</td><td>25.0</td></tr>
<tr><td>Pediatric</td><td>2.5</td><td>3.3</td><td>5.6</td><td>25.0</td></tr>
<tr><td>Neonate</td><td>1.7</td><td>2.8</td><td>4.4</td><td>18.0</td></tr>
</table>
Rational: These limits have been programmed into all Glucose meters by Biomedical Engineering for clinical use. Meters will flag when limits are breached.

Action: Draw a random or FBS sample, accession, analyze on the I-stat or Automated lab analyzer and report as random or FBS as applicable.
</td></tr>
<tr><td>Maintenance</td><td>As Required</td></tr>
<tr><td>Replacing the Battery</td><td>Step</td></tr>
<tr><td></td><td>1</td><td>Press the Power button to enter the Sleep Mode.
<table>
<tr><td>If</td><td>Then</td></tr>
<tr><td>Replace within 20 seconds</td><td>Date/Time settings are not lost</td></tr>
<tr><td>>20 seconds</td><td>Refer to operators manual to set Date/Time</td></tr>
</table>
</td></tr>
<tr><td></td><td>2</td><td>Pull back on the cover latch to release the cover. Take the battery cover off the back of the meter.</td></tr>
<tr><td></td><td>3</td><td>Push up on the battery latch. Remove the drained battery.</td></tr>
<tr><td></td><td>4</td><td>Replace with a fully charged battery.</td></tr>
<tr><td></td><td>5</td><td>Replace the battery cover.</td></tr>
<tr><td></td><td>6</td><td>Place the drained battery into the Charging Station.</td></tr>
<tr><td>Cleaning the Meter</td><td></td><td>Apply 70% Isopropyl Alcohol to a soft cloth and wipe the meter surface. Once complete, immediately dry thoroughly.</td></tr>
</table>

Interfering Substances

The StatStrip Glucose Hospital Meter exhibits no interference from the following substances up to the following concentration levels:

Interfering Substances	Concentration Level	
Acetaminophen	10.0 mg/dL	0.66 mmol/L
Ascorbic Acid	10.0 mg/dL	0.57 mmol/L
Bilirubin	15.0 mg/dL	0.26 mmol/L
Cholesterol	500.0 mg/dL	12.9 mmol/L
Creatinine	6.0 mg/dL	0.53 mmol/L
Dopamine	10.0 mg/dL	0.53 mmol/L
Ephedrine	0.9 mg/dL	0.055 mmol/L
D(+) Galactose	350.0 mg/dL	19.4 mmol/L
Hematocrit (RBC)	20% - 65%	
Ibuprofen	48.0 mg/dL	2.33 mmol/L
L-Dopa	100.0 mg/dL	5.07 mmol/L
D(+) Maltose Monohydrate	240.0 mg/dL	6.66 mmol/L
D(+) Maltotetraose	240.0 mg/dL	3.6 mmol/L
D(+) Maltotetriose	240.0 mg/dL	4.76 mmol/L
Methyl-Dopa	1.0 mg/dL	0.042 mmol/L
Oxygen	All Concentrations	
Salicylate	30.0 mg/dL	1.87 mmol/L
Tetracycline	30.0 mg/dL	0.62 mmol/L
Tolazamide	15.0 mg/dL	0.48 mmol/L
Tolbutamide	45.0 mg/dL	1.67 mmol/L
Triglycerides	750.0 mg/dL	8.78 mmol/L
Uric Acid	20.0 mg/dL	1.05 mmol/L

New or Replacement Meters

Prior implementing for patient testing.

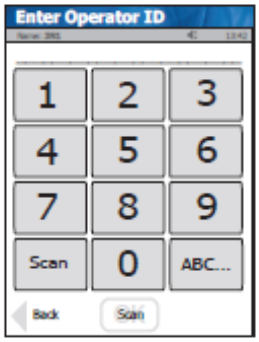
HSC & SBH	All Other Sites
Run all 5 levels of the Linearity solutions and the two level of QC. Evaluate against acceptance criteria and document for accreditation purposes	Request the validation documentation from your Biomedical Engineering when you pick up the meter. Run the two levels of QC. Evaluate against acceptance criteria and document with the validation documentation from Biomedical Engineering.

Troubleshooting	Refer to the Nova Instructions for Use Manual Call clinical Biomedical department for your site or region Contact Nova Biomedical Technical Support toll free at 1-800-545-NOVA.
Associated Documents	MediaLab TACA, 230-10-57 QC for StatStrip Blood Glucose POC Meter - F110-10-17
Reference	StatStrip Glu IFU 1.86 PN53083C EN DSM Lab Information Manual SOP 110-130-01 v2 WRHA Program clinical ranges (HSC Biomedical Engineering)

Stat Strip®

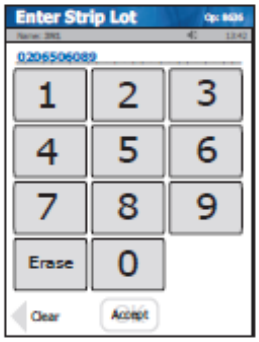
Glucose Monitoring System Quick Operating Guide

1 From Home screen, press **Login**.

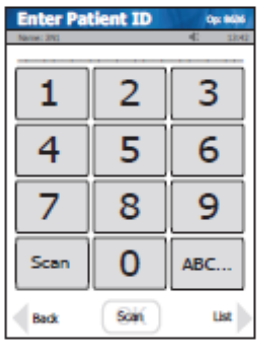


2 Enter or scan Operator ID and press **Accept**.

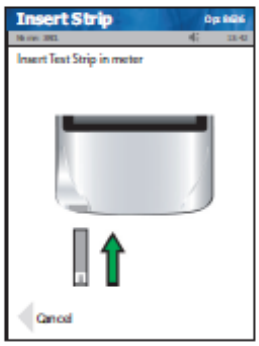
3 From Patient Test screen, press **Accept**.



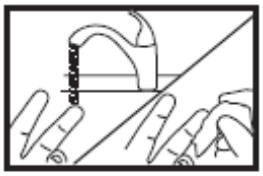
4 Check Strip lot no. and press **Accept**.



5 Enter or scan Patient ID and press **Accept**.

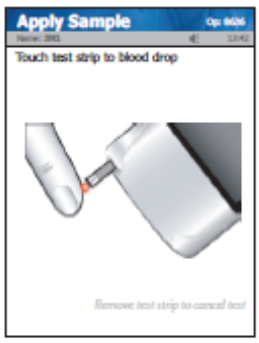


6 Insert Test Strip into Meter.



7 Wash patient's hand thoroughly and massage finger to stimulate blood flow.

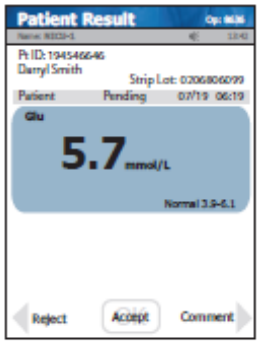
8 Use safety lancet to puncture finger / squeeze finger to form blood drop. Wipe away the first blood drop.



9 Touch strip to blood drop. Result will appear within 6 seconds.

10 *Warning!*

*The test strip must fill completely upon touching the blood droplet. **If the test strip does not fill completely, do not touch the blood droplet a second time.** Discard the test strip and repeat the test with a new test strip.*



11 To accept result, press **Accept**. To reject result, press **Reject**.

12 To review other results, press **Review** from Patient Test screen.

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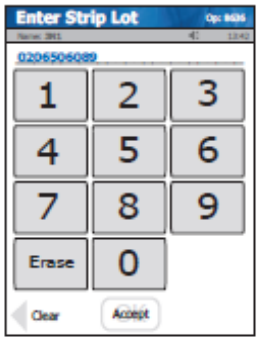
Stat Strip®

Glucose Monitoring System Quick QC Guide

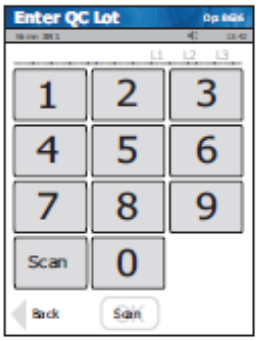
1 From Home screen, press **Login**.

2 Enter or scan Operator ID and press **Accept**.

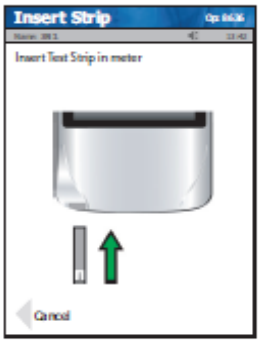
3 From Patient Test screen, press **QC**.



4 Check Strip lot no. and press **Accept**.



5 Enter QC lot no. and press **Accept**.

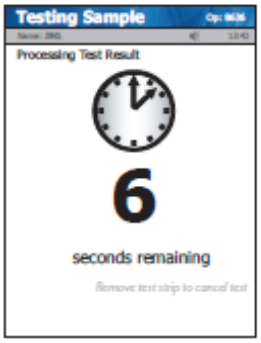


6 Insert Test Strip into Meter.

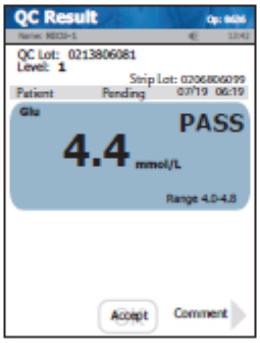
7 Touch drop from QC bottle to strip. Result will appear within 6 seconds.

8 *Warning!*

*The test strip must fill completely upon touching the QC droplet. **Do not add a second QC drop to the test strip.** Discard the test strip and repeat the test with a new test strip.*



9 Result will appear within 6 seconds.



10 To accept result, press **Accept**.

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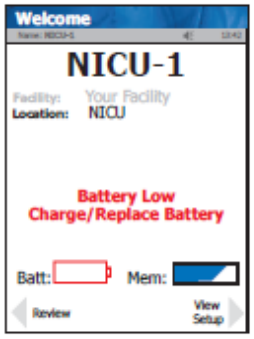
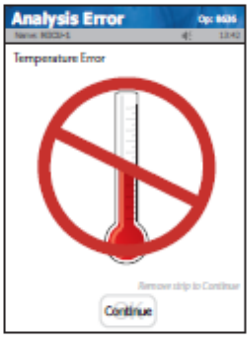
Glucose Monitoring System Troubleshooting Guide

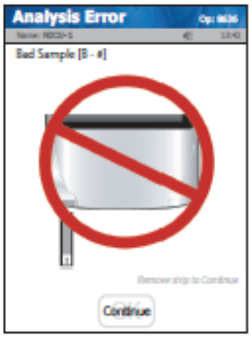


1 Change battery or place meter into charging/docking station.

2 The test has been cancelled, repeat the test with a new test strip. Leave the test strip in place until the result is displayed on the screen.

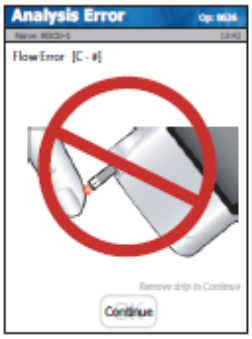


3 Meter will only work in a temperature range of 59-104°F (15-40°C).



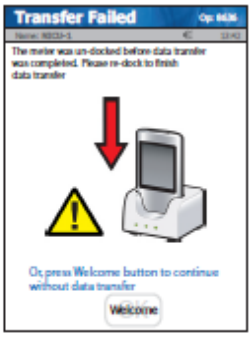
4 Insert new strip and repeat test. If the error code persists, perform the test using an alternate strip vial or alternate method.

5 Occurs after test strip insertion or during analysis. Insert another strip and repeat the test. If the error code persists, perform the test using an alternate strip vial or alternate method.



6 Either insufficient sample or the sample was applied incorrectly. Repeat test with a new strip. If the error code persists, perform the test using an alternate method.

7 Server refuses to allow dialog with meter or connection to server was broken. Check network settings, network status, or contact your administrator for assistance.



8 Meter was removed before data transfer was complete. Re-dock the meter.

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APPENDIX A:

Stat Strip Glucose Monitoring System
Quick User Guide

Maintenance	Quality control (QC)	Patient Testing
1. Clean Glucose meter between Patient use with OxyvirTB wipes. **2. Dock meter in docking station when not in use.** 3. Test Strips expire at **6 months** once vial open. Date vial once opened. 4. QC bottles expire at **3 months** once vial opened. Date vial once opened. 5. When testing ,**keep meter flat. Remove test stripe before accepting results.** ***Tilting meter up may result in fluid entering and damaging the meter.***	**1. QC to be completed every 24 Hrs.** Visual message warning when QC due. 2. From welcome screen, press **login.** 3. Enter operator Id (1) & press **Accept.** 4. From Pt test screen, press **QC.** 5. Scan test stripe lot no. 6. Scan QC lot no**.** 7. Insert test strip into meter, touch drop from QC bottle to tip of strip. QC result within range, press accept. 8. Complete Qc with both Qc bottles (Low and High)	1. From welcome screen, press **login.** 2. Enter operator Id (1) & press **accept.** 3. From patient test screen, press **Accept.** 4. Scan test stripe lot no. 5. Enter Patient Id (1) , press **Accept.** 6. Insert test strip into meter, touch tip of strip to pt blood drop. **Do not add second Blood drop. Keep meter flat or tilted downward.** 7. Wait 6 sec. Choose Accept or reject test results. 8. Meter range allow **low-0.5 , high-33mmol/l.**

M. Ash CRN ICMS Nov5/10

APPENDIX B:

Running a Linearity Test

1. From the Patient Test screen, press Menu.
2. From the Menu screen, press Linearity.
3. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode.
4. Press Accept if the lot number is correct.
5. The Enter Linearity Lot screen displays. Enter the Linearity lot number, select from the Linearity Lot List screen (press the List button), or scan the barcode.
6. Press Accept if the lot number is correct.
7. The Insert Strip screen displays. Insert a Test Strip as shown on the screen.
8. With the test strip correctly inserted, the Apply Sample screen displays.
9. Gently mix the StatStrip Linearity Solution before each use.
10. Discard the first drop of linearity solution from the bottle to avoid contamination.
11. Place a drop of linearity 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 sample has been drawn into the strip, an audible beep is sounded by the meter.
12. Recap the linearity solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.
13. When the meter completes the test, the Linearity Result screen displays with the results.
14. Document the result on the Linearity Check & Meter validation Data Log.
15. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.