



**Department of Pathology and Laboratory Medicine  
Capital District Health Authority  
Nova Scotia**

<b>TITLE:</b> POCT Glucose Testing Using Nova StatStrip Meter procedure	<b>Doc #:</b> 26395
<b>Section:</b> \\Management System\PLM\General\PLM Website\Point of Care Testing\Glucose Meter\	<b>Version:</b> 1.0 Current
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<b>Final Approval:</b> Dr Bassam Nassar	

**Purpose** This procedure provides instructions for glucose testing using the Nova StatStrip meter.

**Abbreviations**

RT = Room Temperature	N = No
BX = box	POC = Point of Care
QC = Quality Control	CAP = College of American Pathologists
Y = yes	BioMed = Biomedical Engineering
Hct = hematocrit	

**Materials**

Reagents	Stability and Storage
<i>StatStrip</i> ® Glucose Test Strips 50 strips/vial SAP#175556  <b>NOTE: DO NOT</b> transfer strips from one bottle to another. Date test strips when opened. Keep vial closed on StatStrips – they are affected by heat, light, and humidity. Listen for SNAP that lid is closed.	<b>Store at RT</b>  <b>Stability:</b> 24 month from date of manufacture. <b>Expire:</b> 180 days or 6 months after opening.
<i>StatStrip</i> ® Glucose/Ketone Control Solution Level 1 (Low) SAP# 176175  <b>Note:</b> Date control solutions when opened.	<b>Store at RT</b>  <b>Stability:</b> 24 months from date of manufacture. <b>Expire:</b> 90 days or 3 months after opening.
<i>StatStrip</i> ® Glucose/Ketone Control Solution Level 3 (High) SAP# 176174 <b>Note:</b> Date control solutions when opened.	<b>Store at RT</b>  <b>Stability:</b> 24 months from date of manufacture. <b>Expire:</b> 90 days or 3 months after opening.



**Materials  
Cont'd**

<b>Supplies</b>
Lancets Unistick Comfort 3 SAP# 42214
Small Alcohol pads 200/BX SAP# 100019
Large Alcohol pads 100/BX SAP# 158228
43607 Soft Meter Isolation Bag (box=100) (protective sleeve) <b>Compulsory supply</b> SAP# 176441
Clorox ® Germicidal wipe, EPA Reg. No. 67619-12 SAP#165851
46827 StatStrip Batteries SAP# <b>Non-Stock item</b> Manufacturer: Nova Biomedical
Binder-For storage of Daily checklists and POC Accuracy Check Forms

<b>Equipment</b>
<i>StatStrip</i> ® Glucose Meter Model# 50088; Manufacturer: Nova Biomedical
<i>StatStrip</i> ® Docking Station Model# 4225; Manufacturer: Nova Biomedical
<i>StatStrip</i> ® Carrying Case; Manufacturer: Nova Biomedical
<i>StatStrip</i> ® Angled Wall Mount product # 46027 Kit Manufacturer: Nova Biomedical

**Data storage:** Patient tests: 1000  
 QC Tests: 200  
 Users: 4000

**Battery life:** 6 – 8 hours in use (approximately 40 tests). Return meter to docking station when not in use to maintain life of battery.

**Docking Station:**

The left light is green if the station is connected to the network.

The middle light flashes green if data is transferring.

The right light is green when the battery is fully charged or amber when charging.

**Reagents and Strips are available through CDHA stores.**



Sample	Sample type	Amount required	Transport and Storage	Stability
	Whole Blood: Arterial, venous, or capillary. Capillary whole blood from a finger prick is recommended	1.2 µL sample or drop of blood.	None	None

**Limitations:**

If needed, blood containing Sodium Heparin, Lithium Heparin, and Ammonium Heparin are the only acceptable anticoagulants used with the *StatStrip*® Glucose Meter.

**DO NOT** use blood samples containing EDTA, Citrate, Oxalate, and Sodium Fluoride anticoagulants with the *StatStrip*® Glucose Meter.

**Sample retention:** None

**Special Safety Precautions**

To ensure patient and operator safety users must follow the CDHA infection prevention and control guidelines and policy IC04-002. All patient samples, as well as the materials they contact, are to be considered biohazardous and therefore capable of transmitting infection or cross contamination. All CAP Survey samples are treated the same as they would be patients and thus all the same safety precautions are required.



**Maintenance**

**1. Meter Maintenance**

Step	Action
1.1	Clean the meter with a Clorox ® Germicidal wipe, EPA Reg. No. 67619-12 or equivalent <b>after each patient use</b> . Allow for a cleaning contact time of 1 minute and then immediately follow with a water-dampened cloth to remove all cleaning residue. Dry thoroughly with a soft cloth or lint-free tissue.  <b>Note:</b> The meter <b>must be kept horizontal</b> to avoid cleaning solution entering strip port which will cause damage to the meter. <b>DO NOT</b> immerse the meter or hold the meter under running water. <b>DO NOT</b> spray the meter with a disinfectant solution.
1.2	Clean monitor with a Clorox ® Germicidal wipe, EPA Reg. No. 67619-12 or equivalent when it becomes visibly soiled to remove all foreign matter allowing contact with the cleaner for one minute. Once visible soiling has been removed, repeat Step 1.1

**Note:** If replacement battery is required it is the responsibility of the individual cost center to order these replacement batteries.

**2. Daily Maintenance**

Step	Action
2.1	Clean meter. See step 1.1.
2.2	Clean meter tote using Clorox ® Germicidal wipe, EPA Reg. No. 67619-12 or equivalent.
2.3	Check Strip and QC bottles are dated. Discard any that have reached their “open date” expiry. See Materials section.
2.4	Check manufacturer expiry dates on strips and QC. Discard any that have reached their expiry date.
2.5	Run QC every 24 hours. See Procedure 4.
2.6	Place meter in docking station to recharge battery and download information.
2.7	Check off Daily/Monthly checklist. Retain in a binder available for review.

**3. Semi Annual Maintenance/ Troubleshooting**

Step	Action
3.1	Select patient that requires morning blood work for glucose.
3.2	Process patient for glucose monitoring testing within one hour of blood work being drawn. See Step 5.



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<b>Maintenance Cont'd</b>	3.3	Record serial number of meter on POC Accuracy Check Form.
	3.4	Record patient's glucometer result on POC Accuracy Check Form.
	3.5	Record patient's laboratory result on POC Accuracy Check Form.
	3.6	Fax result to Lab.
	3.7	File POC Accuracy Check Form in binder available for review.

**Frequency:** Every six months (March and September) on all unit glucometers and as required for troubleshooting.

**Note:** For checking accuracy of all glucometers. If there are any issues with a particular meter, the unit will be contacted by lab to send glucometer to BioMed.

**Calibration** Requires no calibration codes.

**Quality Control**

Control	Level	Stability	Frequency of Testing
StatStrip® Glucose/Ketone Control Solution	1 (Low)	<b>Store at RT.</b> <b>Stability :</b> 24 months from date of manufacture.  <b>Expire:</b> 90 days or 3 months after opening.	Daily
StatStrip® Glucose/Ketone Control Solution	3 (High)	<b>Store at RT.</b> <b>Stability:</b> 24 months from date of manufacture.  <b>Expire:</b> 90 days or 3 months after opening.	Daily

**Note: DO NOT** hold meter upright when applying blood or QC sample. Gently shake QC solution vial prior to performing QC testing. QC results reported in mmol/L.

- When to run QC** - Every 24 hours,
- When a new lot of test strips is started
  - If the meter has been dropped or damaged
  - To identify problems with the meter
  - Prior to running a repeat confirmation patient test



Procedure

1. Running Quality Control

Step	Action
1.1	Remove meter from docking station.
1.2	Turn meter on/Wake up meter. <b>Note: DO NOT touch screen with end of pen or hard nails, use soft pad of finger tips or eraser end of pencil. This prevents damage to the screen.</b>
1.3	Press <b>LOGIN</b> from Welcome or Home screen.
1.4	<b>Scan</b> Operator ID. <b>Note:</b> ID can also be entered using the touch screen. Buttons and touch screen are interchangeable.
1.5	Press <b>Accept</b>
1.6	Select <b>QC</b> icon on the "Patient Test" screen. <b>Note:</b> Meter goes into "sleep mode" after 90 seconds if no data entered. Touch screen to wake up. Will retain your last data entry.
1.7	Go to "Enter Strip Lot" screen.
1.8	Press "OK" if lot number is correct.
1.9	Go to "Enter QC Lot" screen. If lot number is incorrect
1.10	Scan QC Lot bar code from the side of the strip container.
1.11	Go to "Insert Strip" screen.
1.12	Insert strip in meter.
1.13	Go to apply sample screen.
1.14	Gently shake QC solution, discard first drop and place one drop from QC bottle to strip. Keep the meter horizontal and hold the strip to the drop and allow the tip of strip sip the drop rather than squeezing the drop from the bottle. <b>Note:</b> If the test strip does not fill completely <b>do not</b> touch droplet a second time. Discard strip and repeat. The meter <b>must be kept horizontal</b> when applying solution to avoid QC solution entering strip port which will cause damage to the meter.
1.15	Go to "testing sample" screen. Wait 6 seconds for results.
1.16	Remove and discard strip when result displays.
1.17	Go to "QC Result" screen. QC result will display as: <b>PASS</b> result appears in <b>Blue</b> <b>FAIL</b> result appears in <b>Red</b>  <b>Note:</b> If QC result is FAIL, check quality of QC solution used. Ensure the correct level is being used and is not past its expiry date. Repeat QC test. If second FAIL result obtained, do <b>NOT</b> use meter. Send meter to Biomed for investigation.
1.18	Repeat process with second QC solution.



Procedure  
Cont'd

**2. Patient Testing**

Step	Action
2.1	Place patient identification label on Capital Health patient record form.
2.2	Remove meter from docking station.
2.3	Place monitoring equipment on a cart or clean surface outside the patient's bed space. <b>Caution: The protective sleeve is compulsory</b> for the meter when entering a patient's room with a known or suspected infectious disease.
2.4	Decontaminate hands with alcohol hand rinse and don clean procedure gloves.
2.5	Turn meter on/Wake up meter. <b>Note: DO NOT touch screen with end of pen or hard nails, use soft pad of finger tips or eraser end of pencil. This prevents damage to the screen.</b>
2.6	Press <b>LOGIN</b> from Welcome or Home screen.
2.7	<b>Scan</b> the Operator ID. <b>Note:</b> ID can also be entered using the touch screen. Buttons and touch screen are interchangeable.
2.8	Select <b>Accept</b> on the "Patient Test" screen. <b>Note:</b> Meter goes into "sleep mode" after 90 seconds if no data entered. Touch screen to wake up. Will retain your last data entry.
2.9	Go to "Enter Strip Lot" screen
2.10	Scan the test strip lot bar code.
2.11	Press and quickly release scan icon or OK button. <b>Caution:</b> Do NOT hold button/icon as meter may skip screens.
2.12	Check patient information using two unique patient identifiers. Policy# CH 70-040
2.13	Go to "Enter Patient ID" screen.
2.14	Scan the patient ID. (Capital Health STAR encounter number) <b>Note:</b> ID can also be entered using the touch screen. Buttons and touch screen are interchangeable.
2.16	Press <b>Accept</b> .
2.17	Go to "Insert Strip" screen.
2.18	Insert test strip into meter.
2.19	Wash patient's hand thoroughly and massage finger to stimulate blood flow. If using alcohol or equivalent, ensure finger is dry before puncture.
2.20	Puncture finger using safety lancet. Dispose of lancet in sharps container.



<b>Procedure Cont'd</b>	2.21	Squeeze finger to form blood drop.
	2.22	Wipe away first drop of blood.
	2.23	Squeeze finger again to form blood drop.
	2.24	Go to "Apply Blood Sample" screen.
	2.25	Apply blood sample from patient to end of test strip. Keep the meter horizontal and hold the strip to the drop and allow the strip to take in the drop. (Sip the drop) <b>Note:</b> Place meter horizontal on bedside table or hold meter with wet test strip slanted downward.
	2.26	Go to "Testing Sample" screen. Wait 6 seconds for analysis. <b>Note: Do Not</b> touch blood droplet a second time if test strip does not fill completely. Discard strip and repeat. Meter allows 3 attempts to obtain sample if needed.
	2.27	Go to "Patient Result" screen.
	2.28	Remove and dispose of test strip in sharps container after results are displayed.
	2.29	View result and document on Capital Health patient record form.
	2.30	Select to Accept or Reject patient's results. <b>Note:</b> Rejection may be due to wrong patient, improper collection, or improper cleaning techniques before sampling.
	2.31	Log out
	2.32	Clean meter. Refer to Step 1.1
	2.33	Return meter to docking Station.

**Caution:** Critical results should **always** be confirmed by sending a sample to the lab and must be reported to a patient care provider who can take appropriate action.

If patient symptoms are inconsistent with results from the glucometer and procedural error is ruled out, the results should always be confirmed by sending a sample to the lab. If the lab result and the meter result do not correlate, take meter out of service and contact BioMed.

At sites where 24 hour lab service is not available, repeat sample (on a different device if available). A confirmatory lab test is strongly recommended.

**Note: Hand Hygiene**

- Wear gloves during blood glucose monitoring and during any other procedure that involves potential exposure to blood or body fluids
- Change gloves between patient contacts. Change gloves that have touched potentially blood-contaminated objects or finger stick wounds before touching clean surfaces. Discard gloves in appropriate receptacles
- Perform hand hygiene immediately after removal of gloves and before touching other supplies





**Procedure  
Cont'd**

**3. Viewing Other Test Results**

Step	Action
3.1	Remove meter from docking station.
3.2	Turn meter on/Wake up meter.
3.3	Press <b>LOGIN</b> from Welcome or Home screen.
3.4	<b>Enter or Scan</b> the Operator ID.
3.5	Select <b>Review</b> icon on the "Patient Test" screen.
3.6	Touch screen to highlight test result that you wish to view. Ensure correct time and date sample was selected to view.
3.7	Select <b>VIEW</b>
3.8	Use <b>up or down arrows</b> to view previous or next result.

**Result  
Interpretation**

- Blood Glucose Results appear:
- Normal range in **Blue**
  - Low or High in **Red with one Arrow**
  - Critical Low or High in **Red with two Arrows**

**Expected  
Values**

Analyte	Reference Range	Critical range	Analytical Range	Units
AC Glucose	3.6-5.6			
Random Glucose	3.9-7.8	<2.5 or >25.0	0.56–33.3	mmol/L

**Note:** In critical care areas the reference range may vary upon insulin infusion.



**Limitations**

If needed, sodium, lithium, and ammonium heparin are the recommended anticoagulants for use with the *StatStrip*® Glucose Meter.

When liquid heparin is present in excess, it may cause dilution errors.

EDTA, citrate, oxalate, and sodium fluoride are **NOT** recommended for use.

The Statstrip Glucose Meter exhibits no interferences from the following substances up to the following concentration levels:

<b>Interfering Substance</b>	<b>Concentration (mmol/L)</b>
Acetaminophen	0.55
Ascorbic Acid	0.55
Bilirubin	0.83
Cholesterol	27.7
Creatinine	0.33
Dopamine	0.55
Ephedrine	0.05
D (+) Galactose	19.4
Hematocrit (RBC)	20%-65%
Ibuprofen	2.6
L-Dopa	5.5
D (+) Maltose Monohydrate	13.3
D (+) Maltotetraose	13.3
D (+) Maltotriose	13.3
Methyl-Dopa	0.055
Oxygen	All Concentrations
Salicylate	1.7
Tetracycline	1.7
Tolazamide	0.83
Tolbutamide	2.5
Triglycerides	41.6
Uric Acid	1.1



**Procedural  
Notes**

**Cleaning / Disinfection of Glucometers:**

- ALL glucometers will be cleaned and disinfected using Clorox ® Germicidal wipe, EPA Reg. No. 67619-12 or equivalent.
- A 1:10 bleach solution is also acceptable (1 part bleach to 9 parts water)
- ALL glucometers that will be shared by multiple patients will be thoroughly wiped with disinfectant and allowed to air dry after every use and between every patient
  - Use a fresh Clorox wipe each time you clean a glucometer
  - Wipe all surfaces, top, bottom and sides, avoiding the bar code scanner and electrical connection
  - All to air dry before using on next patient
- A patient who is on additional precautions should have dedicated equipment
- If a glucometer being used for a patient on additional precautions (contact, droplet, or airborne) has to be used for more than one patient, then:
  - Glucose testing of a patient on additional precautions will be tested as last patient (if possible)
  - The glucometer to be used on a patient on additional precautions will be placed in a plastic isolation sleeve prior to use. The sleeve will be discarded after the single use
  - The glucometer to be used on a patient on additional precautions will be thoroughly wiped with disinfectant and allowed to air dry before being reused
- ALL glucometers that are visibly soiled will be cleaned and disinfected using the detailed cleaning procedure below.
- Prior to being returned to the docking station, ALL glucometers are cleaned and disinfected using the detailed procedure below:
  - Use a fresh germicidal wipe to thoroughly clean all external surfaces (top, bottom, sides) avoiding the bar code scanner & electrical connector. Discard the wipe.
  - Using a fresh germicidal wipe, thoroughly wipe all external surfaces of the meter in both horizontal and vertical directions avoiding the bar code scanner & electrical connector
  - Gently wipe the surface area of the test strip port making sure that no fluid enters the port
  - Ensure the meter stays wet for 1 minute and is then allowed to dry an additional minute.



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<b>Procedural Notes Cont'd</b>	<p><b>Points to remember:</b> Meter goes into “sleep mode” after 90 seconds if no data entered. Touch screen to wake up. Will retain your last data entry.</p> <p>Buttons and touch screen are interchangeable.</p> <p>Keep vial closed on Statstrips – they are affected by heat, light, and humidity. Listen for SNAP that lid is closed.</p> <p>Hold meter 10-13 cm away from barcode when scanning.</p> <p><b>Do Not</b> hold meter upright when blood sample or QC sample is wet.</p> <p>Always pay attention to blue dialogue box at top of each screen to ensure you are on the correct screen.</p> <p><b>When to contact BioMed :</b></p> <ul style="list-style-type: none"><li>- If unit will not turn on after battery charging is complete.</li><li>-If there is any physical damage to the screen or screen malfunctioning.</li><li>-If glucometer has been dropped.</li><li>- If glucometer has been submerged in a fluid.</li><li>- Any problems or error messages that indicate the meter is not functioning properly.</li></ul> <p><b>Maintaining Proficiency</b> For Accreditation Standards, an operator must complete the following within one year: one set (high and low) of daily QC <b>OR</b> five patient tests</p> <p><b>CAP Surveys (Proficiency Testing)</b> These surveys are received three times per year and compares CDHA glucometer results with other organizations. For Accreditation Standards, an operator may be required to perform this testing.</p> <p><b>Clinical Chemistry Comment</b> Comprehensive evaluations of Nova glucose meter have been performed. The meters show excellent precision and accuracy with a total CV&lt; 5% and bias &lt;3% when the glucose results from the Nova meter are compared to those from the core lab instruments. The glucose results from the Nova meters do not show significant interferences from maltose, abnormal Hct, acetaminophen, galactose, fructose, ascorbic acid and TPN. Although the Nova meters show excellent analytical performance, based on the guidelines, glucose results from POCT devices cannot be used as a tool for the diagnosis of diabetes. In addition, physicians are encouraged to confirm critical glucose results from the meters by referring venous blood glucose testing to the labs.</p>
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**Principle**

Glucose dehydrogenase is impregnated into the test area of a reagent strip (also called an electrode). This reacts with the glucose present in a blood sample and produces an electrical signal. This is detected by the meter and translated into a glucose result in mmol/L. The strength of signal produced is directly proportional to the amount of glucose in the blood.

**Related Procedures and Documents**

Document Name	Document #	Location
[Paralink:]	27042	Paradigm
Patient Identification and Same Name Alert	CH 70-040	Intranet
Diagnostic Tests - Requesting, Reporting of Results and Follow-up	CC 85-017	Intranet
Point of Care testing (POCT)	CH 70-110	Intranet
Hypoglycemia, Treatment for the Reversal of Mild, Moderate, and Severe	CC 15-025	Intranet

**Job Aid**

Document Name	Document #	Location
[Paralink:< <a href="#">Troubleshooting Nova StatStrip Glucometer Job Aid</a> >]	26463	Paradigm

**Reference**

Nova BioMedical StatStrip Glucose Hospital Meter: Instructions for Use Manual