



Nova StatStrip Glucometer General Information, Components and Supplies

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Nova StatStrip® Glucometer: General Information, Components and Supplies

Purpose:

This procedure provides a general overview of the Nova StatStrip® Glucose Hospital Meter System as well as information on related meter components, accessories and supplies.

I. General Information

Intended Use	The Nova StatStrip® Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of whole blood glucose.
Measurement (Technical) Range	<p>0.6 to 33.3 mmol/L Glucose</p> <p><u>Normal results</u> are displayed in BLUE.</p> <p><u>Abnormal patient results</u> will display on the meter in RED with a single red arrow for high or low.</p> <p><u>Critical high and low results</u> are identified in RED with double red arrows to alert the operator.</p> <p>If the value is outside the technical range of the meter, the low or high end of the technical range value displays as <0.6 (LO) or >33.3 (HI).</p>
Provincial Correction Factor	<p>0.3 mmol/L correction factor is added to the raw glucose result obtained from the Nova StatStrip® glucometer to correct for the negative bias when compared against plasma glucose levels</p> <p>The corrective programming of the meters is performed in the Aegis middleware, which eliminates further end-user correction or intervention.</p> <p><u>Correction equation:</u></p> $\begin{matrix} \text{Corrected Nova} & & \text{Default Nova} \\ \text{StatStrip® Glucose} & = & \text{StatStrip® Glucose} + 0.3 \text{ mmol/L} \\ \text{(mmol/L)} & & \text{(mmol/L)} \end{matrix}$

Written by: Juliето C. Tumalak
 Reviewed by: Juliето C. Tumalak
 Reviewed on: 2021-06-08
 Renewed by: Juliето C. Tumalak
 Renewed on: 2021-06-11



Approved by (sign.):
 Approved by (name): Li Wang
 Approved on: 2021-06-10
 Revision Date: 2024-06-11

	<p>The suitability of the correction equation will be reassessed with each glucose strip lot change by means of testing proficiency testing samples from CEQAL reference method laboratory.</p> <p>NOTE: CW in-house meter validation data reveal slightly higher difference in some patient sample comparisons; however, this difference is within acceptable limits based from both International Standards Organization (ISO) 15197:2013 and Clinical Laboratory Standards Institute (CLSI) POCT 12-A3 acceptability criteria (± 0.6 mmol/L or 15%, whichever is greater for 95% of the samples tested).</p>												
<p>Reference Ranges/ Meter Configurations</p>	<p>Province-wide glucose reference ranges:</p> <table border="1" data-bbox="570 810 1427 1152"> <thead> <tr> <th></th> <th>Normal Range</th> <th>*Critical Results</th> </tr> </thead> <tbody> <tr> <td>NEONATE (<28 days)</td> <td>2.6-7.0 mmol/L</td> <td><2.0 mmol/L >20.0 mmol/L</td> </tr> <tr> <td>NON-NEONATE (≥ 28 days)</td> <td>4.0-7.0 mmol/L</td> <td><2.6 mmol/L >25.0 mmol/L</td> </tr> <tr> <td>*ADULT (≥ 17 years old)</td> <td>4.0-11.0 mmol/L</td> <td><2.6 mmol/L >25.0 mmol/L</td> </tr> </tbody> </table> <p>NOTE:</p> <ol style="list-style-type: none"> Meters in CW and Affiliate Sites will either have Neonate or Non-Neonate configurations. Meters in BCMHA will only have the Adult configuration. NEVER move a meter from one ward/area to another ward/area. 		Normal Range	*Critical Results	NEONATE (<28 days)	2.6-7.0 mmol/L	<2.0 mmol/L >20.0 mmol/L	NON-NEONATE (≥ 28 days)	4.0-7.0 mmol/L	<2.6 mmol/L >25.0 mmol/L	*ADULT (≥ 17 years old)	4.0-11.0 mmol/L	<2.6 mmol/L >25.0 mmol/L
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<p>Acceptable Specimens</p>	<p>*Capillary whole blood (finger stick) Venous whole blood Arterial whole blood *Neonate heel stick specimens</p> <p><i>*Caution should be exercised when testing capillary whole blood due to potential pre-analytical variability in capillary specimen collection.</i></p>												
<p>Contraindications</p>	<p>Neonate cord blood specimens Screening or diagnosis of diabetes mellitus</p>												

Limitations	<ol style="list-style-type: none"> 1. Use only whole blood. Do NOT use serum or plasma. 2. Fresh whole blood or whole blood collected in lithium heparin collection devices should be used. If collected in plain syringes, make sure sample is mixed well and tested immediately to prevent clots. 3. Fluoride, EDTA, Sodium, and Ammonium blood collection devices should NOT be used for arterial and venous specimens (StatStrip Glu IFU, 2018, p. 1-7).
Sample Size	1.2 uL
Interfering Substances	See Appendix A.
Measuring Technology	<p>Enzyme, Amperometric Glucose Enzyme (Aspergillus sp., >1.0 IU)</p> <p>The glucose measurement is based on the following methodology:</p> $\text{Glucose} + \text{Enzymes(oxidized form)} \longrightarrow \text{Gluconic Acid} + \text{Enzymes(reduced form)} \quad \text{Equation 1}$ $\text{Enzymes(reduced form)} + \text{Ferricyanide} \longrightarrow \text{Enzymes(oxidized form)} + \text{Ferrocyanide} \quad \text{Equation 2}$ $\text{Ferrocyanide} \xrightarrow[\text{Electrode}]{-e^-} \text{Ferricyanide} \quad \text{Equation 3}$ <p>The current generated at the electrode is proportional to the glucose concentration of the sample.</p> <p>No calibration codes required.</p>
Analysis Time	<p>6 seconds</p> <p>NOTE:</p> <ol style="list-style-type: none"> a. There is no OFF switch. The meter is always ON. b. Meter goes to sleep mode after 90 seconds of inactivity. c. Touch the meter screen to wake it up: 4 seconds

Chemistry Measurement	The typical imprecision for glucose both for within-run and day-to-day:	
	Glucose Levels	%CV
	2.8 mmol/L	8%
	8.3 mmol/L	6%
	22.2 mmol/L	4%
	33.3 mmol/L	4%
Meter Memory	1000 Patient tests 200 QC tests 4000 Operators	
Environmental Factors	1. Operating temperature range: 15C to 40C. 2. Operating relative humidity range: 10-90% non-condensing 3. Operating maximum altitude: Up to 4500 meters	

II. Hardware Components

<p>Meter Dimensions</p>	<p>Height: 146 mm (5.8 in) Width: 79 mm (3.1 in) Depth: 30 mm (1.18 in) Weight: 220 g (0.49 lb)</p>
<p>Meter Front View</p>	 <p>Labels in the diagram:</p> <ul style="list-style-type: none"> Laser Barcode Scanner Screen Title Touch Screen On-screen Keypad Forward or Right Soft Key OK, Scan, Accept, etc. Soft Key Strip Port with GLU Strip Back or Left Soft Key
<p>Meter on Docking or Charging Station</p>	 <p>Labels in the diagram:</p> <ul style="list-style-type: none"> Charging Light for Spare Battery Green light on when connected to the network (Ethernet) Green light on when data is flowing Charging Light: Amber = Charging, Green = Fully Charged <p>The Ethernet <...> connection is at the back of the station</p>

III. Consumable Supplies

A. Glucose Test Strips

- 2 vials per box, 50 strips per vial
- Once opened, test strips are stable at room temperature for up to **180 days** (approximately 6 months) or until the manufacturer's expiration date, whichever comes first.
- **ALWAYS** write the Date Opened and Discard Date on the vial.
- Do NOT reuse test strips. It should be disposed after a single use.
- Blue color is top
- Gold end is inserted into the strip well at the bottom of the meter
- White end is the working part of the strip where the blood sample is applied



Keep vials tightly closed when not in use.
Store strips in original vial at room temperature (<30°C).



B. Quality Control Solutions

- Two levels of Quality Control (QC):
 - a. Level 1 – LOW (Green)
 - b. Level 3 – HIGH (Red)
- Once opened, QC material is stable at room temperature for up to **90 days** (approximately 3 months) or until the expiration date, whichever comes first.
- **ALWAYS** write the Date Opened and Discard Date on the vial.
- Always mix vials before testing.
- Discard the first drop of the solution prior to use.



Keep vials tightly closed when not in use.
Store controls at room temperature (<30°C).

C. Lancets

SteriLance (Domrex) Flex 3 Rose Red lancet

- Adjustable depth settings: 1.3mm, 1.8mm, 2.3mm
- Width specification: **30G**
- **Indicated for finger pokes in older children and adults**
- Suggested depth settings to use:
 - a. 1.3mm – young children
 - b. 1.8mm – teenagers
 - c. 2.3mm – adults
- See Appendix B for instructions on how to adjust lancet depth



SteriLance (Domrex) Flex 3 Yellow lancet

- Adjustable depth settings: 1.3mm, 1.8mm, 2.3mm
- Width specification: **26G**
- Approved **alternate** product
- **Indicated for finger pokes in older children and adults**
- Suggested depth settings to use:
 - a. 1.3mm – young children
 - b. 1.8mm – teenagers
 - c. 2.3mm – adults
- See Appendix B for instructions on how to adjust lancet depth



Safe-T-Lance Pink

- Fixed depth: 1.2mm
- Width specification: 1.5mm
- Indicated for neonate/infant heel pokes (all weights)



IV. Accessories

A. Battery

Rechargeable/replaceable 3.7V lithium polymer

Typical life of fully charged battery is 8 hours or 40 tests (when not docked).

Do NOT disassemble, expose to heat above 100°C, or incinerate batteries.

Batteries have expiration date, and it can be found in the upper right hand corner of the label next to the hour glass.

Dispose of battery when it exhibits any of the following:

- has exceeded its expiration date
- swelling, cracking, or damage to the battery case
- leakage
- failure to hold a proper charge

Batteries can be ordered by wards/clinical sites directly from supply stores.



B. Docking/Charging Station – Front View

Meter docking/charging stations come in different types: single, dual and quad.



The right indicator light color is amber when the meter is charging.



The right indicator light will turn green when the battery is fully charged.



The left light shows that the dock is linked to the hospital network via an Ethernet connection.

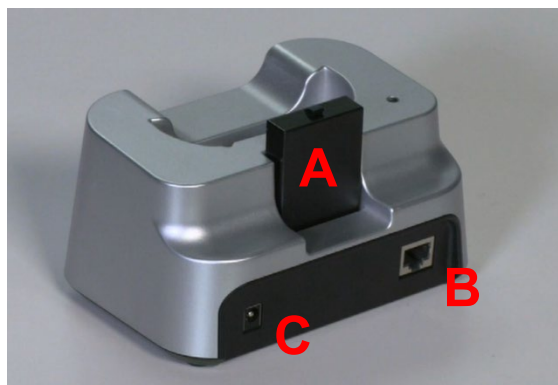


The center activity light will flash, indicating that there is network activity.



C. Docking/Charging Station – Back View

- A. All docking/charging stations provide compartments for storing and charging spare batteries.
- B. Ethernet adaptor port
- C. Power adaptor port

**D. Carrying Case**

Carrying cases can be used for transporting the meter, but NOT for storing the meter.

All contents of the carrying case are restocked by the ward/clinical site.

**References:**

1. BC Provincial Laboratory Medicine Group. Notice of Provincial Correction Factor for Nova StatStrip® Glucometers. November 13, 2020.
2. Domrex Pharma: SteriLance Flex 3 Depth Adjustable Safety Lancet Information Sheet, SteriLance Medical, V.201608.
3. Nova Biomedical. StatStrip® Glucose Hospital Meter System: Instructions for Use Manual. REF 55848. September 2018.
4. Nova Biomedical. Nova StatStrip® Glucometer Operator Training Video (Provincial Health PHSA 1.75 & Wireless Glucose MMOL CA).

Appendices:

Appendix A: Interfering Substances

Appendix B: SteriLance Flex 3 Lancet: Instructions for Use

Appendix A

Interfering Substances

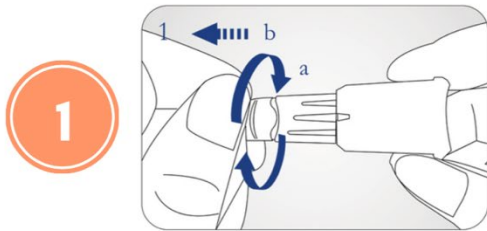
The Nova StatStrip® Glucose Hospital Meter System exhibits NO interference up to the following concentration levels:

Tested Interfering Substances	Tested Concentration Level	
Acetaminophen	20.0 mg/dL	1.323 mmol/L
Acetoacetate	51.0 mg/dL	5 mmol/L
Acetone	69.7 mg/dL	12 mmol/L
Acyclovir	0.6 mg/dL	0.027 mmol/L
Albuterol	0.06 mg/dL	0.0025 mmol/L
Amitriptyline	0.06 mg/dL	0.0022 mmol/L
Amoxicillin	5 mg/dL	0.137 mmol/L
Ampicillin	0.8 mg/dL	0.0229 mmol/L
Ascorbic Acid	22.5 mg/dL	1.278 mmol/L
Atropine	0.01 mg/dL	0.000346 mmol/L
Beta-hydroxybutyrate	166.6 mg/dL	16 mmol/L
Bilirubin	29.3 mg/dL	0.5 mmol/L
Captopril	0.6 mg/dL	0.0276 mmol/L
Carbamazepine	1 mg/dL	0.0423 mmol/L
Cefaclor	35 mg/dL	0.952 mmol/L
Cholesterol	1000 mg/dL	25.86 mmol/L
Cimetidine	5 mg/dL	0.198 mmol/L
Citric Acid	384.3 mg/dL	20 mmol/L
Creatinine	6 mg/dL	0.53 mmol/L
Digoxin	0.3 mg/dL	0.0038 mmol/L
Diltiazem	0.1 mg/dL	0.0024 mmol/L
Dopamine	20 mg/dL	1.306 mmol/L
Enalapril	0.5 mg/dL	0.0133 mmol/L
Ephedrine	1 mg/dL	0.0605 mmol/L
Ethanol	399.9 mg/dL	86.8 mmol/L
Famotidine	0.042 mg/dL	0.0012 mmol/L
Fluconazole	2 mg/dL	0.0653 mmol/L
Fluoxetine Hydrochloride	2 mg/dL	0.0647 mmol/L
Fructose	500 mg/dL	27.75 mmol/L
Furosemide	3 mg/dL	0.0907 mmol/L
Galactose D(+)	500 mg/dL	27.75 mmol/L
Galactose-1-Phosphate	500 mg/dL	19.22 mmol/L
Gentamicin sulfate	12 mg/dL	0.2513 mmol/L
Glycerol	500 mg/dL	54.30 mmol/L
Heparin	1.2 mg/dL	N/A
Hydrochlorothiazide	2 mg/dL	0.0672 mmol/L
Hydrocortisone	20 mg/dL	0.552 mmol/L
Ibuprofen	48.0 mg/dL	2.33 mmol/L
Ketoprofen	6 mg/dL	0.236 mmol/L
Lactose	500 mg/dL	14.61 mmol/L
Lansoprazole	20 mg/dL	0.542 mmol/L
L-dopa	5 mg/dL	0.25 mmol/L
Levofloxacin	1.8 mg/dL	0.0498 mmol/L

Tested Interfering Substances	Tested Concentration Level	
Lidocaine	0.7 mg/dL	0.0299 mmol/L
Lisinopril	0.5 mg/dL	0.0123 mmol/L
Maltose D(+)	500 mg/dL	14.61 mmol/L
Maltotetraose D(+)	240 mg/dL	3.6 mmol/L
Maltotriose D(+)	240 mg/dL	4.76 mmol/L
Mannitol	6000 mg/dL	329.4 mmol/L
Mannose	500 mg/dL	27.75 mmol/L
Methy-dopa	1.0 mg/dL	0.042 mmol/L
Metoprolol Tartrate Salt	1.8 mg/dL	0.0673 mmol/L
N-acetylcysteine	81.6 mg/dL	5 mmol/L
Naproxen	40 mg/dL	1.74 mmol/L
Nifedipine	0.02 mg/dL	0.00058 mmol/L
Norepinephrine	10 mg/dL	0.591 mmol/L
Nortriptyline Hydrochloride	0.02 mg/dL	0.00076 mmol/L
Olanzapine	0.02 mg/dL	0.00064 mmol/L
Pancuronium bromide	0.4 mg/dL	0.0070 mmol/L
Penicillin	72 mg/dL	2.02 mmol/L
Phenytoin	2.5 mg/dL	0.099 mmol/L
Prednisone	1 mg/dL	0.0279 mmol/L
Propofol	3.2 mg/dL	0.18 mmol/L
Propranolol Hydrochloride	0.3 mg/dL	0.012 mmol/L
Ranitidine hydrochloride	1 mg/dL	0.032 mmol/L
Salicylate	120.0 mg/dL	7.50 mmol/L
Sodium Chloride <i>Deviation from a normal sodium or chloride level</i>	234 mg/dL	40 mmol/L
Sodium Nitroprusside dihydrate	0.05 mg/dL	0.0019 mmol/L
Sorbitol	500 mg/dL	27.45 mmol/L
Sucrose	500 mg/dL	14.61 mmol/L
Sulfamethoxazole	1.5 mg/dL	0.059 mmol/L
Tetracycline	30 mg/dL	0.675 mmol/L
Theophylline	2 mg/dL	0.111 mmol/L
Tolazamide	45 mg/dL	1.45 mmol/L
Tolbutamide	50 mg/dL	1.85 mmol/L
Triglyceride	1500 mg/dL	16.9 mmol/L
Uric Acid	23.5 mg/dL	1.4 mmol/L
Vancomycin hydrochloride hydrate	3 mg/dL	0.021 mmol/L
Verapamil Hydrochloride	0.1 mg/dL	0.0022 mmol/L
Warfarin	1.2 mg/dL	0.039 mmol/L
Xylose	500 mg/dL	33.3 mmol/L
Hematocrit	20% and 70%	
Oxygen	All concentrations	
pH	6.6 and 8.0	

Appendix B

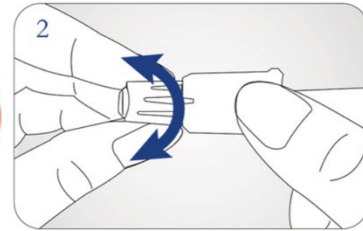
SteriLance Flex 3 Lancet: Instructions for Use



1

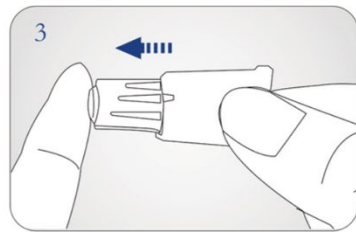
Twist off the cap first, then pull it gently.

***It is important to completely twist the cap at 360° before removing it and DO NOT apply force to pull it out.**



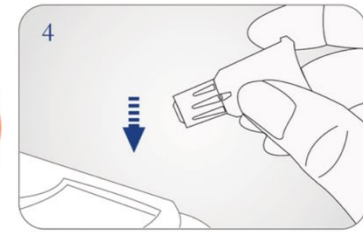
2

Rotate the adjustable tip (white part) to set the desired depth.



3

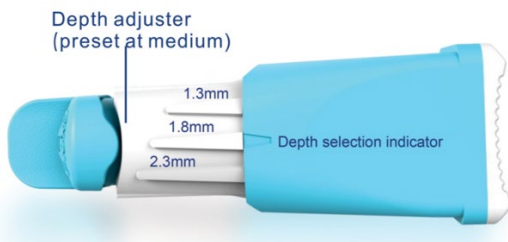
Place the lancet body firmly against the puncture site to activate the device.



4

Dispose of the used lancet in a suitable sharps container.

Depth adjuster and settings the same across lancet models.



Blue: For illustration purpose only



Flex 3 Rose Red
(Approved for use)

Source:

Domrex Pharma: SteriLance Flex 3 Depth Adjustable Safety Lancet Information Sheet, SteriLance Medical, V.201608.

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