XXX##-Nova Stat Strip Glucometer Procedure

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1.0 PURPOSE:

1.1 To describe the procedure for use of the Nova Stat Strip glucometer as a point of care device

2.0 INTENDED USE:

2.1 The StatStrip Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in whole blood samples throughout all hospital and all professional healthcare settings.

3.0 PRINCIPLE:

3.1 The NOVA StatStrip Hospital Meter quantitatively measures glucose in whole blood both enzymatically and amperometrically.

4.0 SCOPE:

4.1 Personnel of the New York Presbyterian Brooklyn Methodist Hospital who have been trained and found competent to perform waived testing procedures.

4.2 Applies to PFI listed below:

- 4.2.1 PFI# 4579
- 4.2.2 PFI#8960
- 4.2.3 PFI#X848
- 4.2.4 PFI#S875

5.0 INSTRUMENT / EQUIPMENT:

5.1 StatStrip Glucometer

- 5.1.1 StatStrip Glucometer: store at 15 C to 40 C (59 to 104 F)

5.2 Docking Station

5.3 Lithium Battery

- 5.3.1 Battery: store below 60 C (140 F).
- 5.3.2 Discard properly after expiration date on the label or after battery damage.
- 5.3.3 Battery replacement (when low battery is indicated):
  - 5.3.3.1 Pull back on the back-cover latch and remove the cover.
  - 5.3.3.2 Grasp the battery and remove it.
  - 5.3.3.3 Replace the battery with spare in base.
  - 5.3.3.4 Place drained battery in docking station for recharging.

5.4 Troubleshooting

Condition	Explanation	Action
Low Battery	Battery charge too low to continue.	Replace battery or return meter to docking/charging station.
Analysis Cancelled	Test Strip was removed or loosened	Repeat test with new Test Strip. Leave strip in place until result is displayed on screen.
Temperature Error	Temperature must be 59-104°F.	Re-locate the meter to an environment within specified temperature range.
Bad Sample	Sample not accepted.	Repeat the test with a new strip. If the error recurs, use alternate testing method.
Replace Strip	Strip damaged.	Repeat the test with a new strip.
Flow Error	Insufficient sample or incorrect sample application.	Repeat the test with a new strip. If the error recurs, use alternate testing method.

Manufacturer/Contact: Nova Biomedical, 200 Prospect Street, Waltham, MA 02454, 1-800-545-6682. www.novabiomedical.com.

6.0 SPECIMEN:

6.1 Venous whole blood (fingerstick or neonatal heel stick)
6.2 Arterial whole blood
    6.2.1 Collected in a heparinized syringe or Lithium Heparin tube.
6.3 Sample volume: 1.2 uL

7.0 SAFETY INFORMATION:

7.1 All point of care devices can potentially transfer biohazardous materials and employees must use appropriate PPE when using them (i.e. gloves when handling devices and eye cover when handling liquid control materials).

8.0 ENVIRONMENTAL REQUIREMENTS:

N/A

9.0 REAGENT / MEDIA:

Reagent	Storage	Open Expiration Date
StatStrip Glucose Test Strips	15-30C	6 months or original printed date; whichever is sooner

StatStrip Glucose Control-Level 1	15-30C	3 months or original printed date; whichever is sooner
StatStrip Glucose Control-Level 3	15-30C	3 months or original printed date; whichever is sooner

10.0 SUPPLIES / MATERIALS:

10.1 For Cleaning and Disinfection:
- 10.1.1 Clorox Healthcare Germicidal Bleach Wipes, EPA Registered 67619-12
- 10.1.2 Frequency – Clean and Disinfect after EVERY patient.

11.0 CALIBRATION:

N/A

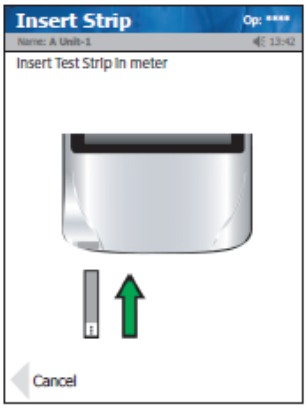
12.0 QUALITY CONTROL:

12.1 Level 1 and 3 controls must be performed once every 24hours.
12.2 Verify strip and QC materials are within expiration date.
12.3 Press <Log-In> on the glucometer
12.4 Enter employee ID
- 12.4.1 Scan small barcode on employee ID badge
- 12.4.2 Alternatively, manually enter the employee ID number into the device.

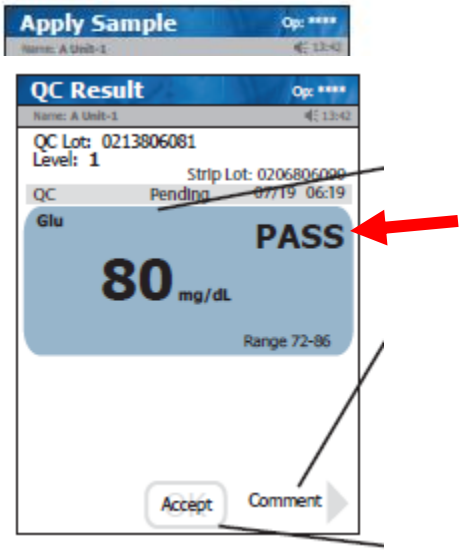
12.5 Press “Accept”
12.6 If QC is required, the device will alert the user with one of the following messages:
- 12.6.1 QC Due: XX:XX hrs
- 12.6.2 LOCKED: Perform QC before Patient Testing
- 12.6.3 QC Required
- 12.6.4 NOTE: if an “Invalid Reagent” message is received, it may indicate a new lot of QC material is in use and requires validation and activation from the POC staff. Notify POC staff during the next business day.

12.7 If the message “Press OK to begin testing” appears, skip to step….
12.8 Press the <QC> key
- 12.8.1 The device will prompt “Enter Strip Lot”.
  - 12.8.1.1 If the Strip Lot is New, scan the barcode on the side of the StatStrip Vial, by pressing Clear, followed by Scan.
  - 12.8.1.2 If the Lot is Current, press Accept.
- 12.8.2 The Device will prompt “Enter QC Lot”.
  - 12.8.2.1 Press <scan> at the bottom of the screen and scan the barcode on the side of the control vial. The device will automatically recognize if it is level 1 or 3.
  - 12.8.2.2 Once the correct lot number appears at the top of the screen press <Accept> at the bottom of the screen

12.8.3 The Insert Strip screen will display. Insert a Test Strip as shown (below).



12.8.4 With the test strip correctly inserted, the "Apply Sample" screen displays.
12.8.5 Gently mix the STatStrip Glucose Control Vial before use
12.8.6 Place a drop of control solution from the bottle on the end of the test strip until it is drawn into the well of the test strip. An audible beep will sound when enough sample has been drawn into the strip.



12.8.7 When the test is complete, the QC result screen displays the result and either "PASS" or "FAIL" message. Discard the test strip.
12.8.7.1 If the QC result is acceptable, press the <Accept> key and skip to step 12.8.8.
12.8.7.2 If the QC result is unacceptable, repeat the test with a new strip after confirming the reagents are not past expiration.
12.8.7.2.1 If the second test fails, inspect and clean the instrument.
12.8.7.2.2 If a third test fails, contact the POC department during the next business day.
12.8.8 Repeat steps 12.8 with the other control level.
12.8.9 Controls should also be performed under the following circumstances:

12.8.9.1 Each new operator
12.8.9.2 If patient results are lower or higher than expected
12.8.9.3 Any indications the that the system is not working properly

13.0 PROCEDURE:

13.1 From the “Welcome” screen, press the <Login> button.

13.2 “Enter Operator ID” will appear at the top of the screen:

13.2.1 Press <Scan> and scan the user barcode, or enter the user ID manually using the keypad.

13.2.2 Press <Accept>, the “Patient Test” screen will appear.

13.3 From the “Patient Test” screen, press the <Accept> key.

13.4 The “Enter Strip Lot” screen displays:

13.4.1 Press <Scan> and scan the strip lot number.

13.4.2 Verify that the strip lot number displayed is correct and press <Accept>.

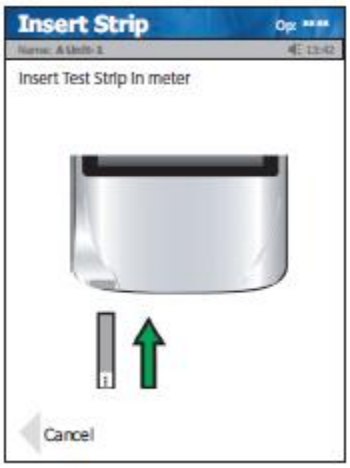
13.5 The “Enter Patient ID” screen will appear:

13.5.1 Enter Patient ID (Financial Number, scanned from bracelet), by scanning the patient’s wristband

13.5.2 Verify the patient information on the screen and press <Accept>.

13.6 The “Insert Strip” screen will appear;

13.6.1 Insert the test strip into the glucometer’s strip port, gold end first.

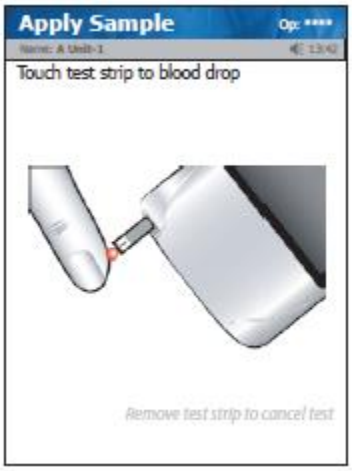


13.7 The “Apply Sample” screen will appear:

13.7.1 Perform the finger or heel stick procedure, ensuring that the site is clean and dry.

13.7.2 Squeeze the site gently to form a drop of blood. Wipe away the first drop of blood and then squeeze the finger to form a second drop.

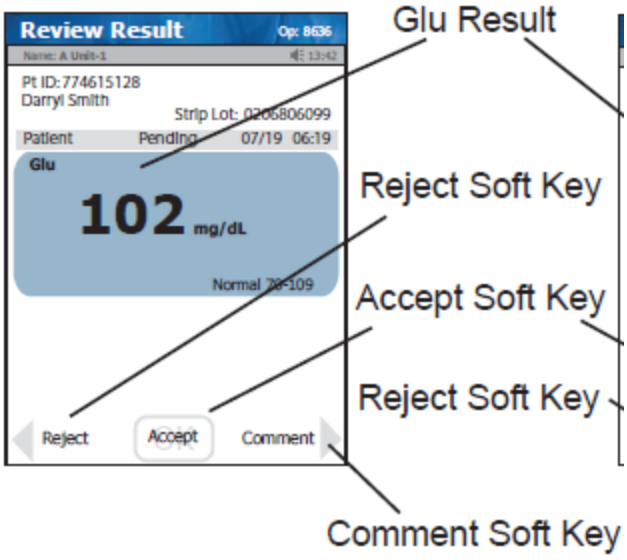
13.7.3 Touch the end of the TestStrip to the blood drop, maintaining contact until the 6 second countdown begins and a beep is heard.



13.7.4 Alternately, apply a drop of well mixed heparinized whole blood from a tube or syringe.

13.8 Once the result appears, remove the TestStrip manually or use the strip ejector at the back of the meter and discard into appropriate waste container.

13.9 Select <Reject>, <Accept>, or <Comment>:



13.9.1 If "Accept" is selected, the glucometer will be ready for the next patient.

13.9.2 If "Comment" is selected, choose the comment by touching it on the screen. It will highlight in black. Press <Accept>. You may select up to three comments per result.

13.9.3 If "Reject" is selected, add comments, if required, and repeat the test as necessary.

13.9.4 If the result is Critical, see Results Section below.

13.10 After Every patient use, clean the glucometer by wiping the external surface of the device thoroughly with a fresh germicidal disinfecting bleach wipe:

13.10.1 Thoroughly wipe the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally followed by 3 times vertically avoiding the barcode scanner and electrical connector.

13.10.2 Gently wipe the surface area of the TestStrip port making sure that no fluid enters the port.

13.10.3 Ensure that the glucometer surface stays wet for 1 minute and is allowed to air dry for an additional 1 minute.

13.10.4 Remove any residue with a soft cloth dampened with water.

13.10.5 The Cleaning of the Glucometer must be documented..

13.10.5.1 Select the Comment Section on the Glucometer Screen.

13.10.5.2 The Comment Menu will appear.

13.10.5.3 Select "Cleaned Meter".

13.10.5.4 Accept Result.

13.11 Once testing is complete, return the glucometer to the docking station. Ensure that the glucometer is securely seated in the dock and that all lights are illuminated on the base.

14.0 RESULTS:

14.1 The Glucometer allows you a Selection of Reject, Accept, and/or Comment for each result.

14.1.1 When a Critical Value is apparent, this will appear on the Glucometer Screen in Red with a "Critical" sign. The Critical Result reporting must be documented.

14.1.1.1 When the Critical Value occurs, the Comment Screen will pop up, automatically.

14.1.1.2 Select "MD Notified", which should be the first selection on the Comment List.

14.1.1.3 Accept the Result. These Comments will be transferred to EPIC, along with Glucose Value.

14.1.2 Free Text option can also be selected, once you are on the Comment Screen, and messages can be entered in text fashion.

14.1.3 Up to three Comments can be accepted for each Result.

14.2 Result is transferred from the glucometer to the patient chart via WiFi wireless transfer.

14.2.1 Alternately, if WiFi service is unavailable or interrupted; data will transfer after docking the device.

15.0 CRITICAL VALUE(S):

15.1 ADULTS: Blood glucose results of < 41 mg/dl or > 449 mg/dl are critical and should be verified by sending a specimen to the laboratory. This is at the discretion of the physician.

15.2 NEONATES: Blood glucose results of < 41 mg/dl or > 200 mg/dl are critical and should be verified by sending a specimen to the laboratory. This should be at the discretion of the physician.

16.0 TEST PERFORMANCE SPECIFICATIONS:

N/A

17.0 ALTERNATIVE TESTING:

Serum glucose performed in the Core Lab

18.0 METHOD LIMITATIONS

N/A

REFERENCE(S):

Nova Biomedical. Instructions for Use Manual StatStrip Glucose Hospital meter System. REF:55848.

RELATED DOCUMENT(S):

N/A