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IV. Performance of Quality Control

- A. Purpose: To detect any errors due to system failures or operator performance
- B. Frequency: Levels 1 and 3 controls are run every 24 hours of use.

C. Quality Control Testing Procedure: ALWAYS keep meter on a flat surface when performing QC tests. This avoids getting QC material inside strip port.

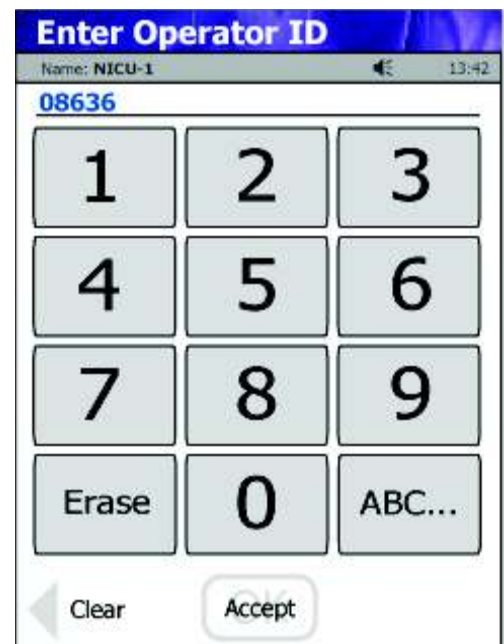
1. Remove StatStrip meter from docking/charging station
2. At the WELCOME screen, press LOGIN button.
3. At the Enter Operator screen, scan or type assigned operator ID.


NOTE:

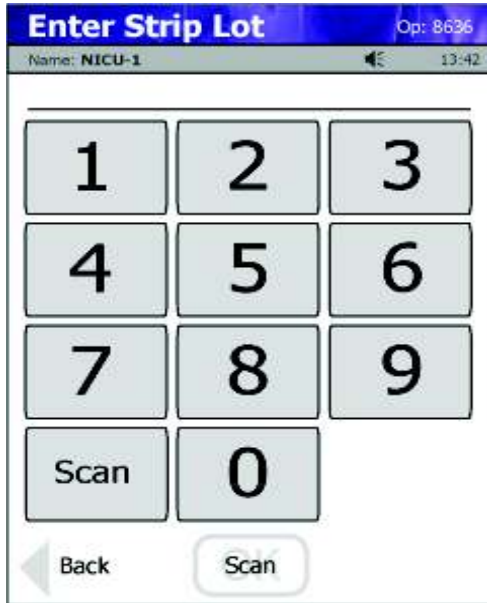
- Only operators who have been trained can use the StatStrip Glucose meter.
- Operator ID's are stored in a central database maintained by the Point of Care testing coordinator.
- Non-validated operators are "locked-out and cannot access the meter.

4. Press ACCEPT Key

5. From the PATIENT TEST screen, touch the QC soft button.



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6. At the ENTER STRIP LOT screen, enter test strip lot number by pressing the SCAN button and scanning the barcode on the test strip vial.
7. When lot number has been scanned and appears, press ACCEPT
8. At the ENTER QC LOT screen, press the scan button and scan the barcode on the vial of QC material.

NOTE: The Quality control may be performed in any order.

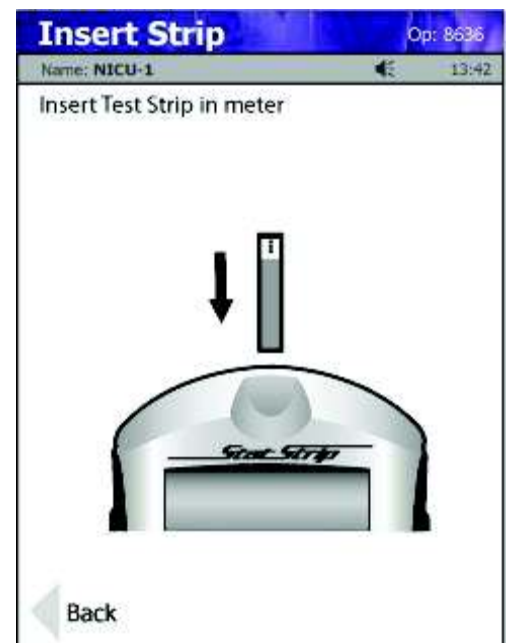
9. When the QC lot is successfully scanned, the INSERT STRIP screen will be presented (see right).


10. Remove a test strip from vial and insert as shown.

NOTE: If bottle is opened for the first time, you must write date opened and 6 month discard date where indicated on vial.

11. When the test strip is inserted, the APPLY SAMPLE screen will display.

NOTE: If QC vial is opened for the first time, you must write 3 month discard date on vial.



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NOTE: Screen will display which bottle of control needs to be applied to the strip. If Level 1 bottle was scanned, display will read, “ Touch test strip to Level 1” bottle.

12. With the meter level, place a drop of the control solution from the bottle to 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. The meter will count down 6 seconds once the sample has been properly applied.

13. Result is displayed as either a PASS or FAIL.
- a. If the QC level PASSES – repeat steps C. 1 – 13 with alternate level of control.
 - b. If the QC level FAILS –
 - The operator will be required to enter a comment
Procedure Error – use if operator scanned one level but performed the test on the alternate level
Repeat QC – should be applied to all Failed QC
 - Mix QC vial and repeat test
 - If QC FAILS again, use another QC vial
 - If QC FAILS with another QC vial – contact POC Coordinator at 688-5212.

NOTE: The operator will not be able to perform patient testing until both QC levels PASS.

14. IMMEDIATELY, remove test strip and discard.

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V. Patient Testing

NOTE: Gloves must be worn when performing patient testing:

1. Remove StatStrip meter from docking/charging station.
2. At the WELCOME screen, press LOGIN button.
3. At the Enter Operator screen, scan or type assigned operator ID.

NOTE:

- Only operators who have been trained can use the StatStrip Glucose meter.
- Operator ID's are stored in a central database maintained by the Point of Care testing coordinator.
- Non-validated operators are "locked-out" and they cannot operator the meter.



4. Press ACCEPT Key

5. At the PATIENT TEST Screen, press ACCEPT key.

NOTE: GLU Test is automatically highlighted


6. At the ENTER STRIP LOT screen, enter test strip lot number by pressing the scan button and scanning the barcode on the test strip vial.

7. When lot number has been scanned and appears, press ACCEPT.

8. At the ENTER ACC# screen, scan the barcode located on the Patient's wristband. The ACC # is the patient's EPIC CSN #.

9. Press ACCEPT.



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10. If the patient’s registration information has been uploaded to the meter, the screen will display, “Valid Patient ID message”. The patient demographics will appear at the bottom of the screen.

- a. The operator must confirm this is the patient they want to test (confirm patient name and date of birth)
- b. If the incorrect patient demographics appear, select the BACK button and re-enter the CSN number.

NOTE: Only valid patient CSN numbers will allow results to cross from the meter to the patient’s electronic medical record.

- If a valid patient ID is not available when patient testing is needed , alternative identification is:

Unidentified Number for ED patients
 Patient Date of Birth (MMDDYYYY)

If none of these are available – use of 0000000 can be used. The POCT coordinator must be notified of the patient’s identity for the results to be entered into their medical record.

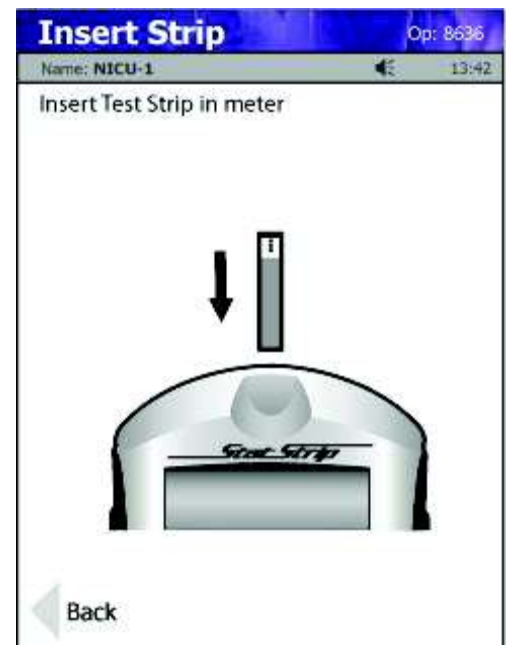
11. If the patient’s registration information has not been uploaded to the meter, the operator will see the CSN number and the message, “Invalid Patient ID”.


- a. The operator must confirm that the number displayed is the correct ID for the patient being tested.
- b. Once they confirm the ID, the operator can press the DOWNTIME OVER-RIDE button to proceed with testing.

12. At the INSERT STRIP screen, remove test strip from vial.

13. Collect sample using standard fingerstick technique.

14. Holding meter in a downward position, touch the tip of the strip to the blood drop until all the wells are filled and the meter beeps (meter will start to count down from 6 seconds).




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*WARNING: The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, remove the strip **DO NOT TOUCH THE TEST STRIP TO THE DROPLET A SECOND TIME.** Discard the test strip and repeat with a new test strip.*

NOTE: Tap meter screen prior to sample application. This prevents the meter from going into “Sleep” mode during testing.

15. After 6 seconds, the patient’s glucose result will display
 - a. Results displayed in blue are considered non-critical results
 - b. Results displayed in red are critical results and require a comment
 - Select from the comment menu on the meter
 - The operator can select up to three comments
16. The operator must press the ACCEPT key to store patient results.
17. Immediately remove strip from meter and discard in appropriate biohazard container.
18. Discard used lancet in sharps container
19. Clean meter to remove any blood on surface. Followed by disinfecting with SuperSani wipes.

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VI. Reporting Results

A. Reference Range: 70 – 100 mg/dL Adult Fasting glucose

B. Critical Results: Test results are flagged in RED to alert the operator of levels that may require immediate action. While these are identified as “critical results”, not all results may be immediately life-threatening. The flags were set at levels meant to initiate early intervention.

1. General Adult and Pediatric alert flags: ≤ 69 and ≥ 300 mg/dL
2. Perinatal alert Flags: ≤ 69 and ≥ 200 mg/dL
3. Newborn/Infant alert Flags: ≤ 45 and ≥ 150 mg/dL

C. Critical Results action

1. First time critical values should be repeated using the glucose meter.
2. Follow unit or service line specific protocols when alerted by a critical value.


D. Reportable Range: 10 – 600 mg/dL

Refers to the detection limits of the meter the meter will not report numbers outside of this range.

1. When a result of LOW appears, the result of less than 10 mg/dL appears in the RED area of the screen.
 - A sample must be sent to the lab for confirmation
 - Notify the physician immediately
2. Then a result of HI appears, the result of greater than 600 mg/dL appears in the RED area of the screen.
 - A sample must be sent to the lab to obtain a definitive result
 - Notify the physician immediately

E. Reporting Results:

1. Document glucose result in appropriate area of the patient’s electronic medical record (electronic flow sheet). Preferred method is to have results upload directly to EMR.

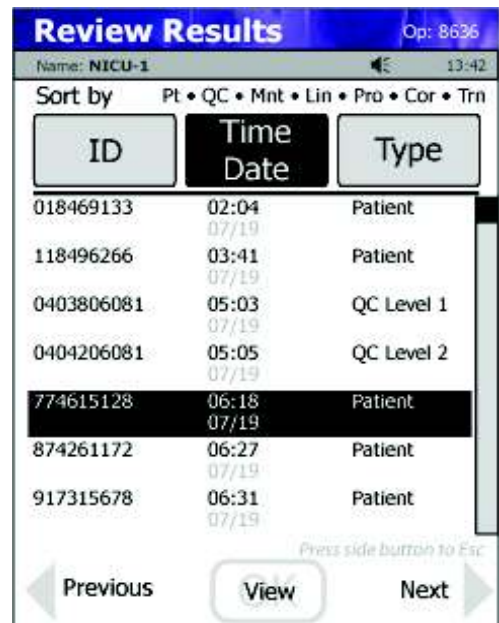
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VII. Review Results

Used to look for results previously performed on the meter.

NOTE: Results can only be seen on the meter the test was performed.


1. Log into the meter with operator ID
2. On the PATIENT TEST screen, select the review button (Lower left of screen)
3. Press on the desired record to highlight.
4. Select the VIEW button to display result.
5. Pressing NEXT or PREVIOUS will scroll up or down the result review screen.



2. Place meter back in docking station for results to upload to electronic medical record.

3. When the left and center lights are green, the docking station is connected to the network. The middle light will blink. The indicator light on the right, when green indicates a fully charged battery.



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VIII. Operator Log out

Log out of the meter when done. The operator is responsible for everything that is done under their operator ID.

There are 4 ways to log out of the meter:


1. Place the meter in the docking station
2. Press the LOG OUT button on the meter
3. Pressing on the operator name on the upper right corner of the meter screen will display the LOG OUT button.
4. After 5 minutes of inactivity, the meter will automatically log off the user.

NOTE: Leaving the meter unattended with the operator's log-in active, may result in another user operating the meter under the wrong operator ID.
DO NOT RELY ON AUTOMATIC LOG OFF>

IX: Maintenance:

A. Cleaning:


1. Frequency
 - a. When using a meter for multiple patient, clean after each patient.
 - b. If a meter is designated for a single patient, clean when there is visible blood on the surface of the meter. The meter must be cleaned before use on a new patient.
 - c. Always clean meter when there is visible blood.
2. Cleaning and disinfecting method:
 - a.. Remove SuperSani-wipe from dispenser. Wipe down surface of meter. If there is visible blood present, wipe to remove debris, then, using a second wipe, disinfect by wiping the meter again.
 - c. Allow the meter to dry for at least 2 minutes before use on another patient.

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B. Battery Change: If meter is left outside the docking station, the battery will discharge. The operator will see a BATTERY LOW message in RED on the screen. Remove the back from the meter and insert new, charged battery. Replace cover. Place meter back in docking station to charge.

NOTE: A spare battery can be charged in the back of the docking/charging station.



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X. Trouble- Shooting

- A. Meter is frozen and will not respond
 - 1. Remove battery, wait 10 seconds and replace the battery,
(Removing the battery will re-boot the meter)
- B. **FLOW ERROR** – the specimen was incorrectly drawn in the test strip due to either insufficient or incorrect sample application. Repeat test with a new strip. If error persists, contact the POCT Coordinator and use an alternate meter.
- C. **TEMPERTURE** – the meter will only work within the temperature range of 59°F to 104°F (15°C to 40°C). A temperature error message will appear on the screen.

XI. References

- A. Nova Biomedical: Instructions for Use Manual, Stat Strip Glucose Hospital Meter. REF 41853. Copyright 2011, Nova Biomedical Corporation, Waltham, MA 02454-9141.
- B. Nova Biomedical Glucose Hospital Meter Test Strip – Package insert. REF 42214. LPN 48372(H)510k. 9/2014.