



POLICY TITLE: Bedside Glucose Meter Procedure-NOVA StatStrip®

Responsible Department: Laboratory Services

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APPROVED BY: Evidence-Based Clinical Practice Council

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SUMMARY & PURPOSE:

The purpose of this procedure is to outline the technique for operating the NOVA bedside glucose meter. The blood glucose management system can be used as a definitive method for the measurement and monitoring of glucose in whole blood on all units by certified staff for the following patients pending a physician's order. It should not be used for the diagnosis of diabetes*.

- Patients with diabetes
- Patients receiving two or more blood glucose levels per day on a routine basis
- Patients receiving Total Parenteral Nutrition (TPN)
- Neonates identified to be at risk for hypoglycemia.
- Others as needed

*Collaborate with physician as to method of blood sugar monitoring (e.g., Lab vs. bedside testing) Quantitative glucose in whole blood is measured amperometrically using an enzyme based test strip. When blood is applied to the test strip, glucose in the blood sample mixes with reagent on the test strip that produces an electric current. The amount of current that is produced depends on how much glucose is in the blood.

Patients receiving radiopharmaceutical therapy, as applicable, must bring their own meter to monitor their own blood sugar results if necessary. This meter must not leave the room while this therapy is being delivered and must be Geiger counted for radioactivity before taken back to the patient's home.

The steps in this procedure are designed to ensure standardization of practice for all patients including those on isolation.

POLICY:

The blood glucose management system can be used as a definitive method for the measurement and monitoring of glucose in whole blood on all units by certified staff.

SCOPE/APPLICABILITY:

There are no exemptions to this policy.

PROCEDURES TO ENSURE COMPLIANCE:

1. Equipment and Material:

a. Equipment:

- i. Nova StatStrip® Glucose Meter
- ii. Docking/Charging Station
- iii. Wall Mount
- iv. Battery: Rechargeable 3.7V Li Polymer PN 46827
- v. Meter Transport Case

b. Materials:

- i. Nova StatStrip® Glucose Test Strips
- ii. Nova StatStrip® Glucose Control Solutions: Levels 1 and 3
- iii. Lancet Devices (single use)
- iv. Gloves
- v. Alcohol wipes (70% Isopropyl)
- vi. Gauze
- vii. Hospital approved disinfectant wipes
- viii. Paper Towel Barrier

c. Storage Requirements:

- i. Store the Nova StatStrip® Meter at 15 to 40° C (59 to 104° F) with humidity below 90%.
- ii. Store the Nova StatStrip® Glucose Test Strip vials tightly closed when not in use at 15 to 30° C (59 to 86° F). Do not refrigerate or freeze. Unopened vials are good until the expiration date on the bottle. Once opened strips are stable when stored as indicated up to 180 days or printed expiration date, whichever comes first. Please label open and expiration date before putting in meter case.
- iii. Store the Nova StatStrip® Glucose Control Solution vials tightly closed when not in use at 15 to 30° C. Do not refrigerate or freeze. Unopened vials are good until the expiration date on the bottle. Once opened, solutions are stable up to 3 months or until printed expiration date, whichever comes first. Please label open and expiration date before putting in meter case.

2. Calibration:

The meter does not require calibration. It is calibrated by Nova to provide plasma equivalent results to laboratory methods.

3. Specimen:

a. Patient Preparation:

- i. At least three patient identifiers (patient name, date of birth and Medical Record/Account number) are used to identify patient before performing test.
- ii. Puncture site should be cleaned with alcohol wipes and thoroughly dried before obtaining sample.

- iii. Follow the Site Preparation and Puncture steps 1-5 for finger stick blood collection in the Laboratory On-line Reference Guide. It is important that the first drop of blood is wiped away with gauze to prevent intracellular and interstitial contamination of the sample. Use second drop of blood for testing.
- b. Type:
 - i. Fresh whole blood, capillary (fingertip puncture or heel on infants), arterial or venous (from syringe) and neonatal blood may be used.
 - ii. Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dl, depending on the time of blood collection after food intake.
 - iii. Do not use fingerstick puncture on patients with decreased peripheral flow, as it may not reflect the true physiological state. Examples include, but are not limited to severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration. Send a specimen to the laboratory.
- c. Handling Conditions:
 - i. Observe Standard precautions when collecting a patient specimen.
 - ii. Do not place meter on patient's bed.
 - iii. Use a paper towel barrier on the surface that the meter and supplies will be on while testing.
 - iv. For all patients, leave tote outside the patient's room. Take only the meter and strip vial into room.
- 4. Maintenance:

Maintenance consists of charging the meter battery, replacing the battery, room temperature monitoring and cleaning/disinfecting the meter surface. An auto sleep feature (SLEEP MODE) conserves battery power when the meter is not in use. A charged battery lasts for 8 hours or 40 patient tests, whichever comes first. Some downloaders are chargers only (red round sticker), and some are combination chargers/downloaders. When downloading data, make sure the meter is inserted in the correct downloader.

 - a. Charging the meter battery:
 - i. The battery is charged every time the meter is placed in the docking/charging station. It is advisable to keep one spare battery in the docking station; this battery will be fully charged and available for replacement.
 - ii. Place the meter on the charger whenever instrument is not in use.
 - iii. When the battery LOW symbol displays on the screen, place the meter into the charging station. If needed, the current battery can be replaced with the spare battery immediately to allow for continuous operation.
 - b. Changing the meter battery:
 - i. Press the Power button to enter the Sleep Mode. This will allow the operator approximately 20 seconds to change the battery. Taking longer than 20 seconds will cause the loss of current date/time settings and they will have to be reset.
 - ii. Push down on the 2 cover latches to release the cover. Take the battery cover off the back of the meter.
 - iii. Push up on the battery latch. Remove the drained battery.
 - iv. Replace with a fully charged battery.
 - v. Replace the battery cover.
 - vi. Place the drained battery into the Charging Station.

NOTE: If it takes longer than 20 seconds to change the battery, power up the Meter, after changing the battery, log in again, and set the date and time as follows:

From the Patient Test screen, press the Menu then the Admin soft button.

- vii. The Admin screen displays. Press the Set Time soft key.
- viii. The Set Time screen displays. To change the hour, press the drop down arrow. Then press the up/down scroll arrow to the current hour. Do the same for the minutes.
- ix. Do the same for the Month, Day, and Year.
- x. If Date and Time are now correct, press the Accept soft button.

NOTE: The battery is keyed to allow only insertion from bottom first then push in top.

WARNING: Replace the battery with Nova Biomedical part number 46827 only. Using another kind of battery may present a risk of fire or explosion. If discarding, dispose of the battery promptly according to your facility's protocol. Keep the battery away from children.

- c. Cleaning the Meter:
 - i. The meter should never be immersed in any cleaning agent.
 - ii. Use a commercial germicidal wipe approved for use by BHSF. Follow the cleaning agent directions. When using the hospital approved wipes, maintain wetness (contact time), according to manufacturer's instructions, even if this means using multiples wipes. For patients on isolation for C. difficile, use a hospital approved bleach based wipes, and follow manufacturer's prescribed contact time. Do not reuse a wipe.
 - iii. Avoid harsh solvents such as benzene and strong acids, or unapproved cleaning agents.
 - iv. Clean meter after each patient use to ensure patient safety.
 - v. Use personal protective equipment when cleaning meter to ensure operator safety.
 - vi. Perform hand hygiene after cleaning meter before leaving the room as a safety measure for patient and staff.

CAUTION: DO NOT immerse the meter or hold the meter under running water. DO NOT spray the meter with a disinfectant solution.

- d. Room Temperature Monitoring:
 - i. Strips and controls must be kept below 30°C. Monitor Room temperature daily and record on Room Temperature log.
 - ii. Contact Engineering if temperature is out of range and verify reagent integrity by running two levels of controls.
 - iii. If controls fail, contact POCT Coordinator.
 - iv. Document corrective actions on Room Temperature Log.

5. Quality Control Notes:

- a. The StatStrip® Glucose Control Solutions have known glucose values that are used to confirm that the meter and test strips are working correctly. The control solution test results should fall within the range of results pre-set by the lab into the meter. The glucose concentration in the control solutions is adjusted to give equivalent results to whole blood samples. The meter is set to display results as PASS or FAIL, and will lock out the user from testing if QC is due or fails. The Quality Control (QC) should be run at the following frequency:
 - i. Level 1 and 3 every 24 hours
 - ii. Before using the StatStrip meter for the first time (performed by POC lab staff)
 - iii. If you drop the meter or if there are other indications that the system is not working properly (contact POC department to troubleshoot meter)
 - iv. Each new operator before using the meter the first time (done in training class)
 - v. Whenever optimum conditions for storage of meter and supplies is exceeded.
 - vi. When receiving a new lot or shipment of reagents (done by POC).

6. Quality Control Procedure:

- a. Press the screen or any hard key to wake up the meter.
- b. From the Home screen, press the Login soft key at the bottom middle of the screen.
- c. At the Enter Operator ID Screen, scan your operator barcode.
 - i. To use the barcode scanner, press the Scan soft key on the Enter Operator ID screen or one of the side buttons to scan your badge with the bottom of the meter.
 - ii. If barcode does not work, press the ABC soft key to display the alphanumeric keypad, and enter the operator ID manually.

All references to Policies must go to the BHSF Master Copy on the BHSF Intranet; do not rely on other versions / copies of the Policy.

- iii. When an invalid ID is entered, the screen displays the invalid ID number with a message "is not a valid ID, Try again."

Warning: Do not stare into the Laser Light or point it towards anyone's eyes while scanning a barcode.

- d. Press the Accept soft key at the bottom of the screen. The meter now displays the Patient Test Screen.
- e. From the Patient Test Screen, press the QC soft key.
- f. The Enter Strip Lot screen displays. Enter the Strip Lot number by scanning the barcode on the side of the container.
 - i. To scan the barcode, press the Scan soft key.
 - ii. If the Strip Lot Number is invalid, the screen displays the invalid number with "is not a valid Strip Lot #. Try again"
- g. Press the Accept soft key if the lot number is correct. The Enter QC Lot screen displays.
- h. Enter the QC lot number by scanning the barcode on the side of the solution container.
- i. Press the Accept soft key if the lot number is correct. The Insert Strip screen displays.
- j. Insert a Test Strip as shown on the screen. The NOVA name must be facing up.
- k. With the test strip correctly inserted, the Apply Sample screen displays.
- l. Gently mix the StatStrip Glucose Control Solution before each use. In areas of infrequent testing, discard the first drop of control solution from the bottle onto a piece of gauze to avoid contamination. This is not necessary for areas that perform QC daily. The StatStrip controls are aqueous solutions and are not a biohazard.
- m. Place the meter in a horizontal or slightly downward position to avoid QC solutions from getting into the meter through the strip port.
- n. Place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip all at once.
- o. Note the screen display as the strip is filled. When enough sample has been drawn into the strip an audible beep is sounded by the meter. At that point, remove the control tip from the strip.
 - i. If strip is not filled all the way at one time, do not add additional sample to the strip.
 - ii. The Testing Sample screen displays with a countdown from 6 seconds. Recap the control solution.
 - iii. The result is displayed as either PASS or FAIL.
- p. To add a Comment to the result, press the Comment soft key.
 - i. The Add Comment screen appears with predetermined comments.
 - ii. There are Page Up and Page Down soft keys to scroll through the comments.
- q. Add the appropriate comment desired from the Comments list.
- r. Once selected, press the Accept soft key to place the comment onto the QC result.
- s. If no comment is to be added to the QC, press the Accept soft key to accept the result.
- t. Repeat the steps with the second QC solution.
Both Levels (1 and 3) must pass to perform patient tests.

7. Reasons for QC failure and Corrective Action:

- a. You may not be performing the test correctly. Repeat test paying close attention to procedure.
- b. Control solution may be expired or contaminated. Check expiration date and whether cap was kept closed. If step above does not work, retest with a new QC solution.
- c. The strip may have expired. Check expiration date and use strip from new vial if expired. Discard expired strip vial.
- d. The test strip may have been damaged. Retest with a new test strip.
- e. The NOVA StatStrip meter may not be working properly. Contact the POC Department for troubleshooting.
- f. Document all corrective action with a note on the Failed results.

8. Patient Testing:

- a. Set up a 'clean space' away from the patient's bedside using a paper towel on a clean dry area.
- b. Place the glucometer and bottle of test strips on the paper towel.

- c. Before proceeding, please verify that the patient's wristband is in place and is the correct band for this facility. Ensure barcode is visible for scanning.
- d. Don gloves.
- e. From the Patient Test screen, press the Accept soft key. The Enter Strip Lot screen displays.
- f. Scan the strip lot number as explained in Quality Control procedure above.
- g. Press the Accept soft key.
- h. At the Enter Patient ID screen, press the Scan button to scan in the patient account number being careful not to let the machine come in contact with the bed, bedrails, or patient.
- i. Verify the patient ID with the three identifiers displayed.
 - i. When an invalid ID is entered, the screen displays the invalid ID number with a message "is not a valid ID. Try again."
 - ii. For patient's that are not registered, follow departmental procedures for the handling of unregistered patients.
 - iii. Press the Accept soft key if the ID belongs to the correct patient
- j. The Insert Strip screen displays. Insert a test strip as shown on the meter screen.

Select the appropriate site to be punctured. Follow procedure for the collection of blood specimen by skin puncture. Make sure to wipe off the first drop of blood with a dry cloth, and add the second drop to the strip.

- k. The Apply Sample screen should be displaying. When the blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.
 - i. The instrument should be in a horizontal or slightly downward position when sampling to avoid blood from running into the Strip Port.
 - ii. The test results will appear in 6 seconds.
 - iii. The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip.
 - iv. Do not remove the test strip while the countdown is in progress.
- l. To accept the result, press the Accept soft key. If not accepted the result will be lost and will not transfer to Clinical Applications.
- m. To add a comment, press the Comment soft key and choose from the comments available.
- n. Discard the test strip. Clean the machine as described under 4.h. Place back on paper towel.

Perform hand hygiene before leaving room. If meter is not working, contact Lab POCT Coordinator for assistance.

9. Result Reporting

The Nova Stat Strip Meter stores test results along with the time and date, operator ID number and patient ID number. Once the test is completed, the operator will then return the Nova Stat Strip meter to its docking station for data downloading to the computer system.

10. Result Alert:

- a. Results within the normal range are displayed in Blue.
- b. Results outside the normal range are displayed in Red.
- c. If the result is outside the reportable range of the meter, it will display as <10 or >600 mg/dl.
- d. A single up arrow displays if the result is above normal range but not critical.
- e. A double up arrow displays if the value is higher than the critical upper limit.
- f. A single down arrow ↓ displays if the result is below the normal range but not in the critical range.
- g. A double down arrow ↓↓ displays if the result is below the critical lower limit.

11. Reportable Range:

The operating range/analytical measurement range of the StatStrip Glucose Meter is 10 - 600 mg/dL.

- a. If HI is displayed, the blood glucose result is higher than 600 mg/dL. If this result is unexpected, repeat the test on the meter. If the result is still >600 mg/dl, order a STAT venipuncture for confirmatory blood glucose by Lab. Notify the nurse or designated healthcare practitioner directly responsible for the patient’s care.
- b. If LO is displayed, the blood glucose result is less 10 mg/dL. Repeat the test on the meter to confirm result. Notify the nurse or designated healthcare practitioner directly responsible for the patient’s care and treat the patient. If result is unexpected and still <10 mg/dl, retest the patient on an alternate meter. If result is different from initial result by more than 15 mg/dl, do not use the meter and contact the POC Department for troubleshooting.

12. Reference Ranges:

- a. The reference ranges for fasting blood glucose include:

Age	Reference Values (mg/dL)
0 H – 24 H	40-60 mg/dL
25 H – 1 M	50-80 mg/dL
2 M – 15 Y	60-99 mg/dL
16 Y – 69 Y	70-99 mg/dL
≥ 70 Y	80-99 mg/dL

- b. The reference ranges for random blood glucose include:

Age	Reference Values (mg/dL)
0 H – 24 H	40-126 mg/dL
25 H – 1 M	50-126 mg/dL
2 M – 15 Y	60-126 mg/dL
16 Y – 69 Y	70-126 mg/dL
≥ 70 Y	80-126 mg/dL

- c. The critical values for glucose include:

Age	Critical Values (mg/dL)	
0 H –3M	<40	>200 mg/dL
≥ 4 M	<60	>400 mg/dL

- d. Target ranges for the general inpatient and outpatient population are:

Age	Target Ranges (mg/dL)
0 H – 1 M	40 – 126 mg/dl
> 1 M	70 – 150 mg/dl

The physician can specify other target ranges for special populations.

13. Procedure For Handling Critical Results:

- a. Unexpected glucose results exceeding critical value limits require repeat testing with a new sample. The critical glucose result is reported to the nurse or designated healthcare practitioner directly responsible for the patient’s care.
- b. Critical results must be reported to the attending physician or caregiver promptly following hospital policy. Neonates, as applicable, do not routinely require verification by the laboratory for glucoses ≤40 mg/dL, but the test must be repeated by the caregiver on the glucose meter or alternate method.
- c. Bedside glucose assays are a definitive test for monitoring glucose levels in patients previously diagnosed with diabetes mellitus and are useful in the process of diagnosing initial hypoglycemic conditions. In conjunction with the bedside glucose assay results and the patient’s expected results, the attending physician will determine on a case by case basis if additional diagnostic laboratory tests are warranted.

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- d. If there are any glucose results which are unexpected by the physician or designated health care practitioner directly responsible for patient care, the physician may request a blood sample to be collected. If physician requests lab confirmation, order a stat glucose test to be performed by the laboratory.
- e. Unexpected Glucose values that exceed the upper limits of the meter require verification by the laboratory >600 mg/dL for adults and neonates. Do not delay treatment waiting for laboratory results if result is expected.
- f. If point of care testing blood glucose results are less than 60 mg/dL and the patient is older than 4 months of age, repeat testing is required. If repeat test is within 15 mg/dL of initial point of care testing blood glucose result, no more testing is necessary. If repeat test is different from initial test by more than 15 mg/dL, the blood glucose result must be verified by the laboratory. Contact the POC department for troubleshooting of the meter.

14. Limitations:

- a. The operating temperature range for Meter operation: 59°F to 104°F(15°C to 40°C)
- b. The relative humidity range for Meter operation: up to 90% non-condensing
- c. The maximum altitude for Meter operation: Up to 15,000 feet(4500 meters)

15. Glucose Interferences:

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

Tested Interfering Substances	Tested Concentration Levels	
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(+) Maltotriose	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

16. Procedure Notes:

Refer to Addendum for Troubleshooting.

SUPPORTING/REFERENCE DOCUMENTATION:

All references to Policies must go to the BHSF Master Copy on the BHSF Intranet; do not rely on other versions / copies of the Policy.

- CAP-College of American Pathologists Jan. 2012
- TJC-The Joint Commission, 2012
- AHCA- Agency for Healthcare Administration, 2012
- StatStrip® Glucose Hospital Meter Instructions for Use Manual (2011). Waltham, MA: NOVA Biomedical Corporation.

RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS:

- WKBH Administrative Policy: 250-3700-105 Waived Testing-Laboratory Services
- WKBH Administrative Policy: 250-3700-101 Point of Care Testing- Laboratory Services
- WKBH Administrative Policy: 250-3700-110 Waived Testing Quality Control Program-Laboratory Services
- WKBH Administrative Policy: 250-5160-005 Isolation Precautions-Infection Control
- WKBH Administrative Policy: 250-3700-201 Laboratory Critical Values-Laboratory Services
- Laboratory On-line Reference Guide (found on the intranet)

ENFORCEMENT & SANCTIONS:

Enforcement of this policy will be performed by the West Kendall Baptist Hospital Laboratory, the Administrative Laboratory Director, Point of Care Testing Manager and Supervisor.