A. Applicability

This policy applies to all licensed nursing personnel involved in blood glucose monitoring and continuous glucose monitoring at all OMH State Operated facilities where these procedures are performed. It covers the use of the Contour Next EZ glucometer and Continuous Glucose monitoring systems for patient care. This procedure screens for hypo/hyperglycemia and provides routine patient monitoring with a frequency not otherwise obtainable with venipuncture and is used in conjunction with venous glucose levels in the management of patients with diabetes. Glucometer testing uniquely allows for easy, quick routine patient self-monitoring and provides clinicians with valuable baseline information.

B. Policy Statement

The purpose of this policy is to establish guidelines for the accurate and safe determination of capillary blood glucose levels using glucometers and continuous glucose monitoring (CGM) devices. This policy aims to:

(a) Screen for asymptomatic hyperglycemia and hypoglycemia;

(b) Confirm symptomatic glycemic reactions;

(c) Assure that glucometers and CGM devices are operating properly;

(d) Maintain staff proficiency in performing blood glucose testing and managing CGM;

(e) Ensure compliance with New York State Department of Health (NYS DOH) regulations and Clinical Laboratory Improvement Amendments of 1988 (CLIA) recommendations regarding waived testing, as well as Joint Commission National Performance Goals (NPG); and

(f) Provide quality assurance for the testing process and equipment.

C. Relevant Statutes and Standards

42 CFR Part 493, Subpart M – Personnel for Nonwaived Testing
Joint Commission Requirements for Hospital Programs HR 11.02.01
Joint Commission National Performance Goals (NPG) 10.01.01
Joint Commission NPG 10.02.01

D. Definitions

1. Point of Care Test (POCT) means medical testing performed at or near the site of patient care, without sending a sample to a clinical laboratory.

2. Waived Tests means a subset of POCTs that are simple laboratory tests permitted under CLIA, often cleared by the FDA for home use, posing minimal risk if performed incorrectly. Glucose testing is a waived test.

3. Glucometer means a device used to obtain a measure of capillary blood glucose level. Specific models mentioned include Contour Next EZ.

4. Continuous Glucose Monitoring (CGM) means a system consisting of a handheld reader and a sensor worn on the skin, intended to determine an individual's glucose level over time.

5. Critical Values means blood glucose results falling outside a predetermined range that requires immediate attention and notification of a prescriber.

E. Body of Directive

This policy directive contains 20 components:

1. Equipment and Supplies
2. Setting Up a New Glucometer/Reader
3. Quality Control (QC) Frequency Testing and Frequency of Quality Control
4. Quality Control Materials
5. Procedure for Quality Control Test
6. Procedure When Quality Control Test Results Fall Outside of the Range
7. Documentation of Quality Control
8. Patient Blood Glucose Testing (Capillary Fingerstick)
9. Procedure for Capillary Fingerstick
10. Continuous Glucose Monitoring (CGM)
11. CGM Patient Testing
12. CGM Removal
13. Contraindications and Warnings for CGM Systems
14. Management of Abnormal/Critical Results
15. Procedure for Abnormal Results
16. Cleaning and Maintenance
17. Documentation and Record Keeping
18. Error Codes and Troubleshooting
19. Disposal
20. Responsibilities

1) Equipment and Supplies

(a) BGM (e.g., Contour Next EZ): Glucometer, Contour Next EZ test strips, Contour Next EZ Level 1 (LOW) and Level 2(NORMAL) Glucose Control Solution, lancets, alcohol swabs, gloves, 2x2 gauze, Band-Aids, and a red sharps container.

(b) CGM may require glucose test strips (for confirmatory fingerstick), Glucose and Ketone Control solutions, CGM sensor applicator, sensor Pack, alcohol swabs, and gloves.

(c) All test strip and control solution bottles must be labeled with the date of opened and the discard date, which is 6 months from opening or the manufacturer's expiration date, whichever comes first.

(d) Assure proper storage of all materials per manufacturer's temperature parameter recommendations. Do not expose to excessive humidity, heat, cold, dust, or dirt.

(e) Monitors and quality control supplies accompany the patient upon transfer to another unit or upon discharge, dependent on patients discharge disposition and/or setting.

2) Setting Up a New Glucometer / Reader

(a) Refer to the owner's manual for specific setup instructions (e.g., page 31 for CONTOUR NEXT EZ).

(b) Set the date and time prior to use to ensure accurate data recording.

(c) For glucometers, ensure "event tags" (e.g., pictures of apple, running figure) are in the off position for inpatient testing.

(d) For CGM readers, set the target glucose range as determined by the prescriber's order.

(e) No coding is needed for Contour Next EZ meters.

3) Quality Control (QC) Testing/Frequency of Quality Control

QC testing of all glucometers must be completed by licensed nursing staff:

(a) Weekly on Wednesday;

(b) Prior to using a new glucometer for the first time;

(c) When clinical presentation and glucometer test results are contradictory;

(d) When malfunctioning of the machine is suspected;

(e) Each time a new lot number of test strips or reagent is changed/opened;

(f) If a bottle of test strips has been left open or exposed to extreme heat, cold, or humidity;

(g) When control solution or test strips expires; and

(h) Two levels of controls (low and normal) **MUST** be run each time QC testing is done.

4) Quality Control Materials

Use Contour Next EZ Level 1 (LOW) Glucose Control Solution and Contour Next EZ Level 2 NORMAL 2 Glucose Control Solution for Contour Next EZ meters.

5) Procedure for Quality Control Test:

(a) Perform hand hygiene and apply gloves.

(b) Check the expiration dates on strips and control solution bottles. Do not use expired materials.

(c) Shake the control bottle well about 15 times before every use.

(d) Remove a test strip from the bottle and immediately close the lid. Insert the test strip fully into the meter with the gray microchip or contact end facing up. The meter will turn on and display a flashing blood drop symbol.

(e) Place a drop of control solution on a clean, non-absorbent surface; **DO NOT APPLY CONTROL SOLUTION DIRECTLY TO THE TEST STRIP FROM THE BOTTLE.**

(f) Immediately touch the tip of the test strip to the drop of control solution, the meter will count down from 5 seconds". The solution is automatically drawn into the test strip.

(g) The control test result will be displayed.

(h) Compare the control test result with the Control Range printed on the test strip bottle label.

(i) Remove the strip by pulling it down. The meter will automatically store the control result and turn off. Discard the test strip.

6) Procedure When Quality Control Test Results Fall Outside of the Range:

(a) Re-check the expiration dates and the open/discard dates on strips and control

solutions.

(b) Review testing technique and repeat the control testing.

(c) Repeat control testing using new bottles of control solutions if results are still out of range.

(d) Repeat control testing with a new lot of strips.

(e) Use another meter.

(f) After using another meter, should Quality Control Test Results continue to fall outside of the Range, have another certified operator perform testing.

(g) If results are still out of range, DO NOT USE THAT GLUCOMETER. Notify the unit nurse, supervisor or Point-of-Care Supervisor RN immediately. Open a new glucometer for the client and complete quality control testing.

7) Documentation of Quality Control

Document all QC activities on the designated Glucometer Quality Control Testing Form (e.g., NS:101, RPC 173). This form must be filled out completely, including meter serial number, test strip lot number, expiration date, control solution lot numbers, expected control ranges, actual results, date of testing, and RN initials. All corrective actions taken must also be documented. QC result records and instrument records are retained for at least two years or per OMH record retention policy whichever is greater.

8) Patient Blood Glucose Testing (Capillary Fingerstick)

(a) Verify prescriber's order for all finger sticks.

(b) Perform hand hygiene and apply gloves.

(c) Verify that the low and normal quality control checks have occurred for the week. If not, perform them before patient testing.

(d) Identify the patient using at least two patient identifiers as per facility policy.

(e) Explain the procedure to the patient and provide patient teaching.

9) Procedure for Capillary Fingerstick

(a) Remove a single test strip from the bottle and immediately close the lid tightly. Insert the into the meter. The meter will turn on and display a flashing blood drop symbol.

(b) Clean the finger puncture site with an alcohol swab and allow the finger to dry thoroughly.

(c) Prepare the lancet. Place the lancing device on the side of the fingertip and depress the trigger.

(d) Discard the used lancet into a red sharps container immediately. Lancets are for single patient use.

(g) Gently press the fingertip to form a drop of blood.

(h) Touch and hold the tip of the test strip to the drop of blood until the meter beeps. Blood is automatically drawn into the test strip. Do not drop blood directly on the flat surface of the strip or press the strip against the finger.

(i) Blood glucose result will appear in the display window.

(j) Remove test strip from the meter by holding it vertically with the strip end pointing down and pulling out. . The meter turns off automatically, and the result is stored.

(k) Discard test strip and gauze and wipe the device with an EPA-registered disinfectant recommended by the device manufacturer, such as PDI Super Sani-Cloth. Allow the device to dry for at least 2 minutes after cleaning.

(l) Remove gloves and perform hand washing.

10) Continuous Glucose Monitoring (CGM)

CGM Application

(a) Verify prescriber's order.

(b) Gather and prepare necessary equipment and supplies.

(c) Confirm individual's identity using at least two patient identifiers.

(d) Explain the procedure to the patient.

(e) Perform hand hygiene and apply gloves.

(f) Select an appropriate sensor site according to manufacturer's guidelines, typically a flat area on the back of the upper arm. Avoid scars, moles, stretch marks, irritation, lumps, and insulin injection sites; rotate application sites.

(g) Clean the intended sensor site with an alcohol pad and allow it to air dry.

(h) Open the sensor packaging. Apply the sensor according to the manufacturer's instructions for use. Do not touch inside the sensor applicator as it contains a needle. Push down firmly on the applicator once over the prepared site until it clicks. Gently pull the applicator away. Make sure the sensor is secured to the site.

(i) Start New Sensor with Reader: Press the Home Button on the reader, touch "Start New Sensor," and hold the reader within 1.5 inches (4cm) of the sensor to scan it. The sensor will be activated and can be used to check glucose after 60 minutes.

(j) Discard used supplies in appropriate receptacles. Document the procedure.

11) CGM Patient Testing:

(a) Turn the reader on or touch "Check Glucose" from the Home Screen.

(b) Hold the reader within 1.5 inches (4cm) of the sensor to scan it. The sensor wirelessly sends glucose readings to the reader.

(c) The reader displays the current quantified glucose reading along with a glucose graph and an arrow indicating the direction of glucose value.

12) CGM Removal:

(a) Verify prescriber's orders.

(b) Perform hand hygiene and apply gloves.

(c) Remove the sensor according to manufacturer's guidelines, by pulling up the edge of the adhesive and slowly peeling it away from the skin in one motion.

(d) Discard the used sensor in sharps container.

(e) Remove gloves and perform hand hygiene. Document the procedure.

13) Contraindications and Warnings for CGM Systems:

(a) The CGM system must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, X-RAY, or high-frequency electrical heat (diathermy) treatment. Exposure may damage the sensor and impact device function, leading to incorrect readings.

(b) Taking ascorbic acid (Vitamin C) while wearing the sensor may falsely raise sensor glucose readings. Taking salicylic acid (aspirin) may slightly lower sensor readings. Ideally, patients should not be prescribed these medications. If symptoms and glucose

readings do not correlate, confirm with fingerstick and notify prescriber.

(c) Symptoms of hyper/hypoglycemia should not be ignored. If symptoms exist, the physician must be notified.

(d) A confirmatory fingerstick glucose test is required if there is suspicion that sensor readings are inaccurate, when experiencing symptoms that do not correlate with sensor readings, during times of rapidly changing glucose, when the sensor does not include a current glucose number, or to confirm hypoglycemia or hyperglycemia as reported by the sensor. Also, if a "Check Blood Glucose" reading symbol appears during the first 12 hours after sensor application.

14) Management of Abnormal/Critical Results

Critical Values:

(a) General: Less than 70 mg/dl or greater than 400 mg/dl (adults and children) or per facility policy and/or prescriber order.

(b) For Contour Next EZ: Meter reads “High” for results above 600 mg/dl; reads “Low” for results below 20 mg/dl. Critical values are less than 70 mg/dl or greater than 400 mg/dl, but venous confirmation is needed for <70 mg/dl or >600 mg/dl.

15) Procedure for Abnormal Results

(a) Immediately notify the prescriber of any unexpected or critical glucose result.

(b) For Contour Next EZ (fingerstick): If an abnormal or inconclusive value, or "Lo" or "Hi" reading, is obtained, perform a repeat fingerstick blood glucose (FSBG) test immediately. If the repeat test is also abnormal/inconclusive, or the patient refuses, notify the provider for further instructions.

(c) For CGM If an abnormal or inconclusive value is displayed, or if the patient's symptoms do not match the reading, perform a confirmatory fingerstick blood glucose test (FSBG) using a glucometer. If the FSBG result is also abnormal/inconclusive, or does not match the patient’s clinical presentation, or if the patient refuses testing, immediately notify the provider for further instructions.

(d) If results are outside the instrument's reportable range (e.g., below 20mg/dl or above 600mg/dl), the nurse is required to repeat the test, notify the prescriber, and obtain blood as per the prescriber’s orders. Symptomatic hypoglycemia should be treated immediately – treatment must not be delayed to repeat BG test or to notify prescriber. Document all corrective actions and notifications.

(e) Follow the prescribed standing orders for insulin (CBG) coverage or hypoglycemic protocol.

(f) Refer to chart for hypoglycemia response procedure. Common symptoms of low blood glucose (diaphoresis, shakiness, irritability, confusion) and high blood glucose (increased thirst, frequent urination, headache) are recognized.

16) Cleaning and Maintenance

(a) Hand hygiene should be performed before using equipment to keep the meter and test strips free of oils and contaminants.

(b) Clean and disinfect the glucometer exterior after each use. Apply gloves and wipe with an **EPA-registered disinfectant** recommended by your device manufacturer, such as PDI Super Sani-Cloth. Allow at least 2 minutes for the device to dry after cleaning.

(c) Avoid spilling any liquids on the meter, as liquids may damage the meter's electronics. Never put the meter in liquids or allow liquids to enter the test port.

(d) Do not expose the meter, reagents, or test strips to excessive humidity, heat, cold, dust, or dirt.

(e) Store the meter in the case provided.

(f) The Contour Next EZ meter uses two (3 Volt Lithium) batteries(CR2032). A low battery symbol will display when the battery is low. turn meter off before replacing the batteries. Replace the battery as soon as possible.

17) Documentation and Record Keeping

1. Document all finger sticks on the diabetic check sheet.

2. Record blood glucose results in the patient's electronic health record.

3. Document nursing observations and interventions associated with symptomatic hypo/hyperglycemia in progress notes (EHR progress notes).

4. Record date, time, results, and if indicated, units of insulin given (with site) on the Blood Glucose Monitoring and Insulin Coverage Administration Record (e.g., Form 360 LIPC, RPC 173).

5. All standing and sliding scale insulin coverage must be documented (e.g., in BCMA).

6. The Point of Care (POC) testing record must be filled out completely and accurately.

7. All QC records, patient test results, and instrument records must be retained for the period specified in the OMH records retention policy. Weekly QC forms are submitted to facility/unit designated point person (s).

18) Error Codes and Troubleshooting

Contour Next EZ Specific error codes and indicators for out-of-range high (HI) or low (LO) results are detailed in the manufacturer's manual and facility procedures. Actions range from repeating the test with a new strip, moving the meter to an appropriate temperature, or replacing the glucometer. All error codes and corrective actions taken must be documented.

19) Continuous Glucose Monitor (CGM)

(a) Error messages interpretation and next steps are provided by the manufacturer. Corrective actions can include repeating the test with a new strip, reviewing instructions, or contacting customer service.

(b) If an error message persists after troubleshooting, or the problem cannot be solved, the glucometer should be taken out of operation and returned for replacement. All error codes and corrective actions taken must be documented.

20) Disposal

(a) Used lancets must be discarded into a red sharps container.

(b) Used test strips, gauze, and gloves are discarded in regular trash.

(c) CGM sensors are disposed of in the sharps container.

(d) Contour Next EZ monitors must be exposed of in accordance with electronic waste disposal.

(e) Continuous Glucose receivers and chargers will be disposed of in accordance with guidelines for electronic waste and/or items containing rechargeable lithium-ion batteries.

21) Responsibilities

(a) **Laboratory Director**: Approves when Waived Test results can be used for diagnosis and treatment, ensures compliance with NYSDOH regulations and accrediting agencies, and completes CLIA certification. The Clinical Laboratory Director is ultimately responsible for the performance, quality control, and records of all bedside blood glucose testing.

(b) **Waived Test Site Supervisors** (e.g., ADONs, Nurse Educators, Nurse

Supervisors): Ensure all personnel performing glucose testing comply with regulations, ensure reagents and controls are in date and stored properly, oversee proficiency testing, review quality control records, monitor performance improvement activities, and ensure orientation, training, and competency assessment for staff.

(c) **Licensed Nursing Personnel** (RNs and LPNs): Perform testing and quality control according to policy, demonstrate competency, follow up on abnormal patient results, identify and report malfunctioning equipment, and assist in training new personnel. They are required to maintain appropriate records. The night shift RN is specifically responsible for weekly quality control testing QC and submitting QC forms to facility/unit designated point person(s).