St. Peter’s University Hospital
Department of Laboratory Medicine and Pathology
Point of Care
Nova StatStrip Whole Blood Glucose Monitoring System

I. Principle:
- Glucose (Glu) is measured amperometrically, using an enzyme based test strip.
- The glucose measurement is based on the following methodology:
  - Glucose + Enzymes(oxidized form) → Gluconic Acid + Enzymes(reduced form)
  - Enzymes(reduced form) + Ferricyanide → Enzymes(oxidized form) + Ferrocyanide
  - Ferrocyanide → Ferricyanide

- The current generated at the electrode is proportional to the glucose concentration of the sample.

II. Specimen:
1. Patient Preparation:
   Capillary blood can be obtained from puncturing the fingertip or heel using a single-use lancing device. The puncture site should be cleaned and thoroughly dried before obtaining the blood sample.
2. Type:
   - Whole Blood: Capillary

   **NOTE:** Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyper-glycemia (with or without ketosis) and severe dehydration.

   **If peripheral blood flow is decreased or questionable, a venous blood sample should be sent to the lab for glucose testing.**

3. Handling Conditions:
   - When not analyzing from a lancing device, whole blood should be analyzed within 30 minutes of collection. Storing samples on ice is not recommended. Sodium, lithium, and ammonium heparin are the recommended anticoagulants when sampling with syringes or vacutainer tubes.
   - Gloves must be worn for all testing events. Gloves must be changed and hand hygiene must be performed between patients according to Standard Precautions.

III. Equipment and Materials:
1. Equipment:
   - Nova StatStrip® Glucose Hospital Meter
   **WARNING:** Do not stare into the Laser light or point it towards anyone's eyes while scanning a barcode.
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- Wireless carrying case for StatStrip or hard wired docking station with power supply
- Docking Station with power supply for wireless carrying case or hard wired docking station with power supply
- Single-use lancing device
- Telcor/QML and NovaLink Blood Glucose Management System software or Hospital Data Log

2. Materials:
   - StatStrip® Glucose Test Strips
   - StatStrip® Glucose Control Solutions: Levels 1 and 3
   - Alcohol Prep Pad and gauze
   - Sani-Cloth wipes

3. Reagent Storage Requirements:
   a. Date the container of all control solutions and test strips upon opening.
   b. Store the StatStrip® Glucose Test Strips at 15 to 30° C. Strips in opened containers are good for up to 6 months after opening if stored under proper conditions.
   c. Store the StatStrip® Glucose Control and Linearity Solutions at 15 to 30° C. Open vials are good for up to 3 months after opening if stored under proper conditions.

4. Cleaning / Disinfecting the Meter
   a. After each patient test, remove a fresh Sani-Cloth® wipe from the canister. Note: To wet the meter surface again, use a new, fresh germicidal wipe. Never re-use a previously soiled wipe. Squeeze excess liquid from Sani-Cloth wipe before using on the meter.
   b. Thoroughly wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally and 3 times vertically avoiding the meter’s bar code scanner and electrical connector.
   c. Gently wipe the surface area of the test strip port making sure that no fluid enters the port.
   d. Use two minute dry time for the purple top Sani-Cloths.
   e. Sani-Cloth® Bleach Wipes must be used to clean and disinfect all equipment, including blood glucose monitors, used on C. difficile positive patients. Allow the bleach to air dry.
   f. CAUTION:
      - DO NOT immerse the meter or hold the meter under running water.
      - DO NOT spray the meter with a disinfectant solution.
   g. Dispose of any used wipes and gloves in an appropriate biohazard container.
   h. Wash your hands thoroughly with soap and water.
5. Battery Replacement
   a. If you have a spare fully charged battery, it can be changed to allow for continuous operation. **WARNING:** Replace the battery with Nova Biomedical Part Number 42215 only. Using another battery may present a risk of fire or explosion. *If discarding, dispose of the battery promptly. Keep the battery away from children.*
   b. Press the Power button to enter the Sleep Mode. This will allow the operator approximately 20 seconds to change the battery and not lose date/time settings. **NOTE:** *If it takes longer than 20 seconds to change the battery, power up the meter, re-login, and set the date and time: see Instrument Manual *Section 1.7.1 Power Up Procedure, Section 1.8 Operator Login, and Section 1.9 Setting the Time/Date.*
   c. Push down on the 2 cover latches to release the cover. Take the battery cover off the back of the meter.
   d. Push up on the battery latch. Remove the drained battery.
   e. Replace with a fully charged battery. **NOTE:** The battery is keyed to allow only insertion from bottom first then push in top.
   f. Replace the battery cover.
   g. Place the drained battery into the Charging Station.

IV. Quality Control:
1. New lot numbers of test strips and controls will be evaluated by the Point of Care Coordinator prior to releasing the supplies for use.

2. StatStrip Level 1 and 3 Glucose Control Solutions are used to check the StatStrip brand blood glucose monitoring system performance:
   - Level 1 and 3 controls are required every 24 hours on each meter and under the following circumstances:
     - If a patient test has been repeated and the blood glucose results are still lower or higher than expected
     - If there are other indications that the system is not working properly
     - Whenever problems (storage, operator, instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter)

3. The meter is programmed with a 24 hour lockout and will not allow patient testing until acceptable controls have been performed.

4. **Running a Quality Control Test:**
   a. From the Patient Test screen, press the QC soft key.
   b. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key. **NOTE:** If the Strip Lot
Number is invalid, the screen displays the invalid number with “is not a valid Strip Lot # Try again.”

c. Press the Accept soft key if the lot number is correct.

d. The Enter QC Lot screen displays. Enter the QC lot number, select from the QC Lot List screen (press the List soft button), or scan the barcode. To scan the barcode, press the Scan soft key. **NOTE:** If the QC Lot Number is invalid, the screen displays the invalid number with “is not a valid QC Lot Try again.”

e. Press the Accept soft key if the lot number is correct.

f. The Insert Strip screen displays. Insert a Test Strip as shown on the screen.

g. With the test strip correctly inserted, the Apply Sample screen displays.

h. Gently mix the StatStrip Glucose Control Solution before each use.

i. Discard the first drop of control solution from the bottle to avoid contamination.

j. 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. When enough sample has been drawn into the strip, an audible beep is sounded by the meter.

k. Recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.

l. When the meter completes the test, the QC result is displayed as only PASS or FAIL.

m. To add a comment to the result, press the Comment soft key.
   - Enter the two comments “Meter Cleaned” and “Rgt/QC Dates OK” which indicates that the meter was cleaned following testing and that the reagent and QC containers are properly dated and within the open container expiration date.

n. To accept the result, press the Accept soft key.

o. Valid results depend on the correct test strip lot number (and corresponding code) being correctly entered in the meter. Results that fall within the range, when testing in the meter’s QC Test mode are indicated by PASSED on the meter display. Results that are not within the range are indicated by FAIL. Control solution test results should fall within the ranges printed on the test strip bottle if the system is working properly and the correct test procedure is followed. If control solution test results fall outside the expected range, the system is not functioning properly. Acceptable control assay ranges are printed on the Nova Glucose Control Solutions vial label.

p. If a QC test does not fall within the specified range, verify that the Nova Glucose Stat Strips and Control Solutions are not past their expiration dates. Repeat the test with a new strip. If the second test fails contact the Point of Care Testing Coordinator / Laboratory at extension 8005 or contact the lab at extension 8506 if the POCT Coordinator is not available.
   - **WARNING:** DO NOT test patient sample until a control solution test result is within expected range.

q. Results that fall outside the expected range may indicate:
   - Procedural error.
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- Old or contaminated glucose control solution.
- Incorrect lot number entered in the meter.
- Test strip damage
- Meter malfunction.
- Control solution outside the 15°C–30°C functional temperature range.

5. In case of instrument malfunction, backup meters available from the Point of Care Coordinator/Laboratory ext.8005/8506. The Point of Care Coordinator will evaluate the malfunctioning meter. If necessary the meter will be sent back to the manufacturer for replacement.

6. If manual glucose meter result entry into the patient medical record is performed, the manager or designee will assess accuracy of documentation weekly by comparing the meter results to the documentation record. The patient name, time and date of the capillary glucose meter reading, and clerical transcription onto the record will be compared for significant discrepancies. A significant discrepancy is defined as a written documented result that is greater than twenty percent above or below the meter value, or one that resulted in the patient receiving an incorrect treatment. The manager is responsible for initiating employee counseling or contacting the Education Department for remediation as deemed necessary. The sampling will be logged on the appropriate documentation form and sent to the Point of Care Coordinator weekly. Three (3) samples per meter per week for a maximum of ten (10) samples per unit will be recorded per week.

7. The laboratory will generate a monthly report from the downloaded data of each meter. This report will contain a QC summary and trend graph as well as information on operator performance and patient result outlier documentation.

8. On a monthly basis the Point of Care Coordinator will meet with the Nurse Managers to review operator performance and meter documentation.

9. The laboratory subscribes to the College of American Pathology Proficiency Survey for bedside glucometer testing. Surveys are received two times per year. These samples are tested randomly by nursing staff as coordinated by the Point of Care Coordinator. Attempts are made to ensure that a different nursing staff member and meter is tested each survey where possible. If a specific meter fails the proficiency survey it will be removed from service and evaluated. Corrective action to address deficiencies will be documented with the CAP proficiency report in the laboratory.

10. The laboratory will verify the linearity of the glucometers before the instruments are placed into use. The Point of Care Coordinator will maintain documentation of all linearity testing.

11. All StatStrip users MUST be certified. Certification is obtained through a training program conducted by the nursing education department prior to meter use. This training is conducted during nursing orientation. All certified users must be assigned an Operator Number. This number will be the Employee ID Number.

12. A copy of the laboratory’s policies and procedures for the Nova StatStrip Hospital Meter will be available on each nursing unit using a meter.
13. All certified StatStrip operators are required to review the StatStrip policies and procedures annually. Documentation of this review will be recorded in HealthStream by Nursing Education.

14. Annual re-certification of all certified StatStrip Meter operators is conducted by the Education and Development Department. Educators are responsible for conducting skills and competency assessment for the Nova StatStrip Hospital meter, with laboratory input on criteria for assessment. Skills and competency assessments take place at Nursing Skills Days. Documentation of all re-certifications will be maintained by the Education and Development Department. The Point of Care Coordinator will maintain certification dates of all operators in the POCT computer using the TELCOR software. All uncertified operators are locked out of the meters.

V. Running a Patient Sample
1. From the Patient Test screen, press the Accept soft key.
2. Enter Patient ID: the Enter Patient ID screen will display.
   a. From the Enter Patient ID screen, enter the Patient ID: by scanning the barcode patient ID. In locations where the scan function is disabled, this can be done by pressing numeric/alphanumeric soft keys (press the ABC... soft key). Community Mobile Health will manually enter the patient ID by using the patient’s initials followed by a six-digit date of birth. Adult Day Care will use the patient’s social security number.
   b. If emergency testing is required prior to obtaining a fin #, scan the barcode on the yellow Emergency Card to perform testing. Complete all the required information on the front of the Emergency Card and apply a patient label, once available, to the back of the Emergency Card. All Emergency Cards must be returned to the Point of Care Coordinator, MOB 6th Floor, for reconciliation. Completed cards may be returned via the pneumatic tube system to the Laboratory tube station #40 or #50.
   c. To scan the patient ID Number, press the Scan soft key on the screen. Or press one of the side Scan buttons. Then scan the patient's wristband barcode, containing the patient’s financial number (fin), with the bottom of the meter. Confirm the accuracy of the patient’s financial number displayed before proceeding further. Never perform testing on a fin # that does not completely match the patient’s wristband.
   d. Once the Patient's ID Number has been entered and verified, press the Accept soft key.
   e. During registration downtime when the FIN and patient information do not cross over into the meter, verify the patient ID following hospital protocol and use the Downtime Override soft key.
3. The Enter Strip Lot screen displays. Enter or scan the strip lot number by scanning the barcode.
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a. Once the Lot Number has been added, verify it against the Lot Number printed on the reagent container and press the Accept soft key.

4. The Insert Strip screen displays. Insert a test strip as shown on the meter screen.
   a. Use alcohol pads to clean area on finger to be punctured for testing; dry thoroughly after cleaning.
   b. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
   c. Use the Safety Lancet to puncture the finger.
   d. Squeeze the finger to form a drop of blood.

5. 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.

WARNING: 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.

6. The test results will appear in 6 seconds.

   NOTE: Do not remove the test strip while the countdown is in progress.

7. To accept the result, press the Accept soft key.
8. To reject the result, press the Reject soft key.
9. To add a comment, press the Comment soft key.
   a. The following comments are to be used with accepted results:
      - Notified PCP (Notified Patient Care Provider)
      - Verified By Repeat (Verified by repeat meter testing)
   b. The following comment is to be used with rejected results:
      - Possible Procedure Error
   c. All Critical results **MUST** be accompanied by a comment indicating the result was called to the appropriate Patient Care Provider.

10. Patient results are posted to the patient’s medical record via a series of computer interfaces after the glucose meter is downloaded.

11. All data are stored into memory. The meter holds results for 10 days or a total of 1000 results whichever occurs first.

12. Calculations - The Nova StatStrip® Glucose Meter automatically performs all the calculations.

VI. Linearity and Unknown Test Procedure:
1. From the Patient Test screen, press the Menu soft key.
2. From the Menu screen, press the Linearity soft key.
3. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key.
   
   **NOTE:** If the Strip Lot Number is invalid, the screen displays the invalid number with "is not a valid Strip Lot Try again."
4. Press the Accept soft key if the lot number is correct.
5. The Enter Linearity Lot screen displays. Enter the Linearity lot number, select from the Linearity Lot List screen (press the List soft button), or scan the barcode. To scan the barcode, press the Scan soft key.
   **NOTE:** If the Linearity Lot Number is invalid, the screen displays the invalid number with "is not a valid Linearity Lot # Try again."
6. Press the Accept soft key if the lot number is correct.
7. The Insert Strip screen displays. Insert a Test Strip as shown on the screen.
8. With the test strip correctly inserted, the Apply Sample screen displays.
9. Gently mix the StatStrip Linearity Solution before each use.
10. Discard the first drop of linearity solution from the bottle to avoid contamination.
11. Place a drop of linearity solution from the bottle at 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.
12. Recap the linearity solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.
13. When the meter completes the test, the Linearity Result screen displays with the results in mg/dL or mmol/L.
   **NOTE:** Result is displayed with either PASS or FAIL, or only PASS or FAIL is displayed without the result.
14. To add a comment, press the Comment soft key. (See Section 2.4 Add Comment to Result.)
15. To accept the result, press the Accept soft key.

**VII. Reporting Results:**

1. **Reference Ranges:**
   - Blood glucose levels for people without diabetes\(^1\) are as follows:
     - Newborn (1 day) 40-60 mg/dL
     - Newborn (>1 day-1 year) 50-80 mg/dL
     - Child (>1 year-12 years) 60-100 mg/dL
     - Adult (>12 years-60 years) 74-106 mg/dL
     - Adult (>60 years) 82-115 mg/dL

2. **Procedures for Abnormal Results:**
   a. Communication to the physician with readback and documentation in the patient’s medical record using the Hospital Information System, where applicable, is required for all critical values.
   b. Any Patients with questionable results or results inconsistent with patient symptoms should have a confirmatory specimen sent to the Laboratory for testing.
   c. The operating range of the StatStrip Glucose Meter is 10 - 600 mg/dL. For samples exhibiting values at or above 600 mg/dL, the screen displays “HI”.

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For samples exhibiting values at or above 600 mg/dL, the screen displays “LO”. If either “HI” or “LO” are obtained, retest using a new test strip. If the same “HI” or “LO” reading is obtained, run a control test to verify instrument performance. All results with no corresponding numerical value or any “unexpected” results should have a specimen sent to the laboratory for confirmatory testing.

d. If a repeat numerical result does not agree within 10% or 10 mg/dL (whichever is greater), a serum sample should be sent to the lab for testing.

e. ICN results > 200 mg/dL in the first 24 hours of life a serum should be sent for a laboratory glucose because renal threshold is greater than 180. Thereafter, results greater than 300 mg/dL require a confirmatory sample to be sent to the Laboratory for the first occurrence and once every twenty-four hours thereafter.

f. ICN results less than 30 mg/dL require a repeat test to be performed on the glucose meter. If the repeat results differ by greater than 10 mg/dL from the first sample, a confirmatory Lab sample is required.

g. Patients with blood concentrations of interfering substances beyond those tested by the manufacturer as described in Section VIII, “Limitations of the Procedure” should not have meter glucose testing performed. Laboratory performed glucose testing should be ordered for these patients.

**Note:** Glycolysis rate in neonatal blood is nearly twice the rate of adult blood. Delays in transporting samples for confirmatory testing should be avoided.

### VII. Transferring Data:

#### 1. Hard Wired Docking/Charging Station

a. When the meter is not in use, place it into the Docking/Charging Station. This will enable the meter to stay fully charged. The Docking/Charging Station is connected to a power source and to the computer network as follows:

b. Plug the fixed power cord from the power supply into the back of the Charging Station.

c. Plug the 2-prong plug of the wall plug cord into the power supply.

d. Plug the 2-prong plug into a wall outlet.

e. Place the meter and/or spare battery into the Charging Station.

f. Connect the Docking/Charging Station to the network through the Ethernet connection at the back of the station. The connection is marked with the Ethernet symbol.
   - The green left light is on if the station is connected to the network.
   - The green middle light is on if data is transferring.
   - The right light is green for fully charged or amber for charging.

#### 2. Wireless Docking/Charging Station

a. When the meter is not in use, place the meter and wireless case in the wireless docking station.
b. Plug the fixed power cord from the power supply into the back of the Charging Station.
c. Plug the 2-prong plug of the wall plug cord into the power supply.
d. Plug the 2-prong plug into a wall outlet.
e. Place 5 batteries in the Wireless Case.
f. Turn the Wi-Fi switch to the on position.
g. The Wi-Fi light is lit amber when transmitting data.
h. The lights in positions 1 through 5 go from red to green as the batteries are charged.
i. Place the case and six spare batteries into the Charging Station.
j. The power button will be lit green. The lights for positions 1 to 6 will go from red to green as batteries are charged.

VIII. Limitations of the Procedure:

1. The StatStrip Hospital Meter System can be used for critically ill patients for the determination of glucose in venous whole blood, arterial whole blood, neonatal arterial whole blood and neonate heel stick specimens. Critically ill patients should not have a capillary, fingerstick specimen tested for glucose using the StatStrip Meter.

2. The StatStrip Glucose Meter should have results that agree with a laboratory result to within 20%. A test result within this range is considered accurate when testing with the Nova StatStrip Meter. See the Performance Characteristics section for accuracy and precision information. However, there are factors that may cause results to differ by more than 20% in some situations. These factors are listed below:
   a. Blood source – Use only whole blood. Do not use serum or plasma.
   b. Venous and capillary blood may differ in glucose concentration by as much as 7 mg/dL (0.6 mmol/L), depending on the time of blood collection after food intake.
   c. Temperature and humidity extremes – Test results are best obtained when Nova StatStrips are used within an operating relative humidity of 10-90% (non-condensing). Testing outside these ranges may cause inaccurate results.
   d. Altitude – There is no effect of altitudes up to 15,000 feet (4500 meters) above sea level.

3. If needed, sodium, lithium, and ammonium heparin are the recommended anticoagulants for use with the StatStrip® Glucose Meter.
   a. Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, the concentrations of heparin may be 20 I.U. per mL to over 100 I.U. per mL. When liquid heparin is present in excess, it may cause dilution errors.
   b. A lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable.

4. EDTA, citrate, oxalate, and sodium fluoride are not recommended for use.
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5. Glucose Interferences: Nova’s Multi-Well system measures and corrects hematocrit interferences as well as interferences from acetaminophen, uric acid, ascorbic acid, maltose, galactose, xylose, and lactose. StatStrip also eliminates oxygen interference to provide accurate glucose results regardless of the sample’s oxygen status.

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

<table>
<thead>
<tr>
<th>Tested Interfering Substances</th>
<th>Tested Concentration Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>15.0 mg/dL</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>500.0 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>6.0 mg/dL</td>
</tr>
<tr>
<td>Dopamine</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Ephedrine</td>
<td>0.9 mg/dL</td>
</tr>
<tr>
<td>D(+) Galactose</td>
<td>350.0 mg/dL</td>
</tr>
<tr>
<td>Hematocrit (RBC)</td>
<td>20% - 65%</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>48.0 mg/dL</td>
</tr>
<tr>
<td>L-Dopa</td>
<td>100.0 mg/dL</td>
</tr>
<tr>
<td>D(+) Maltose Monohydrate</td>
<td>240.0 mg/dL</td>
</tr>
<tr>
<td>D(+) Maltotetraose</td>
<td>240.0 mg/dL</td>
</tr>
<tr>
<td>D(+) Maltotriose</td>
<td>240.0 mg/dL</td>
</tr>
<tr>
<td>Methyl-Dopa</td>
<td>1.0 mg/dL</td>
</tr>
<tr>
<td>Oxygen</td>
<td>All Concentrations</td>
</tr>
<tr>
<td>Salicylate</td>
<td>30.0 mg/dL</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>30.0 mg/dL</td>
</tr>
<tr>
<td>Tolazamide</td>
<td>15.0 mg/dL</td>
</tr>
<tr>
<td>Tolbutamide</td>
<td>45.0 mg/dL</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>750.0 mg/dL</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>20.0 mg/dL</td>
</tr>
</tbody>
</table>

NOTE: Critically ill (non-neonate) patients and patients with known concentrations of interfering substances beyond the concentrations tested as listed above should have glucose testing performed by sending a blood sample to the laboratory for a laboratory performed glucose.

For example, patients with a hematocrit <20% or >65% should not have meter glucoses performed but should have orders placed for a laboratory performed glucose.
For the purposes of this policy, patients should be considered critically ill in illness/conditions that result in decreased peripheral blood flow. Decreased peripheral blood flow can occur in, but is not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.

IX. REFERENCES:

3. Instructions for Use Manual StatStrip Glucose Hospital Meter, REF 41853