PURPOSE:
To provide guidelines for proper use and maintenance of whole blood glucometers to diagnose hypoglycemia or hyperglycemia.

POLICY:

A. Principle
   Precision Xceed Pro (PXP) Blood Glucose Test Strips use biosensor technology. The sample is applied to the target area, covering both the working electrode and the reference electrode. This area is coated with enzymes that react in the presence of glucose to make a small electric current. The size of the current generated is proportional to the amount of glucose present in the blood drop.

B. Clinical Significance
   Point of care blood glucose monitoring systems provide rapid results required to make therapeutic decisions. This type of testing; however, supplements, rather than substitutes for testing in the clinical laboratory.

C. Appropriate PPE is to be used when performing venipuncture and when handling, processing, and testing any patient sample or bio-hazardous reagent. Sharps safety device must be used with any venipuncture and disposed of in a biohazard sharps container.

D. All glucometer operators will be deemed competent through training and competency validation outlined by the hospital.

E. Operators will be taught by those individuals deemed competent to instruct others by the unit manager/director or the Education Department.

F. A record shall be maintained of all individuals who have completed training as competent operators. Upon hire the manager/lead shall complete a security request form and forward it to the LIS coordinator who will issue a unique operator identification number. Completion of glucometer competency shall be accomplished prior to the employee performing any patient tests. The laboratory will enter the new users, QC and strip lot.
information into the glucometer data management system. Any problems concerning these items should be referred to the laboratory.

G. The Education Department will assist in coordinating the annual proficiency/competency testing of all operators.

H. Bedside testing shall be performed only with an order of the physician or by physician approved protocol.

**PROCEDURE:**

I. **PREANALYTICAL PROCEDURE:**

A. **Specimen Requirements**

1. **Patient Preparation**
   Clean and dry the sample site completely before collecting specimen. Refer to Capillary Puncture Procedure for further instruction.

2. **Sample Collection/ Type**
   Capillary, arterial and venous whole blood specimens are acceptable. Heparinized and EDTA whole blood are also acceptable.

3. **Sample Stability/Preservation/Storage**
   Heparinized or EDTA whole blood specimens must be used within 30 minutes of draw.

B. **Reagents and Supplies**

1. Blood Glucose Test Strips- Store strips between 4-30°C. Strips expire on manufacturer’s printed date on the barcode label and outer box. Use strips immediately after opening foil packet. Do not use strip if the foil packet is punctured or torn. Don’t use wet, bent, scratched, used, or damaged test strips.
2. Alcohol Swabs or other approved skin-cleansing product.
3. Lancet
4. Disposable gloves

C. **Instrumentation-Glucometer**

1. When not in use, the meter can be stored in carrying case. The glucometer should be connected to the data upload cable before use. Data is transferred to the glucometer data management system and patient information is uploaded only when the glucometer is connected to the cable.
2. **Cleaning:** Use only alcohol based cleaners. Clean glucometer after each patient use. Turn off the monitor prior to cleaning. Squeeze out excess fluid from cloth prior to use. Do not immerse, spray, or flood glucometer with any liquid.

D. **Calibration-** The meter is calibrated when the test strip barcode is scanned. Linearity is performed by laboratory staff prior to patient testing.

E. **Quality Control**
1. **Material Used**  
MediSense Glucose Control Solutions- 2 levels

2. **Preparation/Storage of Control Reagents**  
Store between 4-30°C with vials capped. When opening new vial, write date, initials and new expiration date on the vial. Vial expires 90 days after opening. Controls must be at room temperature prior to use.

3. **Frequency**  
2 levels of QC should be performed in the following situations:
   a. Every 24 hours  
   b. After a meter has been dropped or damaged.  
   c. When the patient’s result contradicts the patient’s condition.

4. **Procedure**  
a. Invert the control bottle 3-4 times to ensure thorough mixing before each use.  
b. Invert and tap the capped control solution bottle to remove air bubbles from the tip of the bottle.  
c. Wipe the control solution nozzle with a clean gauze or tissue before and after each test.  
d. Place monitor on flat surface while running control tests.  
e. Perform quality control testing in the same manner as patient testing. After pressing On/Off to turn on the monitor, press ‘2’ to select **Control Test**.  
f. Follow prompts on glucometer. Scan barcode on side of control vial when prompted by glucometer for Lot #. If the ‘**Unexpected Level**’ screen appears, you may either enter ‘1’ to reenter the expected level, or enter ‘2’ to continue.  
g. Replace the correct cap on the bottle and tighten the cap immediately after each use.  
h. QC results will display as either ‘PASS’ or ‘FAIL’.

5. **Corrective Action**  
a. If the quality control check FAILS, the glucometer will prompt user to ‘**Scan or enter comment code**’. Enter one of the following codes:  
   i. 1 or 01 “Repeat”  
   ii. 2 or 02 “Procedure Error”  
b. Verify that control material and the test strips have not expired, and then repeat testing. If QC still fails, test with new vial of control. If the values continue to be out of range, call the laboratory for troubleshooting or glucometer replacement.  
c. All quality control/improvement and proficiency records are maintained and reviewed by Laboratory personnel.

II. **ANALYTICAL PROCEDURE:**

A. Verify patient identification.

B. Press the power button.

C. Press 1 to select **Patient Test**.

D. Enter operator ID (last 4 digits of SSN) via the keypad, and then press Enter.
E. Press **Scan** to scan the patient ID barcode (account/visit number).

F. Confirm the Patient ID, if prompted.

1. If the patient identification number is recognized, the glucometer will display patient information and asks to confirm year of birth. Enter the last two digits of the year on the keypad, then press ‘**Enter**’.
2. If the patient identification number is not recognized as valid, the glucometer will prompt user to confirm the patient ID. This happens if an incorrect patient ID is entered or if the glucometer has not been connected to the data upload cable after the patient was admitted. Re-enter the ID (account/visit number) using the keypad or scan the patient ID barcode. If the ID is not found a second time, the glucometer will give 2 options, press ‘1’ to re-enter patient ID (if entered incorrectly), or press ‘2’ to continue and run test.

G. **FOR EMERGENCY DEPARTMENT STAFF ONLY**: In the event that a STAT blood glucose must be performed before the patient is registered, use the date and time of the test and the patient’s last name for patient identification. For example, if the test is done on March 1, 2012 at 3pm, enter “0301121500” via the keypad. Then, after the glucose test is performed, when the glucometer prompts ‘Patient ID 2’ free-text patient’s last name using keypad if available.

H. **FOR WOMEN’S CENTER STAFF ONLY**. In the event that a STAT blood glucose must be performed on a neonate prior to registration, use the baby ID 5 digit band number *preceded* by ‘0000’. After the glucose test is performed, when the glucometer prompts ‘**Patient ID 2**’, freetext the baby’s last name using the keypad. For twins, the letters ‘A’ and ‘B’ will be used after the name.

I. When prompted to ‘**Scan or Enter Strip Lot**’, Press **Scan** to scan the test strip lot number via the keypad, then press Enter. Remove test strip from foil packet and insert into glucometer with contact bars facing up. The glucometer will display ‘**Strip Inserted**’ when test strip is loaded correctly. Prior to inserting the test strip, ensure that the port protector is installed and that it is clean and dry. Bring glucometer to lab for replacement of port protector, if necessary.

J. The display will alternate between ‘**Strip Inserted**’ and ‘**Apply Sample**’. Obtain a blood sample. Touch and hold drop of blood to the target area of the test strip. If adequate sample is applied, the monitor will display ‘**Sample Accepted**’.

**NOTE:** It is important to apply adequate volume (min. 0.6mcL) of sample in one application or a new strip must be used. An error in the glucose measurement will occur if additional sample is added after initial application.

K. When the test is complete, results are displayed. The glucometer will prompt ‘**Patient ID 2**’, if the patient information was verified and a correct patient account/visit number was used, it is acceptable to press ‘**ENTER**’ to bypass field. For emergency situations, where the patient’s account/visit number was not scanned, the patient’s last name must be entered via keyboard in this field.

L. If the patient’s glucose result is outside the established action limits, the glucometer will prompt ‘**Scan or enter comment code**’ Enter one of the following codes to determine if appropriate action was taken:

1. 3 or 03 “Symptomatic”
2. 4 or 04 “Asymptomatic”
3. 5 or 05 “Neonate. WNL”

M. After test completion, one of the following options can be selected.
   1. Press 1- Next Patient
   2. Press 2 Patient History
   3. Press Menu to return to the Menu Mode menu.
   4. Press On/Off to turn off the monitor

N. Remove the test strip from the monitor and discard it in regular waste container.

III. REPORTING

A. Results:

1. If the patient test result is out of range (<50 or >400) by glucometer, and the patient is asymptomatic requiring immediate intervention, care is provided in accordance with the physician orders or standardized procedure. If the patient is not symptomatic, the test is repeated. If the repeated test is still in the critical range, a laboratory sample is obtained to confirm results. For newborns, if glucose is < 40 mg/dL or >250 mg/dL, follow physician orders.

2. If the patient is being treated for elevated blood sugar due to a previously run elevated glucose level and glucose is trending down, it is not necessary to draw lab specimen for confirmation unless the results are in question.

3. Upon diagnosis of hyperglycemia, insulin coverage shall be given only upon the order of the physician as either a one time order, or as a sliding scale based on the quantitative measure of glucose.

4. Upon diagnosis of hypoglycemia, the treatment of critical low glucose levels shall be per physician orders or by physician approved protocol.

B. Limitations of Procedure:

1. The test systems are not designed for use with serum or plasma samples or specimen types other than whole blood. Use of other specimen types will result in falsely elevated glucose results.

2. Use glucometer between 15º-40ºC and 10%-90% humidity.

3. The presence of alcohol when not allowing puncture site to dry before obtaining blood can result in inaccurate results.

4. Do not use during intravenous infusion of high-dose ascorbic acid or during xylose absorption testing.

5. Test strips must be stored between 4-30ºC. Keep away from direct sunlight and heat. Storage outside this range may cause erroneous results.

6. Using an incorrect test strip barcode may cause inaccurate results. Always use the
barcode from the foil package of the test strip being used.

7. Hematocrits below 20% and greater than 70% affect whole blood glucose measurements. Send plasma specimen to lab for accurate analysis.

REFERENCES: