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## Policy and Procedure

<b>Title:</b>	Whole Blood Glucose, SureStepFlexx Glucose Monitoring System		
<b>Origination Date:</b>	10/12/04	<b>Section:</b>	POCT
<b>Effective Date:</b>	Oct 12, 2004	<b>Policy No.:</b>	<a href="#">WT 1.5 V0</a>
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**PURPOSE:** This procedure is used to obtain a quick, accurate, quantitative blood glucose result at the patient's bedside using whole blood. This quantitative measurement is for the purpose of monitoring blood glucose levels.

**PRINCIPLE:** A small drop of blood is applied to the SureStepPro Test Strip. A glucose oxidase reaction occurs between the whole blood and the reagents in the test strip resulting in the formation of a blue color that is visible through the confirmation dot on the back of the test strip. *The darker the blue, the higher the glucose level in the blood sample.* **The meter measures the color intensity and reports a plasma-calibrated glucose result.**

**SCOPE:** Health Care Providers throughout the New Hanover Health Network, who have completed training and maintain annual competency, may perform this test.

**SPECIMEN: Capillary, venous, arterial, and neonatal blood samples may be used.** All specimens obtained for POCT testing must be collected according to approved policies stated in the Online Laboratory Specimen Collection Manual and/or department specific nursing policies as they apply to a collection process from a line. **Ensure all non-capillary samples are well mixed prior to testing.**

**1. Capillary:** Capillary blood can be obtained from a skin puncture using the fingertip or heel and the hospital approved lancing device. The puncture site is cleaned with alcohol and allowed to air dry for 10 – 30 seconds before obtaining the blood sample. A small drop of whole blood is applied directly to strip.

- 5 to 10 µL of sample is needed depending upon patient's Hematocrit and sample application. (Less sample will be required if sample is applied to center of pink sample square on strip.)

- Heel or finger stick collection using hospital approved collection lancets and policies. See Online Laboratory Specimen Collection Manual.
  - ***Avoid excessive squeezing or “milking” of puncture site to get enough blood.***
2. **Venous or Arterial:**
- Whole blood specimens collected with heparin (ABG syringe or green top tube), or EDTA (purple top tube) are acceptable. **Do not use collection tubes containing other anti-coagulants such as gray or blue.**
  - Perform testing with **well-mixed sample within 20 minutes of collection** to minimize effects of glycolysis.
  - See Online Laboratory Specimen Collection Manual and/or department specific nursing policies as they apply to line draws.
3. **Neonate:** Capillary, venous, or arterial samples are acceptable. **Accurate results will depend on the Hematocrit being between 25% and 65%.** If symptoms are inconsistent with meter results and hematocrit is suspected to be outside this range, a laboratory glucose test is required. Obtain and send specimen to lab before making any adjustments in treatment.

**Notes:**

1. **Do not use plasma, serum, or other body fluid samples for determination of glucose using the Flexx meter.**
2. **Whole blood glucose results should agree with the laboratory result within  $\pm 15\%$  most of the time under normal conditions and normal sources of variations.**
3. **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 and peripheral circulation.**
4. Shock, administration of vasoactive agents, and other factors affecting the peripheral circulation may also cause discrepancies between venous and capillary glucose results.
5. Use an adequate amount of blood—just enough to cover the pink test square.
  - **Too much blood may cause inaccurate, high results. If the entire white pad is saturated with blood, you have applied too much blood.** Repeat the application with a new test strip and apply a smaller drop of blood.
  - **Too little blood may cause inaccurate, low results.** If the confirmation dot on the back of the test strip is not completely blue but shows patches of white, you have not applied enough blood. Repeat the application with a new test strip and apply a larger drop of blood.
6. **Hematocrit in Extremes** can affect test results. See limitations for more details.

**PATIENT PREPARATION:** N/A**HANDLING CONDITIONS:**

The blood glucose concentration decreases over time due to red blood cell consumption of glucose.

- **Heparin or EDTA Specimens:** Perform testing **within 20 minutes of collection** to minimize the effect of glycolysis (red cell glucose consumption). Ensure blood in a test tube (Green or lavender top) is well mixed by gently inverting the capped tube 10 times.

- Perform testing on **non-anticoagulated specimens immediately** to prevent clotting and erroneous results.

## PROCEDURAL PREPARATION AND NOTES

### 1. Equipment and Materials: (Hospital Order number)

- **SureStepFlexx meter** and appropriate operator's guide
- **SureStepPro Strips (153002):**
  - a. **Store SureStepPro strips tightly capped in their original bottle/vial at room temperature (15 - 30° C).** Keep away from heat and direct sunlight. Do not refrigerate or freeze.
  - b. **Strips exposed to excessive air or moisture may cause inaccurate results.** Once strip is removed from vial, close vial immediately and use strip as soon as possible. Do not remove more than one strip at a time for testing.
  - c. **Discard any unused strips if not used within 4 months after opening.** Operator must indicate "opened date" on vial when strips are put into use for QC/patient testing.
  - d. Do not transfer strips to a new vial or another container.
- **SureStepPro Controls:** Store SureStepPro control solutions tightly capped in their original bottle at room temperature (15 - 30° C). Do not refrigerate or freeze. **Discard any unused control if not used within 3 months after opening.** Operator must indicate "opened date" on control vial when strips are put into use for QC/patient testing.
  - a. **SureStepPro High Control (153000)**
  - b. **SureStepPro Low Control (153001)**
- Lancets
- AA Batteries (obtained from department par)
- Disposable gloves
- "Towel Bleach Mini Hypewipe 3 X 3" (156136) 09/15/06 PAG

### Notes:

- a. Each department orders and maintains all glucose testing supplies.
- b. Additional strips and controls may be obtained through the hospital "Distribution" department.
- c. Do not use any glucose products beyond the printed expiration date on the bottle/vial label.
- d. **Do not use any test strips that are bent, torn, cut, or damaged in any way.**
- e. The confirmation dot of an unused test strip is off-white. **Do not use a test strip if the confirmation dot is discolored or does not turn blue with proper sample application.**
- f. If scan button does not appear as expected, the battery power is too low to scan. Change batteries as needed.
- g. There are only three times the **Enter** key is needed.
  - Confirmation of entry for Operator ID
  - Confirmation of entry for Patient ID
  - When comments are required for out of range QC and Critical Values.

### 2. Calibration: Code numbers are used to calibrate the SureStepPro Test Strips with the SureStepFlexx meter for accurate results. **Operator must match the code number on the**

**meter display to the code number on the test strip bottle with each test to ensure accurate results.**

3. **Maintenance:** The “**Test Area**” and “**Strip Holder**” are cleaned when needed and visibly dirty. The most common error message for needing to clean the meter is Error 5. However, Error 6 may also occur if contact points have residual bleach on them after cleaning.
4. **Upload (Electronic data transfer) is required every 24 hours. The instrument will indicate when this is due each time it is turned on.**

#### **DAILY QUALITY CONTROL (QC):**

**SureStepPro High and Low Glucose Control Solutions** are used to check the SureStepFlexx meter performance, SureStepPro strip integrity, and operator technique. Network QC ranges are set in the meters using historical standard deviations and network determined means for each lot of strips. The controls and strips used are sequestered lots and will be in use for a minimum of 6 months. All lots of controls and strips are evaluated prior to release to departments and entered into the system by the POCT section of the lab.

#### **Controls are performed as follows:**

- **Two levels (high and low) of controls are required each day (24 hours) of instrument use.**
- **When validity of glucose result is questioned** due to inconsistency of result and clinical disposition of patient. *Valid glucose control results depend on the correct test strip lot number and corresponding code, optimum storage conditions of strips, and proper handling of the controls and strips.*
- **When meter is dropped.**
- **When troubleshooting the system for suspected problems.**

#### **QUALITY CONTROL PROCEDURE:**

1. **Check all opened supplies for “opened dates”.** Ensure controls and strips are not expired due to “opened expiration date”. Discard and replace as needed.
  - **Controls are good for 3 months after opened date.**
  - **Strips are good, when kept tightly closed in original container, for 4 months.**
2. **Turn on meter.**
3. **Review the Status Screen for battery status, upload due time, and QC requirements.** (Upload as needed and then continue with QC if needed.) **Press Cont.**
4. **Select QC Test from the Main Menu.**
5. **Select high control level.**

6. **Scan or enter your operator ID** (badge number). See pages 10 and 11 of Meter Operation Guide on assistance for scanning techniques. (See “Operator ID notes” on next page if bar-coded network badge is not available.)
7. **Select the control lot number** from the list displayed. Upload instrument if selection needed is not listed. (All lot numbers will be entered into the system through the lab data station. You should not have lot numbers that are not available when download is completed. Call POCT Lab personnel (Ext 4849 or 3199) if problem persists.
8. **Select the test strip lot number** from the list displayed. Upload instrument if selection needed is not listed.
9. **Mix control solutions** by shaking vial. Apply one drop of control solution to the pink test square on the test strip.
10. **Check confirmation dot** on back of test strip to ensure it is **completely blue**.
1. **Insert** the test strip, **application side up**, into the test strip holder **within 2 minutes** of applying blood. Firmly push the strip until it comes to a complete stop.
 

**Caution:** If you fail to completely insert the test strip, the instrument will prompt you to remove strip. Remove strip and wait until prompted to insert strip again. ***Do not use strip that has had sample application in place for longer than 2 minutes.***
11. **Result will appear within 30 seconds.**
12. Remove used strip and repeat. Steps “6” through “13” above for the low control.

**Notes:**

- a. Control results should fall within established network QC ranges when the system is working properly and correct testing procedures are followed.
- b. QC Results within acceptable network range, when testing in QC mode, are indicated by PASSED on the meter display. Results that are not within range are indicated by FAILED.
- c. If QC results fall outside the expected range, the system will not allow patient testing until problem is resolved. **Repeat the test and follow steps indicated on the “Troubleshooting and Exchange form.**
- d. If QC fails, press **Enter Note** and choose from 1 to 3 comments to document corrective action taken.

**Failed QC Results May Indicate:**

- Procedural error.
- Old or contaminated glucose control solution.
- Incorrect lot number or code number selected for supplies used.
- Debris in lens area and test strip holder.

- Test strip deterioration. (Repeated periods of uncapped strip vial will lead to moisture contamination with deterioration of strips and erroneous results.)
  - Meter malfunction.
  - Control solution outside the 15°–35°C functional temperature range.
- e. If repeat QC testing also fails or the meter will not perform as expected, refer to the *Blood Glucose: [SureStepFlexx Troubleshooting & Exchange Form](#)*. (Attachment 3) for corrective action. This form must be filled out and brought to the Zimmer building lab if meter exchange is needed.
- f. Additional troubleshooting information can also be found in the troubleshooting section of the SureStep Hospital Operator's Guide.
13. **Once both controls have been completed with acceptable results**, the meter will allow patient testing.

#### OPERATOR ID NOTES:

**All personnel trained to operate the glucose meter must be in the system prior to expected use.** Please ensure Patty Goodlin (POCT Resource Tech) Ext. 4849 has appropriate list of operators **ONE WEEK before expected day of use.** **The network employee badge number is the operator ID.** **If your badge is not available or it will not scan, the following is used for manual entry.**

**Operator ID must be 10 digits and follow the following format:**

1. **Use network badge number preceded by the appropriate number of zeros to make up 10 digits.**
  2. **Nursing Students without a network badge: use the letter "S" five zeros and the last four digits of SS#.**
  3. **Travelers are to use badge numbers. Remember lab must have badge number in system for badge number to work.**
  4. **Faculty of Nursing Schools without a network badge: use the letter "F" five zeros and the last four digits of SS#.**
- **TROUBLESHOOTING AND MAINTENANCE:** Use 10 % Bleach solution for cleaning/disinfecting instrument and parts. "Towel Bleach Mini Hypewipe 3 X 3" (156136) is available in Lawson for this purpose. 09/15/06 PAG

The following cleaning agents **will damage the test area. DO NOT USE:**

- Alcohol or alcohol wipes
- Cleansers with ammonia
- Cleaners with phenol
- Abrasive cleaners
- Windex or other glass cleaners
- Full-strength detergent or bleach

**A. Clean Test Strip Holder**

1. **Remove test strip holder.** Press down on the top of the test strip holder and slide it away from the meter.
2. **Remove debris** by wiping the test strip holder gently with a cotton swab or cloth dampened with water or 10% bleach solution (1:10 dilution of household bleach) in water. Wipe the gray area on the inside cover.
3. **Wash both side of the base (base is hinged such that top and bottom can be cleaned while hanging on to blue part of strip holder);** carefully clean around the hole in the base.
4. **Rinse thoroughly with water to remove any residual bleach.**
5. **Dry completely** with clean gauze, tissue, or paper towel.
6. **Replace test strip holder. Slide test strip holder into the meter and press down at the strip insertion point until it clicks. Make sure the test strip holder is firmly in place and does not extend beyond the meter.**

**B. Clean Test Area and Contact Points**

1. **Clean the surface of the test area** normally covered by the Test Strip Holder. (This area may not look dirty but still needs to be cleaned.)
  - Using a cotton swab or a cloth dampened with water or 10% bleach solution, wipe the lens area.
  - Wipe this area even if it doesn't appear to be dirty.
  - Using a cotton swab or a cloth dampened with water to remove any residual bleach.
  - Dry Test Area by gently blotting with a paper towel or other clean, soft lint-free cloth. Be careful not to scratch the lens area or get water inside the meter.
2. **Replace test strip holder. Slide test strip holder into the meter and press down at the strip insertion point until it clicks. Make sure the test strip holder is firmly in place and does not extend beyond the meter.**

- C. **Disinfect instrument and case** with paper towel or clean cloth moistened with 10% bleach solution in water. Use 10 % Bleach solution for cleaning/disinfecting instrument and parts.

"Towel Bleach Mini Hypewipe 3 X 3" (156136) is available in Lawson for this purpose. 09/15/06  
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**D. Replace meter batteries:** (3 AA batteries)

When the batteries are getting low, the battery symbol will appear on the display.

- a. Obtain 3 AA batteries from department supplies. (These are not furnished by lab.)
- b. Turn the Meter off and turn it over.
- c. Remove the battery door: squeeze the tab and lift up.
- d. Remove the old batteries and dispose of them.
- e. Insert new batteries making sure to align the positive and negative poles correctly.
- f. Close battery door: Insert the two hinges into the slots and press down until the tab catches.

**PROCEDURE – PATIENT TEST:** Gloves must be worn while performing blood glucose testing.

**Procedural Notes:**

- Always match the current test strip lot number (and corresponding code) in the meter. The lot number and code are printed on the SureStepPro Test Strip bottle label.
  - **The confirmation dot of an unused test strip is off-white. Do not use a test strip if the confirmation dot is discolored.** A color chart on the test strip bottle label shows the color of an unused test strip's confirmation dot.
  - Do not use test strips when strip bottle has been left uncapped. Do not use strips in tote that are not in tightly sealed vial.
  - Do not use strips that have been opened for more than 4 months.
  - **You have up to 2 minutes to insert the test strip after applying blood.**
  - All meters programmed for neonates (NICU, Transitional Nursery, and Newborn Nurseries) have the critical values as < 40 mg/dL and greater than 150 mg/dL. The reportable range is  $\leq 200$  mg/dL. **DO NOT use adult meters for testing baby samples or vice versa such that meter programming for critical ranges will be misleading.**
  - **Scanner precautions: This scanner contains a laser. Do not stare into the laser light or point it towards anyone's eyes while laser light is on. The scanner is at the bottom of the instrument to help avoid accidental events.**
2. **Check physician's orders.** (Glucose testing can not be performed without a physician's order)
  3. **Gather all necessary equipment** and items needed for blood testing (gloves are worn in all steps of specimen collection and testing).
  4. **Check all opened supplies for "opened dates" and expiration date.** Discard and replace as needed.
  5. Turn on the meter as needed.
  6. **Check QC and battery status and upload due time.** (Upload as needed and then continue with QC if needed.) **Press Cont.**
  7. Select **Patient Test** from the Main Menu.
  8. **Scan or Enter operator ID** (badge number). See pages 10 and 11 of Meter Operation Guide on assistance for scanning techniques. See "Operator ID Notes" at top of previous page.
  9. **Confirm entry** is correct and press **Enter** to accept.
  10. **Check patient identification and scan patient's armband** (this will be the **Account Number**) for patient ID when prompted.
  11. Press **Enter** to confirm. See "Patient ID Notes" at the end of this section for clinical exceptions when Account is not available.

12. **Confirm entry** is correct and press **Enter** to accept.
13. **Compare displayed strip lot number** with that printed on the strip container. Touch the correct lot number to confirm. Code number and lot must match those on the strips. (If lot is not on screen, download and check again.)
14. Obtain a drop of whole blood for glucose testing
15. Apply blood to the test strip by carefully touching the pink square on the test strip to the drop of blood. Sample will be absorbed into the strip. The confirmation dot is your guide to adequate blood sample. **If the confirmation dot has white patches or streaks, sample technique was not adequate. Repeat sample application with new strip.**

**Note: The center of the pink square on the strip is on the opposite side as the confirmation dot. The blood sample and strip must remain in contact during sample application. Watching the confirmation dot turn uniformly blue will confirm adequate blood application. Once contact is broken, you cannot reapply the strip to blood or add another drop.**

- **Finger or Heel Stick:**
  - Carefully touch the pink test square to the drop of blood on the patient's finger or heel. The test area will quickly absorb the blood.
  - Watch the confirmation dot, now facing you, to ensure it is completely blue. The dot should be completely blue for an accurate test. Repeat the blood application with a new test strip if dot is not completely full. See sampling guide in tote.
- **Syringe:**
  - **Waste first drop of blood from syringe on absorbent pad or gauze (this will usually provides enough blood at tip of syringe for sample application).**
  - Touch tip of syringe to pink test square. Sample will be absorbed from the tip. *(If needed, gently apply slight pressure. As blood emerges from the tip of the syringe, it is absorbed by the test square.)*
  - **Avoid applying too much blood. If the white pad becomes completely saturated, there is too much blood.**
  - Check confirmation dot on the back of the test strip. The dot should be completely blue for an accurate test. Repeat the blood application with a new test strip if dot is not completely full. See sampling guide in tote.
- **Green or Lavender collection tubes:**
  - Apply blood to the test square using a narrow-bore pipette.
  - Avoid applying too much blood. If the white pad becomes completely saturated, there is too much blood.

- Check confirmation dot on the back of the test strip. The dot should be completely blue for an accurate test. Repeat the blood application with a new test strip if dot is not completely *full*. *See sampling guide in tote.*
16. **Insert** the test strip, **application side up**, into the test strip holder **within 2 minutes** of applying blood. Firmly push the strip until it comes to a complete stop.
- Caution:** If you fail to completely insert the test strip, the instrument will prompt you to remove strip. Remove strip and wait until prompted to insert strip again. ***Do not use strip that has had sample application in place for longer than 2 minutes.***
17. The result appears in approximately 30 seconds.
- Press Menu to continue testing.
  - Or, press **Enter Note** and choose one to three comments that correspond to the patient's current situation. Press Ok.
18. Remove the test strip and dispose of it according to your institution's policies and procedures.

**PATIENT ID NOTES: ALL ENTRIES MUST HAVE SEVEN DIGITS.**

1. In circumstances where the glucose testing is needed "STAT" and the patient has not been registered, use the **letter "S" two zeros and the last four digits of the Patient's Social Security Number** in the following format: S009632.
2. In the extremely rare circumstance when patient is not registered and is unable to communicate the last four digits of the social security number, use the letter "S" three zeros and 9 1 1 as Patient ID. (May be a code gray situation.) Example: S000911
3. **The numbers "0000000" are reserved for teaching purposes only. These results are not charted or used in patient treatment in any manner.** This number will usually be the first time a new employee does a whole blood glucose test. There should be a certified operator reviewing the procedure with the employee and a second test should follow within a few minutes using appropriate ID numbers.
4. EMS, Airlink & Vitalink: Unique number associated with "Run number" and/or Ambulance and patient. (Must have 7 digits.)

Examples:

- Run number
- Truck/time

**CALCULATION: Done automatically as programmed in meter setup.**

**REPORTING RESULTS: Reference Ranges Are For Plasma-Calibrated Whole Blood**

**Notes:**

1. **If unexpected high or low glucose results** are obtained, **confirmation of the glucose** result is required and the physician or prescribing healthcare professional consulted before making changes to the patient's feeding/medication program.
2. **Confirmation of proper SureStepFlexx system** performance may consist of two or more of the following steps.
  - Compare confirmation dot on strip with that on the strip vial. Dot must be free of white patches and streaks.
  - Verify test results by repeat testing of patient on Flexx meter using a newly opened bottle of strips **or** repeat testing of both levels of daily controls using same bottle of strips as repeated patient test. (03/22/07 PAG)
  - Confirmation of glucose result with sending specimen to laboratory for glucose testing.
3. **All glucose results are recorded in the patient's chart** (progress notes and/or Diabetic Treatment Record) and reviewed by the primary caregiver. **Test results are for monitoring purposes with follow-up testing being performed as requested. Critical Values are defined and action documented in Flexx meter and chart.**
4. **Instrument Reportable Range All Meters: 0-500 mg/dL. (Monitor display shows "HIGH")**
  - a. **All glucose values above 500 mg/dL (High) must be confirmed by sending a specimen to the lab.**
  - b. **Neonates will get a number over 200 mg/dL; but all results greater than 200 must be confirmed by lab testing.**

➤ **Non-Neonates** (Adults and children > 28 days old)

- Before meals (fasting): 70-112 mg/dL
- One hour after meals: Less than 160 mg/dL
- Test results below 60 mg/dL indicate low blood glucose (hypoglycemia) and are treated according to the nursing Hypoglycemia policy.
- Test results above 240 mg/dL indicate high blood glucose (hyperglycemia) and are treated according to nursing protocols.

**Critical Values:** Less than (<) 50 mg/dL  
Greater than (>) 400 mg/dL

- a. **Confirmation of result is required on all glucose values less than 50 mg/dL (<50) or greater than 400 mg/dL (>400). Repeat testing on Flexx meter is recommended prior to notifying physician.** (Also see "Reporting Results" notes on previous page.)
- b. **Confirmation of testing by lab is required if results are not consistent with patient's clinical disposition.** Report results through the necessary care givers to notify the Physician. **All critical results need appropriate action comments**

**entered in the Flexx meter and follow up testing and/or treatment as ordered by the physician.**

- c. Flexx blood glucose values less than 40 mg/dL or greater than 500 mg/dL (monitor display shows "HIGH") must be confirmed by lab glucose testing.**

➤ **Neonates ( $\leq$  28 days old)**

- Before meals (fasting): 40 - 112 mg/dL {*Pediatric Reference Intervals 5<sup>th</sup> Edition, 2005 AACC; p 103*} (*PAG 06/28/06*)
- Glucose levels drop dramatically in the first 60 to 90 minutes after birth. They recover spontaneously, but levels of 40 to 50 mg/dL can remain during the first few days of life.
- **Test results below 40 mg/dL indicate low blood glucose (hypoglycemia) and are treated according to the nursing "Hypoglycemia in the Newborn" policy.**

**Critical Values:** Less than ( $<$ ) 40 mg/dL  
Greater than ( $>$ ) 150 mg/dL

- a. **Repeat test on same meter using a new vial of strips and notify physician or nurse practitioner for whole blood glucose values less than 40 mg/dL and greater than 150 mg/dL. Send specimens to lab for confirmation if ordered.**
- b. **All glucose results above 200 mg/dL must be confirmed with lab testing.** (Accuracy of meters has been confirmed for neonate samples with glucose values less than or equal to 200 mg/dL.)
- c. **Whole blood glucose values less than 30 mg/dL must be confirmed by lab glucose testing.**

**Additional Precautions for Neonatal Testing:**

- Use caution when interpreting neonatal blood glucose results that are less than 40 mg/dL. If absolutely sure instrument, technique, supplies, and sample are not in question, check confirmation dot for white patches or streaks and compare intensity of blue confirmation dot with bottle. Consult physician for additional orders. (*Repeat testing on same meter or confirmation of result with specimen being sent to lab is recommended; however, patient risks must be considered when repeat collection is required on neonates.*)
- Glycolysis rate in neonatal whole blood is nearly twice the rate of that in adult blood. Delays in transporting samples for confirmatory testing to the lab must be avoided.
- For consistency in comparing like specimens, send same sample type of sample to lab as that - tested at the bedside. (Flexx Arterial Line glucose – Lab Arterial Line sample, Flexx Capillary glucose – Lab Capillary specimen, Flexx Venous glucose – Lab Venous specimen.)

**Note:** *The color chart on the test strip bottle label shows the approximate color of a test strip confirmation dot for 50 mg/dL and 350 mg/dL results. As a check on the result obtained, you may check your meter result by comparing the test strip confirmation dot to the colors on the color chart. **If the color chart and test result are clearly inconsistent, perform another test and/or confirm with an alternate test. Do not use the color chart as a replacement for a meter result.***

**RECORDS:** The following records should be kept current and updated at all times.

1. Glucose Instrument Reports containing QC and patient data are maintained by Lab (POCT) personnel and reviewed by POCT Resource Technologist or designee.
2. Competency validation forms, on all staff doing whole blood glucose testing, are kept on record in the employee's file in the department.
3. POCT personnel maintain instrument Troubleshooting and Exchange forms a minimum of 2 years.

**ATTACHMENTS:**

1. [NHHN Competency Validation Form](#)
2. [NHHN Annual Competency Validation Form](#)
3. [SureStepFlexx Troubleshooting & Exchange Form.](#)
4. [SureStepFlexx performance improvement.](#)
5. [Flexx Glucose Quick Points](#)

**LIMITATIONS:**

1. **Ascorbic Acid:** (Vitamin C) at concentrations up to 3 mg/dL, has no significant effect on glucose results.
2. **Lipemic Effects:** Highly lipemic blood samples with Triglyceride results up to 3000 mg/dL have no significant effect on glucose test results.
3. **Dehydration: Excessive water loss or dehydration may cause inaccurate, low results.** Severe dehydration can lead to many serious medical complications. One complication of particular importance in diabetes management is a hyperglycemic-Hyperosmolar (with or without ketosis), which maybe life-threatening if left untreated. Whenever inadequate fluid intake or excessive water loss occurs, consult the physician immediately. Due to significant water loss and dehydration as in the state, glucose results may be inaccurate.
4. **Altitudes:** Clinical testing demonstrates that altitudes up to 9300 feet do not affect glucose results.
5. **Temperature and humidity extremes:** Accurate test results are obtained when SureStepPro test strips and meters in climate-controlled conditions that encompass an operating temperature of 18-30 °C (64-86 °F) and relative humidity of 30-70% (non-condensing) are expected. Testing outside of these ranges may cause inaccurate results.
6. The following drugs were determined to interfere with blood glucose measurements. These levels, however, are above the normal therapeutic range of treatment.
  - L-Dopa > 20 mg/dL

- Dopamine > 6 mg/dL
- Gentisic Acid > 10 mg/dL
- Mannitol has also been reported to interfere with the SureStep system at concentrations > 5000 µg/mL when glucose concentrations are high. The magnitude of the reported effect is approximately an 8% positive bias at 10,000 µg/mL of mannitol. The therapeutic range is recommended to be < 10, 000 µg/mL to avoid renal failure.

7. **Decreased peripheral tissue perfusion** may result in inaccurate fingerstick blood glucose results secondary to reduced capillary blood flow with altered nutrition at the cellular level. Specimens obtained from an arterial or central venous line will still provide accurate results. Patients with Anasarca (severe generalized edema) may also have inaccurate fingerstick blood glucose results due to excessive interstitial fluid in the blood sample. Consult with the physician to determine if an order for Venipuncture blood glucose is necessary.

**REFERENCES:**

1. *SureStep Hospital, and/or SureStepFlexx Meter Operator’s Guide*
2. *SureStep Hospital, and/or SureStepFlexx Meter Quick Reference Guide*
3. *SureStepPro Test Strips* package insert
4. SureStepPro Glucose Control Solutions (Low and High) package insert
5. DataLink System Administrator’s Guide
6. **Pediatric Reference Intervals, 5<sup>th</sup> Edition; Steven J. Soldin PhD, Carlo Brugnara MD, & Edward C. Wong MD; 2005 American Association for Clinical Chemistry, Inc; page 103 (PAG 06/28/06)**
7. Principles and Practices of Point-of Care Testing; Chapter 17, In Vitro, Ex Vivo, And In Vivo Monitoring Of The Neonate And Premature Infant; John W Berkenbosch, Ryan E Grueber, and Joseph D Tobias; Lippincott Williams & Wilkins; 2002; pages 286 & 286.

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**END**