CONCORD HOSPITAL
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Title: POC GEN Glucose - LifeScan SureStep Flexx

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Created Time: 7/31/2012 9:09:45 AM
Reviewed by: Lundell, Amber (3/20/2013 2:57:28 PM)

Document ID: LTR11260
Version: 1

Uncontrolled when printed

TITLE: Capillary Glucose Testing - *LifeScan SureStep®Flexx Glucometer*

PURPOSE: The Lifescan SureStep Flexx Meter, in conjunction with SureStep Pro test strips, is used for the definitive, quantitative measurement of glucose in capillary whole blood. SureStep Pro test strips are for in vitro diagnostic use.

POLICY: This procedure is intended to be a guideline to all certified/ trained point of care testing personnel at Concord Hospital and Concord Hospital-owned entities. Blood Glucose Monitoring is performed: a) As ordered by a physician; b) Anytime, in an authorized caregiver's judgment, a blood glucose test is warranted in accordance with the applicable Concord Hospital patient care guidelines.

PRINCPLE: A small drop of blood is applied to a SureStep®Pro Test Strip. A glucose oxidase reaction occurs between the blood and reagents in the test strip resulting in the formation of a blue color. This color 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. When the test strip is inserted into the SureStep®Flexx glucometer, the meter measures the color intensity and reports a plasma-calibrated glucose result.

SPECIMEN:

*Patient Preparation***:** Patient identification must be confirmed using two identifiers just prior to the capillary stick (One must be the patient's full name and the second may be the date of birth or medical record number).
Specimen Type: Capillary whole blood from the finger (or heel of child < 1 year)

Specimen collection: Finger stick. (See Concord Hospital Laboratory phlebotomy

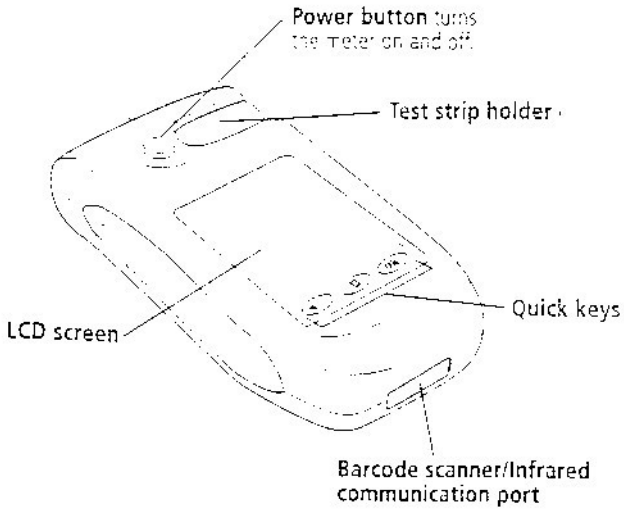
procedure for Skin Puncture by Heel Stick for children < 1 year).

Handling Conditions: Capillary blood is tested immediately.

Alternate Testing Sites: none

All body fluids should be handled as if capable of transmitting infectious diseases. Use Standard precautions when in contact with such materials. Refer to Laboratory Infection Control Policy.

Flexx Glucometer Physical Characteristics:



STATUS (LCD) SCREEN:

1. Turn meter on.
2. The first screen displayed is the meter *STATUS* screen which includes the following from top to bottom:
   - Meter tag and location
   - Meter serial number
   - Countdown when QC is due (each day of patient testing)
   - Displays last upload as passed or failed
   - Displays date and time of last upload
   - Displays battery life with battery life bar
   - Displays current date and time
3. Press the *CONT* button in lower right hand corner to advance to next screen or after 10 seconds, automatically advances to next screen

BARCODE SCANNER:

1. Never stare into the barcode scanner or point it towards anyone's eyes while the laser

light is on.

2. To use the barcode scanner, touch the *SCAN* button in the lower left hand corner of the display screen. Do not "hold down" on the button while scanning.
3. If the *SCAN* button is not displayed on the screen, change the meter batteries.
4. Clean the barcode scanner by wiping the lens with a soft cloth dampened with water.

EQUIPMENT AND MATERIALS:

Equipment:

- SureStep®Flexx meter and operator's guide
- CH approved lancet device, for capillary puncture

Materials:

- SureStep®Pro Test Strips
- SureStep®Pro High and Low Glucose Control Solutions
- OneTouch SureSoft Lancets
- Gloves
- Alcohol wipe
- Gauze pad

Reagent Storage Requirements:

- Store test strips tightly capped in their original bottle in a cool, dry place below 30°C. Keep away from heat and direct sunlight. Do not refrigerate or freeze. When a bottle of test strips if first opened, write the open date in the space provided. The "open" expiration date is four (4) months after the date opened. Do not use after the expiration date printed on the bottle label or the "open" expiration date, which ever comes first.
- Store control solutions below 30°C. Do not refrigerate or freeze. Write the "open date" on the bottle upon opening. Discard any unused portion 3 months after opening. Do not use after the expiration date printed on the vial label.

QUALITY CONTROL:

SureStep®Pro Low and High Glucose Control Solutions are used to check the SureStep®Flexx brand blood glucose monitoring system performance.
When a new bottle of control is put in use, the date that the bottle is opened is written on the bottle in the space provided. The new "open" expiration date is three (3) months from the open date written on the bottle, unless the manufacturer's printed expiration date is sooner
Controls need to be tested:

- each day of patient testing and when opening a new bottle of test strips.
- if a patient test has been repeated and the blood glucose results are still lower or higher than expected.
- when troubleshooting the system.
- if you drop the meter.

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 FAILED. When a level of QC fails, the meter will not allow patient testing to be performed.

PERFORMING A QUALITY CONTROL TEST:

1. Turn on the meter.
2. Check the battery status to ensure adequate power.
3. Press CONT (lower right corner of screen) at the Status Screen, and QC due screen.
3. Select QC Test from the Main Menu.
4. Select the control level you wish to run (High or Low) from the list displayed.
5. Enter your operator ID. Press OK.
6. Select the control lot number from the list displayed.
7. Select the test strip lot number and code number (paired together) from the list displayed.
8. Gently shake the control solution vial. Apply one drop of control solution to the pink test square on the test strip. Check the confirmation dot on the back of the test strip to ensure it is completely blue. If the dot is not completely blue, repeat application of control material to a **new test strip**.
9. With the pink square facing up, insert the test strip into the test strip holder until it comes to a complete stop. The test strip must be inserted into the glucometer within 2 minutes of applying the control solution to the test strip.

   Caution: If you fail to completely insert the test strip, the test may start; however, you may receive an inaccurate result.
10. The result appears in approximately 30 seconds.
    - Results will be displayed as "PASSED" or "FAILED". The expected range is also displayed.
    - If PASSED, press the menu button and continue with the next level of control.
    - If FAILED, select ENTER NOTE and then select the appropriate corrective action taken from the list displayed. Repeat the QC level that failed
11. Remove the test strip and dispose of properly.

NOTE: IF QUALITY CONTROL HAS NOT BEEN DONE AT THE PRESCRIBED INTERVAL OR HAS FAILED, THE OPERATOR WILL BE LOCKED OUT AND UNABLE TO PERFORM PATIENT TESTING.

IMPORTANT FACTS:

- Gently shake each vial of control solution before use.
- Do not use control solution after expiration date printed on vial.
- Write opened date on vial when opened; do not use control solution three (3) months after opening.
- Control solutions are stored at room temperature.

- Both High and Low levels of control must be run each day of patient testing – with acceptable results.
- The Status screen counts down as to when QC is due next.

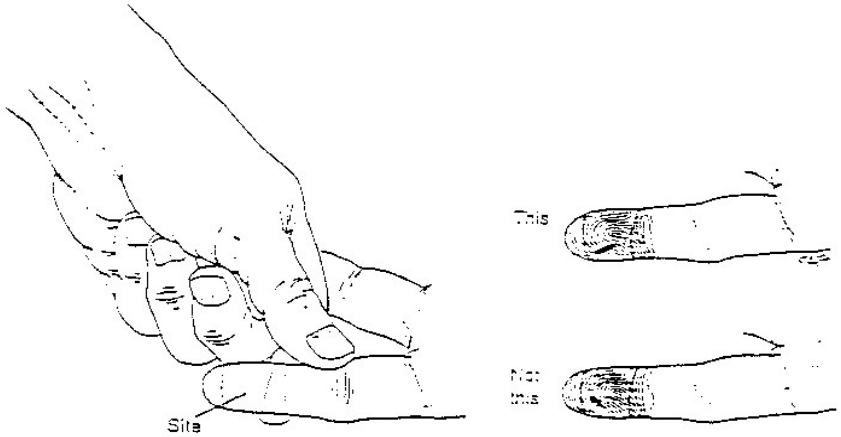
PATIENT FINGER STICK PROCEDURE:

1. Identify the patient using two identifiers: Once must be the patient's full name, the second may be the date of birth or medical record number. Verbally identify the patient, then compare the information on the lab barcode label with the patient's CH arm band. (The patient's room number cannot be used as a patient identifier).
2. Identify yourself and explain the finger stick and test process to the patient.
3. Assemble equipment.
4. Cleanse hands according to Concord Hospital hand hygiene protocol. Put on gloves.
5. Properly position patient either sitting or lying down.
6. Select a site on the pad of the fingertip, preferably on the middle or ring finger (see attached diagram). These fingers are less sensitive to pain than the index finger. Using the thumb or little finger presents a greater probability of injuring the bone.
7. This area should be free of cuts, scars, and bruises.
8. Warm the site if necessary.
9. Hold the patient's selected finger away from the proposed puncture site with your thumb and index finger.
10. Cleanse the selected site with alcohol and either allow to air dry or wipe away with a clean dry gauze. (Not only does wet alcohol cause a stinging sensation, it lyses the red blood cells, which causes a release of glucose, meaning it falsely increases the glucose result).
11. Firmly position the lancet at the incision site on the finger (at 10 o'clock or 2 o'clock, perpendicular to the finger print lines).
12. Depress the firing pad on the side of the lancet to activate the incision device.
13. Remove the lancet from the finger. The incising blade will have already retracted into the body of the lancet.
14. Apply gentle pressure to the selected finger to form a drop of blood at the puncture site.
15. **Wipe away the first drop of blood.**
16. Alternately ease and reapply pressure to the finger as drops of blood appear. Do not squeeze the finger as this may cause hemolysis, which can falsely increase the glucose result.
17. Lower the hand to allow gravity to assist in forming a drop of blood.
18. Place the pink square on the Sure Step Pro test strip against the blood drop. Press the drop into the center of the pink pad and hold it in place for a few seconds to allow the sample to absorb.
19. When collection is complete, use a clean dry gauze pad to apply pressure to the

puncture site.

20. Ensure the oval confirmation dot on the back of the test strip is filled completely. DO NOT perform the test if there is any white remaining in the confirmation dot. Observe the intensity of blue color in the confirmation dot: the darker the blue, the higher the glucose. See the color chart on the test strip bottle for an example. If the results are not as expected, select "Enter note", choose "Procedure Error" then "Ok" while the result is on the glucometer screen to erase the result and repeat the test with the same barcode label. Order a serum glucose to confirm further questionable results.
21. Dispose of the lancet in a biohazard sharps container.
22. Examine puncture site for bleeding and bandage accordingly.
23. Dispose of all used materials in waste receptacles.
24. Take gloves off. Cleanse hands according to the Concord Hospital hand hygiene protocol.

NOTE: The lancet "gentle" has a depth of 1.8mm. This depth is sufficient for the collection of most specimens. In the event that the patient has extremely tough or calloused skin, the lancet "regular" with a depth of 2.0mm may be used.



Recommended site and direction of finger puncture.

PERFORMING A PATIENT TEST:

1. Turn on the meter.
2. Press *CONT* at the Status screen
3. Select *PATIENT TEST* from the main menu.
4. Enter your operator ID #. Press OK.
5. At *PATIENT ID #*:
    a. **Scan the lab barcode label**. Be sure it is for a capillary glucose…***CAPGL***…and for the correct patient, and for the correct date and time of collection. If there is no barcode order, enter the patient's Medical Record # which is found on the patient's ID wristband or scan the CH patient ID bracelet.
    b. CHMG Practices ONLY: Manually enter the patient's date of birth
6. Verify the number you have scanned matches the order label (or manually entered data). Press OK.

7. Select the test strip lot # from the list displayed.
8. The screen displays a message prompting you to apply blood to the strip and insert strip.
9. Perform the finger stick as described above in the "Patient finger stick procedure" section.
10. **Wipe away the first drop of blood.**
11. With a drop of blood formed on the patient's finger, carefully touch the pink test square to the drop of blood.
12. Check the test strip confirmation dot to ensure that it is completely blue. Observe the intensity of blue color in the confirmation dot: the darker the blue, the higher the glucose. See the color chart on the test strip bottle for an example. Do not remove the strip from the finger and then reapply to the finger to apply more blood. If the confirmation dot shows patches of white, the application of blood needs to be repeated with a **new test strip**. With the pink pad side up, completely insert the test strip into the test strip holder until it comes to a complete stop. **The test strip must be inserted within 2 minutes of applying sample**.
13. Patient results will be displayed within 30 seconds.
14. If the results are not as expected, select "Enter note", choose "Procedure Error" then "Ok" while the result is on the glucometer screen to erase the result and repeat the test with the same barcode label. Order a serum glucose to confirm further questionable results.
15. Remove test strip and dispose of properly.
16. **The outside of the meter (and tote, if brought into the patient's room)** ***must be cleaned between each patient, for infection control purposes, using a disinfectant wipe approved by the Health System (Sani-Cloth Plus germicidal disposable cloth or fresh 10% bleach cloth). Care must be taken when using any liquid NOT to get any excess fluid on the meter screen and other openings such as the battery cover and test strip holder opening.***

CALCULATIONS:

Not applicable.

REPORTING:

Capillary glucose results are reported in milligrams per deciliter (mg/dL).

Test results are reportable provided the following guidelines are observed:

- The linearity of the assay (60-400 mg/dl) has not been exceeded. Specimens above linearity are to be reported as ">400". Specimens below linearity are to be reported as "<60". *Test results above or below the linearity can be confirmed by having a serum glucose level drawn STAT and sent to the laboratory for analysis.*
- The correct strip lot number with matching code number has been selected.
- The quality control has been performed and is within the acceptable ranges.
- Repeat capillary glucose testing can be performed to confirm test results in the critical range (<60mg/dL, >400 mg/dL)
- Immediate notification of critical results must be given to the provider. Notification

(provider's name, date and time) must be documented in the patient's chart.

- All patient results are logged on the downtime Patient Result Log, when used.

REFERENCE RANGE:

Blood glucose levels for people without diabetes are as follows:
Fasting: 70-110 mg/dl
One hour after meals: <160 mg/dl

UNEXPECTED RESULTS AND RESULT EDITS:

- Questionable results can be **erased** while the result is displayed on the meter screen by selecting "ENTR NOTE", then "PROCEDURE ERROR" and "OK".
- All result edit or correction requests must be submitted in writing to both Point of Care Specialists, Amber Lundell and Suzanne Chute.
- Send a group-wise message to alundell@crhc.org and schute@crhc.org, containing the following information:
  - Patient's full name
  - DOB
  - Medical Record Number
  - Wrong Result
  - Correct Result
  - Date & Time of test (approximate)
- Be sure to include a title on the subject line of the e-mail that does not include confidential information- we use "Glucometer Edit".

Point of Care Specialists Contact Information:

Amber Lundell x4645 alundell@crhc.org; Suzanne Chute x4643 schute@crhc.org

UPLOADING / DOWNLOADING OF INFORMATION:

In-house and other locations using Laboratory Barcode Labels:

Data transfer is required at least once every 24 hours, but should be done **soon after completing a patient test**. This allows for an exchange of information between the meter and the workstation located in the Point of Care Specialist's office. Entering the barcode order number as the patient ID # allows for interface resulting with the Laboratory Information System, meaning the result will automatically cross the patient's electronic medical record. There is no need for manual result entry in the computer system by the meter operator. If the patient's Medical Record # or CH arm band is used for the patient ID #, the POCS will edit the resulting information, which has been uploaded, to contain the assigned barcode order number for the correct patient, date, and time. The results will then cross via the interface to the LIS and into the patient's electronic medical record.

Most Patient Care Units are equipped with a connection module cradle. To accomplish the transfer of data, place the meter into the cradle. The meter automatically turns on and dials the preprogrammed modem number. A series of messages appear on the screen indicating the status of the transfer. When the transfer is complete, the meter beeps and a message is displayed. The meter is then removed from the cradle and turned off. If the meter is left in the cradle, it will turn off automatically after a short period of time.

Datalink Wireless devices are also available in many patient care departments. The device should remain plugged into an outlet with emergency power, as it must continuously charge. Use the access wire "pigtail" to plug the device into the port at the top of the glucometer. The meter automatically turns on and a series of messages appear on the screen indicating the status of the transfer. When the transfer is complete, the meter will display a message indicating successful data transfer, and then the meter will shut off.

Concord Hospital Medical Group:

Data transfer (uploading/downloading) is done on a **weekly** schedule. This allows for an exchange of information between the meter and the workstation located in the Point of Care Specialist's office at Concord Hospital. Each practice is equipped with a connection module cradle. To accomplish the transfer of data, place the meter into the cradle. Connect the meter by using the access wire and the port at the top of the SureStep®Flexx meter. The meter will automatically turn on and dial the preprogrammed modem number. A series of messages appear on the screen indicating the status of the transfer. When the transfer is complete, the meter beeps and a message is displayed. The meter can then disconnected and removed from the cradle and turned off. If the meter is left in the cradle, it will turn off automatically after a short period of time.

Data transfer allows for the monitoring of Quality Control performance and Operator performance. These reports are generated monthly and sent to the practice. They need to be filed and stored for two (2) years. Current and previous year reports must be stored on site. Other records must be available within 30 minutes time.

CONFIRMATORY TESTING FOR UNUSUAL OR UNEXPECTED RESULTS:

- Personnel performing this test may seek the opinion(s) of other qualified testing staff. When encountering unusual results or when there is uncertainty about a conclusion, collect a new patient sample and repeat the test.
- At the discretion of the ordering provider, an additional patient sample will be obtained and sent to Concord Hospital Laboratory for further work-up.

LIMITATIONS / INTERFERING SUBSTANCES:

1. Use an adequate amount of blood—just enough to cover the pink test square.
2. Do not use blood collection tubes containing fluoride. Sodium fluoride interferes with test results (gray top tubes).
3. Highly lipemic (fatty) blood samples, up to 3000 mg/dL triglycerides, have no significant effect on results.

4. Ascorbic acid, at concentrations up to 3 mg/dL, has no significant effect on results.
5. When inserting the test strip, be sure to firmly push the strip until it comes to a complete stop. If you fail to completely insert the test strip, the test may start; however, you may receive an inaccurate result.
6. Test strip contact with light and moisture can cause inaccurate results.
7. Meter glucose results should agree with the laboratory result to within +/- 20% most of the time under normal conditions and normal sources of variation when results are between 60 mg/dL and 400 mg/dL. Results outside of that range are not reliable.
8. Venous and capillary blood may differ as much as 70 mg/dL, depending on the time of blood collection after food intake.
9. At low hematocrit, meter results will tend to be higher than laboratory results. Very low hematocrit (less than 25%), such as in anemia may cause inaccurate, high results. At high hematocrit, meter results will tend to be lower than laboratory results. Very high hematocrit (greater than 60%) such as in polycythemia, may cause inaccurate, low results.
10. Circulation problems due to shock, administration of vasoactive agents, and other factors affecting peripheral circulation, such as Raynaud's disease may also cause discrepancies (pseudohypoglycemia) between venous and capillary results and may limit the use of fingerstick blood for those patients.
11. 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 state, with or without ketosis, which may be life-threatening if left untreated. Whenever inadequate fluid intake or excessive water loss occurs, consult the physician or other prescribing healthcare professional immediately about the potential for inaccurate low results by fingerstick.
12. If samples have a low oxygen content (for example, venous blood), low hematocrit (near 25%) and high glucose (greater than 200 mg/dL), this may cause inaccurate high results.
13. Test results are best obtained when SureStep Pro test strips are used with meters in climate controlled conditions: within an operating temperature of 18-30 C (64 – 86 F) and operating relative humidity of 30-70% (non-condensing). Testing outside of these ranges may cause inaccurate results.

MAINTENANCE:

1. General Care:
    - Keep meter dry and avoid exposing it to extremes in temperature
    - Do not take meter apart
    - If the meter is dropped, inspect for obvious damage. Perform QC prior to running a patient test
2. Cleaning the Outside of the Meter (and Tote if brought into patient room):
    - Between all patients
    - Wipe down the outside of the meter (or tote) with a CH approved disinfectant wipe (Sani-Cloth plus germicidal disposable cloth or a fresh 10% bleach wipe).

- Care must be taken when using any liquid NOT to get any excess fluid on the meter screen and other openings such as the battery cover and test strip holder opening.

3. Cleaning the Test Strip Holder and Lens:
    - Press down on the left side of the test strip holder
    - Remove it from the meter
    - Open the hinged test strip holder
    - Clean test strip holder with an alcohol wipe
    - Dry with a soft cloth or lint free tissue
    - Set aside the test strip holder
    - Wipe the lens area and contact points with a cotton swab or soft cloth dampened with water.
    - Be careful not to scratch the test area or get water inside the meter
    - Thoroughly dry the lens area with a soft cloth or lint free tissue.
    - Slide the test strip holder back into the meter until it clicks into place
4. Changing the Batteries:
    - Turn off the meter
    - Remove the battery door on the back of the meter
    - Remove the old batteries
    - Replace with three new AA batteries, observing correct polarity
    - Replace the battery door
    - Turn meter on to verify power
5. Contact the Point of Care Specialists for trouble shooting any glucometer problems:
    - Amber Lundell, x4645, alundell@crhc.org
    - Suzanne Chute, x4643, schute@crhc.org

Historical Review:

Gary York, MD — Laboratory Medical Director

April 1, 2011 — Date

REFERENCES

Glucose in Whole Blood- SureStep®Flexx Procedure 8/2008; Concord Hospital, Concord NH 03301
SureStep®Flexx General Operationing Procedure 2/2002; Concord Hospital, Concord NH 03301
SureStep®Pro Test Strip Product Insert; Rev 7/2009 LifeScan Inc. Milpitas CA 95035
SureStep®Flexx Meter Operator's Guide; 2002 LifeScan Inc., Milpitas, CA 95035
SureStep®Flexx Procedure NCCLS format 2002; LifeScan Inc. Milpitas CA 95035

DISTRIBUTION: Concord Hospital and owned entities performing point of care testing

RESPONSIBLE DEPARTMENT/UNIT: Laboratory Point of Care, Concord Hospital, Concord NH 03301

APPROVAL

Initiated by: Amber Lundell, MT (ASCP) Date: 4/1/2011
Reviewed (date): / 2-9-12 AL / / / / / / /
Revised (date): /4-27-12 AL / 7-30-2012 AL / / / / / / /
Supercedes: Glucose in Whole Blood- SureStepFlexx 8/08,SureStep Flexx General Operating Procedure 8/08