

# Lifescan Flexx Glucometer Competency Self-Study Program

Welcome to the CHRISTUS Spohn Flexx Glucometer Self-Study Program. Completion of this program will grant operator access to all 230 glucometers in the Spohn Region. The operator database contains over 2000 Certified Operators working in six hospitals and numerous clinics.

## **Objectives**

**1) Thoroughly review the material linked below**

**Sure Step Flexx Meter Operator's Guide**

**[http://www.lifescan.com/pdf/hospital/ssf\\_operatorsguide.pdf](http://www.lifescan.com/pdf/hospital/ssf_operatorsguide.pdf)**

**Sure Step Flexx Meter Quick Reference Guide**

**[http://www.lifescan.com/pdf/hospital/ssf\\_qrg.pdf](http://www.lifescan.com/pdf/hospital/ssf_qrg.pdf)**

**Test Strip Package Insert**

**[http://www.lifescan.com/pdf/hospital/ssp\\_teststripspi.pdf](http://www.lifescan.com/pdf/hospital/ssp_teststripspi.pdf)**

**2) Thoroughly review CHRISTUS Spohn's glucometer policies**

**[Bedside Blood Glucose Monitoring—Pages 2-6](#)**

**[Lifescan Flexx Glucometer Comment Messages—Page 7](#)**

**[Lifescan Flexx Glucometer Error Reporting--Page 8](#)**

**3) Take the online Initial Competency Test—[instructions on Page 9](#)**

**4) Perform a Return Demonstration—[instructions on Page 10](#)**

**CHRISTUS SPOHN HEALTH SYSTEM  
POLICY AND PROCEDURE MANUAL**

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**TITLE: PPT-173 BEDSIDE BLOOD GLUCOSE MONITORING**

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Date Issued: 10/16/2007

Section: POCT

Date(s) Revised: September 2008

Number:

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Originator: S Baker

Approved By:

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**PURPOSE:** The Lifescan SureStep Flexx Meter, in conjunction with SureStep test strips, is used for the definitive, quantitative measurement of glucose in whole blood.

**POLICY:**

Bedside Blood Glucose Monitoring is performed

- a) As ordered by a physician
- b) Anytime, in a Registered Nurse's judgment, a blood glucose test is warranted.

Only a Certified Operator may perform blood glucose tests with a hospital bedside meter.

- a) Unit staff become certified operators through their respective Unit Trainer, or scheduled classroom training provided by the Education Department or POCT Coordinator. Recertification can be accomplished using online training and performing QC procedures periodically.
- b) Unit Trainers become certified trainers through scheduled classroom training provided by the Education Department or POCT Coordinator.
- c) All training is under the direction of the Laboratory Director.
- d) The bedside meter, Sure Step Manual, and Sure Step Flexx Bedside Unit Operator's Guide are used to guide certification training.
- e) Annual re-certification is required for all operators.
- f) Hardcopy testing records of all certified operators is maintained by the POCT Coordinator.

Unit Trainers are responsible for their respective unit's testing activity. These responsibilities include:

- a) Maintenance of unit hospital meters including battery replacement.
- b) Review of quality management data records and any corrective action.
- c) Monitoring expiration dates of strips, and discarding if not used within 4 months of opening.
- d) Monitoring expiration dates of control solutions and discarding if not used within 90 days of opening.
- e) Assuring ready availability of reference material on the unit.
- f) Performing certification and annual re-certification on bedside meter operators on their respective units.
- g) Providing the POCT Coordinator with accurate records of all trained operators.
- h) Documenting training, quality management review and corrective action.
- i) Performing initial trouble shooting of hospital meters prior to contacting the Laboratory Point-of-Care Coordinator.

The Laboratory Point-of-Care Coordinator will manage the daily operations of all SureStep glucometers.

Responsibilities include:

- a) Providing operational direction and development of quality management policies and procedures.
- b) Providing policy and procedure manuals to all nursing units and reviewing manual annually.
- c) Serve as a resource for Unit Trainers when problems arise.
- d) Serve as the resource for meter repair or replacement.
- e) Supervise Units regarding 1) Quality Control Data 2) Operator Variances 3) Operator Competencies –and issue periodic reports documenting supervision.
- f) Confirm compliance with all applicable regulations.
- g) Supervise the maintenance of the Lifescan Database including 1) entry of certified operators into the operator database 2) entry of test strip lot numbers into the test strip database 3) Setting of parameters in the database to conform with current policy and procedure.

The Director named on the CLIA certificate will be responsible for

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- a) Reviewing this document before any change is implemented or at minimum once every three years.
- b) Determining the context in which this test is used
- c) Approving staff as qualified to perform each role defined in this procedure.
- d) Approving training for all staff.
- e) Approving the written quality control plan included in this policy and procedure.
- f) Overall operation of the program.

**PROCEDURE:**

**Principle—**

The Lifescan SureStep Flexx Meter, in conjunction with SureStep test strips, is used for the definitive, quantitative measurement of glucose in whole blood. This whole-blood glucose test method employs a dry reagent technology based on the glucose oxidase method and is specific for D-glucose. Glucose oxidase catalyzes the oxidation of glucose in whole blood. Two new compounds, gluconic acid and hydrogen peroxide, are produced from this oxidation reaction. The enzyme peroxidase then catalyzes the reaction of the hydrogen peroxide. This reaction produces a blue color. The intensity of the blue color formed correlates with the concentration of D-glucose in the whole blood sample. A plasma-calibrated glucose result is reported by the SureStep Flexx meter.

**Specimen type—**

Whole blood is the only acceptable sample for the Lifescan SureStep Flexx Meter. The preferred sample is fresh capillary whole blood from a finger stick. Venous whole blood containing EDTA (purple top) or heparin (green top) anticoagulants may also be used. Do not use specimen containing fluoride (gray top). Serum or plasma must NOT be used on the SureStep test strip.

**Specimen Limitations—**

Capillary whole blood specimens must be tested immediately upon collection. Anti-coagulated venous whole blood must be tested within 15 minutes of collection to prevent interference. Venous blood must be inverted several times. All red blood cells must be suspended prior to testing. The sample must be applied to the pink square. The dot on the back of the strip will change to a solid blue color when enough blood has been applied. Strips should not be used if the dot initially is any color other than ivory or white. If any white color shows in the dot after blood application, a new strip should be used. Minimum sample size is 5 microliters.

**Reagents / Equipment—**

SureStep Flexx Blood Glucose meter

SureStep Test Strips (available from Central Supply)

SureStep Hi and Low Control Solutions (available from Central Supply)

Lancing device

Alcohol pads and gauze

Mini Hype-Wipe disinfecting towel with bleach (available from central supply)

Disposable gloves

Reagents must be stored at room temperature and away from heat and light in the original bottles. Do not expose the strips to bleach or other fumes. Strips should be tightly capped and only the strips that will be utilized immediately should be removed from the bottle. All reagents must be dated and initialed upon opening. SureStep High and Low control solutions expire 90 days after opening or on the last day of the month and year of the date stamped on the bottle if unopened. SureStep test strips expire 4 months after opening, or on the date stamped on the bottle if unopened. Use only SureStep strips with the SureStep Flexx meter.

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**Bedside Unit Operator's Guide—**

The SureStep Flexx Bedside Unit Operator's Guide will be used as the primary reference for routine operation of the meter. The procedures below incorporate Spohn policy into the routine operating instructions.

**Quality Control—**

QC must be performed once every 24 hours. This QC will include two levels of liquid control. Prompts on the meter will guide the operator through this process. The meter must be checked for cleanliness. The meter should be cleaned as needed with a Mini Hype-Wipe Towelette. Some examples of a meter that requires cleaning are when blood, dirt, or lint is visible. The meter may need to be cleaned as a part of a troubleshooting process. All parts of this meter may be cleaned with Mini Hype-Wipes. Do not use alcohol or phenolic disinfectants on any portion of the meter.

**Control Solution Test:**

Results of every control solution test are stored in the meter memory. To perform a control test, follow these steps:

- 1) Check the expiration date on each vial of Control Solution. Do not use if the expiration date has passed or if it is more than 90 days after the vial was first opened. Vials should be dated and initialed on the day they are opened.
- 2) Check the expiration date on the test strips. These strips should be dated and initialed upon opening. Do not use if the expiration date has passed or if it is longer than 4 months after the strips were opened. Check the strip before using it to insure that the dot on the back of the strip is white. Do not use any strips with a dot that is not white. Strips with a discolored dot should be isolated and not used for patient testing. Report any strips without an ivory or white dot to the Point-of-Care Coordinator at 361-881-3806.
- 3) Press the power button to turn on the unit. A start-up screen appears, followed by the Status screen. The meter will inform you if QC is required.
- 4) Check the battery status to ensure adequate power. The battery bar provides the approximate status of battery power. Press Cont. to continue.
- 5) Select QC test from the main menu
- 6) Enter your Operator ID, either by pressing the touch screen or using the barcode scanner.
- 7) Select the control level you wish to run. Both levels must be run before the meter will allow patient testing.
- 8) Select the test strip lot number from the list displayed. Use the arrows to scroll through the list, if necessary. **IMPORTANT—**To obtain accurate results, you must enter the correct test strip lot number for each new test.
- 9) The QC test screen appears with messages prompting you to apply the control to the strip and then insert the strip.

**Applying Control Solution to the Test Strip**

- 1) Gently shake the control solution vial
- 2) Apply one drop of control solution by gently squeezing the bottle and touching the vial tip to the pink test square. If the white pad becomes completely saturated, you have applied too much control solution.
- 3) Check the confirmation dot on the back of the test strip to verify it has turned completely blue, indicating an adequate amount of control was applied.
- 4) Insert the test strip, application side up, all the way into the test strip holder **IMPORTANT:** Firmly push the test strip into the holder until it stops. If you fail to completely insert the test strip, the test





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**TITLE: LIFESCAN FLEXX GLUCOMETER COMMENT MESSAGES**

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**PURPOSE:**

To establish a standard automated method for preventing errors in the Lifescan Flexx Glucometer database.  
To document critical value results notification.

**POLICY:**

All Lifescan Flexx Glucometer operators will attach comment messages to test results as indicated in the Procedure section of this document. Note: This procedure will be used when an error is known before completion of testing. For errors discovered after testing is complete, see Lifescan Flexx Glucometer Error Reporting.

**ACCOUNTABILITY:**

Each Lifescan Flexx Glucometer Operator will attach comment messages as indicated to each test performed.

**PROCEDURE:**

Attach comment messages to test results using the Enter Notes function as indicated in the following situations:

**1) Procedure Error (wrong control, wrong strip lot, wrong patient, etc.)**

Use this comment message for Quality Control and Patient Testing errors when the error is known.  
Use of this comment message will delete all records of the test.

**2) Repeat Test (results not consistent with clinical observations or results which require confirmation)**

Use this comment message when additional testing will be performed with a Lifescan Flexx Glucometer or by the Laboratory. Use of this comment message will prevent reporting of duplicate test results.

**3) Notify MD**

Use this comment when critical low or high patient test results are reported.  
Use of this comment documents physician notification as required by CLIA and Joint Commission

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**TITLE: LIFESCAN FLEXX GLUCOMETER ERROR REPORTING**

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**PURPOSE:**

This form provides a standardized method of reporting errors involving the Lifescan Flexx Glucometer. This form provides documentation of error reporting and corrective actions.

**POLICY:**

This form will be used to report errors that are discovered after a QC or patient test is completed. This form will also be used to report suspected errors. Errors discovered during a test procedure that are properly marked with a comment message will NOT require this form or any further action. Completed forms will be retained by the POCT Coordinator for at minimum two years.

**ACCOUNTABILITY:**

Each operator that is aware of an error that is NOT flagged with the proper comment message on a completed test procedure will fill this form and submit to the POCT coordinator for follow-up. The POCT coordinator will make any appropriate changes to the Lifescan Database and document that action on this form.

**PROCEDURE:**

Fill the blanks on this form and submit to the POCT Coordinator for follow-up.

State the nature of the error (wrong patient, incorrect ID number, no ID number available at time of test, forgot to enter comment message, etc.)

\_\_\_\_\_

**Incorrect Data** \_\_\_\_\_

**Correct Data or Comment Message** \_\_\_\_\_

**Time and Date of Error** \_\_\_\_\_

**Operator Name and ID number** \_\_\_\_\_

**To be completed by POCT Coordinator    POCT Signature** \_\_\_\_\_

**Date / Time received** \_\_\_\_\_      **Date /Time corrective action taken** \_\_\_\_\_

**Corrective Action** \_\_\_\_\_

# Online Initial Competency Test

1) Read this page—then

Open this link [SureStep Flexx Initial Competency Test](#)

<http://survey.christushealth.org/ss/wsb.dll/38/flexxcompetency.htm>

You must enter an Operator ID that is unique to you along with your Last and First Name.

Spohn Associates—enter the number on the back of your Spohn ID badge. This will allow you to scan your badge when operating the meter after you are Certified.

Students and Non-Associates—enter any number unique to you. Your Student ID number is ideal. An Operator ID number must be all numbers and have at least six characters.

You must enter this same ID number for your Return Demonstration.

You must enter this same ID number when performing QC and Patient Testing after you are Certified.

## SureStep Flexx Initial Competency Test

**1) Enter your Operator ID number, your Last Name, and your First Name. If you have any questions concerning Operator IDs, please call 881-3806 or 881-3922**

Operator ID

Last Name

First Name

Complete the Test and Click “Submit Survey”

Records are Electronic—You do not need to keep proof of completion.

# Return Demonstration

- 1) Obtain any Spohn Flexx Glucometer at any facility.
- 2) Turn the meter on
- 3) If the meter requires QC to proceed, perform both HIGH and LOW QC
- 4) After any required QC tests, Continue to the Main Menu
- 5) On the main menu,  
Select "Patient Test"



6) At the “Enter Operator ID” prompt Enter “931”

Press OK



7) At the “Enter Patient ID” prompt  
Enter the letters “QC” + your  
Operator ID number

Press OK



8) Select the correct strip lot  
And perform the test using the HIGH  
CONTROL

Press the Menu Icon (center), then  
Turn Off the meter



9) Upload the meter by placing it in the nearest upload station. Uploading is automatic once the meter is placed in the upload station.

10) Email or call [stephen.baker@christushealth.org](mailto:stephen.baker@christushealth.org) 361-881-3922  
[debbie.burk@christushealth.org](mailto:debbie.burk@christushealth.org) 361-881-3806  
[lori.boyd@christushealth.org](mailto:lori.boyd@christushealth.org) 361-881-3576

Include your name and Operator ID in your message.