



Professional Blood Glucose
Management System

Glucose Control Solution

(LOW, NORMAL, HIGH)

Intended Use

SureStepPro Low, Normal, and High Glucose Control Solutions are for use with SureStep Brand Blood Glucose Meters and SureStepPro Test Strips to check that the meter and test strips are working together properly.

Summary and Principle

The SureStepPro Low, Normal, and High Glucose Control Solutions each contain a measured amount of glucose that reacts with chemicals on the SureStepPro Test Strip. The test employs a dry reagent technology based on the glucose oxidase method specific for D-glucose. When you apply a drop of control solution to the pink test square on a SureStepPro Test Strip, glucose in the solution reacts with chemicals on the test strip to form a blue color. The intensity of this color directly correlates with the amount of glucose in the solution. This blue color is visible through the confirmation dot on the back of the test strip and is read by the meter – the darker the blue, the higher the glucose level in the solution.

When used according to the same procedure as whole blood, the low, normal, and high control solutions should provide results within the expected range printed on the SureStepPro Test Strip bottle label. Obtaining results outside the expected range may indicate the system is not performing correctly.

NOTE:

Your institution may have performed additional testing to establish a unique control range which may be different from the one printed on the test strip bottle label. See *Expected Values and Limitations*.

Reagents

Each SureStepPro Control Solution is provided as a buffered, stabilized, aqueous solution of D-glucose containing a preservative and other non-reactive ingredients.

The solutions are formulated to react equivalently to a whole blood sample containing the following approximate glucose concentrations:

Low	40 mg/dL	2.2 mmol/L
Normal	106 mg/dL	5.9 mmol/L
High	345 mg/dL	19.1 mmol/L

Actual lot-specific ranges are printed on the SureStepPro Test Strip bottle label.

Precautions

- ◆ For in vitro diagnostic use.
- ◆ Not intended for human consumption.
- ◆ The control solutions contain dye that stains clothing.

Storage and Handling

- ◆ Store at room temperature below 30°C (86°F). Do not refrigerate or freeze.
- ◆ Shake gently before use. No reconstitution or dilution is necessary.
- ◆ Wipe the vial tip clean and reseal the vial tightly after each use.
- ◆ The control solution can be used for 3 months after opening the vial. Write the opened date on the control solution vial when you first open it. Discard any remaining control solution 3 months after the vial was first opened.
- ◆ Do not use control solution that has passed the expiration date. Control solution expires on the last day of the month indicated on the vial label.

Instruments

For use with any SureStep Brand Blood Glucose Meter with SureStepPro Test Strips.

Procedure

Materials Provided

- ◆ SureStepPro Low, Normal, and High Glucose Control Solutions (quantity sufficient for approximately 200 tests per vial)

Materials Required but Not Provided

- ◆ SureStep Brand Blood Glucose Meter and applicable operator's guide
- ◆ SureStepPro Test Strips

Optional Materials

- ◆ DataLink™ Data Management System (DMS) software for quality control analysis or compatible DMS, or DataLog for manually recording results from the SureStep Brand Meter

Test Procedure

To perform a low, normal, or high control solution test, follow the Quality Control Test procedure outlined in the appropriate SureStep Brand Meter operator's guide.

Recording Results:

- ◆ If using the SureStepPro Bedside Unit or SureStepFlexx Meter, you may upload the quality control results to the data management system to record and store the data and generate reports as an option.
- ◆ If using the SureStep Hospital Meter, manually record the quality control results according to your institution's policy.

Enter Code:

- ◆ Using the SureStepPro Bedside Unit or SureStepFlexx Meter: enter the correct test strip lot number (and code) in the meter. The lot number and code can be found on the test strip bottle label.
- ◆ Using the SureStep Hospital Meter: set the meter code to match the code printed on the test strip bottle label.

Check the Strip:

- ◆ 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. It also shows an off-white shade for a new, unused test strip. DO NOT use the test strip if the confirmation dot is darker than this color.

Apply Control Solution:

- ◆ Apply one drop of glucose control solution to the center of the pink test square of the test strip.
- ◆ If the entire white pad on the front of the test strip is completely saturated with control solution, you have applied too much solution. Repeat the application using a new test strip and apply a smaller drop of control solution. Applying too much solution may cause out of range results.
- ◆ After applying the control solution, 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 control solution. Repeat the application with a new test strip and apply a larger drop of control solution. Too little control solution may cause out of range results.

Expected Values

At room temperature and altitudes below 3000 ft (914 m), 95% of low, normal, and high glucose control solution results should fall within the range printed on the test strip bottle label. For altitudes of 3000 feet and above, see section titled *Altitude Adjustments for Control Solutions*.

When testing in the SureStepPro Bedside Unit or SureStepFlex meter's QC Test mode, results that fall within the ranges are indicated by PASSED on the meter display. Results that are not within the ranges are indicated by FAILED. SureStep Hospital Meter displays the control solution result. Control solution test results should fall within the expected ranges if the system is working properly and the correct test procedure is followed.

NOTE:

- ◆ Your institution may have performed additional testing to establish a unique control range which may be different from the one printed on the test strip bottle label.
- ◆ Your institution may have selected a Pass/Fail display for control results instead of a numerical value as an option for SureStepPro and SureStepFlex meters.
- ◆ Check your institution's quality control policy for acceptable quality control ranges.

If your control solution result falls outside the expected range, first repeat the control solution test with a new test strip.

IMPORTANT:

Results that repeatedly fall outside the range may indicate the system is not performing correctly. DO NOT use the system to test patient blood glucose levels until the control solution results fall within the expected range printed on the test strip bottle label or according to your institution's policy.

Possible causes for out-of-range results may include:

- ◆ procedure error
- ◆ control solution is expired, or beyond its discard date, contaminated, or inadequately mixed
- ◆ test strip lot number (and corresponding code) in the meter does not match the lot number on the test strip bottle
- ◆ dirty meter or test strip holder
- ◆ a problem with the test strip (expired, damaged, etc.)
- ◆ Control solution tested outside the 18°–30°C (64°–86°F) system temperature range. Refer to the appropriate SureStep Brand Meter operator's guide for more information.
- ◆ applying too much or too little control solution
- ◆ Testing control solutions at high altitude without applying the correction factors (see below).

If you are unable to resolve the problem, you may have a meter malfunction; call LifeScan for technical help.

IMPORTANT:

Higher than expected values may be obtained when Normal or High control solutions are tested at altitudes ≥ 3000 ft (≥ 914 m). There is no altitude effect on low control solution. See Tables 1 and 2 for Control Solution Altitude Adjustments. Correction factors are only for SureStepPro Glucose Control Solutions.

Limitations

- ◆ The glucose control ranges printed on the test strip bottle label are for SureStepPro Glucose Control Solutions only.
- ◆ The glucose concentrations in these solutions when measured by methods other than SureStep Brand Meters may differ because the amount of glucose added compensates for the different reactivity of glucose in water versus glucose in whole blood.
- ◆ Applying too much or too little control solution to the test strip may cause out of range results. See *Test Procedure* section.

Altitude Adjustments for Control Solutions

A matrix effect¹ is observed when using SureStepPro Glucose Control Solution when testing at altitudes ≥ 3000 feet (≥ 914 m).

Table 1. Altitude at which adjustment becomes necessary

Glucose Control Solution	Feet above sea level	Meters above sea level
Low	-----no correction necessary-----	
Normal	≥ 5000 ft	≥ 1524 m
High	≥ 3000 ft	≥ 914 m

Table 2. Correction Factors for Adjusting Control Ranges

	Testing Altitude (above sea level)				
	2000 ft 610 m	3000 ft 914 m	4000 ft 1219 m	5000 ft 1524 m	6000 ft 1829 m
Low	—	—	—	—	—
Normal	—	—	—	1.02	1.05
High	—	1.05	1.08	1.11	1.14
	Testing Altitude (above sea level)				
	7000 ft 2133 m	8000 ft 2438 m	9000 ft 2743 m	10,000 ft 3048 m	
Low	—	—	—	—	—
Normal	1.08	1.1	1.13	1.16	
High	1.17	1.2	1.23	1.26	

Adjusting Quality Control Range Limits at High Altitudes

1. Determine your location altitude and refer to Table 1 to identify the control level(s) that require adjustment.
2. Find the corresponding correction factor, if any, listed in Table 2.
3. Adjust the control ranges on the test strip bottle label by multiplying both the lower and upper limits for each control level by the appropriate correction factor found in Table 2.

Example: Testing at an elevation of 5200 feet:

Level	Low	Normal	High
Control Ranges (from test strip bottle label)	26 - 50	76 - 114	261 - 391
Multiply by Correction Factor in Table 2	none	1.02	1.11
New Control Ranges	26 - 50	78 - 116	290 - 434

NOTE:

An adjusted target range is not possible when the adjustment would put the upper limit of the target range above 500-mg/dL (27.8-mmol/L), the highest displayed value with Sure Step Brand meters. Contact LifeScan Healthcare Professional Line for further assistance:
 US: 1 800 524-7226
 Canada: 1 888 353-0800



References

1. Roberts WR. A tale of two PT materials. *CAP Today*. 1995;9: 65-66.

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Our goal is to provide you with quality healthcare products and dedicated customer service. If you are not fully satisfied with this product, or if you have questions about the use of any LifeScan products, please call us toll free at:

1 800 524-7226

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