



# Swiss Point of Care Glucose Control Solution Package Insert

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| <b>REF</b> G125-92HB | English |
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## PRINCIPLE AND INTENDED USE

The Swiss Point of Care Control Solution contains a known concentration of glucose. It is used to confirm that your Swiss Point of Care Test Strips and Swiss Point of Care Blood Glucose Meter are working together properly and that you are performing the test correctly.

You should perform a quality control test:

- Before you first use your meter to familiarize yourself with its operation.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- If you think your test results are wrong. Or if they do not match with how you feel.
- If you think your meter is damaged.
- At least once a week.
- After cleaning your meter.

Three levels of control solution are available labeled Control Solution 0, Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for almost all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 0 or level 2 test.

## COMPOSITION

Control Solution 0 contains less than 0.1% glucose (active ingredient), Control solution 1 has less than 0.2 % glucose (active ingredient) and Control Solution 2 has less than 0.4 % glucose (active ingredient). All solutions have preservatives in water based mixture.

## STORAGE AND HANDLING

- Store the control solution at room temperature, 2-35 °C (36-95 °F).
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.

**Note:** All expiration dates are in Year-Month-Date format.

- Use the control solution only for 6 months after you first open it. The control solution will expire 6 months after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

## PRECAUTIONS

- For *in vitro* diagnostic use. Use the control solution to test only outside the body. Do not swallow or inject. For self-testing and professional use.
- Shake well before using.
- To get accurate results, do control solution testing between 10 and 40 °C (50-104 °F).
- The control ranges shown on the test strip vial or on the foil pouch are not a recommended range for your blood glucose level. Figure out your personal blood glucose target ranges with your diabetes healthcare professional.
- Do not touch the end of the test strip to the control solution bottle. This could cause contaminants to get into the control solution bottle.
- Use only Swiss Point of Care brand control solution with your Swiss Point of Care brand meter and Swiss Point of Care Test Strips.

## MATERIALS PROVIDED

- Control Solution
- Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Test Strips

## INSTRUCTIONS FOR USE

1. Insert a new test strip to turn on the meter. Get details on how to record quality control test results and details on operating the meter from your User's Manual.
2. Shake the control solution bottle completely.
3. Squeeze the control solution bottle gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Shake again, and then use.
4. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep to indicate a sufficient sample has been applied.

**Notes:** Do not apply control solution to the test strip straight from the bottle.

If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.

5. Read the result from the meter display.

## EXPECTED RESULTS

Control solution test results should be within the control range. The ranges for CTRL 0, CTRL 1 and CTRL 2 are shown on the test strip vial (or on the foil pouch). For confirmation of results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should fall within CTRL 2 range. If the test results are in these ranges, this means your Blood Glucose Monitoring System is working right and you are doing the procedure correctly.

If the control solution test results do not fall within the ranges shown:

- Check the expiration date of the test strip and control solution. Throw away any expired test strips or control solution.
- Make sure you are testing at a temperature between 10 and 40 °C (50-104 °F).
- Make sure that the test strip vial and the control solution bottle have their caps on tight.
- Confirm that you are using Swiss Point of Care brand control solution.
- Make sure you follow the test procedure right.

After checking everything mentioned above, repeat the control solution test with a new test strip. If your results are still not in the range that is on the test strip vial label (or on the foil pouch), your meter may not be working right. DO NOT use the system to test blood. Contact your distributor for help. For complete instructions, please refer to the User's Manual that comes with your meter. For additional questions or issues with this product, please contact your distributor for help.

## INDEX OF SYMBOLS

|  |                                                     |  |              |  |                   |
|--|-----------------------------------------------------|--|--------------|--|-------------------|
|  | Consult instructions for use                        |  | Use by       |  | Temperature limit |
|  | <i>In vitro</i> diagnostic medical device           |  | Lot Number   |  | Control Range     |
|  | Authorized Representative in the European Community |  | Manufacturer |  | Catalogue number  |

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