# Swiss Point of Care Blood Glucose Test Strips Package Insert

| REF G135-90HB | MODEL OGS-191 | English |
|---|---|---|

## PRINCIPLE AND INTENDED USE

The Swiss Point of Care Test Strips are thin strips. The strips have a chemical reagent system. They work with the Swiss Point of Care Blood Glucose Meter. Together, they measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip. Then the blood is automatically absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction. The blood glucose concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meters are calibrated to show plasma equivalent results.

For *in vitro* diagnostic use. Test strips can be used only outside the body for testing purposes. For self-testing and professional use. They are used to measure the amount of glucose in fresh capillary whole blood. Capillary whole blood can be from the finger, forearm, and palm. The system is also used to monitor how well the diabetes control programs work.

## COMPOSITION

Each test strip has reactive and non-reactive chemicals. These chemicals are: Glucose Oxidase < 25 IU, Mediator < 300 µg, Buffer, and Non-reactive Ingredient.

Each test strip vial has a drying agent.

## STORAGE AND HANDLING

- Store test strips in their protective vial. Store with their cap on tight. This keeps them working good.
- Store test strips in a cool, dry place at room temperature, 2-35 °C (36-95 °F).
- Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This is to make sure you get the right results.
- Do not store or use the test strips in a humid place. For example, a bathroom.
- Do not store the meter, the test strips, or control solution near things that have bleach in them.
- Do not transfer the test strips to a new vial or any other container.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Replace the vial cap immediately after removing a test strip.
- Use the test strip right after you take it out of the vial.
- Do not use your test strips past the unopened expiration date printed on the vial. Using test strips past the expiration date can give you wrong test results.
  ***Note***: All expiration dates are printed in Year-Month-Date format.
- Use a new vial of test strips for only 12 months after opening. The opened vial expiration date is 12 months after the vial was first opened. Write the opened vial expiration date on the vial label after you open it.

## PRECAUTIONS

- For *in vitro* diagnostic use. Use the test strips only outside the body. Use only for testing purposes.
- Do not use test strips after the expiration date on the vial. Expired test strips can give wrong blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way.
- Do not reuse test strips.
- Only apply the sample to the tip of the test strip. Do not apply blood or control solution to the top of the test strip. This can give you false readings.
- Discard the vial and any unused test strips 12 months after you first open it. Constant exposure to air can destroy chemicals in the test strip. This damage can give you wrong readings.
- Keep the test strip vial away from children and animals.
- Talk to your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.

## MATERIALS PROVIDED

- Test Strips
- Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

## INSTRUCTIONS FOR USE

Before use, get complete instructions on getting blood samples from your User's Manual.

1. Open the cap of the test strip vial only to take out a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.
2. Follow the instructions in your user's manual to run the blood glucose test.
3. The blood glucose test result will show on the meter display window. Make sure the result is in the target range told by your healthcare professional. If your results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before changing your treatment plan.

***IMPORTANT:*** The Swiss Point of Care Blood Glucose Monitoring System allows alternative site testing. These are forearm and palm testing in addition to fingertip testing. You should know there are important differences between forearm, palm and fingertip samples.
Important information about forearm and palm glucose testing:

- When blood levels change fast (such as after a meal, insulin dose or exercise), blood from the fingertips may show these changes sooner than blood from other parts.
- Use your fingertips if you test within 2 hours of a meal, insulin dose, and exercise or any time you feel that your glucose levels are changing fast.
- You should test with the fingertips anytime you think there is a chance of hypoglycemia or you suffer from hypoglycemia unawareness.

## RANGE OF EXPECTED VALUES

Work with your healthcare professional to best monitor your glucose. Together you can set your own range of expected blood glucose values. You can also arrange your testing times. In addition, you should discuss the meaning of your blood glucose results together.

Expected blood glucose levels for people without diabetes[1]:

| Time | Range (mg/dL) | Range (mmol/L) |
|---|---|---|
| Fasting and Before Meals | 70 – 100 | 3.9 – 5.6 |
| 2 Hours After Meal | Less than 140 | Less than 7.8 |

## CHECKING THE SYSTEM

Your blood glucose meter must be handled carefully. See your User's Manual for detailed instructions for meter care. The quality control test should be used to check that the meter and test strips are working together properly. Follow the test procedure in your User's Manual to run a quality control test. Three ranges CTRL 0, CTRL 1 and CTRL 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most 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. Contact your distributor for information on buying control solution.

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 the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

***CAUTION:*** If your quality control test result is outside of the control range shown on the test strip vial, DO NOT use the system to test your blood, as the system may not be working properly. If you cannot correct the problem, contact your distributor for help.

## LIMITATIONS

- The Swiss Point of Care Test Strips and other components have been designed, tested and proven to work effectively with the Swiss Point of Care Meters to provide accurate blood glucose measurements. Do not use components from other brands.
- Do not use the meter in any way that is not specified by the manufacturer. If this happens, the system might not work the way it is supposed to.
- Test only fresh capillary whole blood with the Swiss Point of Care Test Strips. Do not use with serum or plasma samples.
- The Swiss Point of Care Blood Glucose Monitoring System is for professional use. It is also for over the counter sale. Both professionals and self-testing users can use the test strips to test fresh capillary blood samples.
- Very high (above 60 %), and very low (below 25 %) hematocrit can give you wrong results. Talk to your healthcare professional to find out your hematocrit level.
- Very high levels of Vitamin C (ascorbic acid) or other reducing substances will give falsely high blood glucose readings.
- The system gives accurate glucose readings between 0.6 and 33.3 mmol/L (10-600 mg/dL).
- Fatty substances (Triglycerides up to 3 000 mg/dL or Cholesterol up to 500 mg/dL) have no major effect on test results.
- The Swiss Point of Care test strips have been tested and shown to work properly up to 10 000 ft. (3 048 meters).
- If you are very ill, do not run the glucose test with the Swiss Point of Care Blood Glucose Monitoring Systems.
- Blood samples from patients in shock, with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested. We do not recommend these samples for testing with Swiss Point of Care Blood Glucose Monitoring Systems.
- Not for neonatal testing.
- Not for persons undergoing Oxygen therapy.
- Throw away blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.

## PERFORMANCE CHARACTERISTICS

The Swiss Point of Care blood glucose monitoring systems comply with the requirements of EN ISO 15197:2015 / ISO 15197:2013 (*in vitro* diagnostic test systems - requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus). The Swiss Point of Care meter is calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument. It is traceable to NIST reference standard.

**Reproducibility and Precision**

Ten replicate assays were each run on ten Swiss Point of Care Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. Three test strip lots were tested. The three lots combined results provided the following estimates.

| MEAN | 2.4 mmol/L (43.7 mg/dL) | 4.8 mmol/L (85.9 mg/dL) | 7.2 mmol/L (130 mg/dL) | 10.5 mmol/L (189 mg/dL) | 17.3 mmol/L (312 mg/dL) |
|---|---|---|---|---|---|
| Standard Deviation mmol/L (mg/dL) or Coefficient of Variation (CV) | 0.08 mmol/L (1.49 mg/dL) (SD) | 0.14 mmol/L (2.60 mg/dL) (SD) | 2.9% | 2.4% | 3.2% |

**Intermediate Precision**

Ten replicate assays drawn from three strip lots were run on ten Swiss Point of Care Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. Three test strip lots were tested. The three lots combined results provided the following estimates.

| Control Solution Level | MEAN | Standard Deviation mmol/L (mg/dL) or Coefficient of Variation (CV) |
|---|---|---|
| Low | 2.3 mmol/L (40.9 mg/dL) | 0.09 mmol/L (1.55 mg/dL) (SD) |
| Normal | 6.6 mmol/L (119 mg/dL) | 3.4% |
| High | 18.4 mmol/L (332 mg/dL) | 3.3% |

**System Accuracy**

A trained technician tested the capillary blood using the Swiss Point of Care Blood Glucose Meter (y). The blood samples were from more than 100 participants. Capillary blood samples were taken from fingertip, palm and forearm. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). Three test strip lots were tested. The three lots combined results were compared.

| Linear Regression Results: Swiss Point of Care (y) vs. YSI Reference (x) | | | | |
|---|---|---|---|---|
| Sample Site | Slope | Intercept (mmol/L)/(mg/dL) | R | N |
| Fingertip | 0.9433 | 0.3394 / 6.1100 | 0.9931 | 666 |
| Palm | 1.0023 | 0.2745 / 4.9416 | 0.9893 | 618 |
| Forearm | 0.9847 | 0.3707 / 6.6723 | 0.9893 | 618 |

Fingertip samples were used for YSI reference measurement.

The sample range was 2.3 - 31.9 mmol/L (40.9 - 574 mg/dL) for Swiss Point of Care Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 2.8 - 27.7 mmol/L (50.4 - 498 mg/dL) for Swiss Point of Care Blood Glucose Meter testing with blood sampled from palm and forearm sites.

| Fingertip Site: System Accuracy Results for Glucose Concentration ≥ 5.55 mmol/L (100 mg/dL) | | |
|---|---|---|
| Within ± 5 % | Within ± 10 % | Within ± 15 % |
| 256/492 (52.0%) | 431/492 (87.6%) | 490/492 (99.6%) |
| **Fingertip Site: System Accuracy Results for Glucose Concentration < 5.55 mmol/L (100 mg/dL)** | | |
| Within ± 0.28 mmol/L (5 mg/dL) | Within ± 0.56 mmol/L (10 mg/dL) | Within ± 0.83 mmol/L (15 mg/dL) |
| 132/174 (75.9%) | 174/174 (100%) | 174/174 (100%) |

| Palm Site: System Accuracy Results for Glucose Concentration ≥ 5.55 mmol/L (100 mg/dL) | | |
|---|---|---|
| Within ± 5 % | Within ± 10 % | Within ± 15 % |
| 199/474 (42.0%) | 378/474 (79.7%) | 471/474 (99.4%) |
| **Palm Site: System Accuracy Results for Glucose Concentration < 5.55 mmol/L (100 mg/dL)** | | |
| Within ± 0.28 mmol/L (5 mg/dL) | Within ± 0.56 mmol/L (10 mg/dL) | Within ± 0.83 mmol/L (15 mg/dL) |
| 76/144 (52.8%) | 126/144 (87.5%) | 144/144 (100%) |

| Forearm Site: System Accuracy Results for Glucose Concentration ≥ 5.55 mmol/L (100 mg/dL) | | |
|---|---|---|
| Within ± 5 % | Within ± 10 % | Within ± 15 % |
| 211/474 (44.5%) | 364/474 (76.8%) | 462/474 (97.5%) |
| **Forearm Site: System Accuracy Results for Glucose Concentration < 5.55 mmol/L (100 mg/dL)** | | |
| Within ± 0.28 mmol/L (5 mg/dL) | Within ± 0.56 mmol/L (10 mg/dL) | Within ± 0.83 mmol/L (15 mg/dL) |
| 76/144 (52.8%) | 128/144 (88.9%) | 144/144 (100%) |

| System Accuracy Results for Glucose Concentration between 2.3 mmol/L (40.9 mg/dL) and 31.9mmol/L ( 574 mg/dL) | | |
|---|---|---|
| Within ± 15 % or ± 0.83 mmol/L (15 mg/dL) | | |
| Fingertip Site | Palm Site | Forearm Site |
| 664/666 (99.7%) | 615/618 (99.5%) | 606/618 (98.1%) |

System accuracy according to EN ISO 15197:2015 / ISO 15197:2013, ≥ 98.1% of measured glucose values fall within the minimum acceptable performance criteria.

**Consumer Study**

A consumer study was held testing three test strip lots. Participants used the Swiss Point of Care Blood Glucose Monitoring System. This study shows that the patient can run the test as well as a trained technician.

| Swiss Point of Care tests: Linear regression of Participant (y) versus YSI Reference value and Linear regression of Technician (y) versus YSI Reference value | | | | | |
|---|---|---|---|---|---|
| Strip Lot | Tested By | Slope | Intercept (mmol/L)/(mg/dL) | R | N |
| Lot 1 | Layperson | 0.9594 | 0.2436 / 4.3856 | 0.9906 | 206 |
| Lot 1 | Technician | 0.9382 | 0.4106 / 7.3900 | 0.9910 | 206 |
| Lot 2 | Layperson | 0.9523 | 0.2649 / 4.7681 | 0.9906 | 206 |
| Lot 2 | Technician | 0.9502 | 0.3066 / 5.5187 | 0.9904 | 206 |
| Lot 3 | Layperson | 0.9654 | 0.2710 / 4.8784 | 0.9914 | 206 |
| Lot 3 | Technician | 0.9509 | 0.2936 / 5.2854 | 0.9901 | 206 |

The study evaluating glucose values from fingertip capillary blood samples obtained by 103 lay persons showed the following results:

100% within ± 0.83 mmol/L (15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL), and 100% within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L (100 mg/dL).

For complete instructions, please refer to the User's Manual included with your meter. For additional questions or issues with this product, please contact your distributor for help.

## REFERENCES


1. ADA Clinical Practice Recommendations, 2013.


### INDEX OF SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | | Use by | MODEL | Model Number |
| IVD | *In vitro* diagnostic medical device | LOT | Lot Number | CTRL | Control Range |
| Σ | Contains sufficient for <*n*> tests | | Do not reuse | 2°C 35°C | Temperature limit |
| EC REP | Authorized Representative in the European Community | | Manufacturer | REF | Catalogue number |


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