

Use with Glucopoint Blood Glucose Monitoring System Only
ver 1.0 2008 - 04-30

Warnings

- ▶ Healthcare professionals and others using this system on multiple patients should be aware that all products or objects that come into contact with human blood should be handled as if capable of transmitting viral diseases, even after cleaning.
- ▶ Please review this instruction sheet and the Glucopoint Blood Glucose Monitoring System Owner's Manual before you use Glucopoint Test Strips. For reliable results and to maintain the manufacturer's complete service, support and warranty, please use Glucopoint Test Strips only.
- ▶ Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- ▶ Discard the used test strips and lancets according to your local regulation.
- ▶ As with all small parts, the test strips and lancets should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.

Intended Use

The Glucopoint Test Strip, when use with the Glucopoint Blood Glucose Monitor, is intended for use in quantitative measurement of blood glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper arm, the calf, and the thigh. It is intended for used by healthcare professionals and people with diabetes mellitus at home. **It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.**

Purpose of Use

Routine blood glucose (sugar) testing can provide you and your doctor with information on how your treatment program affects your blood glucose level. Testing blood glucose regularly can help keep your diabetes under control too. Blood glucose management should be done in conjunction with advice from your healthcare professional.

Storage and Handling

IMPORTANT: Do not use the test strips after expired, or results will be wrong.

- ▶ Test strips expire 90 days after opening. Write the expiry date on the test strip vial when first opening.
- ▶ Store the test strips in a cool and dry place between 4° and 40° C (39° and 104° F). Do not freeze.
- ▶ Operate the test strips at temperature between 10° and 40° C (50° and 104° F), and less than 85% humidity.
- ▶ Keep the test strips away from direct sunlight. Do not store the test strips in areas of high humidity.
- ▶ Test strips must be stored in their original vial ONLY. Do not transfer them to a new vial or other container.
- ▶ Do not touch the test strips when your hands are wet.
- ▶ Use each strip promptly after removing it from the vial. Close the vial lid quickly after removing a new strip.
- ▶ Keep the vial lid closed at all times.
- ▶ Do not bend, cut or alter the test strip. Doing so will lead to inaccurate results.

Calibration

When using the system for the first time, or before using a new vial of test strips, you will need to calibrate the meter. This can be easily done by inserting the code strip into the meter. It is important to make sure that the LCD displayed code is the same as the code on the test strip vial before testing. **Only test blood glucose when the codes are identical, and your test result can be correct.**

- STEP1** Fully insert the code strip into the test strip slot. A single beep will sound and the code number will appear on the display. Make sure that the code number on LCD display, on the code strip, and on the strip vial are the same.
- STEP2** Remove the code strip. The meter is now ready for blood glucose or control solution measurement.

Please refer to the Glucopoint Blood Glucose Monitoring System Owner's Manual for more details.

About Alternative Site Testing (AST)

IMPORTANT: There are limitations for doing AST. Please read the Glucopoint Blood Glucose Monitoring System Owner's Manual and consult your healthcare professional before you do AST.

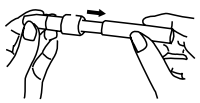
Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. Glucopoint Test Strips provide you to test on the palm, the forearm, the upper arm, the calf, or the thigh with the equivalent results to fingertip testing. We strongly recommend that you do AST **ONLY** in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

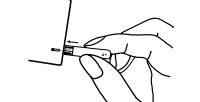
To obtain a blood sample from the alternative sites, please **rub the puncture site about 20 seconds at first** and then follow the penetration procedures in the Glucopoint Blood Glucose Monitoring System Owner's Manual.

Testing your blood glucose

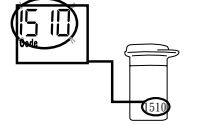
WASH AND DRY YOUR HANDS FIRST BEFORE STARTING.



STEP1 Set the lancing device according to the Glucopoint Blood Glucose Monitoring System Owner's Manual.



STEP2 Fully insert the test strip into the meter with the contact bars end first. The meter turns on automatically and finally displays the flashing code number.

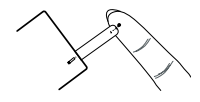


STEP3 This code number shall be same to the code number on the strip vial.



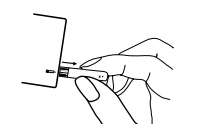
STEP4 Select the puncture site either in finger or in other parts (AST). Hold the lancing device firmly against the puncture site. Press the release button.

STEP5 Gently squeeze the punctured area to get enough drop of blood. Do not squeeze the puncture site excessively.



STEP6 Apply the blood drop to the absorbent hole of the test strip until blood has completely filled the confirmation window. It requires at least 0.7 µL blood for a glucose test.

STEP7 The meter counts down and then displays a result. The reading is automatically stored in the meter memory.



STEP8 Shut the meter off by removing the strip out. Discard the used strip.

Please read consult the Glucopoint Blood Glucose Monitoring System Owner's Manual for testing procedures and AST.



The used lancet and the used test strip may be potentially biohazard. Please discard it carefully according to your local regulations.

Reading Your Result

Your blood glucose test results are displayed either in milligrams of glucose per deciliter of blood (mg/dL) or in millimole of glucose per liter of blood (mmol/L). The meter is able to display test results from 20 to 600 mg/dL or from 1.1 to 33.3 mmol/L.

If your result is below the 20 mg/dL, the meter will read "Lo". This indicates very low blood glucose levels or severe hypoglycemia. Repeat your test with a new strip and immediately seek your healthcare professional for help.

If your results are above the 600 mg/dL, the meter will read "Hi". This indicates very high blood glucose levels, or severe hyperglycemia. Repeat your test with a new strip and immediately seek your healthcare professional for help.

Time of day	People without diabetes
Fasting and before meals*1	70-110 mg/dL(3.9-6.1 mmol/L)
2 hours after meals*2	Less than 140 mg/dL(7.8mmol/L)

*1 Sacks, DB in " Carbohydrates", Burtis, CA, Ashwood, ER(ed), Tietz Textbook of Clinical Chemistry, Philadelphia, WB Saunders Company, 1999.

*2 Source: ADA Clinical Practice Recommendations 2003

Please work with your doctor to determine a target range that works best for you.

Questionable or Inconsistent Results

If you are receiving test results that are unusual or inconsistent with how you are feeling:

- ▶▶ Make sure that the drop of blood completely fills the test area of the test strip.
- ▶▶ Check that the test strips are not expired.
- ▶▶ Make sure that the code number is consistent between the meter and the test strip vial.
- ▶▶ Check the performance of the meter and test strips using the control solution.

Please keep in mind that high or low blood glucose levels can indicate a possibly serious medical condition. If you continue to get results that are unusually high or low, consult your healthcare professional.

Quality Control Testing

GlucoPoint control solutions contain a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, it is able to check that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get correct results. Read the GlucoPoint Blood Glucose Monitoring System Owner's Manual for complete testing details.

IMPORTANT: The control range may change with each new vial of test strips. Always use the control range on the label of your current vial of test strips.

When to perform a quality control test

- ▶▶ When you first get your Glucose Monitor.
- ▶▶ When you begin using a new vial of test strips.
- ▶▶ At least once a week.
- ▶▶ Whenever you suspect that the meter or test strips are not working properly.
- ▶▶ When your blood glucose test results are not consistent with how you feel, or when you think your results are inaccurate.
- ▶▶ When your test strips are exposed to extreme environmental conditions (See Storage and Handling section of this package insert).
- ▶▶ When you want to practice running the test.
- ▶▶ If you drop the meter.

If the Quality Control test result falls outside the specified range

- ▶▶ Review the Quality Control Section of the GlucoPoint Blood Glucose Monitoring System Owner's Manual to confirm your procedure and techniques.
- ▶▶ Repeat the quality control test.
- ▶▶ Check the expiration date of your test strips and control solutions.
- ▶▶ Check your meter for damage (dropping the meter, immersing in liquid).

If you still have a problem, please call your local agent for service.

Test Principle

GlucoPoint Test Strips provide a quantitative measurement of glucose in whole blood. When the absorbent hole is filled by blood sample, the reaction between blood glucose and chemical components in the strip starts and generates an electrical current. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Chemical components of strip

- ▶▶ Glucose oxidase (A. Niger)..... 10%
- ▶▶ Electron shuttle..... 50%
- ▶▶ Enzyme protector..... 8%
- ▶▶ Non-reactive ingredients.....32%

Limitations

- ▶▶ Hematocrit Effect: The glucose result is not affected when hematocrit is between 20% and 60%. Please consult your healthcare professional if you do not know your hematocrit level.
- ▶▶ Neonatal Use: The test strips shall not be used for the testing of newborns.
- ▶▶ Use only fresh capillary whole blood. Do not use serum or plasma.
- ▶▶ Metabolites: Ascorbic acid at normal blood concentration does not significantly affect glucose readings. High concentrations of acetaminophen, dopamine, L-dopa, methyldopa and uric acid may cause inaccurate test results. Blood glucose readings should be interpreted with caution.
- ▶▶ Lipemic Effects: Elevated blood triglycerides up to 2000 mg/dL do not significantly affect the results. However, the glucose test may be affected beyond these levels.
- ▶▶ Altitude Effects: Test strips may be used at altitudes up to 10,742 feet (3,275m) without an effect on test results.
- ▶▶ Do not use iodoacetic acid or fluoride as a preservative for blood specimens.

Performance Characteristics

Accuracy













Within ± 15 mg/dL (0.83 mmol/L) at glucose concentration < 75 mg/dL (4.2 mmol/L) and within $\pm 20\%$ at glucose concentration ≥ 75 mg/dL (4.2 mmol/L).

Precision

CVs (%) of intermediate precision and repeatability are less than 5%.

The product has been tested to meet the requirements of ISO 15197.

Symbol Information

Symbol	Referent
	In vitro diagnostic medical device
	Do not reuse
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by
	Date of manufacture
	Batch code
	Manufacturer
	Biological risks
	Authorized representative in the European Community

At all other times, you should contact your healthcare professional for assistance.



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