

Glucosefine® Pro Blood Glucose Test Strips

Use only with **Glucosefine® Pro Blood Glucose Monitoring System**.

Warnings

- ▶ For *in vitro* diagnostic use (for use outside of the body only).
- ▶ For single use only.
- ▶ Healthcare professionals and other users should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- ▶ Please read this sheet and your Blood Glucose Monitoring System Owner's Manual before you use this test strip. Use only **Glucosefine® Pro Blood Glucose Test Strips** with **Glucosefine® Pro Blood Glucose Monitoring System** to obtain accurate results, and be covered by the manufacturer's warranty.
- ▶ Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- ▶ For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. It may apply under the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycemia, hyperosmolar non-ketotic coma, shock, decompensated heart failure **NYHA Class IV** or peripheral arterial occlusive disease.
- ▶ Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

Glucosefine® Pro Blood Glucose Test Strips, when used together with **Glucosefine® Pro Blood Glucose Monitoring System**, allow your blood glucose levels to be measured by yourself at home or by healthcare professionals. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples from finger, palm, upper arm and forearm, and from venous whole blood sample.

Professionals may use test strips to test capillary and venous blood sample; home use is limited to capillary whole blood testing. This system is not intended for use in the diagnosis or screening of diabetes mellitus.

Test Principle

Your system measures the amount of glucose in whole blood. The test is based on the measurement of electrical current generated by the reaction of the blood glucose with the reagent of the strips. The meter measures the current, calculates the glucose in the blood, and displays the result on the screen. The strength of the current produced by the reaction depends on the amount of blood glucose in the blood sample.

Limitations

- ▶ Lipemic Effects: Blood triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results significantly, but may affect results at higher levels.
- ▶ Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- ▶ Metabolites: Dopamine, L-Dopa, methyl dopa, uric acid, ascorbic acid, and acetaminophen at normal blood concentration do not significantly affect blood glucose test results.
- ▶ There are no significant interference in the presence of galactose, maltose, or fructose observed in blood glucose tests.
- ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- ▶ Use only heparin for anticoagulation of fresh capillary or venous whole blood.
- ▶ Hematocrit: The hematocrit level is limited to between 20% to 65%. Please ask your healthcare professional if you do not know your hematocrit level.

The following compounds when determined to be in excess of their limitation and tested with the **Glucosefine® Pro Blood Glucose Monitoring System** may produce elevated glucose results:

Summary of substances and concentrations in excess of limitation with interference

Substance	Limiting Concentration (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)
Acetaminophen (Paracetamol)	> 6.25	0.45 - 3
Ascorbic Acid	> 5	2
Pralidoxime Iodide	> 5	~ 10 (IV Dose 500 mg)
Uric Acid	> 10	2 - 8

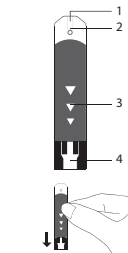
Storage and Handling

⚠ Do **NOT** use the test strips if they have expired.

- ▶ Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and between 10% and 85% relative humidity.
- ▶ Use each test strip immediately after taking it out of the individual foil packet.
- ▶ Keep the test strips away from direct sunlight. Do **NOT** store the test strips in high humidity.
- ▶ Do **NOT** touch the test strips with wet hands.
- ▶ Do **NOT** bend, cut, or alter the test strips.

Chemical Components

Glucose dehydrogenase (*E. coli*) 8%
 Electron shuttle 55%
 Enzyme protector 8%
 Non-reactive ingredients 29%



Strip Appearance

- Absorbent Hole**
Apply a drop of blood here. The blood will automatically be absorbed.
- Confirmation Window**
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.
- Test Strip Handle**
Hold this part to insert the test strip into the slot.
- Contact Bars**
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

ATTENTION: *The front side of the test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.*

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.

- STEP 1**
Insert the test strip fully into the slot of the meter to power on. Wait until the display shows " " and " ". Select the suitable measuring mode by pressing the button "▲".
- STEP 2**
Use the prepared lancing device to puncture the selected site. The sample volume should be about 0.5 µL "●". Touch the blood drop with the absorbent hole of the test strip. Do **NOT** apply a smeared blood sample. The blood will immediately be absorbed. As soon as the confirmation window is fully covered, the meter starts testing. Do not remove your finger, until you hear a beep-sound.
- STEP 3**
After 6 seconds (count down from 5 to 0), the meter will display your blood glucose level. The symbol "☺" or "☹" shows, if your test result is within your determined target range. The test result will be automatically saved in the meter. Discard the used test strip by actuating the strip ejector into a suitable container to dispose. The meter will automatically turn off after removing test strip.

NOTE: Please refer to your Owner's Manual for more information. The used lancet and test strips are potentially biohazardous. Please dispose of them carefully according to your local regulations.

Reading Your Result

The blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%.^{*1} The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes. Your blood glucose readings deliver plasma equivalent results and are displayed either in milligrams of glucose per deciliter of blood (mg/dL) or in millimoles of glucose per liter of blood (mmol/L).

Reference values

Time of day	Normal plasma glucose range for people without diabetes (mg/dL or mmol/L)
Fasting*2 and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meal	Less than 140 mg/dL (7.8 mmol/L)

*1: American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2022 Jan; 45(Supplement 1): S17-S38. <https://doi.org/10.2337/oc22-S002>

*2: Fasting is defined as no caloric intake for at least 8 hours.

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

Questionable or inconsistent results

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

- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiration date of the test strips.
- Check the performance of your meter and test strips with the control solutions.

⚠ Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our control solutions contain a known amount of glucose that can react with test strips. If you are concerned about the meter or test strips are not working properly, you can check the performance of the meter, test strips and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the test strip package. Please refer to the Owner's Manual for complete testing instructions.

⚠ The reference range of the control solutions may vary with each new vial or package of test strips. Make sure you check the range on the label of your current vial or on the current package.

About Alternative Site Testing (AST)

⚠ There are limitations for performing AST. Please read the **Glucosefine® Pro Blood Glucose Monitoring System Owner's Manual** and consult the doctor before you perform AST. Alternative site testing (AST) is when individuals check their blood glucose levels using areas of the body other than the fingertip. The **Glucosefine® Pro Blood Glucose Test Strips** allow AST to be performed on sites other than the fingertip.

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or more than two hours after the last meal.
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- You think your blood glucose is low.
- You may not notice if you are hypoglycemic.
- Your AST results are inconsistent with the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results often fluctuate.

To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds before following the procedures of "Testing Your Blood Glucose".

Additional Information

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary and venous blood sample.

Sample Size: 0.5 µL Reaction Time: 6 seconds
 System Measurement Range: 20 to 650 mg/dL (1.1 to 36.1 mmol/L)
 Hematocrit Range: 20% to 65%

Accuracy

Diabetes experts have suggested that glucose meters should be within ±15 mg/dL (0.83 mmol/L) of the reference method when the glucose concentration is lower than 100 mg/dL (5.55 mmol/L), and be within ±15% of the reference method when the glucose concentration is 100 mg/dL (5.55 mmol/L) or higher. The tables below display how often **Glucosefine® Pro** achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well **Glucosefine® Pro** performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L) (Capillary)

Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.55 mmol/L)	Within ±15 mg/dL* (Within ±0.83 mmol/L)
68.7% (202/294)	96.9% (285/294)	100% (294/294)

Table 2 Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L) (Capillary)

Within ±5%	Within ±10%	Within ±15%*
64.3% (428/666)	90.2% (601/666)	98.2% (654/666)

Table 3 Accuracy results for glucose concentrations between 32.2 mg/dL (1.79 mmol/L) to 572.0 mg/dL (31.78 mmol/L) (Capillary)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
98.8% (948/960)

Table 4 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L) (Venous)

Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.55 mmol/L)	Within ±15 mg/dL* (Within ±0.83 mmol/L)
62.8% (196/312)	91.0% (284/312)	99.7% (311/312)

Table 5 Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L) (Venous)

Within ±5%	Within ±10%	Within ±15%*
55.4% (359/648)	87.3% (566/648)	98.1% (636/648)

Table 6 Accuracy results for glucose concentrations between 35.8 mg/dL (1.99 mmol/L) to 570.0 mg/dL (31.67 mmol/L) (Venous)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
98.6% (947/960)

*Acceptance criteria in ISO 15197:2013 and EN ISO 15197:2015. 95% of all differences in glucose values (i.e., YSI-2300 reference values minus **Glucosefine® Pro's** glucose values) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

NOTE: When **Glucosefine® Pro Blood Glucose Test Strips** results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) are in percent.

User performance

A study evaluating glucose values from fingertip capillary blood samples obtained by 160 lay persons showed the following results:

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

160 subjects tested on the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well **Glucosefine® Pro** performed compared to YSI-2300 reference method results.

Table 7 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5 mg/dL (±0.28 mmol/L)	Difference within ±10 mg/dL (±0.55 mmol/L)	Difference within ±15 mg/dL (±0.83 mmol/L)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/42 (100%)
Forearm	31/42 (73.8%)	39/42 (92.9%)	42/42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

Table 8 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5%	Difference within ±10%	Difference within ±15%
Palm	49/118 (41.5%)	92/118 (78.0%)	118/118 (100%)
Forearm	43/118 (36.4%)	84/118 (71.2%)	115/118 (97.5%)
Upper arm	49/118 (41.5%)	87/118 (73.7%)	116/118 (98.3%)

Precision

The CV (%) is less than 5% both in intermediate precision and repeatability precision.

Symbol Information

Symbol	Referent	Symbol	Referent	Symbol	Referent
	<i>In vitro</i> diagnostic medical device		Batch code		Manufacturer
	Consult instructions for use or consult electronic instructions for use		Caution		Model number
	Temperature limit		Humidity limitation		Do not re-use
	Use-by date		CE mark		Unique device identifier
	Authorized representative in the European Community		Importer		Distributor

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