

GlucoPro **Innova**

Blood Glucose Monitoring System

GlucoPro Test Strips Insert

Strips Model: GlucoPro Innova

IMPORTANT: Please read this information and your GlucoPro Innova Glucose Monitoring System's user manual before using GlucoPro Test Strips.

Warnings

- For *in vitro* diagnostic use (for use outside of the body only).
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system should handle everything that has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this sheet and your Blood Glucose Monitoring System User's Manual before you use this test strip.
- Only use the same model name of test strips and meters 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.
- Low results may be inaccurate when testing on patients in the hyperglycemic-hyperosmolar state, with or without ketosis.
- Please do not use the Glucose Monitoring System on critically ill patients.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

GlucoPro Innova Glucose Test Strips are used with the GlucoPro Innova Blood Glucose Meter for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip. The GlucoPro Innova Glucose Test Strips are for testing outside the body (*in vitro* diagnostic use). The GlucoPro Innova Blood Glucose meter is intended for use in home and in professional settings to monitor blood glucose levels.

Limitations

Hematocrit: The hematocrit level is limited to between 10% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.

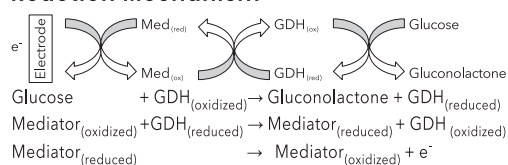
- Metabolites: Dopamine, L-Dopa, methyl dopa, uric acid, ascorbic acid, and acetaminophen at normal concentration do not significantly affect blood glucose test results.

Storage and Handling

- Store at room temperature between 4°C and 35° C (39.2°F and 95° F) and below 85% relative humidity. Do not refrigerate or freeze. Avoid exposing test strips to extreme temperatures.
- Store away from direct sunlight and heat.
- Use each strip immediately after removing it from the vial.
- Store your test strips in their original vial only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to a new vial or any other container.
- After removing a test strip from the vial, recover the vial cap immediately and close it tightly.

- Discard testing strips 3 month after first opening.
- Do not bend, cut, or alter the Test Strip in any way.
- With clean, dry hands you may gently touch the test strip anywhere when removing it from the vial or inserting it into the meter.

Reaction Mechanism



Reference Values

Time of day Normal plasma glucose range for people without diabetes control target.

• Normal Glucose Values

The normal fasting glucose range for a non-diabetic adult is 80 to 130 mg/dL (4.4 to 7.2 mmol/L). One to two hours after meals, normal glucose values should be less than 140 mg/dL (7.8 mmol/L). For people with diabetes, consult your physician or healthcare professional for the target glucose values that are right for you.

• Low Glucose Values

The GlucoPro Innova Blood Glucose Meter displays results between 20 and 700 mg/dL (1.11 and 38.8 mmol/L). If your test result is lower than 20 mg/dL (1.11 mmol/L), "Low" (Lo) will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). You should immediately treat low blood sugar as recommended by your healthcare professional.

• High Glucose Values

If your test result is above 700 mg/dL (38.8 mmol/L), "High" (Hi) will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). You should immediately treat high blood sugar as recommended by your healthcare professional.

• Unexpected Results

Low or high blood sugar readings can indicate a potentially serious medical condition. If your blood glucose is unusually low or high, or if you do not feel the way your results indicate, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTS.

- Insert the test strip fully into the slot of the meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks.
- Collect a blood sample with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip, and wait until the confirmation window is fully covered. Do NOT apply a smeared blood sample. The meter will start counting down.
- After a few seconds, the meter will display your blood glucose level. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.

Chemical Components

Non-reactive ingredients $\geq 1.75\%$ w/v
 Glucose dehydrogenase(FAD-dependent)
 ≥ 3.5 unit/v $K_3Fe(CN)_6 \geq 2.5\%$ w/v

Additional Information for Healthcare Professionals

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 whole blood.

Sample Size: 0.75 μ L

Reaction Time: 5 seconds

System Measurement Range: 20 mg/dL to 700 mg/dL
 1.11 mmol/L to 38.8mmol/L

Hematocrit Range: 10% to 70%

Intermediated Precision Test

Use Control Solution to test 3 batches of Strips for ten consecutive days. The test results are shown as follows:

STRIP BATCH	LOT A			LOT B			LOT C		
	Low	Normal	High	Low	Normal	High	Low	Normal	High
Control Solution									
YSI-2300	39.1	123.5	350.6	39.1	123.5	350.6	39.1	123.5	350.6
Maximum	45	131	365	45	131	365	45	131	365
Minimum	33	116	337	33	116	337	33	116	337
Average	39.0	124.5	352.0	39.7	124.3	350.9	39.3	124.5	352.5
SD	3.03	4.32	7.89	3.16	4.02	7.64	3.51	4.04	7.31
CV%	-	3.47%	2.24%	-	3.23%	2.18%	-	3.25%	2.07%

Repetitive Test

Five different concentrations of blood samples were prepared by adding glucose method, and for three batches of test strips, each concentration was repeated 100 times.

GLUCOSE CONC.	AVG	SD	CV%
40 mg/dL	42.0	3.1	-
81 mg/dL	90.1	3.7	-
125 mg/dL	130.1	5.1	3.9%
210 mg/dL	207.6	6.8	3.3%
352 mg/dL	355.7	8.0	2.3%
500 mg/dL	498.5	13.2	2.7%

Glucose Test Strip Interference Evaluation

Interference Substance	Substance Interference Concentration
Acetaminophen	No interference under 12mg/dL in whole blood
Ascorbate (Ascorbic Acid)	No interference under 2.4 mg/dL in whole blood
Bilirubin	No interference under 20 mg/dL in whole blood
Cholesterol	No interference under 500 mg/dL in whole blood
Creatinine	No interference under 5 mg/dL in whole blood
Dopamine	No interference under 90 μ g/dL in whole blood
EDTA	No interference under 100 μ g/dL in whole blood
Galactose	No interference under 15.12 mg/dL in whole blood
Gentisic Acid	No interference under 1.8 mg/dL in whole blood
Glutathione	No interference under 20 mg/dL in whole blood
Hemoglobin	No interference under 200 mg/dL in whole blood
Heparin	No interference under 300 U/dL in whole blood
Ibuprofen	No interference under 50 mg/dL in whole blood
Icodextrin	No interference under 0.75% in whole blood
L-Dopa	No interference under 4.46 mg/dL in whole blood
Maltose	No interference under 500 mg/dL in whole blood
Methyl-Dopa	No interference under 1.5 mg/dL in whole blood
Pralidoxime Iodide [PAM]	No interference under 3.8 mg/dL in whole blood
Salicylate (Assalicylic Acid)	No interference under 20 mg/dL in whole blood
Tolbutamide	No interference under 64 mg/dL in whole blood
Tolazamide	No interference under 3.16 mg/dL in whole blood
Triglycerides (Total)	No interference under 500 mg/dL in whole blood
Uric Acid	No interference under 7.9 mg/dL in whole blood
Xylose	No interference under 10 mg/dL in whole blood

Accuracy

In professional users of 120 cases of test results: Blood glucose concentration less than 100 mg/dL (5.55 mmol/L) of results:

Within ± 5 mg/dL Within ± 0.28 mmol/L	Within ± 10 mg/dL Within ± 0.56 mmol/L	Within ± 15 mg/dL Within ± 0.83 mmol/L
(161 / 282) 57.1%	(247 / 282) 87.6%	(282 / 282) 100%

Blood glucose concentration more than 100mg/dL (5.55mmol/L) of results:

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
(339 / 438) 77.4%	(420 / 438) 95.9%	(438 / 438) 100%

System accuracy Results for glucose concentrations between 21 mg/dL and 529 mg/dL

Within ± 15 mg/dL Within ± 0.83 mmol/L
720 / 720 (100%)

Lay Person

In non-professional users of 120 cases, each testing twice Blood glucose concentration less than 100 mg/dL (5.55 mmol/L) of results:

Within ± 5 mg/dL Within ± 0.28 mmol/L	Within ± 10 mg/dL Within ± 0.56 mmol/L	Within ± 15 mg/dL Within ± 0.83 mmol/L
(62 / 94) 66.0%	(85 / 94) 90.4%	(94 / 94) 100%

Blood glucose concentration more than 100 mg/dL (5.55 mmol/L) of results:

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
(117 / 146) 80.1%	(141 / 146) 96.6%	(146 / 146) 100%

System accuracy Results for glucose concentrations between 21 mg/dL and 529 mg/dL

Within ± 15 mg/dL or 15% (Within ± 0.83 mmol/L or 15%)
(240 / 240) 100%

The reference blood glucose concentration for Accuracy and Lay person come from the test results of plasma separated from whole blood.

Blood Drop Measure Scope



Symbol Information

	<i>In vitro</i> diagnostic medical device
	Please read the instructions before use
	Do not reuse
	Batch code
	Caution
	No directly sun exposure
	Temperature limitation
	Use by / Expiry date
	Manufacturer

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