GIMA

Blood Glucose Test Strips Package Insert

REF 24118	REF 24119	REF 24120	English

PRINCIPLE AND INTENDED USE

The GIMA Blood Glucose Test Strips are thin strips with a chemical reagent system. They work with the GIMA Blood Glucose Meter to measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip. The blood is then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction which is detected by the meter. The blood glucose concentration is then calculated based on the electrical current. The result is then shown on the meter display. The meters are calibrated to display plasma equivalent results per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes. For self-testing and professional use. GIMA Test Strips are used by people with diabetes at home and by healthcare professionals for the quantitative measurement of glucose in capillary whole blood from the finger, forearm, and palm. It is also used as an aid in monitoring the effectiveness of diabetes control programs. Professionals may also test neonatal, arterial and venous blood samples.

COMPOSITION

Each test strip has reactive and non-reactive chemicals. These chemicals are: FAD-dependent Glucose Dehydrogenase < 25 IU, Mediator < 300 µg, Buffer, and Non-reactive Ingredient. Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Test strips should be stored in their protective vial. The vial's cap must be tightly closed to keep the test strips in good working condition.
- 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.
- To ensure accurate results, use the test strips at room temperature.
- Keep the text side up and blank side down when you insert the strip contact bars into the strip port.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleaches or cleaners that contain bleaches.
- 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 immediately after removing it from the vial.
- Do not use your test strips past the unopened expiration date printed on the vial. Using test strips past the expiration date may produce incorrect test results.
  Note: All expiration dates are printed in Year-Month-Date format.
- A new vial of test strips may be used for 18 months after first being opened. Write the opened vial expiration date on the vial label after opening.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give incorrect blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way.
- Do not reuse test strips.
- The sample must only be applied to the tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.
- Discard the vial and any unused strips 18 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This damage can cause incorrect readings.
- Keep the test strip vial away from children and animals.
- Consult your healthcare professional before making any changes in your treatment plan.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions when disposing of materials.

MATERIALS PROVIDED

- Test Strips
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

INSTRUCTIONS FOR USE

See your User's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial only to remove a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.
2. Run the blood glucose test following the instructions contained in your User's Manual.
3. The blood glucose test result will be shown on the meter display window. This result should fall within the target range. Your healthcare professional should recommend your target range. If your blood glucose test results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: GIMA Blood Glucose Monitoring System allow alternative sites testing for forearm and palm testing in additional to fingertip testing. There are important differences between forearm, palm and fingertip samples that you should know.

Important information about forearm and palm glucose testing:

- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.

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 Control Solution 0 or Control Solution 2 test. Contact your dealer for information on purchasing 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 falls outside 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 GIMA meters, GIMA test strips and other components of the GIMA Blood Glucose Monitoring System have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The GIMA Test Strips are for testing fresh capillary, venous, arterial or neonatal whole blood. Do not use with serum or plasma samples.
- The venous, arterial and neonatal blood must be obtained and tested by healthcare professionals.
- Blood glucose measurement with venous or arterial whole blood samples must be performed within 15 minutes of sample collection.
- Anticoagulant preservatives such as heparin or EDTA are recommended for best results in using venous or arterial whole blood samples. Use of anticoagulants such as iodoacetate, sodium citrate, or those containing fluoride is not advised.
- Very high (above 70%) and very low (below 10%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of Vitamin C or other reducing substances will produce false high blood glucose measurements.
- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 0.6 - 33.3 mmol/L (10 to 600 mg/dL).
- Fats(Triglycerides up to 3,000 mg/dL or Cholesterol up to 500 mg/dL) have no major effect on blood glucose test results.
- The GIMA Blood Glucose Monitoring System shows to work properly in studies at altitudes up to 10,000 ft (3,048 meters).
- Severely ill persons should not run the glucose test with the GIMA Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with GIMA Glucose Monitoring System.

PERFORMANCE CHARACTERISTICS

The GIMA Blood Glucose Monitoring System 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 GIMA meter is calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.

Repeatability Precision

Ten replicate assays were each run on ten GIMA Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following estimates for reproducibility, precision.

MEAN	2.37 mmol/L (42.6 mg/dL)	4.57 mmol/L (82.2 mg/dL)	7.41 mmol/L (133.3mg/dL)	11.39 mmol/L (205.1mg/dL)	18.59 mmol/L (334.6 mg/dL)
Standard Deviation mmol/L (mg/dL) or Coefficient of Variation	0.069 mmol/L (1.24 mg/dL)	0.127 mmol/L (2.28 mg/dL)	2.5 %	2.5 %	2.6 %

Intermediate Precision

Ten replicate assays drawn from three strip lots were run on ten GIMA 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. The results provided the following precision estimates.

#	MEAN	Standard Deviation mmol/L (mg/dL) or Coefficient of Variation (CV)
Strip Lot 1	2.00 mmol/L (36.0 mg/dL)	0.051 mmol/L (0.91 mg/dL)
	7.12 mmol/L (115.3 mg/dL)	2.3 %
	17.83 mmol/L (321.0 mg/dL)	2.1 %
Strip Lot 2	1.99 mmol/L (35.8 mg/dL)	0.061 mmol/L (1.09 mg/dL)
	7.10 mmol/L (115.3 mg/dL)	2.3 %
	17.83 mmol/L (320.9 mg/dL)	2.0 %
Strip Lot 3	2.00 mmol/L (36.0 mg/dL)	0.058 mmol/L (1.05 mg/dL)
	7.08 mmol/L (114.7 mg/dL)	2.7 %
	17.77 mmol/L (319.9 mg/dL)	1.6 %

System Accuracy

A trained technician tested the capillary blood using the GIMA 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). The results were compared.

Linear Regression Results: GIMA (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept	R	N
Fingertip	0.9892	-3.2734	0.9964	798
Palm	0.9750	-2.5412	0.9929	666
Forearm	0.9821	0.4242	0.9913	666

Fingertip samples were used for YSI reference measurement.

The sample range was 1.1 to 29.6 mmol/L (19.6 to 534 mg/dL) for GIMA Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 3.2 to 21.3 mmol/L (57 to 384 mg/dL) for GIMA 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 %
335/582 (57.6 %)	530/582 (91.1 %)	582/582 (100.0 %)
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)
156/216 (72.2 %)	214/216 (99.1 %)	216/216 (100.0 %)

Palm Site: System Accuracy Results for Glucose Concentration ≥ 5.55 mmol/L (100 mg/dL)		
Within ± 5 %	Within ± 10 %	Within ± 15 %
246/516 (47.7 %)	447/516 (86.6 %)	514/516 (99.6 %)
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)
95/150 (63.3 %)	146/150 (97.3 %)	150/150 (100.0 %)

Forearm Site: System Accuracy Results for Glucose Concentration ≥ 5.55 mmol/L (100 mg/dL)		
Within ± 5 %	Within ± 10 %	Within ± 15 %
297/516 (57.6 %)	469/516 (90.9 %)	513/516 (99.4 %)
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)
99/150 (66.0 %)	141/150 (94.0 %)	150/150 (100.0 %)

System Accuracy Results for Glucose Concentration between 1.1 mmol/L (19.6 mg/dL) and 29.7 mmol/L (534 mg/dL)		
Within ± 15 % or ± 0.83 mmol/L (± 15 mg/dL)		
Fingertip Site	Palm Site	Forearm Site
798/798 (100.0 %)	664/666 (99.7 %)	663/666 (99.5 %)
Within ± 12 % or ± 0.56 mmol/L (± 10 mg/dL)		
Fingertip Site		
780/798 (97.7 %)		

System accuracy according to EN ISO 15197:2015 / ISO 15197:2013, >99% of measured glucose values fall within the minimum acceptable performance criteria.

Consumer Study

A consumer study was performed by testing one test strip lot. Participants used the GIMA Blood Glucose Monitoring System. This study showed that the patient can run the test properly.

Linear Regression Results: GIMA (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept	R	N
Fingertip	0.9865	0.7919	0.9904	100
Palm	0.9817	0.2111	0.9874	100
Forearm	1.0152	-2.3603	0.9888	100

The study evaluating glucose values from fingertip capillary blood samples obtained by 100 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).

Venous Study

The venous blood glucose measurements from more than 103 participants were taken by a trained technician using the GIMA Blood Glucose Meter (y). The venous blood sample from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: GIMA (y) vs. YSI Reference (x)

Blood Sample	Slope	Intercept	R	N
Venous	1.0124	4.5900	0.9959	762

Neonatal Study

The neonatal blood glucose measurements from 59 participants were taken by a trained technician using the GIMA Blood Glucose Meter (y). The neonatal blood samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: GIMA (y) vs. YSI Reference (x)

Blood Sample	Slope	Intercept	R	N
Neonatal	1.0054	2.5101	0.9780	354

For complete instructions, please refer to the GIMA Blood Glucose Monitoring System User's manual. For additional questions or issues with this product, please contact your dealer for help.

REFERENCES

1. ADA, Standards of Medical Care in Diabetes-2021

INDEX OF SYMBOLS

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

Manufacturer

***ACON* Laboratories, Inc.**
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San Diego, CA 92121, USA
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EC REP
MDSS GmbH
Schiffgraben 41
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