

EasyGluco™ Blood Glucose Test Strip

**IMPORTANT:** Please read this information and your EasyGluco™ Monitoring System Operation manual before using EasyGluco™ Blood Glucose Test Strips.

**Intended Use :**  
EasyGluco™ Test Strips are only to be used with EasyGluco™ blood glucose meter for the quantitatively measurement of glucose in fresh capillary whole blood. The EasyGluco™ system is plasma-calibrated to allow easy comparison of results with laboratory methods. EasyGluco™ test strips are for testing outside the body (in vitro diagnostic use only). EasyGluco™ could be used for self-control of blood glucose level by diabetes patients.

**General :**  
EasyGluco™ Test Strips adopts a new bio-sensor technology composed of electro-chemical components and requires a small 1.5µL volume of blood giving you less pain. EasyGluco™ can store 200 readings in memory with date & time and with the bio-sensor technology, you can easily store your readings onto your PC (optional). This will provide an easier and better way to control your glucose levels.

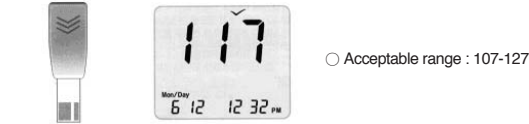
**Storage and Handling :**

- Store the EasyGluco™ test strip vials in a cool, dry place between 36-86°F (2-30°C). Keep out of direct sunlight. Do not freeze. Do not uses test strips which had been stored under inappropriate conditions.
- Store test strips in its original vials only. Do not put the test strips in new vials or in any other container.
- Close the vial cap tightly immediately after removing an EasyGluco™ test strip. This keeps the strips fully functional right up to the expiry date.
- Use test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
- Make a notation of the discard date on the vial label when you first open it. Discard remaining EasyGluco™ test strips 3 months after first opening the vial.
- Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands. All parts of the test strip could be touched with dry and clean fingers.
- Do not bend, cut, or alter an EasyGluco™ test strip.
- EasyGluco™ Test Strips are for single use only.
- Do not perform blood glucose determinations at temperature below +10°C (50°F) or above +40°C (104°F) and above 90% relative humidity.



**Warning!** Keep the test strip bottle away from children. A child could choke on the cap or the test strips. The test strip and the vial wall contain agents that may be harmful if swallowed.

Precautions in obtaining accurate results :



Use the Check Strip. Insert the Check Strip with “<<<” facing up into the test port of the Meter. If the value displayed is ranged between, the Meter is good to use. If the value displayed does not meet the proper range, reinsert the calibration key 2 or 3 more times. If it's still does not meet the proper range, please contact your local distributor for warranty services.

**The procedure for Blood Glucose Measurement :**  
**Materials provided :** EasyGluco™ Test strips  
**Materials required but not provided :** EasyGluco™ Monitor, EasyGluco™ Blood Glucose Test Strip, Operation Manual, auto-Lancet™ Device, sterile lancet.

**Cleanliness:** Wash your hands with warm soapy water. Rinse and dry hands thoroughly. You may also use an alcohol wipe to clean the puncture area. Make sure it is completely dry before you obtain the blood sample. Dirt or perspiration may affect the test result.

**Lancing:** Prepare the lancing device and lancet. Insert a clean needle (lancet) in the lancing device. It holds, positions, and controls how deeply the lancet goes into the skin. (Refer to the EasyGluco™ Monitoring System Operation Manual for more information).

**Step 1: Insert the test strip:**  
Remove test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other strips. With the Arrow side “→” facing up and in the direction of the arrow, insert it into the test port of the Meter firmly.

**Step 2: Compare the code number:**  
The meter will automatically turn on and display the code number. Make sure the code number on display matches the code number on the test strip vial. If the code number does not match, code the meter correctly.

**Step 3: Applying blood sample**  
After 3 seconds of code conformation strip-shape symbol will be displayed on the screen. Prick the area where you have decided to obtain the blood.

**Step 4:** Touch your finger to the tip of EasyGluco™ test strip.

**Step 5:** The applying channel of the test strip will draw automatically the blood of your finger. Your finger should

**Note:**  
Do not force your finger against the test strip. Do no try to apply a smeared sample. Do not add blood to the test strip after the “beep” sound. Do not squeeze the fingertip. Do not prick the tip of your fingertip it will be more painful instead prick the SIDE of your fingertip.

**Accurate Results in Seconds.**  
Your blood glucose result will be displayed in 9 seconds. Check that the right measurement unit is displayed. Your blood glucose results are automatically stored in the meter memory.

**Test Results:**  
Blood glucose test results are displayed on the EasyGluco™ meter as either milligrams of glucose per deciliter of blood (mg/dL) or mill moles of glucose per liter of blood (mmol/L) depending upon the measurement unit selected. The EasyGluco™ meter displayed results between 10–600 mg/dL (0.6–33.3 mmol/L)  
If the test result is below 10 mg/dL (0.6 mmol/L), “Lo” will show up on the meter display. “Lo” results indicate severe hypoglycemia (low blood glucose). You have to treat this hypoglycemia as recommended by your physician and you should seek medical assistance.  
If the test result is above 600 mg/dL (33.3 mmol/L), “HI” will show up on the meter display. “HI” result indicated severe hyperglycemia (high blood glucose). Consult your physician immediately.  
In case of err messages; please follow the instructions of the EasyGluco™ meter manual.

**Range of Expected Values :**  
Self-testing of blood glucose levels provides a way to control your diabetes. Consult with your physician to determine the best range of expected blood glucose values for you.  
Expected blood glucose levels for people without diabetes:

Time	Range (mg/dL)	Range (mmol/L)
Before Breakfast:	70-105	3.9-5.8
Before lunch or dinner:	70-110	3.9-6.1
1 hour after meals:	Less than 160	Less than 8.9
2 hours after meals:	Less than 120	Less than 6.7
Between 2 and 4 AM	Greater than 70	Greater than 3.9

**IMPORTANT NOTE:**

- Follow your physician's advice when to measure your blood glucose.
- Self-testing of blood glucose levels provides a way to control your diabetes. Consult with your physician to determine the best range of expected blood glucose values for you.
- If you have a test result below 60 mg/dL (3.3 mmol/L) or over 240 mg/dL (13.3 mmol/L) contact your physician immediately.
- If your blood glucose result is unusually low or high, or you do not feel the way the result indicates, repeat the test again with a new test strip.
- If the results are still inconsistent, please consult your physician before making any changes to your diabetes therapy.
- If you experience any symptoms that are consistent with your blood glucose test results and you have followed the instruction described in your EasyGluco™ operation manual, call you physician.
- Do not ignore physical symptoms without consulting your physician.
- Blood glucose measurement at alternative test sites could result in blood glucose values different from measurement at finger tip. These changes are most prominent if the blood glucose level is changing rapidly e.g. after a meal, after insulin injection or during physical activity. Talk to your doctor before starting measurements at alternative sites.
- Object which had been in contact with blood bears the potential risk for infectious disease. Please discharge these materials according to the local regulations.

**Reagent Composition :**  
Each EasyGluco™ Test Strip contains:

Glucose Oxidase:	7 Units
Mediator (Potassium Ferricyanide):	345 µg
Buffer:	18.5 µg
Stabilizer:	168 µg
Binder:	0.7 µg

**Test Principle:**  
The enzyme glucose oxidase on the test strip reacts specifically with the blood glucose. The current generated is converted and displayed as blood glucose value.

**Limitations of System:**  
EasyGluco™ Test Strips provide accurate results when the following constraints are observed:

- Use only the EasyGluco™ Test Strips with the EasyGluco™ Meter.
- Use fresh capillary whole blood only. Do not use plasma or serum.
- The test strips are for single use only. Do not reuse.
- Dehydration may lower test results. If you are severely dehydrated, contact you physician immediately.
- Do not use for neonate.

- Inaccurate results may occur when in shock, hypotensive individuals, hyperglycemic or hyperosmolar state, with or without ketosis.
- EasyGluco™ Test Strips may be used at altitude up to 3,050 m (10,000 feet) without an effect on test results.

**Quality Control (System Maintenance) :**  
The EasyGluco™ Control Solution is used to check that the meter and the test strips are properly working together to provide you with the most accurate reading.  
Note: The EasyGluco™ Control Solution is sold separately. Both, the low and high level control solution can be obtained through Infopia Co.,Ltd.

Control Solution Test can only be used with the EasyGluco™ System and should be used during the following:

- When a new vial of test strips are opened.
- Any suspicion that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with your symptoms, or if you think they are not accurate.
- If you drop the meter.
- Use routinely to obtain accurate results.

When the control solution is applied to the top edge of the EasyGluco™ Test Strip, you should get results within the expected range printed on the label of the test strip vial. If the control solution test results fall outside the range, repeat the test. Results that fall out-side the range may be caused by:

- Error in performing the test.
- Failure to shake the control solution vial well enough (must shake vigorously).
- Failure to discard the first drop of control solution.
- Expired or contaminated control solution.
- Test Strip deterioration.
- Meter malfunction (Use the Check Strip in your EasyGluco™ Kit to check the meter).
- Control solution that is too warm or cool.

**IMPORTANT NOTE:** If the EasyGluco™ Control Solution test results, continuously, falls outside the range printed on the vial, the EasyGluco™ system may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result that falls within the range. If you continue to have problems, call your Customer Support and Service.

**Physicians - Please note the following interferences that may affect test results :**

- Hematocrit: Extremes in hematocrit may affect test results. Hematocrit levels less than 30 % may cause falsely high reading and hematocrit levels greater than 55 % may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professional.
- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Lipemic samples: Cholesterol up to 500 mg/dL or triglycerides up to 2,890 mg/dl do not significantly affect the results. Glucose values, however, in specimens beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen (e.g. after Oxygen therapy) may lower the test result.
- Dopamine, Gentistic acid treatment may increase the test result.
- Antiglycolysis and anticoagulants in blood samples may affect the test results.

**Performance Characteristics :**  
The performance of EasyGluco™ Test Strips has been evaluated in laboratory and in clinical tests.

**Measurement Range:** The measurement range of the EasyGluco™ System is 10 to 600 mg/dL (0.6-33.3 mmol/L).

**Accuracy :**  
The accuracy results obtained with the EasyGluco™ System were compared to glucose results obtained with the Hitachi Glucose Auto-analyzer 747, a laboratory instrument. Glucose levels were measured on 402 fresh capillary specimens at three different clinical centers.

System accuracy results for glucose concentration < 75 mg/dL (4.2 mmol/L)		
Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
30/42 (71 %)	40/42 (95 %)	42/42 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
196/360 (54%)	282/360 (78%)	337/360 (94%)	354/360 (98%)

The study shows that the EasyGluco™ System compares well with the laboratory method.

**User Performance :**  
The user performance of the EasyGluco™ System was assessed by comparing blood glucose results obtained EasyGluco™ System with those obtained using the Hitachi Glucose Auto-analyzer 747, a laboratory instrument. Glucose levels were measured on 201 fresh capillary specimens by 201 diabetic patients and three healthcare professionals at three different clinical centers.

	Healthcare professionals	Diabetic patients
Slope	1.0147	0.9977
y-intercept	-2.6	-1.2
Correlation coefficient(r)	0.980	0.980
No. of samples	201	201
Range tested	26-563 mg/dL	24-512 mg/dL
<b>Precision:</b> EasyGluco™ Meter Precision Results for Venous blood samples and Control solutions.		
Within Run Precision	Blood <sub>av</sub> 40 mg/dL	SD = 2.6 CV = 6.6
	Blood <sub>av</sub> 81 mg/dL	SD = 3.3 CV = 4.1
	Blood <sub>av</sub> 135 mg/dL	SD = 3.8 CV = 2.8
	Blood <sub>av</sub> 206 mg/dL	SD = 4.1 CV = 1.9
	Blood <sub>av</sub> 364 mg/dL	SD = 5.4 CV = 1.5
Total Precision	Control <sub>av</sub> 46 mg/dL	SD = 2.0 CV = 4.4
	Control <sub>av</sub> 133 mg/dL	SD = 2.7 CV = 1.9
	Control <sub>av</sub> 258 mg/dL	SD = 5.2 CV = 1.5

**IMPORTANT:**

- Before using the EasyGluco™ Meter and Test Strips, read all of the operating instructions (EasyGluco™ Monitoring System Booklet) to practice for safe and accurate testing.
- Consult with your physician with use of the EasyGluco™ Meter and daily management of your diabetes.
- Please pay extreme attention when handling blood. Improper procedures may cause serious injury to your health.
- If you have any questions about use of the EasyGluco™ product, please contact your customer service or go to **www.infopia21.com**.

References :

- 1) National Committee for Clinical Laboratory Standards. Point-Care Blood Glucose Testing in Acute and Chronic care Facilities; Approved Guideline, 2<sup>nd</sup> Edition.  
NCCLS Document C30-A2 (ISBN1-56238-471-6)
- 2) National Committee for Clinical Laboratory Standards. Statistical Quality Control for Quantitative Measurements ; Principle and Definitions; Approved Guideline, 2<sup>nd</sup> Edition.  
NCCLS Document C24-A2 (ISBN1-56238-371-X). 1999
- 3) National Committee for Clinical Laboratory Standards. User Demonstration of performance for Precision and Accuracy ; Approved Guideline. NCCLS Document EP15-A (ISBN1-56238-451-1)
- 4) National Committee for Clinical Laboratory Standards. Interference Testing in Clinical Chemistry ; Proposed Guideline. NCCLS Document EP7-P (ISSN 0273-3099)

OUR COMMITMENT TO YOU :

We understand that self-testing of blood glucose level provides a way to control your diabetes, and may give you peace of mind by testing regularly. As a result, EasyGluco™ was developed to provide you with a FAST and Accurate reading with a convenient and simple process. Our goal, at EasyGluco™ , is to provide the best quality healthcare products coupled with superior customer service. If you have any questions or comments, please contact your physician or diabetes healthcare professional or visit our website at [www.infopia21.com](http://www.infopia21.com).

Consult operating instructions

Used by

This product fulfills the requirements of Directive 98/79/EC on invitro diagnostic medical devices.

Caution, consult accompanying documents

In vitro diagnostic device

Batch code

Catalogue number

Store at

Do not re-use

Manufacturing date

Self-testing Used

Authorized Representative

Manufacturer

**OSANG Healthcare**  
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Dongan-gu, Anyang-si, Gyeonggi-do,  
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