

Intended Use

The **EASYMAX®** SMBG System is intended for the quantitative measurement of glucose in fresh venous blood and capillary whole blood samples drawn from the fingertip, palm and forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for self-testing by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. The system is to be used on neonates (**IMPORTANT**: Only with **EASYMAX® MU**), is not for the diagnosis of or screening for diabetes mellitus, and that alternate site testing can only be used during steady-state blood glucose conditions.

Important : Please read this insert and the **EASYMAX®** User's Manual before using **EASYMAX®** Blood Glucose Test Strips. If you have any questions and/or need assistance, please contact our authorized distributors in your country.

Principle^{1,2}

Apply a blood sample to the blood collection area at the tip of the strip. The test strip will draw the blood sample into the reaction zone. The FAD-binding glucose dehydrogenase catalyzes the glucose dehydrogenation. It will produce gluconolactone. During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample. After 5 seconds, the **EASYMAX®** Series meter will show glucose concentration on the screen.

Reagent Composition

Each test strip contains the following reagent:

6 (w/w) %	FAD glucose dehydrogenase (<i>Aspergillus oryzae</i> , 2.0 IU/test strip)
56 (w/w) %	Potassium ferricyanide
38 (w/w) %	Non-reactive ingredients

Storage and Handling

- Store the test strip package in a cool, dry place. Temperature between 2°C to 30°C (36°F to 86°F).
- Do NOT freeze. Keep out of direct sunlight and heat.
- Write the date on the bottle when first opened.
- Use test strips within 12 months after first opening date. (6 months for a vial of 50 pieces.)
- Replace the cap quickly after taking the test strip from the bottle.
- Handle the test strip only with dry and clean hands.
- Store your test strips in their original bottle only. Do not move them to any other bottle or container.

Warnings and Precautions

- For *in vitro* diagnostic use only. Do not swallow.
- Do not use the test strip after the expiration date.
- Do not re-use test strips.
- Do not cut, bend, scratch, or alter the test strip in any way.
- Warning for potential biohazard³:
This warning is for the healthcare professional who use this system on multiple patients. They should know the product comes in contact with human blood. After cleaning, dispose of the product properly as if avoid transmitting viral disease.
- If the readings are not consistent to your symptoms, check the manual first. Make sure you have followed all instructions, and then contact your healthcare professional.
- Never make any changes to your diabetes control program without consulting your healthcare professional.
- Operational temperature of SMBG system is between 10°C to 40°C (50°F to 104°F), which is able to avoid occurring error results from test strips.

Supplies For Testing Your Blood Glucose

- EASYMAX®** Meter.
- EASYMAX®** Test Strip.
- Lancing device.
- Lancets.
- EASYMAX®** User's Manual.

Sample Collection And Preparation

This system is for use in venous blood or fresh capillary blood. Use the blood sample immediately. The blood sample volume requires at least 0.6 micro-liters. To obtain a drop of blood, follow these steps:
 Step 1: Wash and dry your hands thoroughly.
 Step 2: Prepare lancing device according to the manual.
 Step 3: Use an alcohol swab. Make sure that your finger is entirely dry before lancing.
 Step 4: Puncture and get a drop of blood. Avoid pressing too hard against the punctured site.

Alternate Site Testing (AST)

- AST results may differ from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
- AST can only be used during steady-state blood glucose conditions. AST should only be performed under the following conditions:
 - Testing before a meal.
 - In a fasting state.
 - 2 hours or more after a meal.
 - 2 hours or more after insulin dosing.
 - 2 hours after physical activity.
- Consult with your healthcare professional before you test palm or forearm.

- Fingertip test only.
- If sick.
 - If blood glucose is low.
 - After exercising.
 - When you have just taken insulin.
 - Two hours or less after eating.
 - If you often do not notice when your blood glucose is low.
 - After injecting rapid-acting insulin (2 hours or less).

Testing Your Blood Glucose Level

Make sure check the system by using Control Solutions before testing. Please follow these steps to test:
 Step 1: Insert Test Strip.
 Take a test strip and replace the bottle cap quickly. Insert the test strip into the slot of the meter.
 Step 2: Apply Sample.
 Follow the sample collection procedures to get a drop of blood. While the "♦" appears, bring your blood to the collection area. The test strip will draw the blood sample into the reaction zone. The meter will begin to run.
 Step 3: Accurate Results after 5 seconds.
 Your result will appear on the screen after 5 seconds and be stored in the meter.
 For detailed information on the test procedure, please refer to the User's Manual.

Quality Control

- It is recommended to run control test whenever you:
- Begin using a new bottle of test strips.
 - Question your blood readings.
 - Check that the meter and test strips are working properly, and that you perform the test correctly at least once.
 - Suspect the meter or test strips are working incorrectly.
 - Drop the meter.
 - Expose the test strips to temperatures outside the storage conditions. (2°C to 30°C, 36°F to 86°F)

Use the **EASYMAX®** Glucose Control Solution to check the SMBG system performance. Please follow the "Control Solution Test" section in Manual. Don't use other control solution. Other control solution may provide incorrect results.

Important : If the control solution test results are outside the range, your meter and test strip may not be working as a system. Follow the correct procedures and repeat the control solution test. Make sure the control solution is clean without contamination. (e.g. Turbid.) Do not use the meter until test results fall within the appropriate range. If the problem continues, please contact our local dealer.

When the results fall within the specified ranges printed on the strip bottle label, the system is working properly. If your control solution readings are outside the range, repeat the control solution test. Results that fall outside the range may be caused by:

- Expired or contaminated control solution.
- Meter malfunction.
- Error in performing the test.
- Test strip deterioration.

DO NOT use the system to test your blood until you get a control solution test result within the specified range.

Readings

If "LO" appears on the screen, your blood glucose level is lower than 20 mg/dL (1.1 mmol/L). If "HI" appears, that your blood glucose level is higher than 630 mg/dL (35.0 mmol/L). When you get any questions for the readings, check the following items first and then repeat the test. If the results are still questionable, consult your healthcare professional:

- If the strips are within the expiration date.
- Make sure the drop of blood in the whole reaction zone.
- Check meter and test strip performance with Glucose Control Solutions.

Expected Results:

- The **EASYMAX®** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results.
- For Non-Diabetic⁴
The American Diabetes Association recommends a post-meal glucose level of less than 140 mg/dL (7.8 mmol/L) and a pre-meal glucose of less than 100 mg/dL (5.6 mmol/L).
 - For Non-Pregnant Adults with diabetes⁵
The American Diabetes Association recommends a post-meal glucose level of less than 180 mg/dL (10.0 mmol/L) and a pre-meal glucose of 80–130 mg/dL (4.4-7.2 mmol/L)

CAUTION:

Any low or high blood glucose readings can indicate a potentially serious medical condition. If the readings do not reflect your symptoms, repeat the test with a new strip. Contact your healthcare professional when your reading is:

- Not consistent with your symptoms.
- Less than 60 mg/dL (3.3 mmol/L).
- Higher than 240 mg/dL (13.3 mmol/L).

Limitations

- EASYMAX®** Blood Glucose Test Strips are used for fresh venous blood and capillary whole blood samples.
- DO NOT use serum or plasma sample.
 - DO NOT use anticoagulant NaF or potassium oxalate for venous sample preparation.
 - Use neonatal blood sample only with the device of **EASYMAX® MU**.
 - Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
 - The system is designed to use at temperatures between 10°C and 40°C (50°F and 104°F). Outside this range, the system may yield erroneous results.
 - DO NOT reuse the test strips. The test strips are intended for single use only.
 - Hematocrit (HCT): **EASYMAX® Tag**: Hematocrit below 10% may cause higher results. Hematocrit above 65% may cause lower results. Other **EASYMAX®** meters: Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results. If you do not know your HCT level, please consult with your doctor.
 - Altitude up to 3,150 meters (10,334 ft) above sea level has no effect on readings.

Healthcare providers – Please note these additional Limitations.

- If the patient has the following conditions, the result may be inaccurate:
 - Severely dehydrated.
 - Severely hypotensive.(low blood pressure)
 - In shock.
 - In hyperglycemic-hyperosmolar state.(with or without ketosis)
- Lipemic samples: Cholesterol level up to 400 mg/dL (10.32 mmol/L) and triglycerides up to 800 mg/dL (9.04 mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with **EASYMAX®** SMBG system.
- DO not use home-use blood glucose meters to test critically ill patients.
- DO NOT use during xylose absorption testing. Xylose in the blood will interfere the **EASYMAX®** Self-Monitoring Blood Glucose System.
- Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the readings.

Concentrations of the interference tested	Bias		Glucose Level		250-500 mg/dL (13.9-19.4 mmol/L)
	50-100 mg/dL (2.8-5.6 mmol/L)				
Acetaminophen	7 mg/dL (0.46 mmol/L)	8.1 mg/dL (0.53 mmol/L)	7 mg/dL (0.46 mmol/L)	8.1 mg/dL (0.53 mmol/L)	5.3%
Ascorbic Acid	4 mg/dL (0.26 mmol/L)	6.6 mg/dL (0.43 mmol/L)	4 mg/dL (0.26 mmol/L)	6.6 mg/dL (0.43 mmol/L)	5.8%
Bilirubin-unconjugated	3.3 mg/dL (0.056 mmol/L)	0.2 mg/dL (0.003 mmol/L)	3.3 mg/dL (0.056 mmol/L)	0.2 mg/dL (0.003 mmol/L)	5.2%
Cholesterol	400 mg/dL (10.32 mmol/L)	9.6 mg/dL (0.25 mmol/L)	400 mg/dL (10.32 mmol/L)	9.6 mg/dL (0.25 mmol/L)	7.2%
Creatinine	30 mg/dL (2.7 mmol/L)	1.3 mg/dL (0.12 mmol/L)	30 mg/dL (2.7 mmol/L)	1.3 mg/dL (0.12 mmol/L)	1.6%
Dopamine	2.2 mg/dL (0.14 mmol/L)	8.0 mg/dL (0.51 mmol/L)	2.2 mg/dL (0.14 mmol/L)	8.0 mg/dL (0.51 mmol/L)	3.2%
Galactose	20 mg/dL (1.11 mmol/L)	6.2 mg/dL (0.34 mmol/L)	20 mg/dL (1.11 mmol/L)	6.2 mg/dL (0.34 mmol/L)	2.5%
Galacturonic Acid	7 mg/dL (0.45 mmol/L)	9.8 mg/dL (0.63 mmol/L)	7 mg/dL (0.45 mmol/L)	9.8 mg/dL (0.63 mmol/L)	3.6%
Glutathione	1 mg/dL (0.03 mmol/L)	3.7 mg/dL (0.11 mmol/L)	1 mg/dL (0.03 mmol/L)	3.7 mg/dL (0.11 mmol/L)	6.5%
Haemoglobin	300 mg/dL (0.05 mmol/L)	3.8 mg/dL (0.0006 mmol/L)	300 mg/dL (0.05 mmol/L)	3.8 mg/dL (0.0006 mmol/L)	5.2%
Ibuprofen	50 mg/dL (2.43 mmol/L)	3.9 mg/dL (0.19 mmol/L)	50 mg/dL (2.43 mmol/L)	3.9 mg/dL (0.19 mmol/L)	2.7%
Icodextrin	1094 mg/dL (0.66 mmol/L)	5.4 mg/dL (0.003 mmol/L)	1094 mg/dL (0.66 mmol/L)	5.4 mg/dL (0.003 mmol/L)	4.8%
L-Dopa	2 mg/dL (0.10 mmol/L)	10.0 mg/dL (0.50 mmol/L)	2 mg/dL (0.10 mmol/L)	10.0 mg/dL (0.50 mmol/L)	8.7%
Maltose	278 mg/dL (7.78 mmol/L)	2.7 mg/dL (0.076 mmol/L)	278 mg/dL (7.78 mmol/L)	2.7 mg/dL (0.076 mmol/L)	4.4%
Methylodopa	4 mg/dL (0.19 mmol/L)	9.0 mg/dL (0.43 mmol/L)	4 mg/dL (0.19 mmol/L)	9.0 mg/dL (0.43 mmol/L)	3.7%
Praiodoxime iodide	5 mg/dL (0.14 mmol/L)	2.8 mg/dL (0.08 mmol/L)	5 mg/dL (0.14 mmol/L)	2.8 mg/dL (0.08 mmol/L)	3.3%
Sodium Salicylate	40 mg/dL (2.5 mmol/L)	4.3 mg/dL (0.27 mmol/L)	40 mg/dL (2.5 mmol/L)	4.3 mg/dL (0.27 mmol/L)	2.2%
Tolbutamide	100 mg/dL (3.70 mmol/L)	1.4 mg/dL (0.05 mmol/L)	100 mg/dL (3.70 mmol/L)	1.4 mg/dL (0.05 mmol/L)	2.3%
Tolazamide	2.5 mg/dL (0.08 mmol/L)	3.6%			
Triglycerides	800 mg/dL (9.04 mmol/L)	9.3 mg/dL (0.11 mmol/L)	800 mg/dL (9.04 mmol/L)	9.3 mg/dL (0.11 mmol/L)	5.6%
Uric acid	16.5 mg/dL (0.99 mmol/L)	7.2 mg/dL (0.43 mmol/L)	16.5 mg/dL (0.99 mmol/L)	7.2 mg/dL (0.43 mmol/L)	4.0%
Xylose	9.5 mg/dL (0.63 mmol/L)	7.0 mg/dL (0.46 mmol/L)	9.5 mg/dL (0.63 mmol/L)	7.0 mg/dL (0.46 mmol/L)	7.5%

Use the anticoagulant EDTA or sodium Heparin or Lithium Heparin to preserve the venous blood and capillary blood specimens would not affect the readings of **EASYMAX®** SMBG System. If the specimen was preserved by the anticoagulant NaF/potassium Oxalate contained sodium fluoride, the reading of **EASYMAX®** SMBG System would be seriously interfered.

Performance Characteristics

The test range is between 20 to 630 mg/dL (1.1–35.0 mmol/L). Validate the test strips performance in both laboratory and clinical tests.

PRECISION

Three lots of the **EASYMAX®** blood glucose test strips have been tested to assess the precision of blood glucose measuring system. This includes a repeat assessment using venous blood and a laboratory precision assessment using the control material. The blood glucose content of the venous blood samples ranges from 42.7 to 418.0 mg/dL and control material from three concentrations is used.

	Blood _{av} mg/dL (mmol/L)	36 (2.0)	SD=2.0
Within-Run	Blood _{av} mg/dL (mmol/L)	59 (3.3)	SD=3.5
	Blood _{av} mg/dL (mmol/L)	127 (7.1)	CV=3.2%
	Blood _{av} mg/dL (mmol/L)	214 (11.9)	CV=3.1%
	Blood _{av} mg/dL (mmol/L)	330 (18.3)	CV=3.1%
	Blood _{av} mg/dL (mmol/L)	433 (24.1)	CV=3.3%
	Total-Run	Control _{av} mg/dL (mmol/L)	71 (3.9)
Control _{av} mg/dL (mmol/L)		136 (7.6)	CV=1.1%
Control _{av} mg/dL (mmol/L)		351 (19.5)	CV=0.8%

ACCURACY STUDY

The **EASYMAX®** blood glucose monitor in comparison with the YSI. Three lots of **EASYMAX®** blood glucose test strips have been tested to assess the system accuracy of the **EASYMAX®** blood glucose measuring system and to compare it with the reference method in which capillary whole blood concentrations of 34.4 to 442.8 mg/dL have been used.

Result of the system accuracy of glucose concentrations <100 mg/dL (<5.55 mmol/L)

within±5mg/dL (Within ± 0.28 mmol/L)	within±10mg/dL (Within ± 0.56 mmol/L)	within±15mg/dL (Within ± 0.83 mmol/L)
141/222 (63.5%)	211/222 (95.0%)	222/222 (100.0%)

Result of the system accuracy of glucose concentrations ≥ 100 mg/dL (≥ 5.55 mmol/L)

within±5%	within±10%	within±15%
362/582 (62.2%)	522/582 (89.7%)	578/582 (99.3%)

Results of the system accuracy for combined glucose concentrations between 34.4 mg/dL (1.91 mmol/L) and 442.8 mg/dL (24.60 mmol/L)

Within ± 15 mg/dL or ±15% (Within ± 0.83 mmol/L or ±15%)
800 / 804 (99.5%)

In comparison to the YSI, the **EASYMAX®** met the ISO 15197:2013/EN ISO 15197:2015 standard, whereby 95% of the blood glucose values measured have to fall within the following zones: either ±0.83 mmol/L (±15 mg/dL) of the measured average value when using the reference measuring procedure for blood glucose concentrations <100 mg/dL (<5.55 mmol/L) or ±15% for blood glucose concentrations of ≥ 100 mg/dL (≥ 5.55 mmol/L). 99% of the individual measured blood glucose values must fall within zones A and B of the Consensus Error Grid (CEG) for diabetes type 1.

USER PERFORMANCE EVALUATION

A study to assess the glucose values of blood samples of capillary blood from the fingertips, which were obtained from 103 individuals that had no special training, produced the following results: 96.7% within ±15 mg/dL (± 0.83 mmol/L) and 95.9% within ± 15% of the values obtained in the medical laboratory with glucose concentrations of at least 100 mg/dL (5.55 mmol/L). You will find further details and information regarding blood glucose results and various technologies in generally relevant specialist medical literature.

References

- Cass, A.E.G. et al., Anal. Chem., 56 (1984) p.667
- Tietz N.: Fundamentals of clinical chemistry , 3rd Ed., W.B. Saunders Co., Philadelphia, PA, 1987, p.427
- NCCLS document M29-A, Protection of the laboratory worker from instrument biohazards and infectious disease transmitted by blood, body fluids, and tissue, 1997.
- American Diabetes Associations: 2. Classification and diagnosis of diabetes; Standards of Medical Care for Patients with Diabetes, Diabetes Care, 2019, 42 (Suppl. 1): S13-S28.
- American Diabetes Associations: 6. Glycemic Targets; Standards of Medical Care for Patients with Diabetes, Diabetes Care, 2021, 44 (Suppl. 1) : S73-S84.

Labeling And Information

	Consult instructions for use		Caution
	Batch code		Do not reuse
	<i>In vitro</i> diagnostic medical device		Temperature limitation
	Use by		Catalogue number
	Manufacturer		Control
	Serial number		Blood glucose test result in mg/dL
	Sufficient for		Blood glucose test result in mmol/L
	Authorized representative in the European Community		
	This product meets the requirements of Directive 98/79/EC <i>in vitro</i> diagnostic medical devices		

EASYMAX Headquarter
Hsinchu Science Park, Hsinchu, Taiwan 30076
www.easymax-diabetescare.com

CE 0537

Obelis s.a.
Boulevard Général Wahis 53, B-1030 Brussels, Belgium
Tel: (32) 2.732.59 54 Fax: (32) 2.732.60 03 E-Mail: mail@obelis.net

EPS Bio Technology Corp.
No.8, R&D Road III, Hsinchu, Taiwan 30076