

**Intended Use**

The EASYMAX<sup>®</sup> Series 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 not to be used on neonates (*IMPORTANT: EASYMAX<sup>®</sup> MU model is excluded*), 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<sup>®</sup> Series User's Manual before using EASYMAX<sup>®</sup> Blood Glucose Test Strips. If you have any questions and/or need assistance, please contact our authorized distributors in your country.

**Principle<sup>1,2</sup>**

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<sup>®</sup> Series meter will show glucose concentration on the screen.

**Reagent Composition**

Each test strip contains the following reagent:

Table with 2 columns: Reagent Name and Concentration. Includes FAD glucose dehydrogenase (Aspergillus oryzae), Potassium ferricyanide, and Non-reactive ingredients.

**Storage and Handling**

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

**Warnings and Precautions**

- 1. For *in vitro* diagnostic use only. Do not swallow.
2. Do not use the test strip after the expiration date.
3. Do not re-use test strips.
4. Do not cut, bend, scratch, or alter the test strip in any way.
5. Warning for potential biohazard<sup>3</sup>.

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.

- 6. 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.
7. Never make any changes to your diabetes control program without consulting your healthcare professional.
8. 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<sup>®</sup> Series Meter.
◆ EASYMAX<sup>®</sup> Test Strip.
◆ Lancing device.
◆ Lancets.
◆ EASYMAX<sup>®</sup> Series 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)**

- 1. 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).
2. 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.
3. Consult with your healthcare professional before you test palm or forearm.

**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:

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

Use the EASYMAX<sup>®</sup> 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:

- 1. Expired or contaminated control solution.
2. Error in performing the test.
3. Meter malfunction.
4. 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:

- 1. If the strips are within the expiration date.
2. Make sure the drop of blood in the whole reaction zone.

- 3. Check meter and test strip performance with Glucose Control Solutions.

**Expected Results:**

The EASYMAX<sup>®</sup> Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results.

- ◆ For Non-Diabetic<sup>4</sup> 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 diabetes<sup>5</sup> 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 70-130 mg/dL (3.9-7.2 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 test strip. Contact your healthcare professional when your reading is:

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

**Limitations**

EASYMAX<sup>®</sup> Blood Glucose Test Strips are used for fresh venous blood and capillary whole blood samples.

- 1. DO NOT use serum or plasma sample.
2. DO NOT use anticoagulant NaF or potassium oxalate for venous sample preparation.
3. DO NOT use neonate blood sample. (IMPORTANT: EASYMAX<sup>®</sup> MU model is excluded.)
4. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
5. 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.
6. DO NOT reuse the test strips. The test strips are intended for single use only.
7. Hematocrit: the test strip results are not significantly affected by hematocrits in range of 20% to 60%. Hematocrit level less than 20% may cause incorrect high readings and hematocrit levels greater than 60% may cause incorrect low readings.
8. Altitude up to 3048 meters above sea level has no effect on readings. Healthcare providers – Please note these additional Limitations.
1. If the patient has the following conditions, the result may be inaccurate:
- Severely dehydrated.
- Severely hypotensive (low blood pressure)
- In shock.
- In hypoglycemic-hyperosmolar state. (with or without ketosis)
2. Lipemic samples: Cholesterol level up to 500 mg/dL (12.92 mmol/L) and triglycerides up to 3,000 mg/dL (33.6 mmol/L) do not affect the results. Do not test grossly lipemic patient samples with EASYMAX<sup>®</sup> Series SMBG system.
3. DO not use home-use blood glucose meters to test critically ill patients.
4. DO NOT use during xylose absorption testing. Xylose in the blood will interfere the EASYMAX<sup>®</sup> Series Self-Monitoring Blood Glucose System.
5. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the readings.

Table with columns: Concentrations of the interference tested, Bias, Glucose Level, and three glucose levels (80, 250, 500 mg/dL).

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<sup>®</sup> Series SMBG System. If the specimen was preserved by the anticoagulant NaF/potassium Oxalate contained sodium fluoride, the reading of EASYMAX<sup>®</sup> Series 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**

Precision of the EASYMAX<sup>®</sup> Series Self-Monitoring Blood Glucose System was measured with both venous blood and control solution in the laboratory. The results are shown in the table below:

Table with columns: Run Type (Within-Run, Total-Run), Control, and SD/CV values.

**ACCURACY STUDY**

The accuracy of the EASYMAX<sup>®</sup> Series Self-Monitoring Blood Glucose System was assessed by comparison which was used in laboratories. The results below were obtained by 159 subjects with diabetes at three independent clinical sites. The regression statistics are derived from a plot of the EASYMAX<sup>®</sup> capillary data versus YSI plasma data.

Table with columns: Metric (Slope, Intercept, Correlation coefficient, Number of subject, Range tested, R-square) and values.

In comparison to the YSI, EASYMAX<sup>®</sup> met the EN ISO 15197:2013 standard, whereby 95% of the blood glucose values measured must lie within the following ranges: either ±15 mg/dL (± 0.83 mmol/L) 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.

**References**

- 1. Cass, A.E.G. et al., Anal. Chem., 56 (1984) p.667
2. Tietz N.: Fundamentals of clinical chemistry, 3<sup>rd</sup> Ed., W.B. Saunders Co., Philadelphia, PA, 1987, p.427
3. NCCLS document M29-A, Protection of the laboratory worker from instrument biohazards and infectious disease transmitted by blood, body fluids, and tissue, 1997.
4. American Diabetes Association. Standards of medical care in diabetes. Diabetes care. 2013; Vol. 36, Suppl 1, S13.
5. American Diabetes Association. Standards of medical care in diabetes. Diabetes care. 2013; Vol. 36, Suppl 1, S21.

**Labeling And Information**

Table with columns: Symbol/Label (i, LOT, IVD, REF, CONTROL, SN, mmol/L, EC REP, CE) and Description/Requirement.

EASYMAX US Office
9550 S. Eastern Ave. Suite 253 Las Vegas, NV 89123
www.easymaxdiabetescare.com

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.
Hsinchu Science Park, Hsinchu, Taiwan 30077