

IMPORTANT:

Please read the EASYMAX® series product User's Manual before using EASYMAX® Glucose Control Solutions.

Intended Use

The EASYMAX® series product Self-Monitoring Blood Glucose Test System is intended for the quantitative measurement of glucose in fresh venous blood and capillary whole blood from 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® 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.

Summary and Description

Glucose control solutions allow you to perform quality control checks to ensure that your EASYMAX® series product SMBG is working properly and your blood glucose test results are reliable.

The control solution contains a known amount of glucose, which reacts with EASYMAX® Blood Glucose Test Strips. If the result is within the acceptable range, you know that your system is working right. Acceptable control ranges for control tests with EASYMAX® series product SMBG System are shown on the test strip vial label.

Control solutions should be used when

- Using the your blood glucose meter for the first time.
- You open a new vial of test strips.
- You think the meter or test strips may be working incorrectly.
- Your test results do not reflect how you feel.
- If you drop the meter.
- If you have repeated a test, and the test results are still lower or higher than expected.
- For teaching or learning how to use the system.

Reagent Composition

Glucose Level 1 Control Solution:

0.07(w/w)%	D-glucose
99.93(w/w)%	Non-reactive ingredients

Glucose Level 2 Control Solution:

0.14(w/w)%	D-glucose
99.86(w/w)%	Non-reactive ingredients

Glucose Level 3 Control Solution:

0.37(w/w)%	D-glucose
99.63(w/w)%	Non-reactive ingredients

Materials Provided

- Level 1 Control Solution Volume: 4.0 mL.
- Level 2 Control Solution Volume: 4.0 mL.
- Level 3 Control Solution Volume: 4.0 mL.

Warnings and Precautions

- EASYMAX® Glucose Control Solution is for *in vitro* diagnostic use only.
- EASYMAX® Glucose Control Solution is not intended for human consumption or injection.
- Use the EASYMAX® Glucose Control Solution only for testing with EASYMAX® series product SMBG and EASYMAX® Test Strips.
- Shake the control solution gently before each use.

Storage and Handling

- Store the EASYMAX® Glucose Control Solution at temperatures between 2°C to 30°C (36°F to 86°F).
- DO NOT freeze.
- Indicate the first opening date on the control solution vials.
- Discard any unused portion 3 months after first opening date.
- Use before the expiration date shown on the vial.

Procedures

Please follow the test procedures for using the control solution.

Step 1: Insert Test Strip. Remove a test strip from the vial and immediately replace the vial cap. Insert the test strip into the slot of the meter, and then the meter will turn on automatically.

Step 2: Apply Sample. When the “●” symbol is displayed, shake the glucose control solution gently. Holding the glucose control solution vial, discard the first drop of


control solution. Then squeeze a drop of control solution slowly onto a plastic plate, remove the control solution vial and recap immediately. Let the control solution on the plastic plate touch the blood collection area at the tip of the test strip. The control solution will be drawn into the strip automatically. Remove the control solution when the reaction zone is full. The meter will begin counting.

Step 3: The reading will appear on the display after 5 seconds.

Step 4: Check if the reading falls within the range printed on the test strips vial.

EASYMAX® MU Model, check below:

Step 1: Insert Test Strip. Remove a test strip from the vial and immediately replace the vial cap. Insert the test strip into the slot of the meter, and then the meter will turn on automatically.

Step 2: Apply Sample. When the “●” symbol is displayed, Press ← (Left button) to select the testing mode of Control Solution and the icon of  flashes. The reading is stored in the Control Solution mode. Shake the glucose control solution gently. Holding the glucose control solution vial, discard the first drop of control solution. Then squeeze a drop of control solution slowly onto a plastic plate, remove the control solution vial and recap immediately. Let the control solution on the plastic plate touch the blood collection area at the tip of the test strip. The control solution will be drawn into the strip automatically. Remove the control solution when the reaction zone is full. The meter will begin counting.

Step 3: The reading will appear on the display after 5 seconds.

Step 4: Check if the reading falls within the range printed on the test strips vial.

Interpretation the Reading

















If the reading of your test falls within the expected range printed on the test strips vial label, then the test strip and the glucose meter are working together correctly. The results of your blood glucose tests are reliable.

If the reading falls outside the expected range, your meter may not be working properly. Check the following :

- Have the control solution or test strips been used after their expiration date? Has the control solution been contaminated?
- Did you forget to replace the cap on the vial of control solutions or test strips?
- Did you follow the test procedures correctly?

Please repeat the test. In addition, if the reading is still not acceptable, contact your local authorized distributor.

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 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