EASYMAX®

Mini Self-Monitoring Blood Glucose System

User's Manual

Please read this User's Manual thoroughly before using your blood glucose meter.

Dear EASYMAX® Mini SMBG System user,

Thank you for choosing the **EASYMAX® Mini** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be reliable, use-friendly and efficient to help you monitor your blood glucose on a regular basis.

Please read this manual thoroughly before you begin testing. This manual provides you and your diabetes care team with important information and step-by-step direction to use the **EASYMAX® Mini** Self-Monitoring Blood Glucose System.

Once again, thank you for choosing the **EASYMAX® Mini** SMBG System.

Intended Use

The **EASYMAX® Mini** Self Monitoring Blood Glucose Test System is intended for the quantitative measurement of glucose in fresh capillary whole blood and venous blood from fingertip, palm or forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for self-testing (over the counter [OTC]) 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, 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.

Standard Accessories

Your new **EASYMAX® Mini** Blood Glucose Meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- **Blood Glucose Meter**
- **CR2032 Battery (1 ct.)**
- **Lancet (10 pcs)**
- **Lancing Device**
- **User's Manual**
- **Warranty Card**
- **Carrying Case**

Optional Accessories

- **AST Lancing Device Cap**
- **Blood Glucose Test Strips (25 pcs)**
- **Level 1 Control Solution**
- **Level 2 Control Solution**
- **Level 3 Control Solution**

EASYMAX® Control Solutions and Blood Glucose Test Strips are available. For purchase, please contact your local dealer.

Why is it so important to test blood glucose regularly?

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We've made this SMBG system as simple as possible to help you to use it regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

Do you need Help?

If you have questions or need assistance, please contact your healthcare professional or visit EASYMAX® Website www.easymaxdiabetescare.com for diabetes management tools and product demonstrations.

Although the EASYMAX® Mini SMBG System is easy to use, you may need to consult with your healthcare professional (this may be your doctor, pharmacist or diabetes nurse educator) for instructions on how to use the system. Only the correct use of the system will ensure accurate results.

Important Information about Your New EASYMAX® Mini

- **EASYMAX® Mini** Blood Glucose Meter is designed and approved for testing fresh venous blood or capillary whole blood samples from your fingertip, palm or forearm. The meter is for *in vitro* diagnostic use ONLY (for testing outside the body). It should not be used to diagnose diabetes.
- **EASYMAX® Mini** Blood Glucose Meter can only be used with **EASYMAX®** Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimens.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect readings. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car or a bathroom, or refrigerator.
- Keep the meter, test strips and lancing device away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.

- Remove batteries if the meter will not be used for one month or more.
- Please dispose device according to the local rule of the disposition of electronic device / accessory waste.
- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.
- Consult with your healthcare professional before testing on your fingertip, palm or forearm.

Health-Related Information

- If you are experiencing dehydration, frequent urination, have low blood pressure, in shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your healthcare professional right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, or if you have questions, please contact your healthcare professional.
- Please read your test strip instructions carefully for additional health-related information.

Warning for potential biohazard:
Healthcare professionals using this system on multiple patients should handle all products or objects in contact with human blood carefully to avoid transmitting viral disease, even after cleaning.

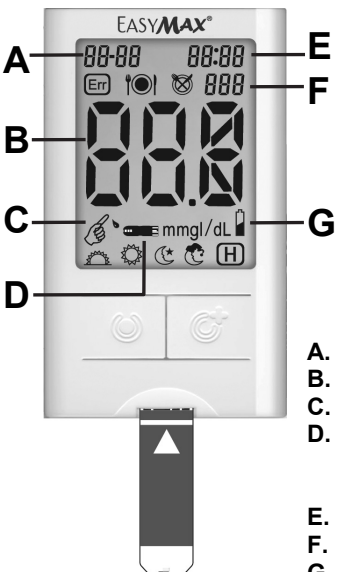
Explanation of Symbols

	Consult instructions for use		Caution
LOT	Batch code		Do not re-use
IVD	*In vitro* diagnostic medical device		3V (CR2032) x 1 battery only
	Use by		Temperature limitation
	Manufacturer	REF	Catalogue number
SN/	Serial number	CONTROL	Control
	Sufficient for	EC REP	Authorized representative in the European Community
mg/dL	Blood glucose test result in mg/dL		Keep away from sunlight
	Green Dot / Duales System Deutschland GmbH (DSD)	CE	This product meets the requirements of Directive 98/79/EC *in vitro* diagnostic medical devices

Table of Contents

Chapter 1: Understanding Your Meter

EASYMAX® Mini Blood Glucose Meter



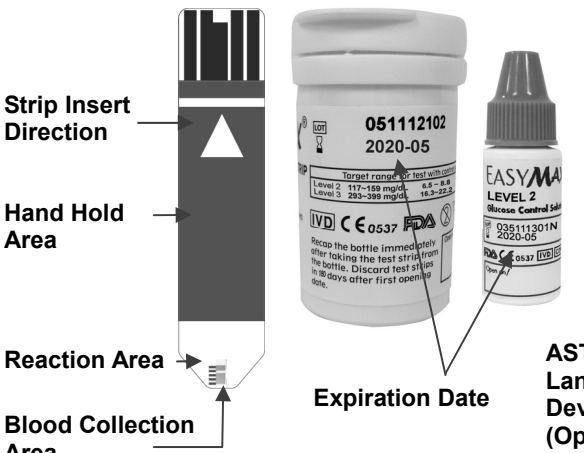
A. Month and date
B. Test result
C. Application of blood
D. Insert test strip or Application of control solution
E. Time
F. Test records
G. Battery status

Explanation of Meter Symbols

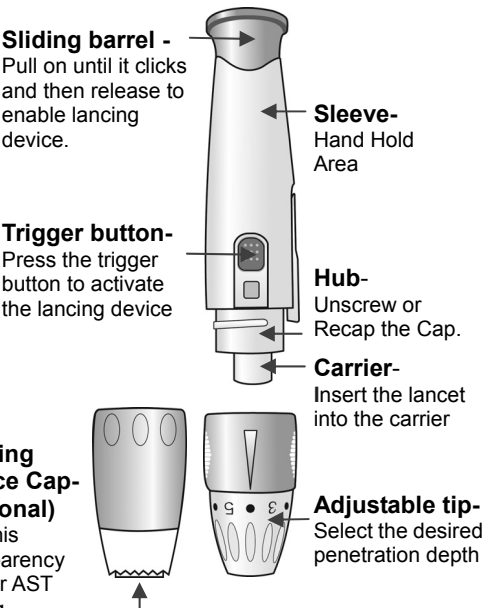
Err	System fault
	Before meals
	After meals
	Morning, from 4:00 am to 10:00 am
	Noon, from 10:00 am to 04:00 pm
	Evening, from 04:00 pm to 10:00 pm
	Night: from 10:00 pm to 04:00 am
H	Hypoglycemia 20~60 mg/dL
	Left button
	Right button

The EASYMAX® Blood Glucose Test Strip And Accessories

Blood Glucose Test Strip



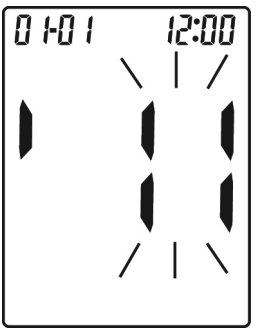
Lancing Device



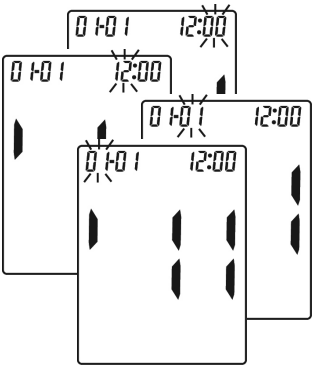
Setting The Time And Date — First Time Use

Setting the current time and date in your meter is important if you intend to use the meter memory.

1. Put a battery into the slot and the meter turns on automatically.



2. The last 2-digits of the year flash at the center of the display. Press to adjust the year and press to confirm the setting.



3. Repeat step 2 to set the date and time. The flashing field is the one you are currently setting.

The unit of Blood Glucose Meter is set at mg/dL without any modification function.

Using EASYMAX® Blood Glucose Test Strips

- Use only with **EASYMAX® Mini** Blood Glucose Meter.
- Keep the test strips in their original bottle.
- After you take a test strip out of the bottle, close the bottle immediately.
- Use the test strip within 3 minutes after you taking it out of the bottle.
- The test strip is for single use only. Do not reuse it.
- Write down the date on strip bottle when the strip bottle is first time opened. Be sure to check the expiration date on the test strip bottle. The test strip will be expired either in six months after the date of the bottle is opened or till the expiration date printed on the bottle.
- Store the test strip bottle and your meter in a shady and arid place.
- Store the test strips between 2°C - 30°C (36°F- 86°F). Do not freeze.
- Do not apply blood or control solution to the test strip before you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.
- **EASYMAX® Mini** Self-Monitoring Blood Glucose Test System is a “no code” system and does not require any meter calibration.

Chapter 2: Control Solution Testing

Why Run A Control Solution Test

We recommend that you run the **EASYMAX®** Level 2 control solution test because it lets you know that your meter and test strips are working properly to give you reliable results. You should run the control solution test when:

- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.

Professional users are instructed to follow federal, state, and local guidelines.

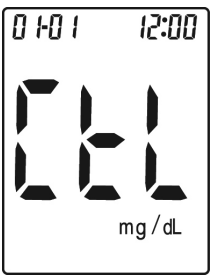
About The Control Solutions

- Use only with **EASYMAX®** Test Strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- Control solution can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store control solution at room temperature, between 2°C- 30°C (36˚F - 86°F). Do not freeze.
- If you would like to purchase **EASYMAX®** Control Solutions**,** please contact your local dealer.

Running A Control Solution Test

You need the meter, a test strip, and control solution.

1. Put a test strip into the meter in the direction of the arrow and the icon of shows itself.



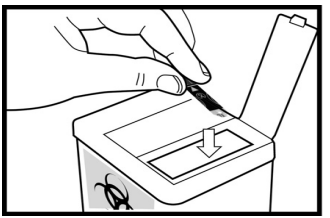
2. Press twice to set **"CtL "** and press to confirm the setting.

3. Place the meter on a flat surface, like a table.

4. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.

1. If display stays at or and no any setting is made, the test results will always in or .

2. If you do not choose "CtL", the test results will be included in the memory of blood test.



5. Squeeze the bottle until a tiny drop forms at the tip of the control solution cap.

6. Touch the drop to the Blood collection area at the end of the test strip.

7. Do not put control solution on top of the test strip.

8. When you hear the beeper, you have enough control solution in the test strip.
The meter starts to count down from 5 seconds and will show the results.

9. A result appears on the display. Don't remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.

10. Remove the test strip and throw it away after you have compared the reading to the range printed on the test strip bottle.

Understanding Control Solution Test Results

The label on your test strip bottle shows the acceptable ranges for the Control Solutions. The result you get should be inside the acceptable range for the appropriate control solution level. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:

Control Solution values will not be included in the memory and averages.

Troubleshooting Checks	*Action*
✓ Was the test strip exposed to open air for a long period of time?	If yes, repeat the control test with properly stored strips.
✓ Does test strip cap close tightly? Or was test strip cap left open?	If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.
✓ Is the meter functioning well?	You can use control solution to verify the meter's functions. (Chapter 2)
✓ Is the control solution expired or contaminated?	If yes, replace with new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	If no, repeat the control test with properly stored strips or control solutions.
✓ Did you follow the testing steps properly?	Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to obtain the inaccurate results. If you have questions or need assistance, please contact your local dealer.

Chapter 3: Testing Your Blood Glucose

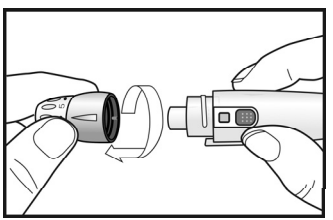
Using The Lancing Device

- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.

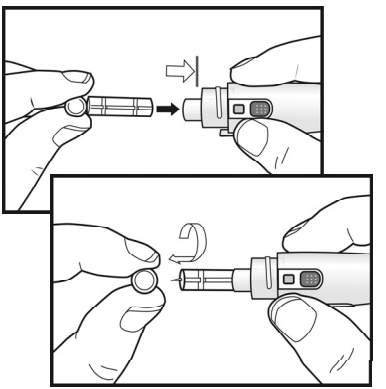
Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. Users may discuss methods for disposing of used test strips and lancets with their healthcare professional.

Inserting A Lancet Into The Lancing Device

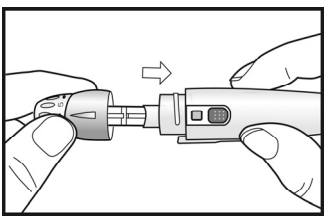
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.

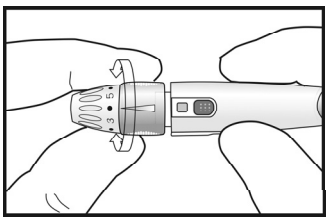


2. Insert the lancet into the lancing device firmly then twist off the protective cover.

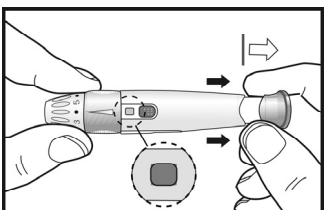


3. Recap the front cap.

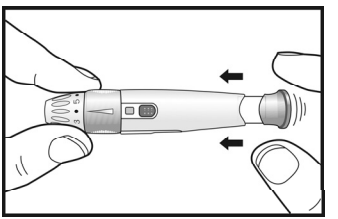
Lancets are for use only and a new, sterile lancet should be used each time you perform a test.



4. Select the desired penetration depth.



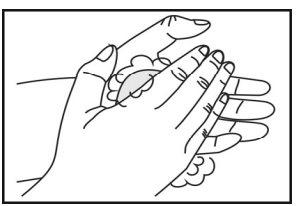
5. Pull on the sliding barrel of the lancing device until it clicks and then release.
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.

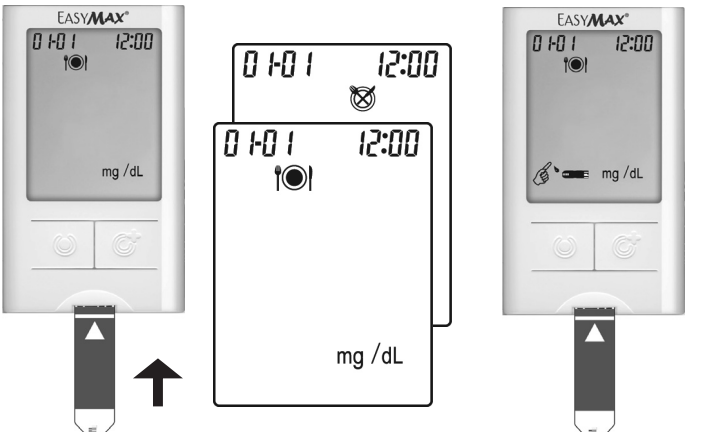


6. Set the lancing device aside until later in the test.

1. **Select 1-2 for soft or thin skin, 3-5 for average, and 6-7 for thick or calloused skin.**
2. **Lancing device and lancets are not to be shared between users. Sharing lancing devices and lancets may transmit blood borne pathogens, such as viral hepatitis.**

Running A Blood Glucose Test With Blood From Your Fingertip



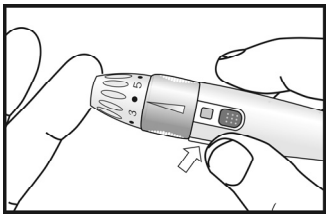


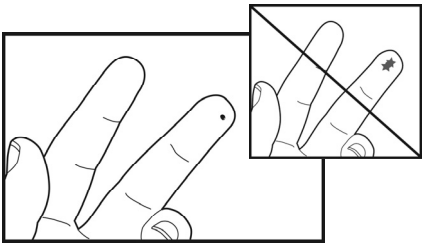
1. Wash your hands with soap and warm water. Rinse and dry thoroughly.

2. Insert a test strip into the meter in the direction of the arrow and the icon will appear.

3. Press to set or and press to confirm the setting.

4. When the blood drop flashes on the display, obtain a drop of blood from your fingertip, using the lancing device.





5. Place the lancing device against the tip or side of your finger; press the trigger button to activate the lancing device.

6. Gently squeeze your finger to assist the flow of blood. This helps you get a blood drop.

7. Touch the blood drop to the tip of the transparent window of the test strip. **Do not put blood on top of the strip.** Be sure to get enough blood on the strip's reaction zone.

8. The meter will beep when enough blood has entered the strip's reaction zone. The result will appear on the display after 5 seconds.

9. Remove the test strip and the meter turns off automatically.

Alternate Site Testing (Optional)

Understanding Alternate Site Testing (AST)

What is AST?
Besides the fingertip, you can test the forearm or palm.

What is the advantage of AST?
You have the option of testing other places on your body besides the fingertip.

Consult your healthcare professional before you begin using the forearm or palm for testing. Blood glucose test results obtained from your forearm or palm may differ significantly from fingertip samples. **We strongly recommend that you:**

Do AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do NOT use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Fingertip test only:

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

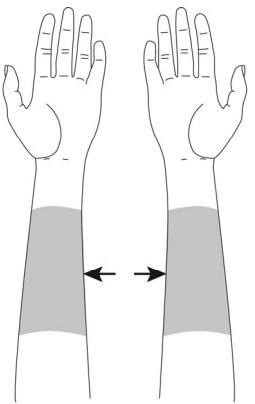
AST Results:

- If the blood glucose test result from the alternate site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of *an alternate site* result, do a fingertip test to confirm the result.

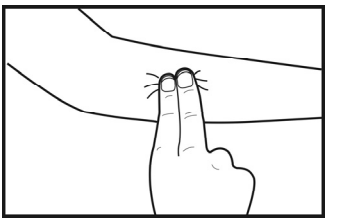
- Talk with your healthcare professional before you test with your fingertip, palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm samples.
- Do NOT change your treatment just because of a result.

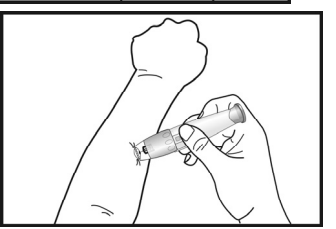
Running A Blood Glucose Test With Blood From Your Forearm (Optional)

Please use the clear cap with the lancing device for AST testing.

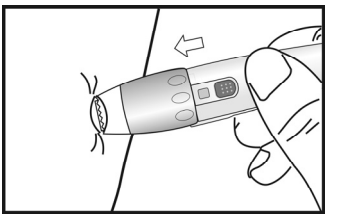


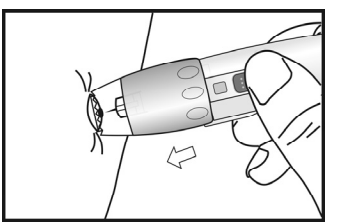
1. Massage the puncture area of forearm for a few seconds.





2. Press and hold the device with clear adjustable tip against the forearm.

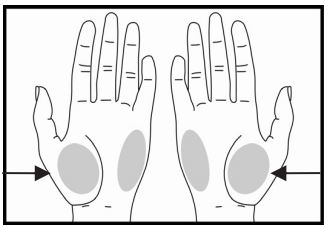




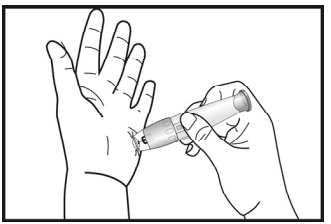
3. Press the trigger button to activate the lancing device.

4. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

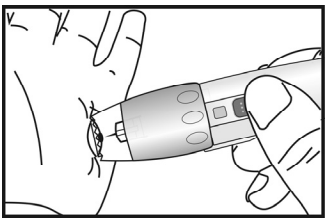
Running A Blood Glucose Test With Blood From Your Palm (Optional)



1. Massage the puncture area of palm for a few seconds.



2. Press and hold the device with one clear adjustable tip against the palm.

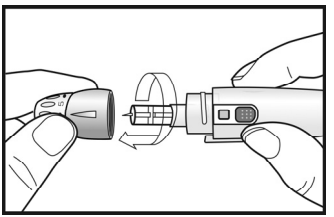


3. Press the trigger button to activate the lancing device.

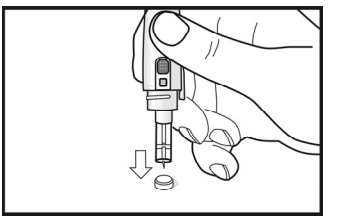
4. Hold the device against palm and increase pressure until the blood sample size is sufficient.

Check with your healthcare professional before testing other sites than fingertip.

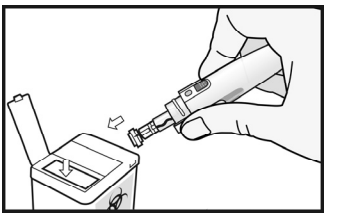
Discarding Used Lancets



1. Unscrew and remove the cap.



2. Without touching the used lancet, stick the lancet tip into its protective cover.



3. Pointing the lancing device toward a container for sharp or biohazard material, slide the ejection button down to release the covered lancet into the container.

Understanding Your Test Results

The **EASYMAX®** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for non-pregnant adults with diabetes is 70-130 mg/dL (3.9~7.2 mmol/L)*. Two hours after meals, the blood glucose range for non-pregnant adults with diabetes is less than 180 mg/dL (10 mmol/L). For further queries about diabetes: please consult your healthcare professional for the blood glucose range appropriate for you.

* Reference: American Diabetes Association. Standards of medical care in diabetes. Diabetes care. 2013; Vol. 36, Suppl 1, S21.

Unusual Test Results

If your test result doesn't match the way you feel, please follow these steps:

1. Run a control solution test, Chapter 2 "Control Solution Testing."
2. Repeat a blood glucose test, Chapter 3 "Testing Your Blood Glucose."
3. If your test results still don't reflect the way you feel, call your healthcare professional immediately.

1. **Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.**
2. **Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.**
3. **Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.**

Symptoms Of High Or Low Blood Glucose

Being aware of the symptoms of high or low blood glucose can help you understand your test results and decide what to do if they seem unusual. Here are the most common symptoms:

Greater than 240 mg/dL (13.3 mmol/L)

What It Means:
The test result is higher than reference normal range. (70-130 mg/dL or 3.9-7.2 mmol/L)

Symptoms:
Fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

What to Do:
- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is greater than 240 mg/dL (13.3 mmol/L) and you have symptoms of high blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Below 60 mg/dL (3.3 mmol/L)

What It Means:
The test result is lower than reference normal range. (70-130 mg/dL or 3.9-7.2 mmol/L)

Symptoms:
Sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

What to Do:
- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is below 60 mg/dL (3.3 mmol/L) and you have symptoms of low blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Comparing Your Meter Result To A Lab Result

A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to the doctor's office for a blood glucose test. The results will probably not match, even if you are fasting. This is typically not a problem with your meter, it just means that time has elapsed and your blood glucose has changed.

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than **EASYMAX® Mini** Blood Glucose Meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

In comparison to the YSI, EASYMAX® 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.

For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Chapter 4: Meter Memory, Setup

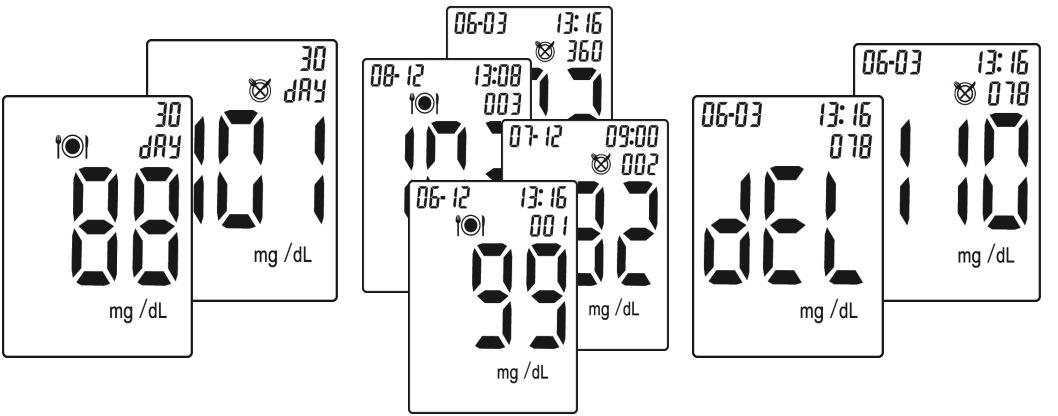
Memory, Storing Test Results

Your meter stores a maximum of 360 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

1. **Do not change your therapy based on one individual result in memory.**
2. **The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting The Time And Date" in Chapter 1.**
3. **Once 360 results are in memory, adding a new result causes the oldest one to be deleted.**

Viewing And Deleting Test Results

You can review them at any time without inserting a test strip.



1. Press ◉ to review test results of 30 days in ⦿ or ⊗ .

2. Press ◉ to review all results in order from records of 360 to 001.

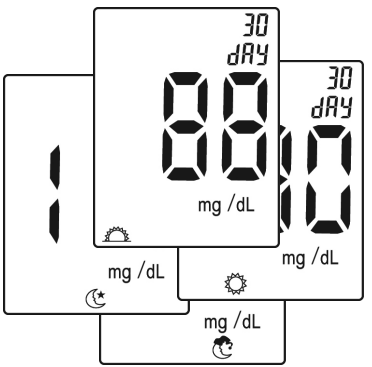
3. To delete a test result, press ◉ for 3 seconds and display shows **"dEL".**

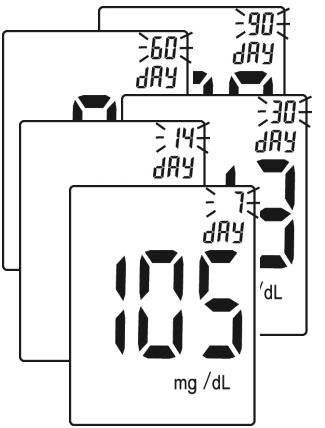
4. Press ◉ to keep reviewing test results.

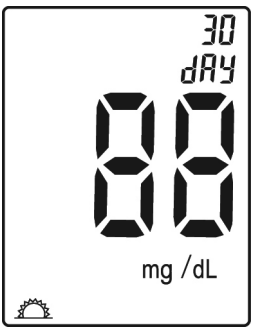
5. The meter will turn off in 1 minute automatically.

Meter Memory

You can review them at any time without inserting a test strip.







1. Press to review test results of 30 days in , , , or .

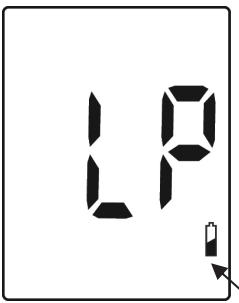
2. Press to review results of 7, 14, 30, 60 or 90 days.

3. Press to go back the display of .

4. Meter will turn off in 1 minute automatically.

Chapter 5: Maintenance And Troubleshooting

Inserting Battery



The meter uses one CR2032 Lithium Battery. Battery will normally last for more than 1000 tests. Other types of CR2032 Lithium Battery are also acceptable, but the capacity of test times may differ. Insert the battery when you first use the meter or replace with new battery when the **"LP"** (Low Power) message and the low battery symbol appear on the display.

Low battery symbol

1. **The meter won't delete earlier records after you replace the battery.**
2. **You should reset the time and date again after you replace the battery. See Section "Setting The Time And Date" in Chapter 1.**
3. **CR2032 Lithium Battery is available at most stores. You may take the old battery with you for replacement.**
4. **Remove the battery when you will not be using the meter for one month or more.**

Cleaning Your Meter

Caring for your **EASYMAX® Mini** SMBG system does not require special cleaning. Please keep the meter free of dirt, dust, bloodstain, and water stains. Follow these guidelines carefully to help you get the best performance possible:

Do:

- Make sure the meter is turned off.
- Gently wipe the meter's surface with a soft cloth slightly dampened with ethanol (70~75%).

Do Not:

- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

Cleaning Your Lancing Device

- To clean the lancing device, wipe it with a soft cloth dampened with water and mild detergent. **DO NOT** places the entire device under water.
- To disinfect the cap after cleaning, place it in 70%-75% rubbing alcohol for 10 minutes at least once a week. Allow the cap to air-dry after disinfecting.

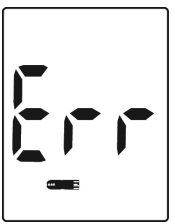
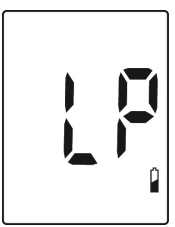
Maintenance And Testing

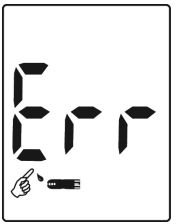
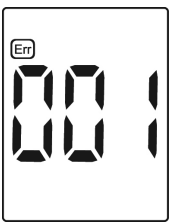
Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

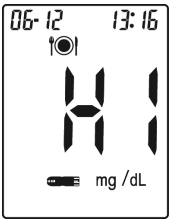
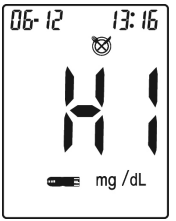
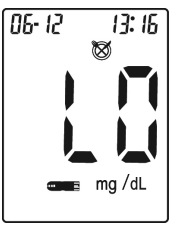
To make sure the display is working properly, turn off the meter. Press and hold ◎ to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please contact your local dealer.

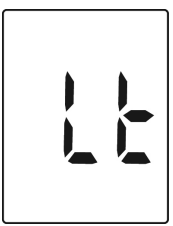
Screen Messages and Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, please contact your local dealer or healthcare professional.

Message	*What it means?*	*What to do?*
	**Humidified / Used strips** The meter has detected a problem with the test strip.	**Repeat the test with a new strip.** Refer to pages 24-25 for information on sample application.
	**Low power** The meter batteries do not have enough power to perform a test.	**Replace the new batteries.**

Message	*What it means?*	*What to do?*
	**Volume detector error** The volume of blood or control solution is NOT enough.	**Replace with a new strip.** If **Err** appears again, please contact your local dealer.
	**System error** There may be a problem with the meter.	**Replace the batteries first.** Refer to page 37. If **Err 001** appears again, please contact your local dealer.
	**The test result is among 20~60 mg/dL. (H)**	**Please call your healthcare professional.**

Message	*What it means?*	*What to do?*
 	**The test result is higher than 630 mg/dL.**	**Re-check your glucose level.** If the result is **HI** again, obtain and follow instructions from your healthcare professional without delay.
 	**The test result is lower than 20 mg/dL.**	This may require immediate treatment according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.

Message	*What it means?*	*What to do?*
	**The “Ht” and thermometer icon appears. Temperature is too high, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.**	Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).
	**The “Lt” and thermometer icon appears. Temperature is too low, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.**	Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).

Chapter 6: Technical Information

Specification

Brand name		**EASYMAX® Mini** Blood Glucose Meter
Range		20~630 mg/dL
Test time		5 seconds
Memory sets		360 test results
Operating condition	Temp.	10°C - 40°C (50°F - 104°F)
	Relative Humidity	R.H. ≦ 90%
Storage and transportation condition	Temp.	-20°C - 50°C (-4°F - 122°F)
	Relative Humidity	R.H. ≦ 90%
Blood sample		0.6 µL
		Fresh blood from fingertip, palm or forearm
Hematocrit (Hct)		20-60%
Power		CR2032 Lithium Battery
Battery life		Over 1000 tests
Display dimension		1.65” x 1.26” (42.0 × 32.0 mm)
Device dimension H × W × D (mm)		2.95” x 1.73” x 0.39” (75.0 × 44.0 × 10.0 mm)
Weight		1.06 oz (30.0 grams) w/o batteries
Principles		Electrochemical biosensor technology

Limitation

The test strips are used for fresh venous blood or 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.
4. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
5. The system should be used at a temperature between 10°C - 40°C (50°F - 104°F). Outside this range, the system may get incorrect results.
6. DO NOT reuse the test strips. The test strips are for single use only.
7. Hematocrit: The hematocrits between 20% and 60% will not affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.
8. Altitude up to 3,048 meters above sea level has no effect on readings.

Healthcare Professionals – Please note these additional Limitations

1. If the patient has the following conditions, the result may fail:
   - Severe dehydration
   - Severe hypotension (low blood pressure)
   - Shock
   - A state of 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. Grossly lipemic patient samples have not been tested and are not recommended for testing with **EASYMAX® Mini** Blood Glucose Meter.

3. Critically ill patients should not be tested with **EASYMAX® Mini** Blood Glucose Meter.
4. DO NOT use during xylose absorption testing. Xylose in the blood will interfere Self-Monitoring Blood Glucose System.
5. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Bias / Glucose Level Concentrations of the interference tested			80 mg/dL (4.4 mmol/L)	250 mg/dL (13.9 mmol/L)	500 mg/dL (27.8 mmol/L)
Ascorbic Acid	4 mg/dL	(0.26 mmol/L)	10.89%	-1.76%	4.55%
Ibuprofen	50 mg/dL	(2.43 mmol/L)	3.10%	2.88%	4.62%
L-Dopa	1.8 mg/dL	(0.09 mmol/L)	10.59%	7.91%	4.90%
Sodium Salicylate	50 mg/dL	(3.12 mmol/L)	-2.59%	9.42%	-0.84%
Tetracycline	1.5 mg/dL	(0.03 mmol/L)	-5.32%	3.81%	3.20%
Tolbutamide	100 mg/dL	(3.7 mmol/L)	-2.60%	12.30%	0.89%
Bilirubin-unconjugated	2.4 mg/dL	(0.04 mmol/L)	-2.52%	4.05%	-0.23%
Uric acid	8 mg/dL	(0.48 mmol/L)	2.71%	9.55%	-1.75%
Xylose	4 mg/dL	(0.27 mmol/L)	-5.12%	-1.64%	-4.44%

Device Information

EASYMAX® Mini SMBG System,
EASYMAX® Blood Glucose Test Strips,
EASYMAX® Mini Blood Glucose Meter.

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

EC REP **Obelis s.a.**

CE 0537

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

Manufacturer:
EPS BIO TECHNOLOGY CORP.
Hsinchu Science Park, Hsinchu, Taiwan 30077

P/N. 718063946_0887_02