# **EME**

Self-Monitoring Blood Glucose System

## **User's Manual**



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

## Dear EME SMBG System Owner,

Thank you for using the **EME** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be dependable, easy-to-use, compact, lightweight and portable 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 **EME** Self-Monitoring Blood Glucose System. To start testing quickly, you can also refer to the Quick Reference Guide.

Thanks again for choosing the **EME** SMBG.

#### Intended Use

The **EME Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from fingertips, palm and 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.

#### Standard Accessories

Your new **EME** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- EME Blood Glucose Meter
- Alkaline Battery (2 ct.)
- Glucose Test Strips (10 pcs)
- Lancets (10 pcs)
- Lancing device
- AST Lancing Device Cap
- **Optional Accessories** 
  - Low Control Solution
  - High Control Solution

- User's Manual
- Quick Reference Guide
- Test Strip Instructions
- Self-Test Log Book
- Normal Control Solution
- Glucose Control Solution Instructions
- Carrying Case



- 1. Normal control solution is included with the system.
- 2. Low control solution and High control solution are available. For purchase, please contact your healthcare provider.

## 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 have made this SMBG system as simple as possible to help you 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 provider.



Although the EME 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 Meter

- **EME** blood glucose meter is designed and approved for testing fresh capillary whole blood samples from your fingertips, palm and forearm. The meter is for in vitro diagnostic use ONLY (for testing outside the body). It should not be used to diagnose diabetes.
- **EME** blood glucose meter can only be used with **EME** 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, 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 a viral disease.



- Consult with your healthcare professional before testing on your palm or forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 3,048 meters above sea level has no effect on readings.

#### **Health-Related Information**

- If you are experiencing dehydration, frequent urination, low blood pressure, 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 doctor right away.
- If you have followed the steps in the user's manual, but still have symptoms that do not seem to match your test results, or if you have questions, please contact your healthcare provider.
- 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**

i	Consult instructions for use	lack	Caution
LOT	Batch code	2	Do not reuse
IVD	In vitro diagnostic medical device	LR3/AAA + DC 3V 2XAAA	1.5V(AAA) x 2 batteries only
Σ	Use by	<i>\_</i>	Temperature limitation
	Manufacturer	REF	Catalogue number
SN	Serial number	CONTROL	Control
Σ	Sufficient for	EC REP	Authorized representative in the European Community
mg/dL	Blood glucose test result in mg/dL	mmol/L	Blood glucose test result in mmol/L
0	Green Dot / Duales System Deutschland GmbH (DSD)		

Z	Separate collection for WEEE- Waste of electrical and electronic equipment
CE	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices

## **Explanation of Symbols (continued)**

6 M	Discard 6 months (180 days) after opening	* *	Large LCD screen
$\bigcirc$	Hypo alarm	*/	Keep away form sunlight
	5-seconds result		0.6 μ L blood volume
	Alternative site testing		Human-factor flow

## **Explanation of Meter Symbols**



Folder Symbol		Meaning	
88-88	Date	Show the moment of month and day.	
88:88	Time	Show the moment of time.	
888	Test result	Show the test result.	
888	Record/Average display	Tracking all the test results or average of /14/30/90 days.	
[5	Control Solution	Control Solution test and the result is not included in the memory.	
R	AM	Indicate before noon	
Р	PM	Indicate after noon	
	Batteries status	When the battery symbol appears, prepare new batteries for installation.	
•	AC = ante cibos	Indicate before meal	
<b>É</b>	PC = post cibos	Indicate after meal	
lacksquare	Insert strip	Insert the test strip to test blood glucose.	
	Thermometer	When the thermometer icon appears, the temperature is too high or too low.	
×	Error	The meter system is in fault.	
M	Memory	Show the memorized results	
	Apply blood	Apply blood to the test strip	
mg/dL	Glucose unit	The testing unit of blood glucose is mg/dL.	
mmol/L	Glucose unit	The testing unit of blood glucose is mmol/L.	

## **Table of Contents**

Chapter 1: Understanding Your Meter	13
The EME Blood Glucose Meter	13
The EME Accessories	14
Inserting Batteries	15
Setting The Time and Date	16
Using EME Blood Glucose Test Strips	17
Chapter 2: Control Solution Testing	18
Why Run a Control Solution Test	18
About The Control Solutions	
Running a Control Solution Test	20
Understanding Control Solution Test Results	22
Chapter 3: Testing Your Blood Glucose	24
Using the Lancing Device	
Inserting a Lancet into the Lancing Device	
Running a Blood Glucose Test with Blood from Your Fingertips	27
Alternative Site Testing (AST)	30
Running a Blood Glucose Test with Blood from Your Forearm	32
Running a Blood Glucose Test with Blood from Your Palm	
Discarding Used Lancets	34
Understanding Your Test Results	35

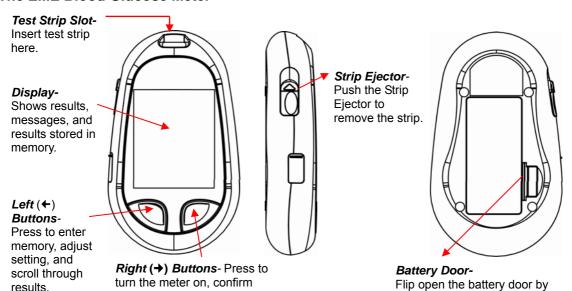
Unusual Test ResultsSymptoms of High or Low Blood GlucoseComparing Your Meter Result to a Lab Results	36
Chapter 4: Meter Memory, Setup	38
Memory, Storing Test Results	38
Viewing Test Results	39
Chapter 5: Maintenance and Troubleshooting	40
Inserting Batteries	40
Cleaning Your Meter	
Cleaning Your Lancing Device	41
Maintenance and Testing	42
Screen Messages and Troubleshooting	43
Chapter 6: Technical Information	46
Specifications	46
Limitations	
Device Information	49
Warranty	

## **Chapter 1: Understanding Your Meter**

setting, and scroll through

results.

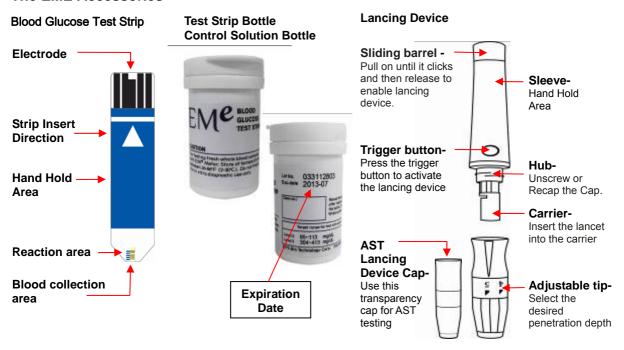
#### The EME Blood Glucose Meter



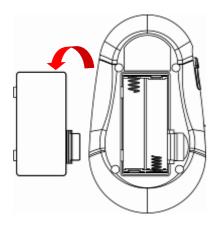
Flip open the battery door by pushing the tab in the direction of the arrow and pulling the door up.

13

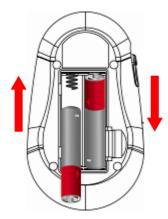
#### The EME Accessories



## **Inserting Batteries**



 Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.



**2.** Insert two batteries and the meter beeps.



Put the battery door back in place and snap it closed. The meter turns on automatically.

#### **Setting The Time and Date**

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

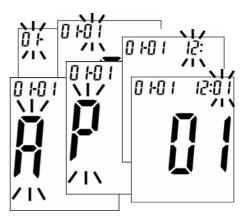


1. Press → (right button) to turn the meter on.



The display shows the last
 2-digit of the year that flashes at the top of display as well. Press
 ← (left button) to adjust the year and press → (right button) to

confirm the setting.



Repeat step 2 to set the date and time. The flashing field is the one you are currently setting. (A=AM, P=PM)

## **Using EME Blood Glucose Test Strips**

- Use only with **EME** Blood Glucose Meters.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original bottle.
- After you take a test strip out of the bottle, tightly close the bottle immediately. This keeps the test strips dry.
- Use the test strip within three minutes after taking it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the expiration date on the test strip bottle. The test strip is good for 6 months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry 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.

## **Chapter 2: Control Solution Testing**

#### Why Run a Control Solution Test

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

- You use the **EME** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- 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.
- You are practicing the test procedure.



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

#### **About The Control Solutions**

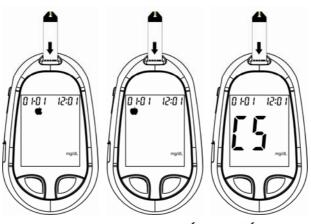
- Use only with **EME** test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- Control solutions 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 EME Control Solutions, please contact your healthcare provider.

## **Running a Control Solution Test**

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



 Put a test trip into the meter as the direction of the arrow on the test strip. The meter turns on automatically.



2. Press ← (left button) to set **(AC)**, **(PC)** or CS Mode, then press → (right button) to confirm the setting.



3. The icons (insert strip) and (apply blood) show themselves.



- **4.** Place the meter on a flat surface, like a table.
- **5.** Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.
- Squeeze the bottle until a tiny drop forms at the tip of the bottle.
- 7. Touch the drop to the Blood collection area at the tip of the test strip. Do not put control solution on top of the test strip.
- 8. The meter starts to count down from 5 seconds and then shows the test result.
- Do not remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.
- **10.** Push the Strip Ejector to Remove the test strip.
- 11. Throw the test strip away after you have compared the reading to the range printed on the test strip bottle.



Be aware that there are Normal and High ranges listed on your test strip bottle. The Normal and High refer to the three different control solutions that are available. Please be sure that you are looking at the correct range.

## **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:



- 1. If "[ ] " is not set, then the control test values will be counted into 7/14/30/60/90 days average mode.
- 2. If "[ ] " is set, the control solution values will not be counted into averages, but only in the memory for review.

## **Troubleshooting Check**

#### 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 the control solutions to verify the meter's functions.

✓ Is the control solution expired or contaminated?

If yes, replace with a 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.

## **Chapter 3: Testing Your Blood Glucose**

#### **Using the Lancing Device**

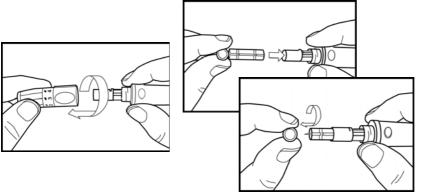
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.

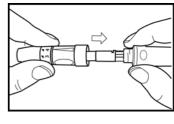


Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. Users may discuss methods for disposing used test strips and lancets with their doctor.

## **Inserting a Lancet into the Lancing Device**

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





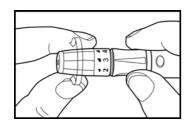
1. Unscrew the Cap.

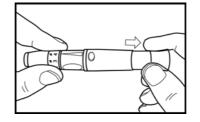
2. Insert the lancet into the lancing device firmly then twist off the protective cover.

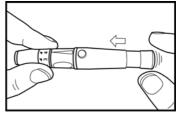
3. Recap the front cap.



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 for average, and 4-5 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.

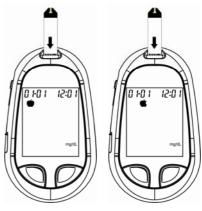
## Running a Blood Glucose Test with Blood from Your Fingertips



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



**2**. Put a test strip into the meter in the direction of the arrow. The meter turns on automatically.



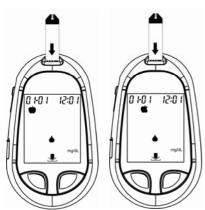
3. Press ← (left button) to set

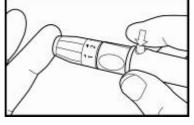
(AC) or (PC)

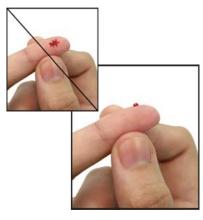
Mode, then press → (right button) to confirm the setting.



You can also turn on the meter by inserting a test strip.







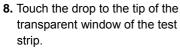
4. The icons (insert strip) and (apply blood) show themselves.

When the blood drop flashes on the display, obtain a drop of blood from your finger.

- 5. Hold the lancing device firmly against the side of your finger. Press the trigger button. Then remove the lancing device from your finger.
- **6.** Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.
- **7.** Wipe away the first drop with a tissue and use the second drop.





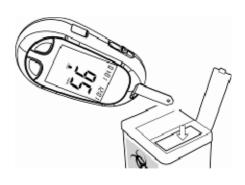


## Do not put blood on top of the strip.

Be sure to get enough blood in the strip's confirmation window. Otherwise, an inaccurate reading may yield.



**9.** The meter starts to count down from 5 seconds and then shows the test result.



- **10.** Push the Strip Ejector to remove the test strip.
- **11.** Throw it away after you have compared the reading to the range printed on the test strip bottle.

## **Alternative Site Testing (AST)**

#### **Understanding Alternative Site Testing**

#### What is AST?

Besides the fingertip, you can test your palm or forearm.

#### What is the advantage of AST?

You have the option of testing other places on your body besides the fingertip.

Consult your health care professional before you begin using the palm or forearm for testing. Blood glucose test results obtained from your palm or forearm may differ significantly from fingertips 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)

#### **AST Results:**

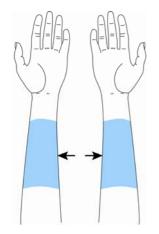
- If the blood glucose test result from the alternative site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of an alternative site result, do a fingertip test to confirm the result.
- If you often do not notice when your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

#### Caution:

- Talk with your healthcare professional before you test with your palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertips 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

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

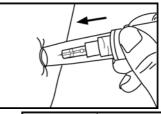


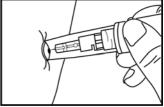
 This graphic shows where the meter cleared for alternate site testing.





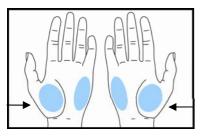
- **2.** Massage the puncture area of forearm for a few seconds.
- Press and hold the device with a clear adjustable tip against the forearm.

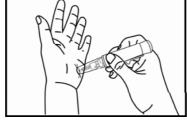


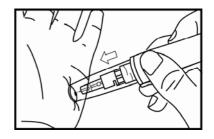


- **4.** Press the trigger button to activate the lancing device.
- Hold the device against forearm and increase pressure until the blood sample size is sufficient.

#### Running a Blood Glucose Test with Blood from Your Palm





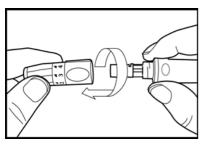


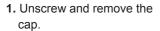
- **1.** Massage the puncture area of palm for a few seconds.
- 2. Press and hold the device with a clear adjustable tip against the palm.
- **3.** Press the trigger button to activate the lancing device.
- Hold the device against palm and increase pressure until the blood sample size is sufficient.



- 1. Check with your healthcare professional before testing sites other that the fingertip.
- 2. Please do NOT use the first drop of blood sample.

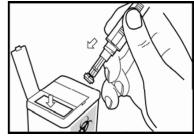
## **Discarding Used Lancets**







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



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

#### **Understanding Your Test Results**

The **EME** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult with diabetes is 70-130 mg/dL (3.9~7.2 mmol/L)\*. Two hours after meals, the blood glucose range for an adult with diabetes is less than 180 mg/dL (10.0 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-Table 10. Diabetes care. 2011; Vol. 34, Suppl 1, S21.

#### **Unusual Test Results**

If your test result does not match the way you feel, please follow these steps:

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



- 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 (13.33 mmol/L)

#### What It Means:

The test result is higher than reference normal range. (70-130 mg/dL or 3.89-7.22 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 (13.33 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 (3.33 mmol/L)

#### What It Means:

The test result is lower than reference normal range. (70-130 mg/dL or 3.89-7.22 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 (3.33 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 fingertips 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 **EME** blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result

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

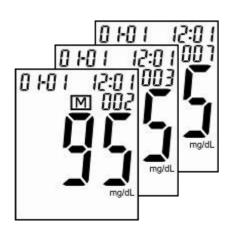
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the latest is added, so it is very important to have the correct time and date set in the meter.



- 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 for future readings. See Section "Setting the time and date" in Chapter 1.
- 3. Once 480 results are in memory, adding a new result causes the oldest one to be deleted.

### **Viewing Test Results**

The meter provides 7, 14, 30 and 90 days averaging to help track your blood glucose result soundlessly.



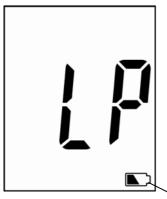
- **1.** Press → (right button) until turning the meter on.
- 2. Press ← (left button) to view the latest test result.
- All results are shown in turn from records of M480 to M001.



**4.** Press →to view averages of 30day-AC/PC and 7/14/30/90 days.

# **Chapter 5: Maintenance and Troubleshooting**

### **Inserting Batteries**



The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries are also acceptable, but the capacity of test times may differ. Insert the batteries when you first use the meter or replace with new batteries when the "LP" (low power) message and the low battery symbol appear on the display.

The meter will not turn on the first time batteries are inserted.

Please press and hold → (right button) or insert the test strip to turn your meter on.

The meter will turn off automatically. Or you can press and hold → (right button) to turn your meter off.

### Low battery symbol



- 1. The meter won't delete earlier records after you replace batteries.
- 2. You should reset the time and date again after you replace the batteries.
- 3. 1.5V (AAA) x 2 batteries are available at most stores. You may take the old batteries with you for replacement.
- 4. Remove batteries when you will not be using the meter for one month or more.

## **Cleaning Your Meter**

Caring for your **EME** 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.)

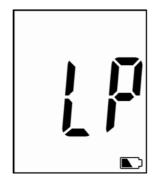
To make sure the display is working properly, turn off the meter. Press and hold → (right button) to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please contact your healthcare provider.

# **Screen Messages and Troubleshooting**

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



**Humidified/Used strips** *Action:* Replace with a new strip.

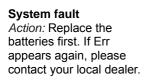


**Low power**Action: Replace with new batteries.



**System fault** *Action:* Replace the batteries first. If **ERROR 001** appears again, please contact your local dealer.







Test result is higher than 630 mg/dL (35.0 mmol/L).

Action: Test again. If the result is still the same try a control solution.

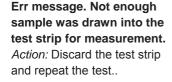
Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please call your healthcare provider.

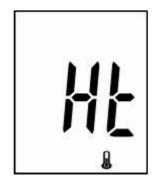


The test result is lower than 20 mg/dL (1.1 mmol/L).

Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please call your healthcare provider.



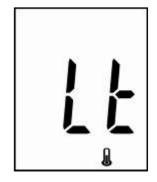




The "Ht" and thermometer icon appears. Temperature is too high, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.

Action: 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.

Action: Relocate the meter to a location with temperature between 10°C - 40°C (50°F -

104°F).

# **Chapter 6: Technical Information**

# **Specifications**

Brand name		EME Blood Glucose Meter	
Range		20~630 mg/dL (1.1~35.0 mmol/L)	
Response time		5 seconds	
Memory sets		480 test results	
Operating condition	Temp.	10°C-40°C (50°F -104°F)	
	Relative Humidity	R.H. ≦ 90%	
Storage and transportation condition	Temp.	2°C -30°C (36°F -86°F)	
	Relative Humidity	R.H. ≤ 90%	
Blood sample		0.6 μL	
		Fresh blood from fingertips, palm, or forearm	
Hematocrit (Hct)		20~60%	
Power		2 Alkaline 1.5V (AAA)	
Battery life		Over 2000 tests	
Display dimension		1.4 x 1.7 inches (35.0 x 43.0 mm)	
Device dimension H × W × D		98 x 57 x 22 mm (3.9 x 2.2 x 0.9 inches)	
Weight		53.2 grams (1.88 oz.) w/o battery	
Principles		Electrochemical biosensor technology	

#### Limitations

The test strips are used for fresh 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 temperatures between 50°F and 104°F (10°C and 40°C). 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 hematocrit 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 fails:
  - Severe dehydration
  - ♦ Severe hypotension (low blood pressure)
  - Shock
  - ◆ A state of hyperglycemic-hyperosmolar state (with or without ketosis)
- Lipemic samples: Cholesterol level up to 500 mg/dL (12.92 mmol/L) and triglycerides up to 3,000 mg/dL (33.6mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with EME Blood Glucose Meter.

- 3. Critically ill patients should not be tested with EME blood glucose meters.
- 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 (0.26mmol/L)	10.89%	-1.76%	4.55%
Ibuprofen, 50 mg/dL (2.43mmol/L)	3.10%	2.88%	4.62%
L-Dopa, 1.8 mg/dL (0.09mmol/L)	10.59%	7.91%	4.90%
Sodium Salicylate, 50 mg/dL (3.12mmol/L)	-2.59%	9.42%	-0.84%
Tetracycline, 1.5 mg/dL (0.03mmol/L)	-5.32%	3.81%	3.20%
Tolbutamide, 100 mg/dL (3.7mmol/L)	-2.60%	12.30%	0.89%
Bilirubin-unconjugated, 2.4 mg/dL (0.04mmol/L)	-2.52%	4.05%	-0.23%
Uric acid, 8 mg/dL (0.48mmol/L)	2.71%	9.55%	-1.75%
Xylose, 4 mg/dL (0.27mmol/L)	-5.12%	-1.64%	-4.44%

#### **Device Information**

EME SMBG System,
EME Blood Glucose Test Strips,
EME Blood Glucose Meter,
EME Normal Control Solution,
EME High Control Solution,
EME Low Control Solution



#### 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



#### Manufacturer:



#### **EPS BIO TECHNOLOGY CORP.**

No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30077

E-mail: info@epsbio.com.tw Website: http://www.epsbio.com

# Warranty

EPS warrants the original purchaser for a period of 3 years from the date of purchase. This means during the warranty period if the Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.

#### **Lancing Device & Lancet**

Meets the requirements of MDD 93/42/EEC



Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

68# LiTangHe RD, XiangCheng, Suzhou, China 215131 Tel: +86 512 65799308 Fax: +86 512 67217663

P/N: 71800415B 0044B 02