EM44

Self-Monitoring Blood Glucose System

User's Manual

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

Dear EM44 SMBG System Owner,

Thank you for using the **EM44** 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 **EM44** Self-Monitoring Blood Glucose System.

Thanks again for choosing the **EM44** SMBG.

Intended Use

The **EM44 Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, or forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can be only used during steady-state blood glucose conditions.

Important Safety Instructions

Lancets and meters are for single use only. A new, sterile lancet should be used one time you perform a test. The lancing device, lancets and meter are NOT to be shared between users or other family members. Do NOT use on multiple individuals. Sharing a lancing device and lancets may transmit blood borne pathogens, such as viral hepatitis.

All parts of the kit are considered biohazardous and may transmit infection, even if you have performed cleaning and disinfection. Wash hands thoroughly with soap and water after handling the meter or lancing device.

For further information, please see: *"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication"* (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Standard Accessories

The **EM44** Blood Glucose meter and accessories are working together to measure the amount of glucose in your blood. The system includes:

- **Carrying Case**
- **User's Manual**
- **Self-Test Log Book**
- **EM44 Blood Glucose Meter**
- **Test Strip Instructions**
- **EM44 Glucose Test Strips (10 pcs)**
- **CR2032 Lithium Cell 3V Battery (2 pcs)**
- **Lancing device**
- **Lancets (10 pcs)**
- **AST Lancing Device Cap**
- **Glucose Control Solution Instructions**
- **EM44 Level 2 Control Solution**

Optional Accessories

- **EM44 Level 3 Control Solution**

Note:

1. **EM44 Level 2 Control Solution is included with the system.**
2. **EM44 Level 3 Control Solution is available. For purchase, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM).**

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 call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.

Please complete your warranty card and mail it, so you receive the best customer service possible and news about product update.

Note:
Although the EM44 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

- EM44 blood glucose meter is designed and approved for testing fresh capillary whole blood samples from your fingertip and forearm. The meter is for in vitro diagnostic use ONLY (for testing outside the body). It should not be used to diagnose diabetes.
- EM44 blood glucose meter can only be used with EM44 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.

Note:

- Consult with your healthcare professional before testing on your 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 10,000 feet 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 don't seem to match your test results, contact your Healthcare Professional or physician immediately. If you have questions regarding the use of the meter, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.
- Please read your test strip instructions carefully for additional health-related information.

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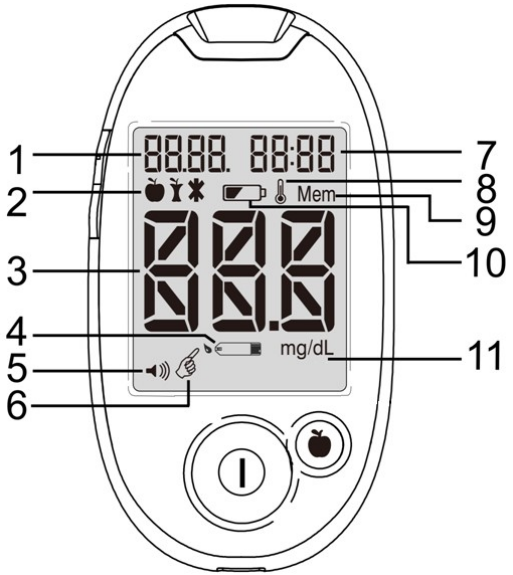
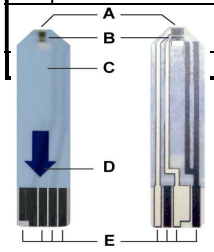
Chapter 1: Understanding Your Meter

The EM44 Blood Glucose Meter

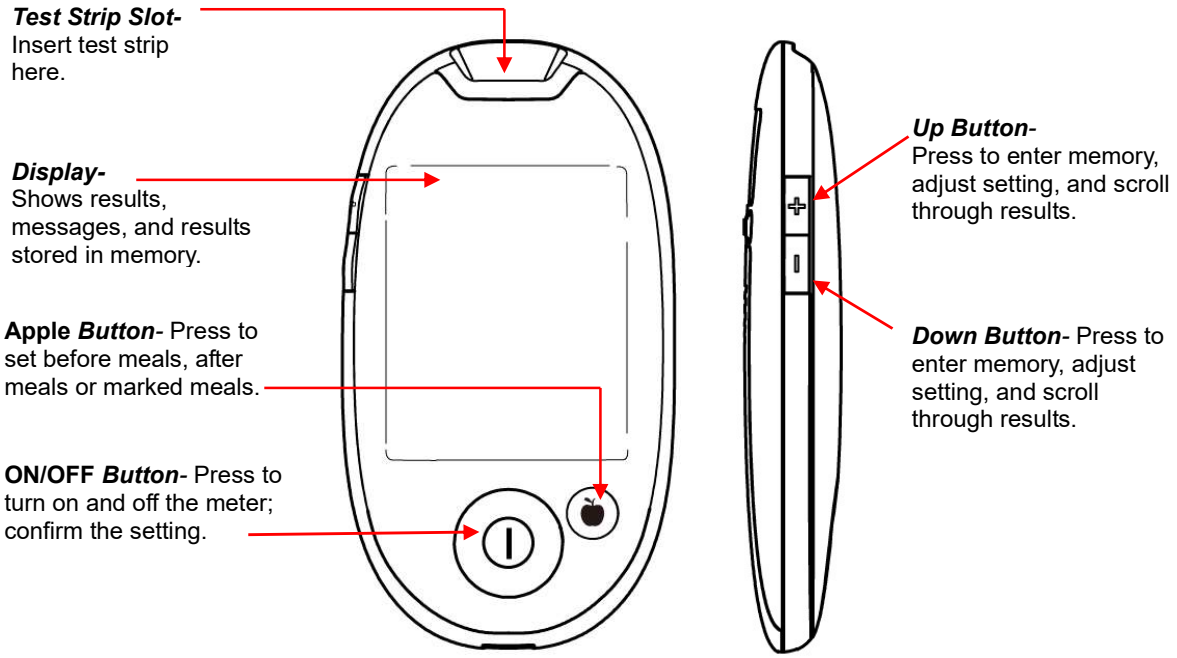


	The Overview of the Display	Meaning
1	month and date	Shows the month and date
2	Meal	Before meal, after meal or marked meal.
3	Test result	Shows the test result
4	Insert test strip	Insert the test strip to start testing blood glucose
5	Sound volume	Beep function can be turned on/off
6	Application of blood or control solution	Test your level of blood glucose
7	Time	Shows the time
8	Thermometer	The thermometer icon appears when the temperature is too high or too low
9	Memory	The meter will automatically record all test results
		When the battery symbol appears,
		[illegible]



The Overview of the Test Strip

A. Blood collection area.
B. Reaction area.
C. Holding area.
D. Strip insert's direction
E. Electrode

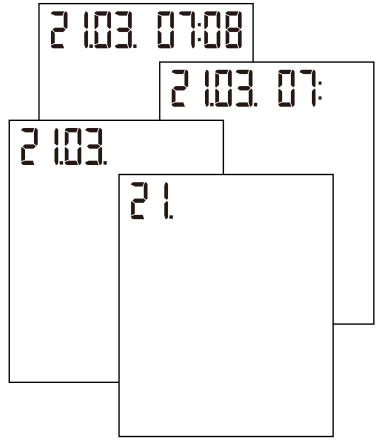

Test Strip Slot-
Insert test strip here.
Display-
Shows results, messages, and results stored in memory.
Apple *Button*- Press to set before meals, after meals or marked meals.
ON/OFF *Button*- Press to turn on and off the meter; confirm the setting.
***Up Button*-**
Press to enter memory, adjust setting, and scroll through results.
***Down Button*-** Press to enter memory, adjust setting, and scroll through results.

Setting the Time, Date, Sound Volume and Memory

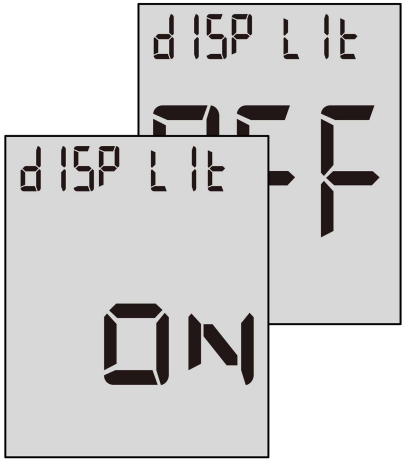
Setting the current time and date in your meter is important if you use the meter memory.

1. Press up and ON/OFF button for 3 seconds or insert batteries, the meter beeps and turns on.

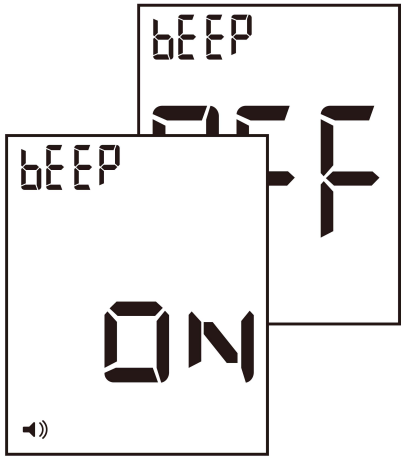
2. The last 2-digits of the year flash at the top of the display. Press up button to increase year or press down button to decrease year and press ON/OFF button to confirm the setting.



3. Repeat step 2 to set the date and time. The flashing field is the one you are currently setting.
(Hour setting: 24hr)



4. Press up or down button to set the backlight and press ON/OFF button to confirm the setting. (Defaulted setting: ON)
.



5. Press up or down button to turn on or turn off the volume and press ON/OFF button to confirm the setting. (Defaulted setting: ON)
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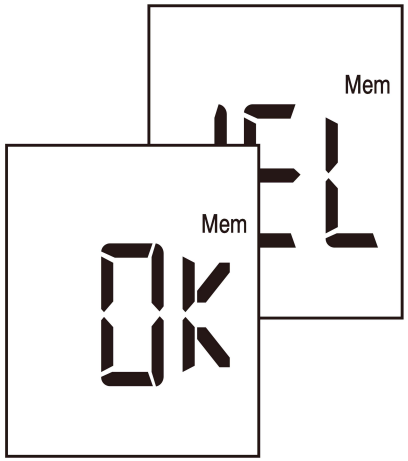


5. Press up or down button to decide whether to delete all memories.

6. If you decide to delete all memories, press ON/OFF button to confirm the setting. The meter will beep and you can start to insert a test strip.

Using EM44 Blood Glucose Test Strips

- Use only with EM44 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 three 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 35.6°F - 86°F (2°C ~30°C). 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.
- EM44 Self-Monitoring Blood Glucose Test System is a “no code” system and does not require any test strip calibration.

Chapter 2: Control Solution Testing

Why Run a Control Solution Test

We recommend that you run the EM44 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:

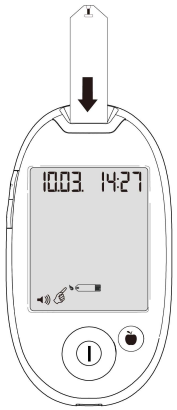
- You use the EM44 Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.

About The Control Solutions

- Use with EM44 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 the solution, 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 35.6°F - 86°F (2°C~30°C). Do not freeze.
- If you would like to purchase EM44 level 2 and level 3 Control Solutions**,** please contact your local dealer.

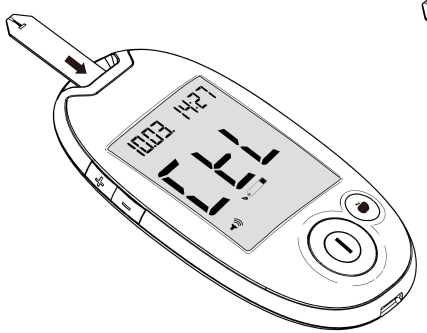
Running a Control Solution Test

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



1. Press ON/OFF button or put a test strip into the meter in the direction of the arrow. The meter will turn on automatically.

2. Press up or down button, the display shows “CtL” and the meter is ready to run a control solution test.



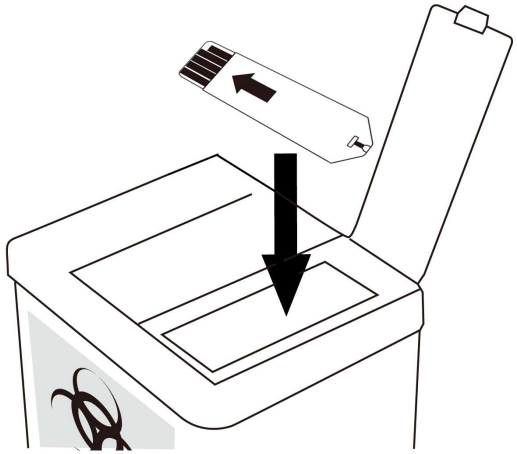
3. Place the meter on a flat surface, like a table.

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

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

6. Touch the drop to the Blood collection area at the end of the test strip.
Do not put control solution on top of the test strip.
When you hear the meter beep, you have enough control solution on the test strip.
The meter starts to count down from 5 seconds and will show the results.

7. 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.



8. 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 this range. 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:

Note:
Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.

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 the cap on the bottle keep tightly prevent moisture or humidity from affecting strips?	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.
✓ Was the meter functioning well?	You can use the control solutions to verify the meter's functions.
✓ Are the control solutions 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

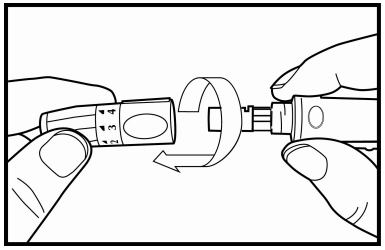
Using the Lancing Device

- 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.
- If the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person. For the disinfection instruction, please refer to Chapter 5: Maintenance And Troubleshooting "Cleaning and disinfect your meter"

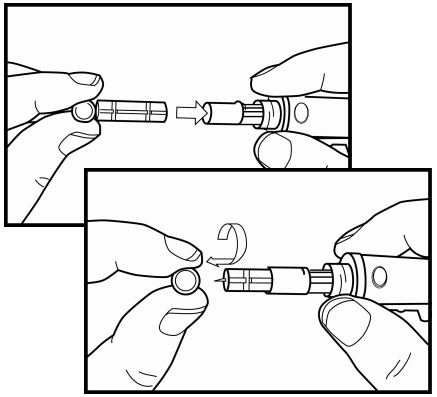
Note:
Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. Users may discuss methods for disposing used test strips and lancets with their doctor.

Inserting a Lancet into the Lancing Device

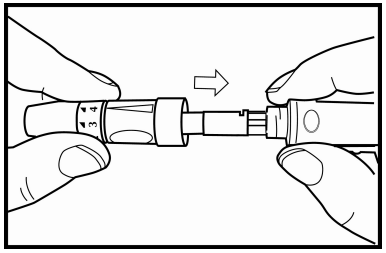
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.

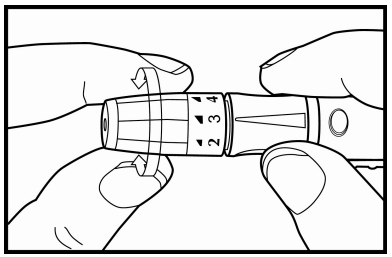


2. Insert the lancet into the lancing device firmly then twist off the protective cover.

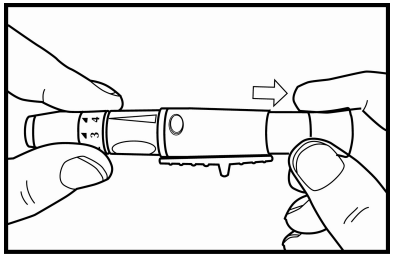


3. Recap the front cap.

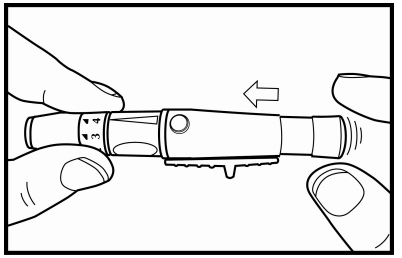
Note:
Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.



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.



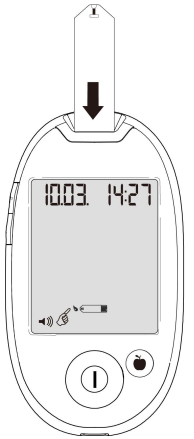
6. Set the lancing device aside until later in the test

Note: 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 Fingertip

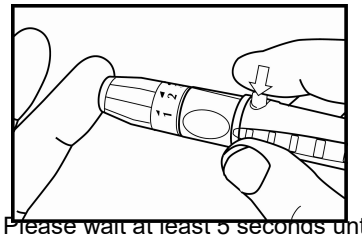
1. Wash your hands with soap and warm water.
Rinse and dry thoroughly.

2. Press ON/OFF button to turn on the meter.



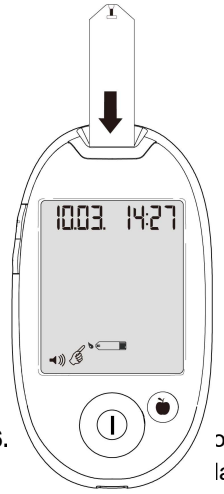
3. When the test strip flashing on the display, put a test strip into the meter in the direction of the arrow. The hand and blood drop appear.

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

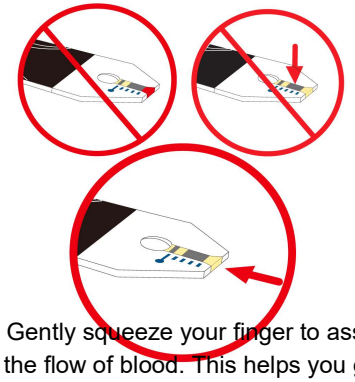


4. Please wait at least 5 seconds until the intended area is dry and clean before sampling the blood.

5. Place the lancing device against the pad of your finger. Press the trigger button to activate the lancing device.



6. op
lay,
obtain a drop of blood from your fingertip.



7. Gently squeeze your finger to assist the flow of blood. This helps you get a blood drop.
Touch the 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.
Otherwise, an inaccurate reading may result.

Note: **1. please make sure to apply blood when the blood drop appears on the display.**
2. Backlight is only on, if backlight setting is "ON".

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. Press apple button to mark the result as before meals values ( ), after meals values ( ) or other marked values ( )

10. Wash hands thoroughly with soap and water after handling the meter, lancing device and test strips.

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 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.
- If you are pregnant.

Fingertip test only:

- If sick
- If blood glucose is low
- After exercising
- Two hours or less after eating
- When basal insulin is most active

What NOT to do:

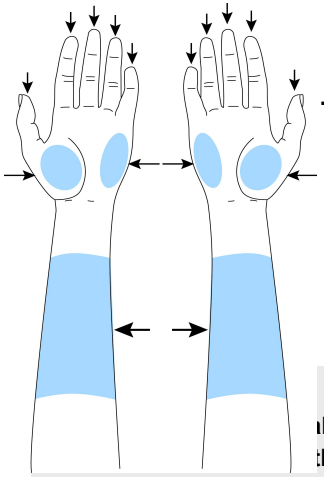
- If the blood glucose test result from the alternative site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of *an alternative site* result, do a fingertip test to confirm the result.
- If you often do not notice when your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

Caution:

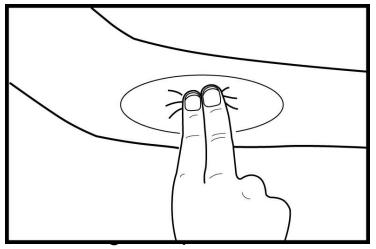
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm samples.
- Measurements from alternative site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.

Running a Blood Glucose Test with Blood from Your Palm or Forearm

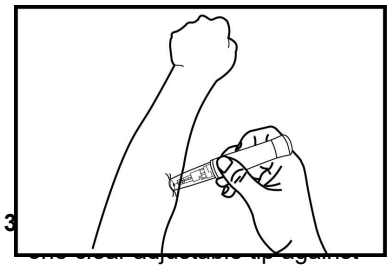
Please use the clear cap with the lancing device for AST testing



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

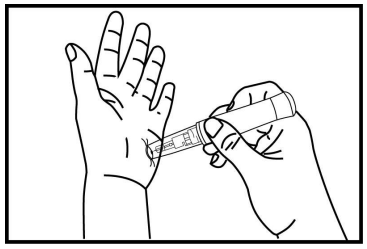


forearm or palm for a few

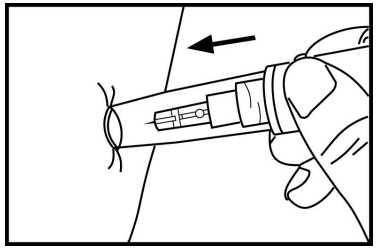


lthcare professional before test other sites than fingertip.
he first drop of blood sample.

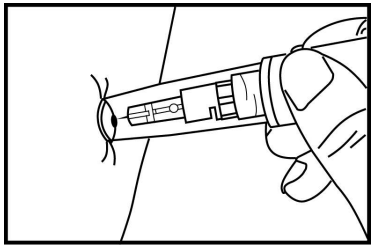
Running a Blood Glucose Test with Blood from Your Palm or Forearm (continued)



4. If you choose the palm, repeat step 1-3 to obtain a drop of blood sample.

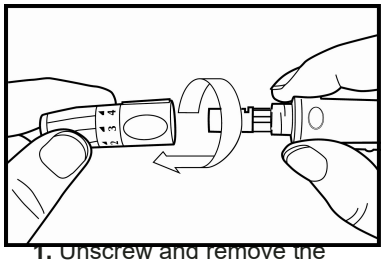


5. Press the trigger button to activate the lancing device.

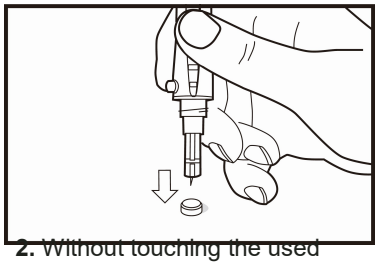


6. Hold the device against forearm or palm and increase pressure until the blood sample size is sufficient

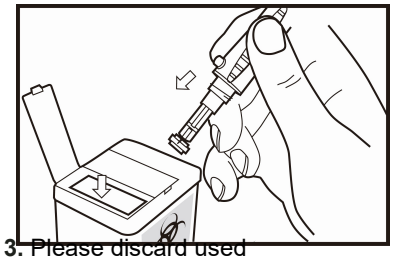
Discarding Used Lancets



1. Unscrew and remove the cap.



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



3. Please discard used disposable lancets according to the recommendations of your healthcare professional. Or discard the used disposable lancet into an appropriate sharps or biohazard container. After discarding, wash hands thoroughly with soap and water. Rinse and dry thoroughly.

Expected Values*

The EM44 Blood Glucose test strips are whole-blood referenced and calibrated for easier comparison to lab results. The American Diabetes Association recommends a post-meal glucose level of less than 180 mg/dl and a pre-meal glucose of 70–130 mg/dL*.

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 doctor immediately.

Note:

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.**

Comparing Your Meter Result to a Lab Results

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 your **EM44** 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

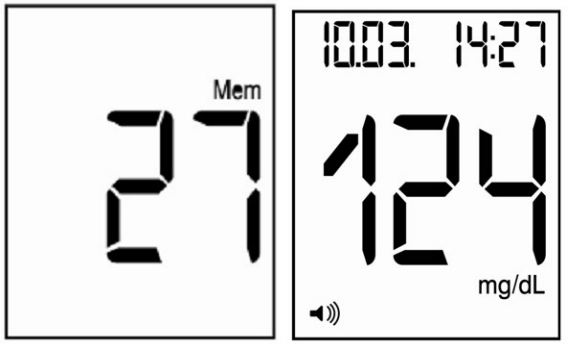
Memory, Storing Test Results

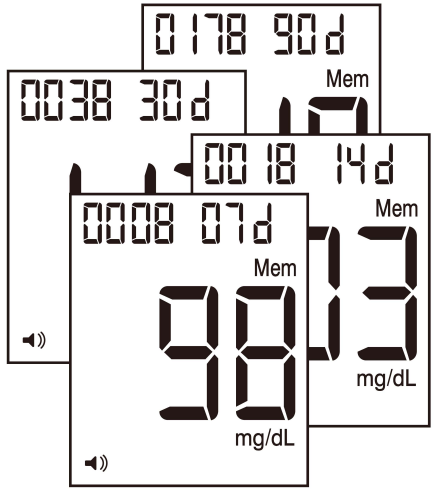
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

Note:

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 480 results are in memory, adding a new result causes the oldest one to be deleted.**
4. **Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.**

Viewing Test Results



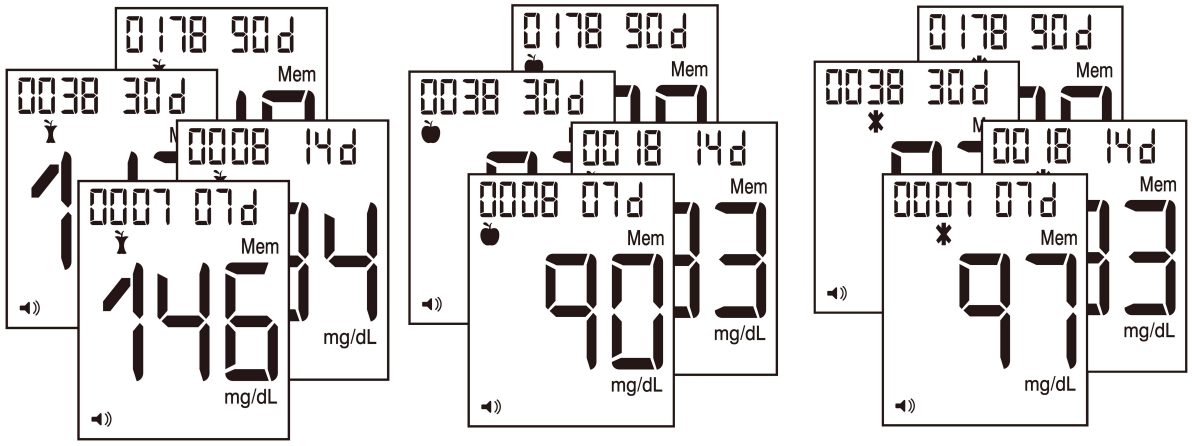


1. Short press on up or down button to enter the memory mode.

2. Press down button to view test results .The meter shows the number of total recordings first and then shows the result of this storage place.

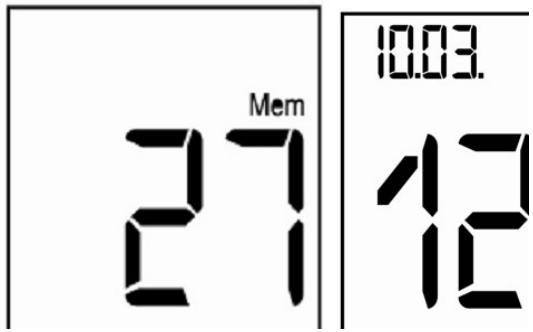
3. Or press up button to view 7, 14, 30 and 90 day averages.

Note: If there is no value available for average calculation, the display show “- - -” for average.



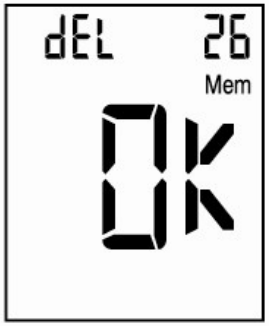
4. The 7, 14, 30 and 90 day average results shows in a order of all values, before meals values, after meals values and other marked values.

Deleting a single Test Result



1. While viewing results, if you would like to delete any record, take Memory # 26 for example, press ON/OFF button, keep it pressed and press down button in addition for two seconds.

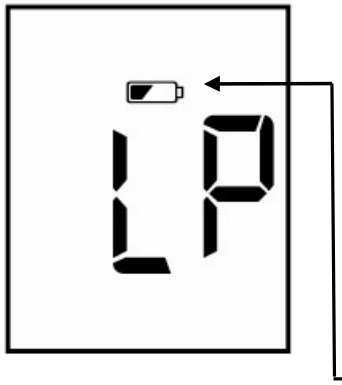
2. The display shows "dEL" on the top of the screen, press ON/OFF button to confirm the deletion.



3. The meter beeps and the display shows “OK”, the memory is successfully removed.

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses two batteries of CR2032 Lithium Cell 3V. Batteries will normally last for over 2000 tests. Other types of CR2032 Cell 3V batteries are also acceptable, yet the capacity of test times may differ. Install the batteries when you first use the meter or replace with new batteries when the "LP" message and the low battery symbol appear on the display.

Note:

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. **CR2032 Cell 3V batteries are available in shops. 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 and Disinfecting Your Meter and Lancing Device

Choosing the disinfectant

The recommended EPA-registered disinfected product is as follow:

PDI® Super SANI-CLOTH® Germicidal disposable wipe (EPA Reg. No.:9480-4)

Super Sani-Cloth germicidal wipe contains active ingredients: n-Alkyl (60% C_{14}, 30%C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chlorides and n-Alkyl (68%C_{12}, 32%C_{14}) dimethyl ethylbenzyl ammonium chlorides and they have been shown to be safe for use with the EM44 meter, but any other disinfectant product with the EPA registration number may be used on this device.
Please find the Super Sani-Cloth germicidal wipe in any pharmaceutical store or purchase on the PDI website: http://www.pdipdi.com/healthcare/surface_disinfect.aspx

Cleaning and Disinfection Instruction

Please keep the meter and lancing device free of dirt, dust, bloodstain, and water stains. EM44 blood glucose meter and lancing device should be used only on one patient and not shared. Follow these guidelines carefully to clean your meter

After every use, follow the cleaning instruction to prevent the growth of any microorganism and also to help improving the effectiveness of disinfection. Then follow disinfection instruction once per week which could effectively kill blood borne pathogens, such as viral hepatitis and prevent cross-contamination. Therefore, if the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

Cleaning Instruction: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold and use first germicidal wipe to remove heavy soil after every use.

Disinfection Instruction: Unfold a clean wipe and thoroughly wet all the surface of the meter, including the strip port and other connection port. Unfold a clean wipe and thoroughly wet all the surface of the lancing device, including cap or AST cap if used. Treated area must remain visibly wet for a full 2 minutes. Use additional wipe(s) is needed to assure continuous 2 minute wet contact time. Let the devices air dry for 0.5 minute. Do disinfection once per week.

Do:

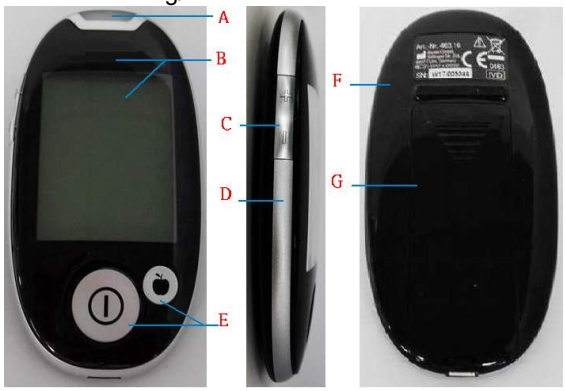
- Make sure the meter is turned off during cleaning and disinfection.
- Keep the test strip vials tightly closed when performing the cleaning and disinfection procedures because the fumes from the disinfectant may affect the performance of the strip
- After cleaning or disinfection, please perform the physical appearance and performance check of devices.

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.

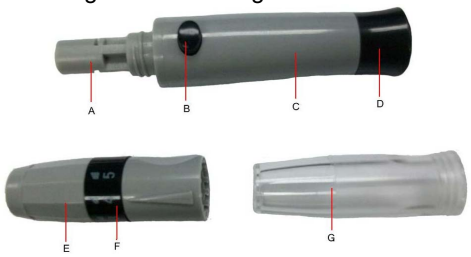
Note:
After disinfection, users' gloves should be removed and hands should be thoroughly washed with soap and water before proceeding to the next patient.

1. Meter clearing/disinfection area



Code	Name	Possibility of contact with blood
A	Strip Slot	High
B	Front Case	High
C	Side Button	High
D	Side Case	High
E	Front Buttons	High
F	Back Case	Medium
G	Battery Cover	Medium

2. Lancing device clearing/disinfection area



Code	Name	Possibility of contact with blood
A	Lancet holder	High
B	Trigger button	High
C	Body	High
D	Sliding barrel	High
E	Cap	High
F	Depth adjust ring	High
G	AST Cap	High

1-1. Physical Appearance check of the meter after each cleaning or disinfection

Check item	Accept Result
Is it clear to see through the transparency part, like display?	Yes
Is there NO erosion happened on the strip slot or other parts?	Yes
Is the labeling on the meter legible?	Yes
Action: If any of the results is “No” the user should call the Customer Care Service toll-free at 866-994-3345(Eastern Time, Mon-Fri 9:00AM~5:00PM) for assistance.	

1-2. Performance check of the meter

Steps	Check item	Accept Result
After each cleaning		
1. Press and hold on/off button for 3 sec.	Is meter powered on?	Yes
	Is meter beep?	Yes
2. Press and release up and down buttons.	Is it correctly stored in the memory?	Yes
	Is it clearly to read the result?	Yes
After each disinfection		

1. Insert test strip	Is meter powered on?	Yes
2. Apply Level 2 control solution	Any reading?	Yes
	Is the reading within control range?	Yes
3. Remove test strip	Is meter powered off?	Yes
4. Press and hold on/off button for 3 sec.	Is meter powered on?	Yes
	Is meter beep?	Yes
5. Press and release up and down buttons.	Is it correctly stored in the memory?	Yes
	Is it clearly to read the result?	Yes
Action: If any of the results is “No”, stop using the device. Please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM) for replacement with a new meter.		

2-1. Physical Appearance check of the lancing device after each cleaning or disinfection

Check item	Accept Result
Is there NO erosion happened on any parts?	Yes
Action: If any of the results is “No” the user should call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM) for assistance.	

2-2. Performance check of the Lancing device

Step	Check item	Accept Result
After each cleaning		
1. Cap the normal cap to the lancing device.	Can the cap be screwed on the lancing device?	Yes
2. Pull on the sliding barrel and then release.	Can the lancing device click?	Yes
3. Press trigger button.	Can the lancet be fired?	Yes
After each disinfection		
1. Install the lancet on the lancet holder.	Can the lancet be fixed on the lancet holder?	Yes
2. Cap the AST cap to the lancing device.	Can the AST cap be screwed on the lancing device?	Yes
3. Remove the AST cap. Recap the normal cap to the lancing device.	Can the cap be screwed on the lancing device?	Yes
	Can the penetration depth ring be adjusted?	Yes
4. Pull on the sliding barrel and then release.	Can the lancing device click?	Yes
5. Press trigger button.	Can the lancet be fired?	Yes
Action: If any of the results is “No”, please call the Customer Care Service toll-free at 866-994-3345(Eastern Time, Mon-Fri 9:00AM~5:00PM) for replacement with a new device.		

Cleaning and Disinfection Frequency

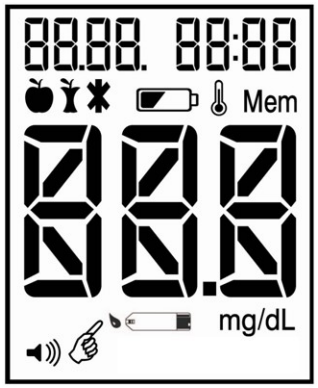
At least 14,600 validated cycles for the meter and lancing device were done and 10,000 cycles of cleaning and 4,600 cycles of disinfections were included. **4** cycles of cleaning per day and **1** cycle of disinfection per week with allow the user to use the device for **4** year.

Cleaning Frequency: 4 cycles/day X 365 days/year X **4** year warranty = 5840 cycles of cleaning
< 10,000 validated cycles of cleaning.

Disinfection Frequency: 1 cycle/week X 52 weeks/year X **4** year warranty = 208 cycles of cleaning
< 4,600 validated cycles of disinfection

4 year warranty is for properly cleaning and disinfection. After 4 year, the meter must be replaced with a new meter.

Maintenance and Testing

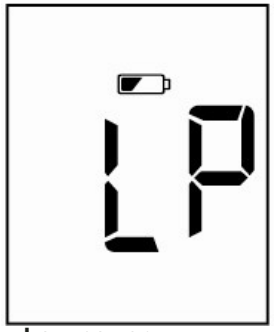


Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

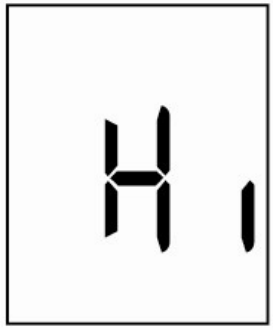
To make sure the display is working properly, turn off the meter. Press and hold ON/OFF button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.

Screen Messages and Troubleshooting

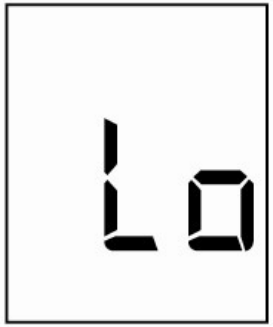
Never make treatment decisions based on an error message. If you have any concerns, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM).



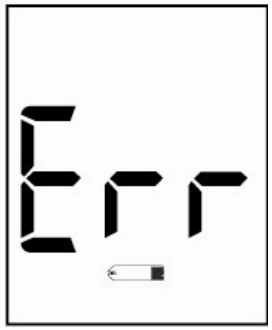
Low power
Action: Replace with new batteries.



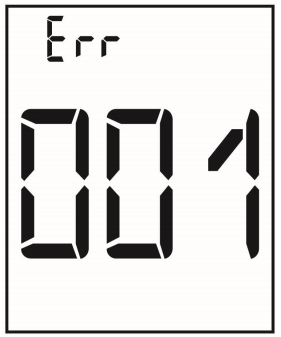
The test result is higher than 600 mg/dL.
Action: Test again. If the result is still the same, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.



The test result is lower than 20 mg/dL.
Action: Test again. If the result is still the same, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.

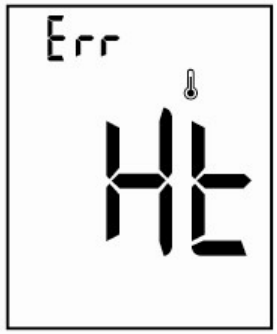


Humidified / Used strips
Action: Replace with a new strip.



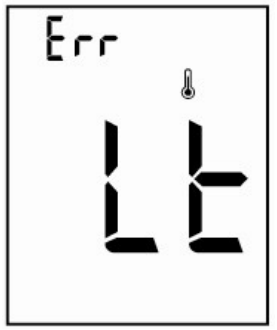
System fault
Action: Replace the batteries first. If 001 ERROR appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.

Less blood detected
Action: Discard the test strip and try to apply blood to a new test strip again.



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

Action: Relocate the meter to a location with temperature between 50°F-104°F (10°C-40°C).



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

Action: Relocate the meter to a location with temperature between 50°F-104°F (10°C-40°C).

Chapter 6: Technical Information

Specifications

Brand name		EM44 Blood Glucose Meter
Range		20~600 mg/dL
Response time		5 seconds
Memory sets		480 test results
Operating condition	Temp.	50°F -104°F (10°C-40°C)
	Relative Humidity	R.H. ≦ 90%
Storage and transportation condition	Temp.	35.6°F -86°F (2°C -30°C)
	Relative Humidity	40-85 % RH
Blood sample		0.6 µL
		Fresh blood from fingertip, palm, or forearm
Hematocrit (Hct)		20~60%
Power		CR2032 Lithium Cell 3V (2 pcs)
Battery life		Over 2000 tests
Device dimension H × W × D		3.8 x 2.0 x 0.6 inches
Weight		1.38 oz. (without batteries)
Principles		Electrochemical biosensor technology

Limitations

The test strips are used for fresh capillary whole blood samples.

1. DO NOT use neonate blood sample.
2. Extreme humidity may affect the results. A relative humidity greater than 90 % may cause incorrect results.
3. 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.
4. DO NOT reuse the test strips. The test strips are for single use only.
5. 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.
6. Altitude up to 10,000 feet above sea level has no effect on readings.

Healthcare Professionals – Please note these additional Limitations

7. Patients undergoing oxygen therapy may have inaccurate results.
8. 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)
9. Lipemic samples: Cholesterol level up to 500 mg/dL and triglycerides up to 3,000 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with EM44 Pro Glucose Meter.
10. Critically ill patients should not be tested with EM44 Pro glucose meters.
11. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Exogenous Interference data				
Exogenous Substances	**highest Conc. tested**	**interference or no**	**Bias @ blood glucose Conc.**	**Note**
Acetaminophen	8 mg/dL	Yes	14.2%@80 mg/dL 14.9%@120 mg/dL	The highest no interference concentration is 7 mg/dL
Ascorbic Acid	4 mg/dL	No	NA	
Dopamine	5.2 mg/dL	Yes	31.0%@80 mg/dL 18.2%@120 mg/dL	The highest no interference concentration is 2.6 mg/dL
Gentisic Acid	6 mg/dL	No	NA	
Ibuprofen	50 mg/dL	No	NA	
L-Dopa	4 mg/dL	Yes	16.3%@80 mg/dL 11.4%@120 mg/dL	The highest no interference concentration is 2 mg/dL
Methyldopa	2 mg/dL	No	NA	
Sodium Salicylate	50 mg/dL	No	NA	
Tetracycline	1.5 mg/dL	No	NA	
Tolbutamide	100 mg/dL	No	NA	
Galactose	20 mg/dL	No	NA	
Maltose	20 mg/dL	No	NA	
Xylose	8 mg/dL	Yes	10.1%@80 mg/dL	The highest no interference concentration is 6 mg/dL
Fructose	30 mg/dL	No	NA	
Manose	10 mg/dL	No	NA	
Sucrose	50 mg/dL	No	NA	
Xylitol	200 mg/dL	No	NA	
Glipizide	8 mg/dL	No	NA	

Endogenous Interference data				
Endogenous Substances	**highest Conc. tested**	**interference or no**	**Bias @ blood glucose Conc.**	**Note**
Bilirubin- unconjugated	25 mg/dL	No	NA	
Cholesterol	500 mg/dL	No	NA	
Creatinine	30 mg/dL	No	NA	
Triglycerides	1000 mg/dL	No	NA	
Uric Acid	15.9 mg/dL	Yes	14.3%@80 mg/dL 17.5%@120 mg/dL	The highest no interference concentration is 11.9 mg/dL

Device Information

EM44 SMBG System,
EM44 Blood Glucose Test Strips,
EM44 Blood Glucose Meter,
EM44 Level 2 Control Solution,
EM44 Level 3 Control Solution

Reference:

* American Diabetes Association. Standards of medical care in diabetes-Table 10 Diabetes care. 2011; Vol. 34, Suppl. 1, S21.

Manufacturer:

EPS BIO TECHNOLOGY CORP.
No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30077
TEL：+886-3-6686868 FAX：+886-3-6686866
E-mail：info@epsbio.com.tw Website：http://www.epsbio.com.tw

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

No. 32 Xinlian RD. Pingjiang Suzhou P.R. China 215031
TEL：0086 (512) 67217661 FAX：0086 (512) 67217663
E-mail：guopings@xinda-medical.com

Lancet

Meets the requirements of MDD 93/42/EEC

Manufacturer:

SAE HAN MEDICAL CORP.

700-113 PUB GOT-DONG, IL SAN-GU, GOYANG-CITY, KYUNGGI-DO, KOREA
TEL：82-31-923-4330 FAX：82-31-923-4331
E-mail：saehan@saehanmed.com

Warranty

EPS warrants the original purchaser for a period of 4 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.

Please read EM44 User's Manual before operation. If you have any questions and/or need assistance, please contact us as follows:
Within the USA, call toll-free: 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.
Outside the USA, call your authorized representative or write to:
Customer Service E-mail: info@epsbio.com.tw

Distributor:

GEMCO MEDICAL

5640 Hudson Industrial Parkway P.O. Box 429, Hudson, OH 44236
Customer Line： 800-733-7976 Fax：330-342-9444
Website：http:// www.gemcomedical.com

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