MDT2 BLE

Self-Monitoring Blood Glucose System

User's Manual

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

Dear MDT2 BLE SMBG System Owner,

Thank you for using the **MDT2 BLE** 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 **MDT2 BLE** Self-Monitoring Blood Glucose System.

Thanks again for choosing the **MDT2 BLE** SMBG.

Intended Use

The **MDT2 BLE Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh venous blood and 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. Alternate 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 **MDT2 BLE** Blood Glucose meter and accessories are working together to measure the amount of glucose in your blood. The system includes:

- **MDT2 BLE Blood Glucose Meter**
- **MDT2 BLE Glucose Test Strips (10 pcs)**
- **Carrying Case**
- **CR2032 3V Battery (2 ct.)**
- **Lancets (10 pcs)**
- **Lancing device**
- **AST Lancing Device Cap**
- **User's Manual**
- **Test Strip Instructions**
- **Self-Test Log Book**
- **MDT2 BLE Level 2 Control Solution**
- **Glucose Control Solution Instructions**
- **Quick Reference Guide**

Optional Accessories

- **MDT2 BLE Level 3 Control Solution**

Note:
1. **MDT2 BLE Level 2 Control Solution is included with the system.**
2. **MDT2 BLE Level 3 Control Solution is available. For purchase, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).**

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 Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.

Note:

Although the MDT2 BLE 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

- **MDT2 BLE** blood glucose meter is designed and approved for testing fresh venous blood and capillary whole blood samples from your fingertip, palm or forearm. The meter is for *in vitro* diagnostic use ONLY (for testing outside the body). It should not be used to diagnose or screen for diabetes.
- **MDT2 BLE** blood glucose meter can only be used with **MDT2 BLE** 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.

- It`s not necessary to require servicing, and maintenance while in use.
- It`s prohibited to change or modify the glucose device at will.

Note:

- Consult with your healthcare professional before testing on your fingertip, 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 10,000 feet above sea level has no effect on readings.
- It should not be used to diagnose or screen for diabetes.

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 Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.
- Please read your test strip instructions carefully for additional health-related information.

Table of Contents

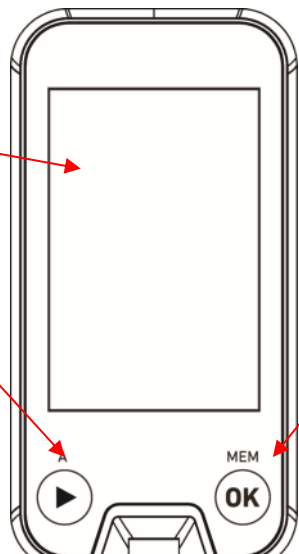
Chapter 1: Understanding Your Meter

The MDT2 BLE Blood Glucose Meter

Display-
Shows results, messages, and results stored in memory.

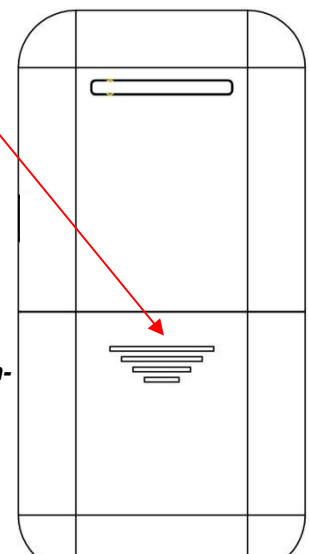
Left (▶) Button-
Press to enter memory, adjust setting, and scroll through results.

Test Strip Slot-
Insert test strip here.

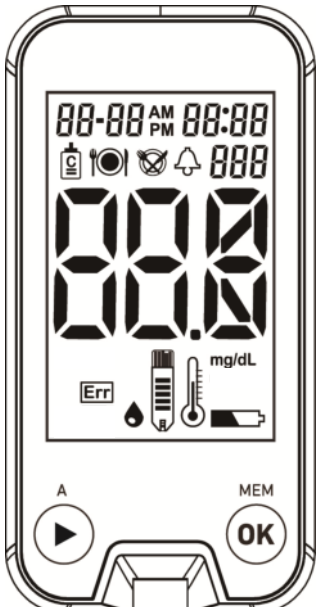


Battery Door-
Flip open the battery door by pushing the tab in the direction of the arrow.

Right (OK) Button-
Press to enter memories, adjust setting, and scroll through results.



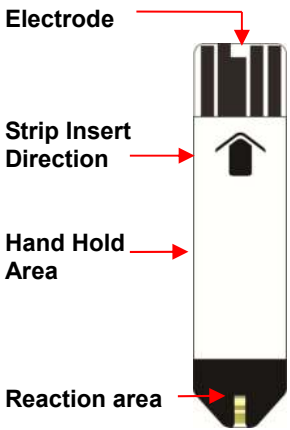
Explanation of Meter Symbols



88-88	Date (on the left side)	AM	AM (Before Noon)
88:88	Time (on the right side)	PM	PM (After Noon)
	Control Solution		AC (Before Meal)
	Alarm		PC (After Meal)
888	Record	Err	Error
	Insert strip		Temperature
	Application of blood	mg/dL	Unit
			Battery

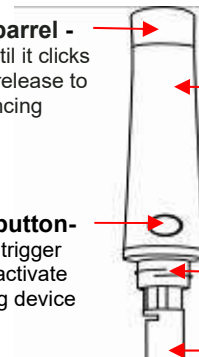
The MDT2 BLE Accessories

Blood Glucose Test Strip



Test Strip Bottle
Control Solution Bottle

Lancing Device



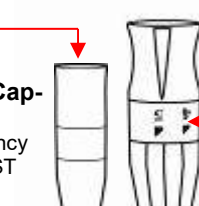
Sliding barrel -
Pull on until it clicks and then release to enable lancing device.

Sleeve-
Hand Hold Area

Trigger button-
Press the trigger button to activate the lancing device

Hub-
Unscrew or Recap the Cap.

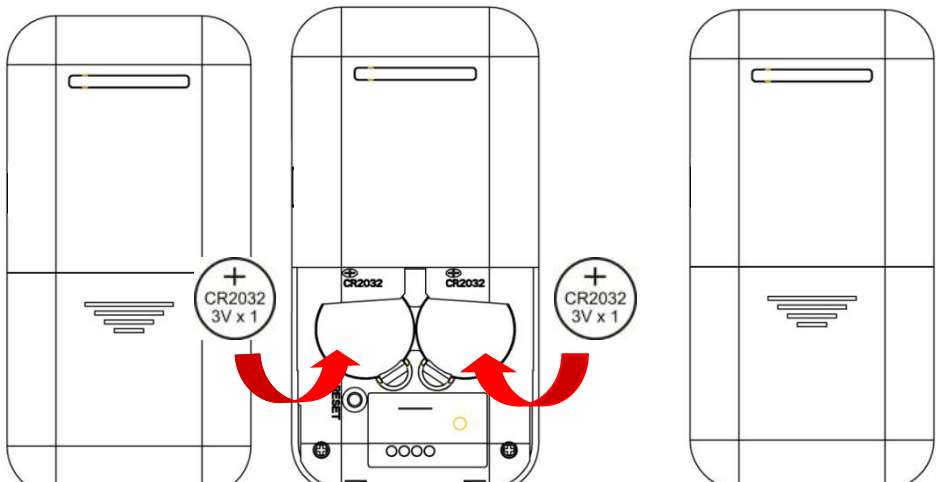
Carrier-
Insert the lancet into the carrier



AST Lancing Device Cap-
Use this transparency cap for AST testing

Adjustable tip-
Select the desired penetration depth

Inserting Batteries



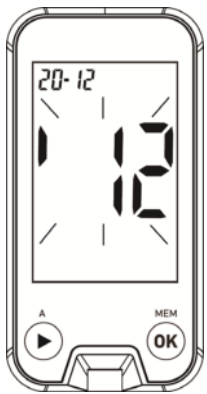
1. Open the battery door on the back of the meter by pushing the tab in the direction of the arrow.

2. Insert two batteries. The meter will beep to confirm the batteries are inserted correctly.

3. Put the battery door back in place and snap it closed.

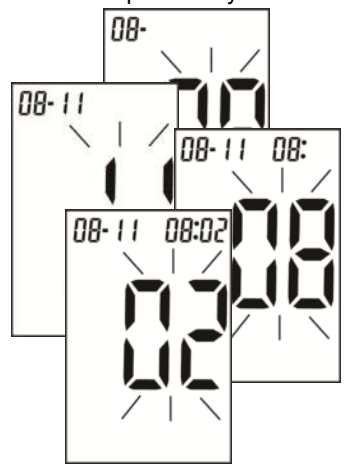
Setting The Time and Date — First Time Use

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

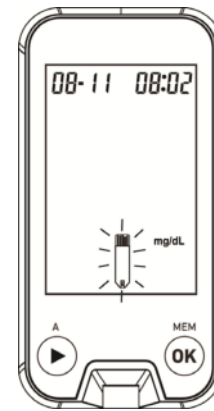


1. After inserting batteries, the meter turns on automatically.

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



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



4. The icon of  flashes on the display. The meter is ready to run the test.

The unit of blood glucose meter is set at mg/dL. If the display shows the wrong unit, please contact your local dealer for repair.

Using MDT2 BLE Blood Glucose Test Strips

- Use only with **MDT2 BLE** 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 36°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.
- **MDT2 BLE** 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 **MDT2 BLE** control solution 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 **MDT2 BLE** 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.

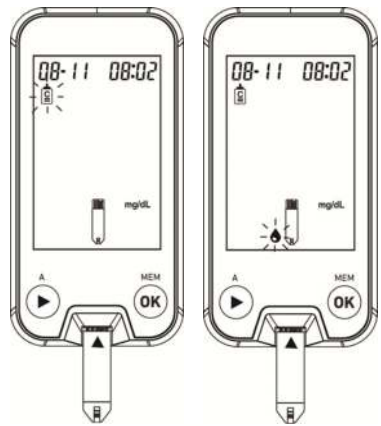
About The Control Solutions

- Use with **MDT2 BLE** Blood Glucose test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for 3 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 36°F - 86°F (2°C~30°C). Do not freeze.
- If you would like to purchase **MDT2 BLE** level 2 and level 3 Control Solutions**,** please contact your local dealer.

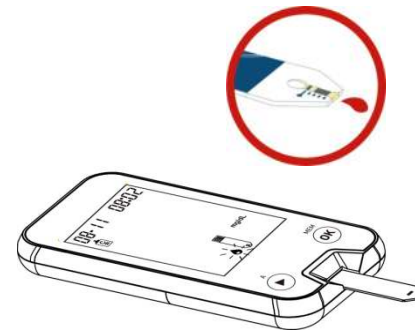
Running A Control Solution Test

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

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



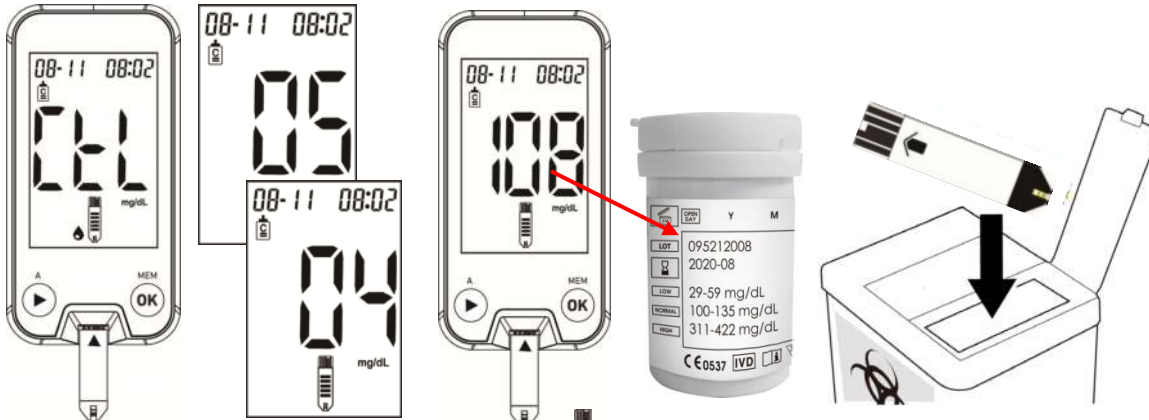
2. Press ▶ to set the mode of control solution " ". Press **OK** to confirm the setting.



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

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

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



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

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

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

8. When the icon of shows, the meter beeps, you have enough control solution for the test.

9. The meter starts to count down from 5 seconds and will show the results. A result appears on the display.

10. Don't remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.

11. 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 – Level 2 and Level 3. 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:

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?	If you have followed the steps properly, contact physician. If you continue to have problems please contact Customer Support at 1-866-994-3345.

Chapter 3: Testing Your Blood Glucose

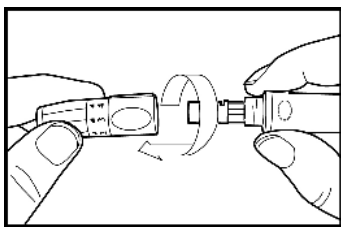
Using the Lancing Device

- 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 and supplies".

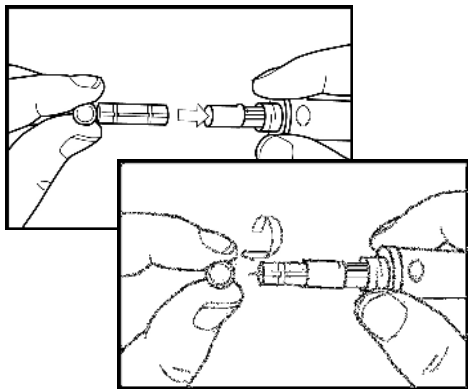
Note:
Used test strips and lancets are considered bio-hazardous waste in accordance with U.S. local regulations and should be handled as if capable of transmitting infection. The users may discuss methods for disposing used test strips and lancets with their doctor.

Inserting a Lancet into the Lancing Device

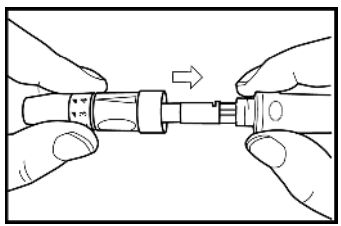
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.

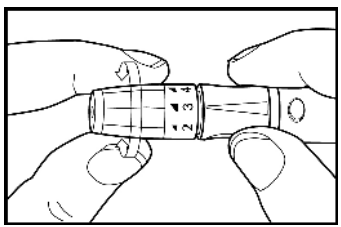


2. Insert the lancet into the lancing device firmly then twist off the protective cover.

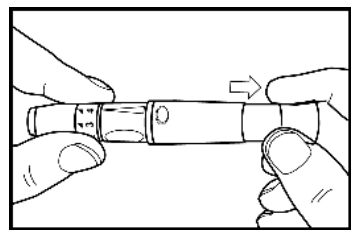


3. Recap the front cap.

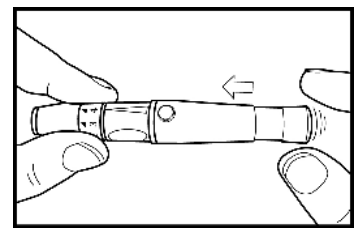
Note:
Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.



4. Select the desired penetration depth.



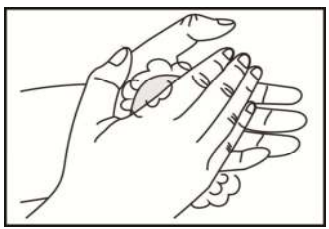
5. Pull on the sliding barrel of the lancing device until it clicks and then release.
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.



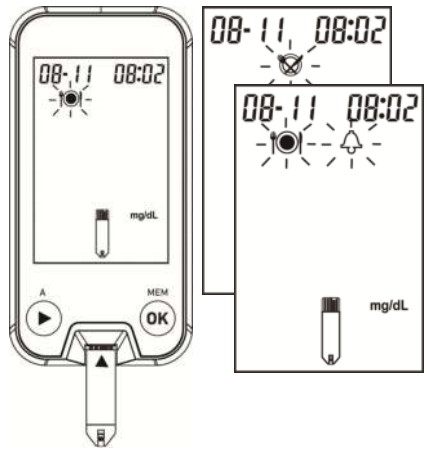
6. Set the lancing device aside until later in the test.

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

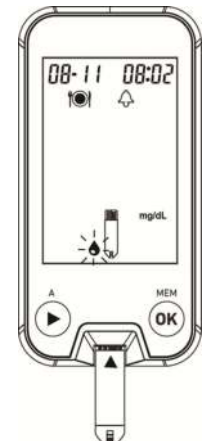


1. Wash your hands with soap and warm water. Rinse and dry thoroughly.



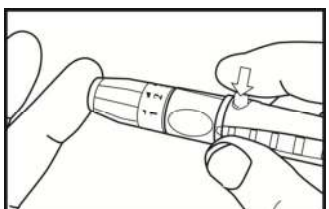
2. Insert a test strip into the meter in the direction of the arrow and the icon flashes.

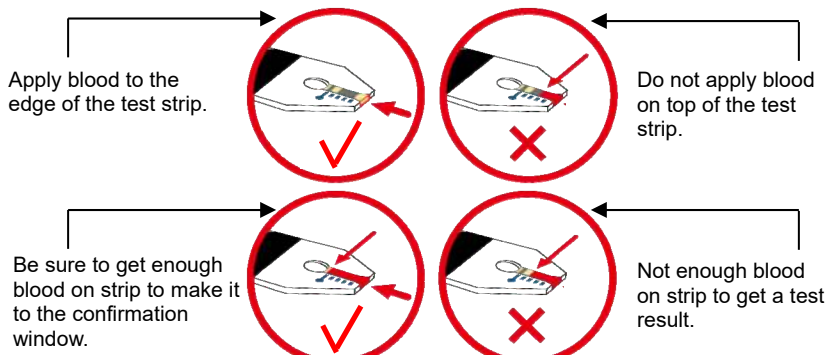
3. Press ▶ to set , or and press **OK** to confirm the setting.



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

5. Gently squeeze your finger to assist the flow of blood.



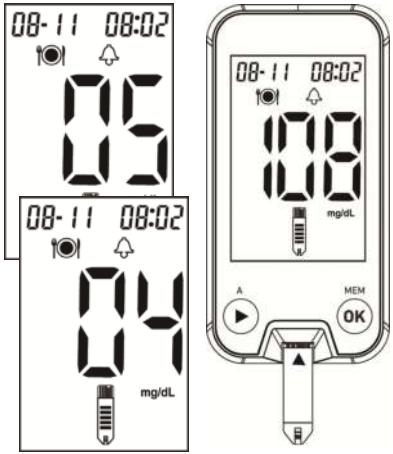


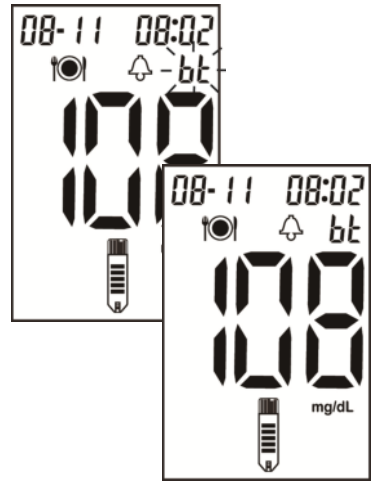
6. Place the lancing device against the tip or side of your finger; press the trigger button to activate the lancing device.

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

8. Touch the blood drop to the tip of the transparent window of the test strip. **Do not put blood on top of the strip.**

9. Be sure to get enough blood on the strip's reaction zone. Otherwise, an inaccurate reading may result.





Note:
If you didn't run "bt" function after testing results, please refer to the section "Running with your GlucoManager™ by Bluetooth" to upload multiple testing results in one time.

10. When the icon of shows, the meter beeps, sufficient blood is applied to the strip's reaction zone.
11. The meter starts to count down from 5 seconds.
12. A result will appear on the display afterwards.
13. The icon of "**bt"** will flash after a beep and the meter is connecting to your GlucoManager™.
14. When this test result is uploaded, the icon of "**bt"** will stop to flashing.

Alternate Site Testing (AST)

Understanding Alternate 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 you have just taken insulin
- After injecting rapid-acting insulin (two hours or less)

AST Results:

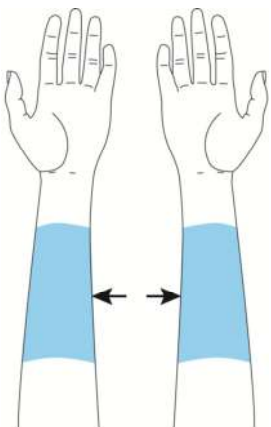
- If the blood glucose test result from the alternate site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of an alternate site result, do a fingertip test to confirm the result.
- If you often do not notice when your blood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

Caution:

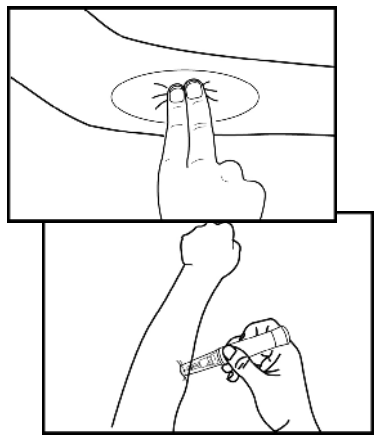
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm and palm samples.
- Measurements from alternative site testing should never be used to 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 Forearm

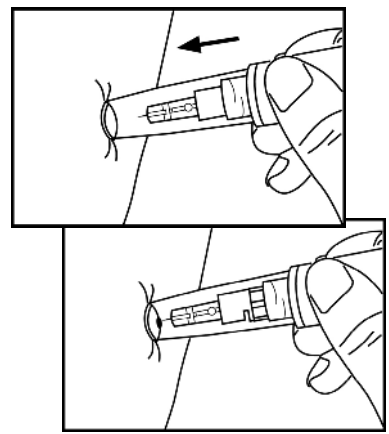
Please use the clear cap with the lancing device for AST testing



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



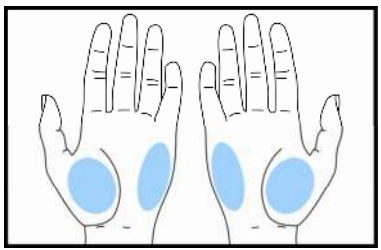
2. Press and hold the device with a clear adjustable tip against the forearm.

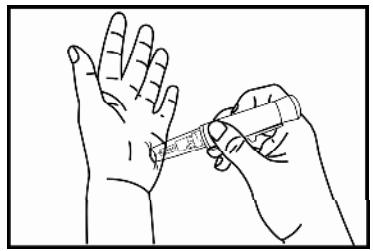


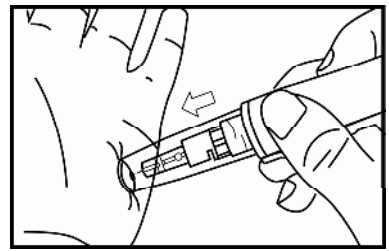
3. Press the trigger button to activate the lancing device.

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

Running A Blood Glucose Test With Blood From Your Palm







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

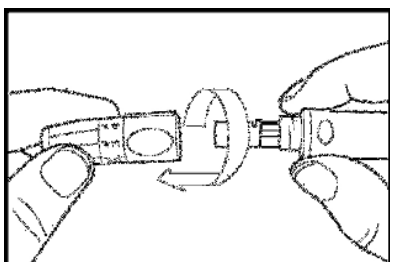
2. Press and hold the device with a clear adjustable tip against the palm

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

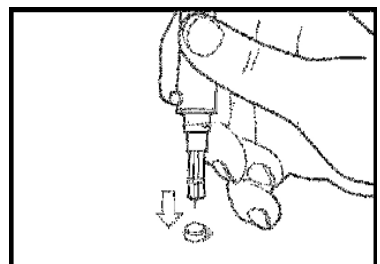
4. Hold the device against palm and increase pressure until the blood sample size is sufficient.

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

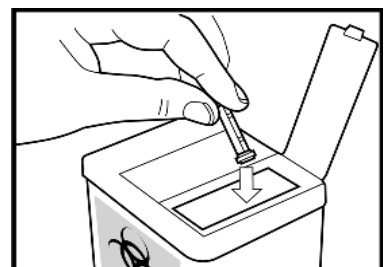
Discarding Used Lancets



1. Unscrew and remove the cap.



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



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

Understanding Your Test Results

Expected Values*

The **MDT2 BLE** 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*. For people with diabetes: please consult with your doctor for the appropriate blood glucose range.

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.

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

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.**

Comparing Your Meter Result To A Lab Result

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

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than **MDT2 BLE** 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, Transfer

Memory, Transferring 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.

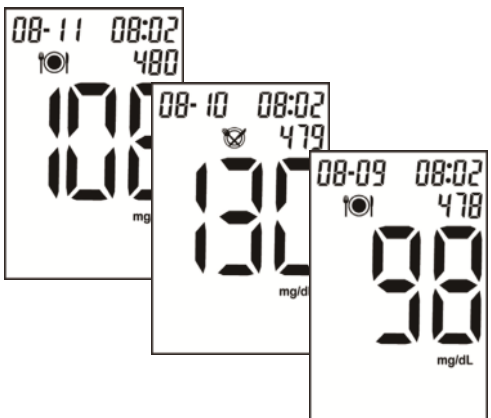
For further analysis, you can transfer test results to your personal or tablet computer etc. through Bluetooth and then use GlucoManager™ to check your glucose value.

Note:

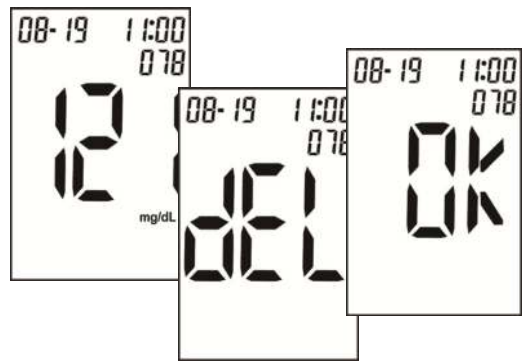
1. **Do not change your therapy based on one individual result in memory.**
2. **The memory is not lost when you replace the battery. You do need to check that the time and date are still correct for future readings. See Section "Setting the time and date" in Chapter 1.**
3. **Once 480 results are in memory, adding a new result causes the oldest one to be deleted.**
4. **Control Solution values will NOT be included in the memory.**
5. **To transfer data, you can choose transfer modes of Bluetooth. To run 2 transfer modes at the same time, an incorrect upload will occur.**

Viewing & Deleting Test Results – Memory Mode

You can review them at any time without inserting a test strip. The display flashes the icon of .
Each review requires the user to go back to the main screen (testing mode) by pressing **OK** for 2 seconds and then get into the Memory Mode.



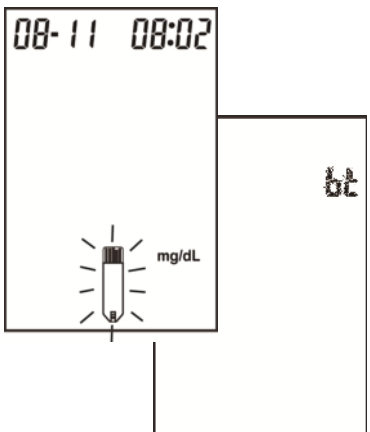
1. Press ► to review all results in order from records of 480 to 001.

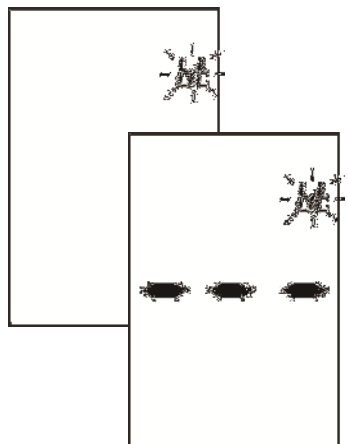


2. Select a test result to delete, press ► **and OK** for 3 seconds together and display shows **"dEL".**
3. Press **OK** to delete the test result. The display shows **OK**.
4. Press ► to cancel the delete and the meter will turn off in 1.5 minutes automatically.

Running With Your GlucoManager™ by Bluetooth

Multiple test results can be transferred to your mobile with Bluetooth Dongle.

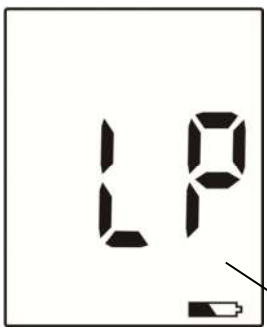




1. Turn on the meter and strip flashes.
2. Click ◀ to get into the Bluetooth mode and the icon of "**bt**" appears.
3. When "**bt**" flashed, the meter is connecting GlucoManager™.
4. When "**---**" appears, the meter is uploading the data to GlucoManager™.
4. When "**OK**" appears, all data is uploaded into GlucoManager™.

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses two CR2032 3V batteries. Batteries will normally last for more than 2000 tests. Other types of CR2032 3V batteries are also acceptable, but the capacity of test times may differ. Install 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 installed. Please press and hold power button or insert the test strip to turn your meter on. The meter will turn off automatically. Or you can press and hold power button to turn your meter off.

Low battery symbol

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. See Section "Setting the time and date" in Chapter 1.**
3. **CR2032 3V 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 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 **MDT2 BLE** Blood Glucose Meter, but any other disinfectant product with the EPA registration number may be used on this device.

Please purchase in retail stores like Walmart and Office Depot. You could also purchase on the PDI website:http://www.pdipdi.com/ or online retail sites like amazon.com, medline.com, and Expression medical supply Inc. http://www.exmed.net/.

Cleaning and Disinfection Instruction

Please keep the meter and lancing device free of dirt, dust, bloodstain, and water stains. Please follow the following guidelines to clean and disinfect your meter and lancing device.

The meter and lancing device have been validated so that they can withstand cleaning for up to 9 times per day. 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. If the devices 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. Let the devices air dry for 0.5 minute. Do disinfection once per week.

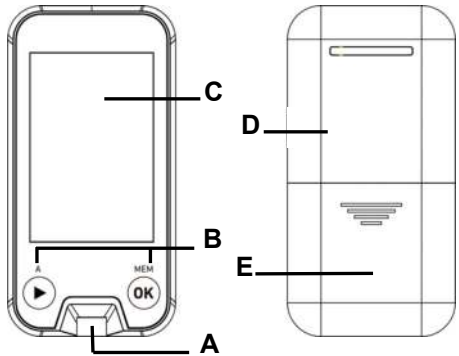
Do:

- 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.
- Please follow the instruction on page 41 to 43.

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.

1. Meter clearing/disinfection area



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

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

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
Are the strip slot and other components free from erosion?	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 Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.	

Performance check of the meter

Steps	Check item	Accept Result
After each cleaning		
1. Press and hold ⏻ button for 3 sec.	Is meter powered on?	Yes
	Did the meter beep?	Yes
2. Press and release ← or → button.	Is the testing result correctly stored in the memory?	Yes
	Can the result be clearly read?	Yes

After each disinfection		
1. Insert test strip	Is the 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 ⏻ button for 3 sec.	Is meter powered on?	Yes
	Did the meter beep?	Yes
5. Press and release ← or →button.	Is the testing result correctly stored in the memory?	Yes
	Can the result be clearly read?	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 Standard Time, Mon-Fri 8:00AM~6:00PM) for replacement with a new meter.		

Physical Appearance check of the lancing device after each cleaning or disinfection

Check item	Accept Result
Are all components free from erosion?	Yes
Action: If any of the results is "No" the user should call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.	

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 Standard Time, Mon-Fri 8:00AM~6:00PM) for replacement with a new device.		

Cleaning and Disinfection Frequency

The meter and lancing device can sustain 14,000 cleaning cycles and 208 disinfection cycles which represents cleaning 9 times per day and disinfecting (with a pre-clean step) once per week over the 4 year use life of the device.

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

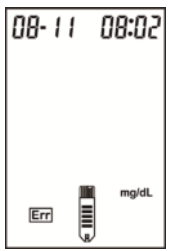
Maintenance and Testing

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.)

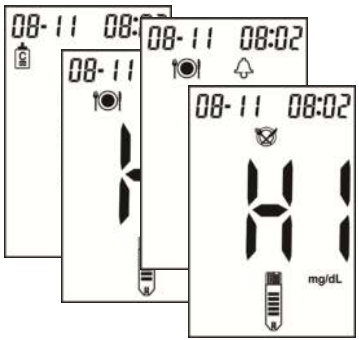
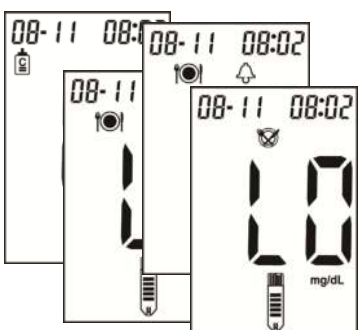
To make sure the display is working properly, turn off the meter. Press and hold power button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.

Screen Messages and Troubleshooting

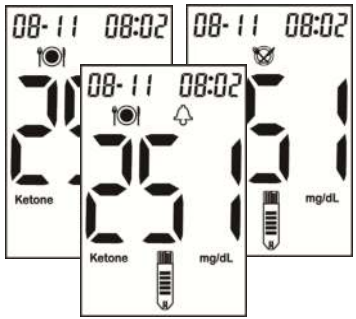
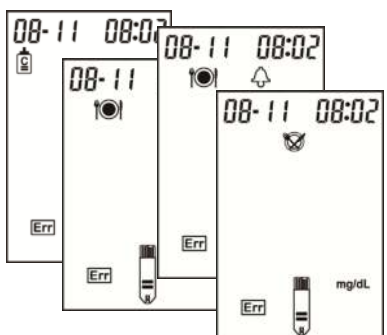
Never make treatment decisions based on an error message. If you have any concerns, call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).

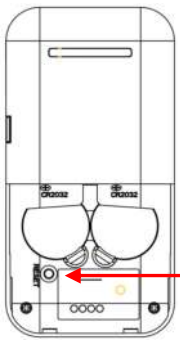
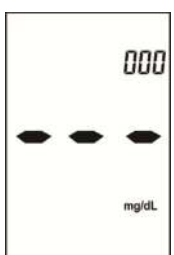
Message	*What it means?*	*What to do?*
	**Humidified / Used strips** The meter has detected a problem with the test strip.	**Repeat the test with a new strip.** Refer to pages 26-28 for information on sample application.
	**Low power** The meter batteries do not have enough power to perform a test.	**Replace the new batteries.**

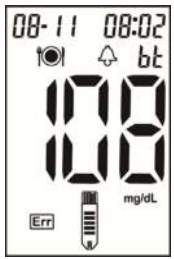
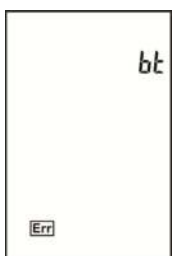
Message	*What it means?*	*What to do?*
	**Memory Error**	**Replace the batteries first.** If **ERROR 005** appears again, please contact your local dealer.
	**System error** There may be a problem with the meter.	**Replace the batteries first.** Refer to pages 14 and 40. If this error message appears again, please contact your local dealer.

Message	*What it means?*	*What to do?*
	**Test result is higher than 600 mg/dL (33.3 mmol/L).**	**Re-check your glucose level.** If the result is HI again, obtain and follow instructions from your healthcare professional without delay.
	**The test result is lower than 20 mg/dL (1.1 mmol/L).**	This may require immediate treatment according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.

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

Message	*What it means?*	*What to do?*
	**The test result is more than or equal to 251 mg/dL.** The function of Ketone detector doesn't apply to the mode of control solution.	**Re-check your glucose level.** If the result appears again, obtain and follow instructions from your healthcare professional without delay.
	**Volume detector error** The volume of blood or control solution is NOT enough.	**Repeat the test with a new strip.** If **Err** appears again, please contact your local dealer.

Message	*What it means?*	*What to do?*
 **The Resetting button**	**Reset the meter**	The re-setting button on the back side of the meter is to let the meter back to the initial status. To re-set the meter, set your meter in the time and date setting mode or memory mode first and then press the re-setting button for 3 seconds.
	**No result in memory** The meter doesn't run any test yet.	**You can still perform a blood glucose test and get an accurate test result.**

Message	*What it means?*	*What to do?*
	**Bluetooth transfer error** Error happened to upload a single test result by Bluetooth.	**Use the way of uploading multiple results.** Refer to the page 39 of “Running with your GlucoManager™ by Bluetooth”. If **ERROR** appears again, please contact your local dealer.
	**Bluetooth transfer error** Error happened to upload multiple test results by Bluetooth.	**Check the connection between GlucoManager™ and meter first.** Please re-run the page 41 of “Running with your GlucoManager™ by Bluetooth”. If this error message appears again, please contact your local dealer.

Chapter 6: Technical Information

Specifications

Brand name		**MDT2 BLE** 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%
Strip Storage and transportation condition	Temp.	38°F ~86°F (2°C ~30°C)
	Relative Humidity	R.H. 40~85 %
Meter Storage and transportation condition	Temp.	-4°F ~122°F (-20°C ~50°C)
	Relative Humidity	R.H. ≦ 90%
Blood sample		0.6 µL
		Fresh blood from fingertip, palm, or forearm
Hematocrit (Hct)		20~60%
Range of atmospheric pressure		700 ~1060 hPa
Power		CR2032 3V Battery (2 pcs)
Battery life		Over 2000 tests
Display dimension		55.7 x 36.7 mm
Device dimension H × W × D		98 x 49.9 x 11.3 mm
Weight		49 grams (without batteries)
Principles		Electrochemical biosensor technology

Limitations

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

1. DO NOT use neonate blood sample.
2. Not to be used for diagnosis or screening of diabetes.
3. Alternate site testing with this system can be used only during steady-state blood glucose conditions.
4. Measurements from alternate site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.
5. Extreme humidity may affect the results. A relative humidity greater than 90 % may cause incorrect results.
6. The system should be used at a temperature between 50°F and 104°F (10°C and 40°C). Outside this range, the system may get incorrect results.
7. DO NOT reuse the test strips. The test strips are for single use only.
8. Hematocrit: The hematocrits between 20% and 60% will not significantly affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
9. Altitude up to 10,000 feet above sea level has no effect on readings.
10. The below substances up to the test concentration will not affect the test results.

Interfering substance	Concentration tested up to (mg/dL)
Gentisic Acid	6
Ascorbic Acid	4
Ibuprophen	50
Methyldopa	2

Sodium Salicylate	50
Tetracycline	1.5
Tolbutamide	100
Galactose	20
Maltose	20
Manose	10
Sucrose	50
Xylitol	200
Glipizide	8
Bilirubin	25
Cholesterol	500
Creatinine	30
Triglycerides	1000
Fructose	30

11. Interference was observed with the substances below at the concentrations listed.

Interfering substance	**Interference observed at (mg/dL)**
Acetaminophen	8
Dopamine	5.2
L-Dopa	4
Xylose	8
Uric Acid	15.9

Technical Information

***Bluetooth*® Wireless Technology**

This device complies with United States Federal Communication Commission (FCC) standards. The device complies with FCC Part 15 Rules. Operation of the device is subject to the following conditions:

1. This device may not cause harmful interference and
2. must accept any interference received, including interference that may cause undesired operation.

Compliance with these guidelines means that under normal, daily circumstances, the device should not affect the operation of other devices. In addition, the device should operate normally in the presence of other devices.

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off Bluetooth wireless technology on the meter. Changes or modifications to the device not expressly approved by EPS bio Technology Corp. could void the user's authority to operate the device.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by

one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance (i.e. the manufacturer) could void the user's authority to operate the equipment.

CAUTION:

To assure continued FCC compliance:

1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.
2. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.
3. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Device Information

MDT2 BLE SMBG System,
MDT2 BLE Blood Glucose Test Strips,
MDT2 BLE Blood Glucose Meter,
MDT2 BLE Level 2 Control Solution,
MDT2 BLE 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

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 **MDT2 BLE** 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 Standard Time, Mon-Fri 8:00AM~6:00PM). 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

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

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