



Voice Blood Glucose Monitoring System

User's Manual for Blood Glucose Meter

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

Dear EASYMAX User,

Thank you for using the **EASYMAX** Blood Glucose Monitoring (BGM) 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 **EASYMAX** BGM System.

Thanks again for choosing the **EASYMAX** BGM System.

Intended Use

The **EASYMAX Voice** BGM 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. 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. Always wash hands well with soap and water as well as dry them well before and after testing, handling the meter, test strips, or lancing device. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

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: Considerations for Blood Glucose Monitoring and Insulin Administration" (2024) https://www.cdc.gov/injection-safety/hcp/infection-control/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

The System Includes

The **EASYMAX Voice** blood glucose meter with battery, the **EASYMAX** blood glucose test strips*, the **EASYMAX** glucose control solutions*, the **EASYMAX** lancing device*, and sterile lancet for single use*.

*Some items may not be included in the kit. They are a separate purchase.

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 BGM 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 **EASYMAX Voice BGM 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

- **EASYMAX Voice** blood glucose meter is designed and approved for testing fresh 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.
- **EASYMAX Voice** blood glucose meter can only be used with **EASYMAX** Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimens.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect readings. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car, 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 non-ketotic 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.

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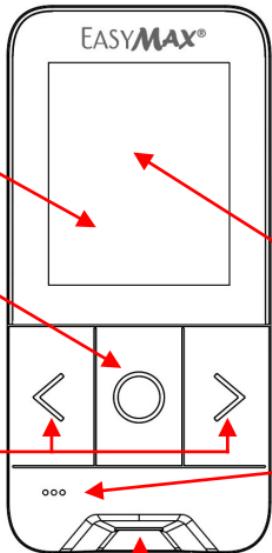
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Chapter 1: Understanding Your Meter

The EASYMAX Voice Blood Glucose Meter

Display-

Show results, messages, and results stored in memory.



Power Button-

Press to confirm the setting.

Right & Left Button-

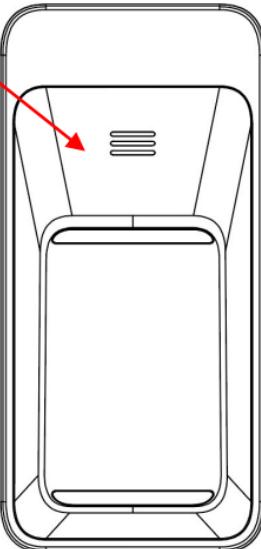
Press to enter 7/14/30/90 memory, adjust setting, and scroll through results.

Test Strip Slot-

Insert a test strip here.

Battery Door-

Flip open the battery door by pushing the tab down and pulling



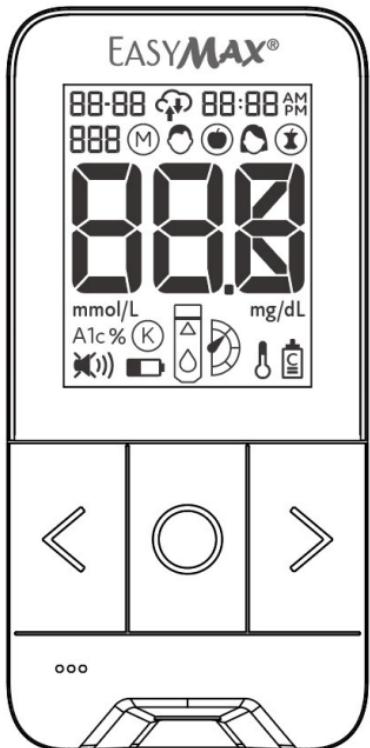
NFC sensor -

Receive data through the smartphone with the NFC tag.

Voice Buzzer -

Two voice choice of male and female.

Explanation of Meter Symbols



88-88	Date (on the left side)	88:88	Time (on the right side)
	AC (before meal)		PC (after meal)
	Male voice		Female voice
mg/dL	Unit of measurement		memory
mmol/L			
AM	AM (before noon)	PM	PM (after noon)
	Insert a strip & Apply blood glucose indicator	888	Result
	Temperature		Battery
	Blood volume detection		Control solution test

The EASYMAX Accessories

Blood Glucose Test Strip

Electrode

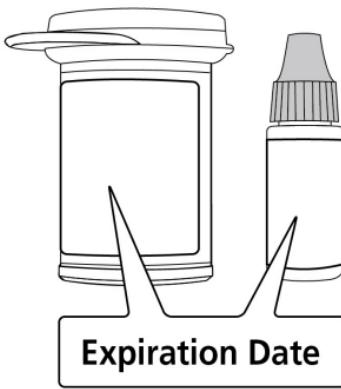
Strip Insert
Direction

Hand Hold
Area

Reaction area

Blood collection
area

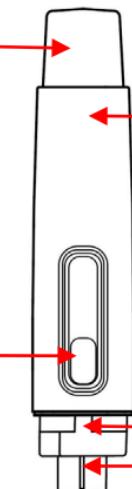
Test Strip Bottle Control Solution Bottle



Lancing Device

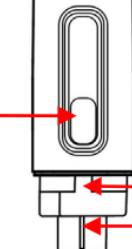
Sliding barrel -

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

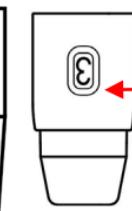
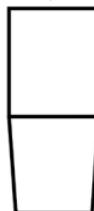


Trigger button-

Press the trigger button to activate the lancing device



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



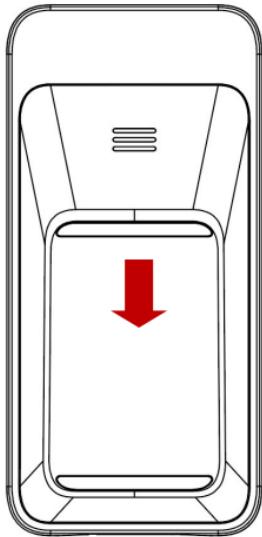
Sleeve-
Hand Hold
Area

Hub-
Unscrew or
Recap the Cap.

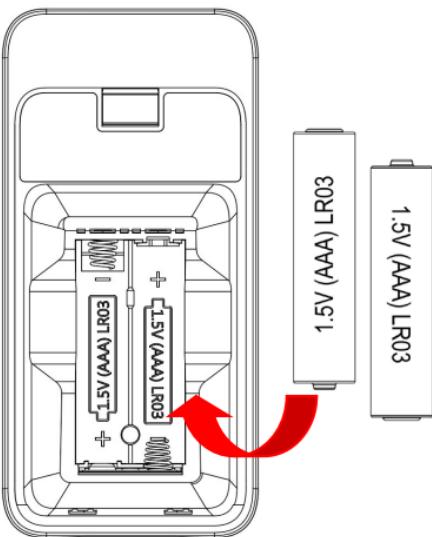
Carrier-
Insert the lancet
into the carrier

Adjustable tip-
Select the
desired
penetration depth

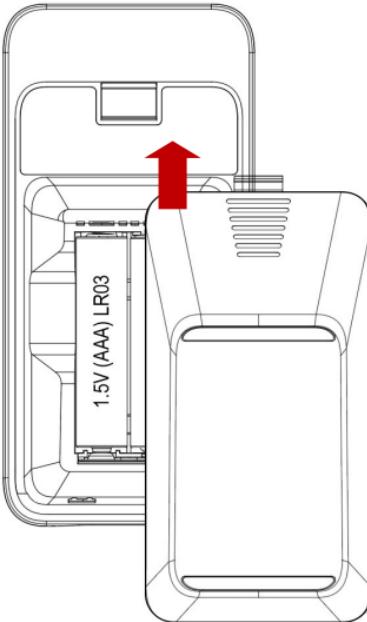
Inserting Batteries



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

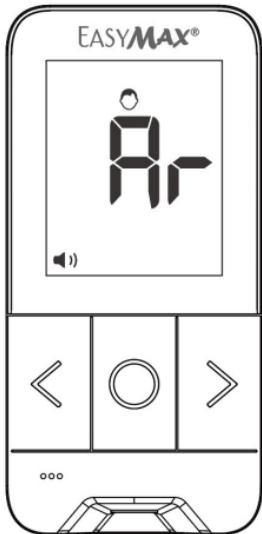


2. Insert a battery. The meter will beep to confirm the batteries are inserted correctly.

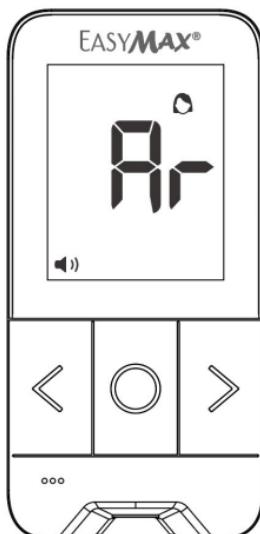


3. Put the battery door back in place and snap it closed.

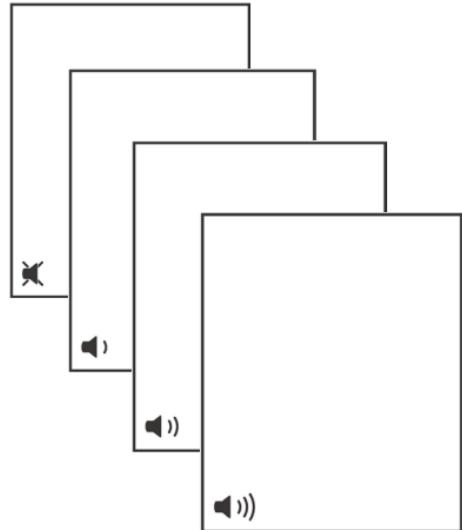
Setting The Voice And Volume — First Time Use



1. Press **Power** button to turn on the meter. Press **Right or Left** button to select male or female voice.



2. And press **Power** button to confirm the setting.

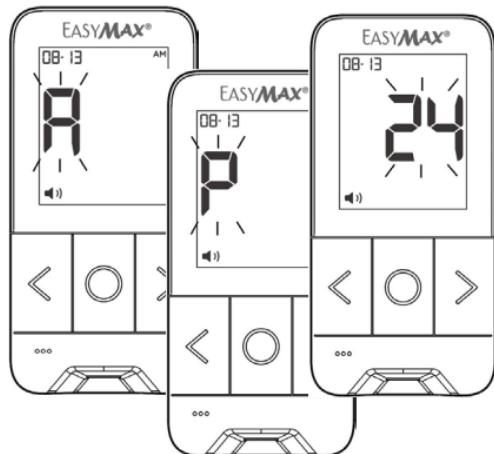
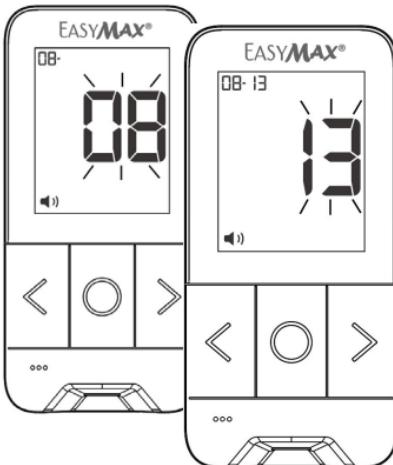
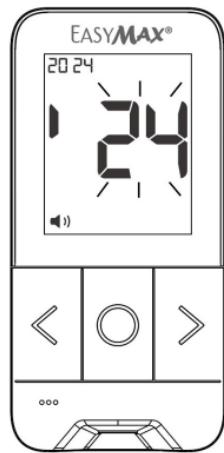


3. Repeat step 1 and 2 to set the volume.

NOTE: Press Power Button to turn on the meter and then press Right button to re-set the voice, volume, time and date.

Setting The Year and Hour Clock

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 flashes at the center of the display. Press **Right or Left** button to adjust the year and Press **Power** button to confirm the setting.
3. Repeat step 2 to select P, A or 24 mode and then set the time. (P=PM, A=AM, 24=24hr mode.)

NOTE: If the display shows the wrong setting, please press Right and Left buttons together to re-set for 2 seconds.

Using EASYMAX Blood Glucose Test Strips

- Use only with **EASYMAX Voice** 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 12 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.
- **EASYMAX Voice** Blood Glucose Monitoring 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 **EASYMAX** 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:

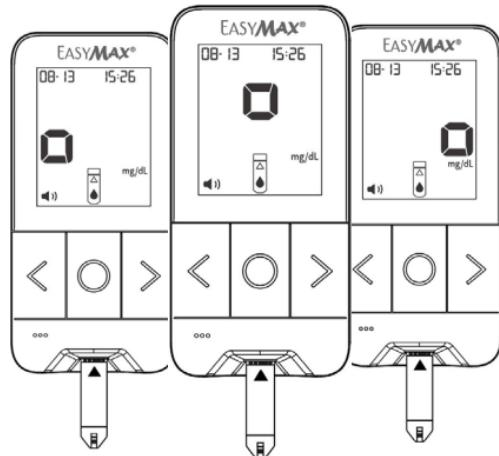
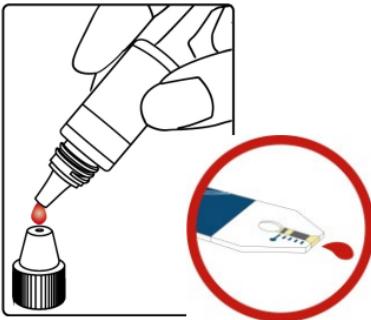
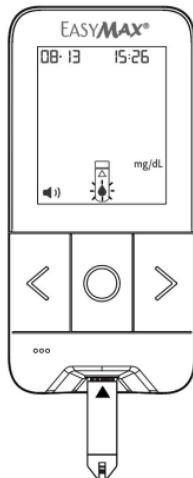
- You use the **EASYMAX Voice** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing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

About The Control Solutions

- Use with **EASYMAX** Blood Glucose test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- Control solutions can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store control solution at room temperature, between 36°F - 86°F (2°C~30°C). Do not freeze.
- If you would like to purchase **EASYMAX** level 2 and level 3 Control Solutions, please contact your local dealer.

Running a Control Solution Test

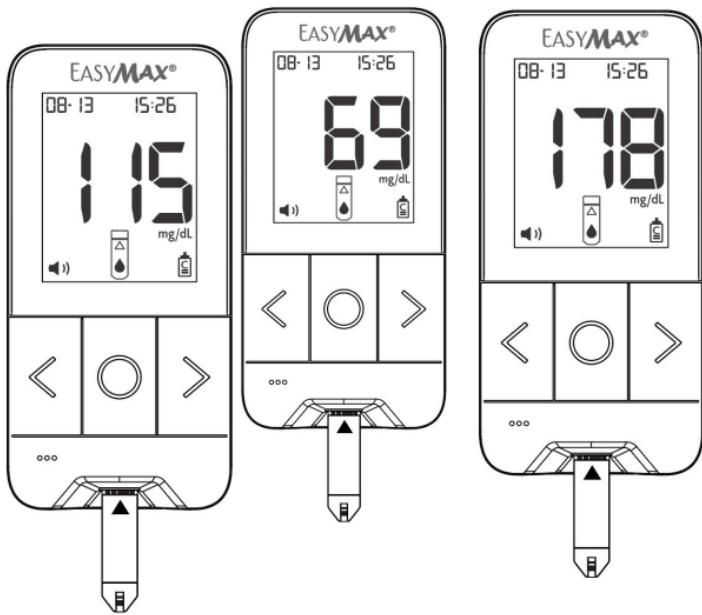
You need the meter, a test strip, and control solution.



1. Put a test strip into the meter in the direction of the arrow and the icon of shows itself.
2. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip of the control solution cap.
3. Touch the drop to the collection area at the end of the test strip.
4. When the icon of shows, the meter beeps, you have enough control solution for the test.
5. The meter starts to count down from 5 seconds.

NOTE :

- Do not put control solution on top of the test strip.
- EASYMAX® Voice Meter will automatically identify your control solution test, so that results will be NOT included in the memory of blood test.



7. The meter will automatically identify the results in control solution mode with  icon.

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



9. 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

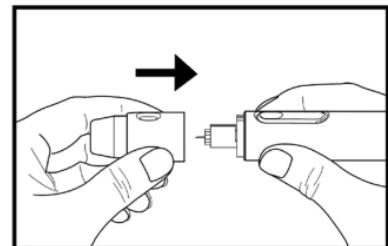
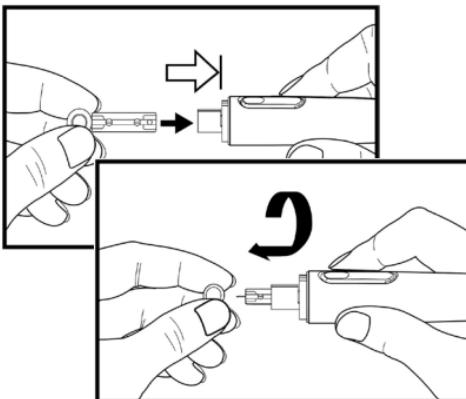
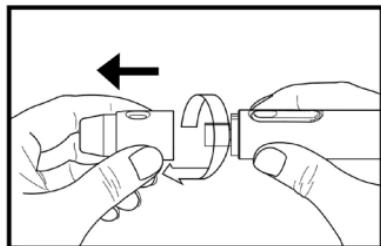
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.
- If the meter and lancing device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

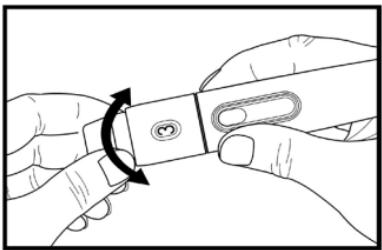


1. Unscrew the Cap.

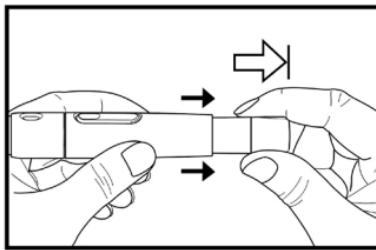
2. Insert the lancet into the lancing device firmly then twist off the protective cover.

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.

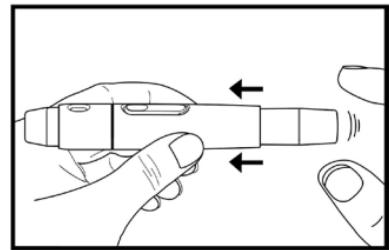


4. Select the desired penetration depth.



5. Pull on the sliding barrel of the lancing device until it clicks and then release.

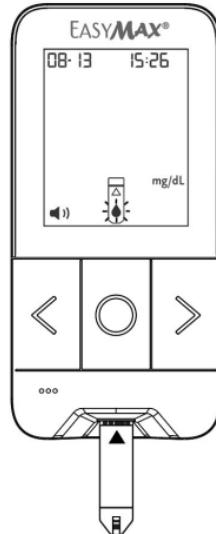
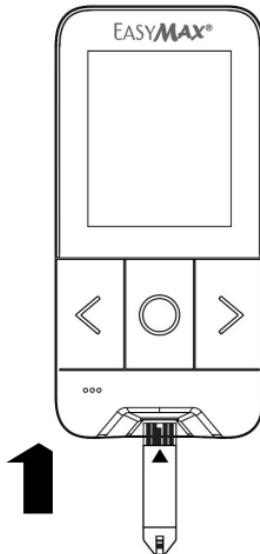
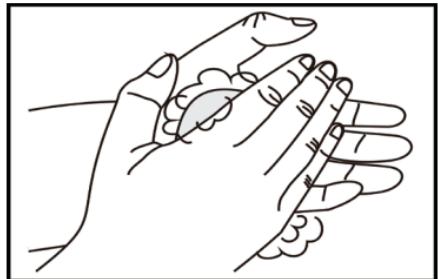
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.



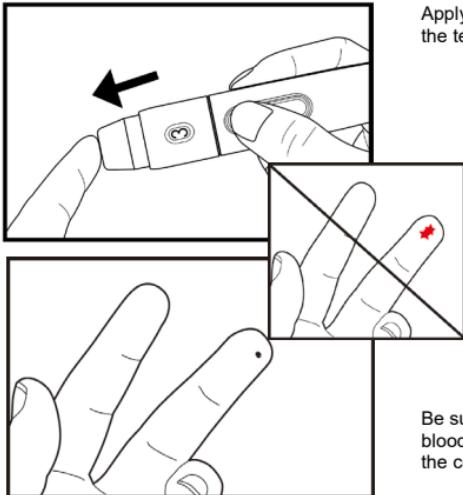
6. Set the lancing device aside until later in the test.

NOTE: 1. Select 1-2 for soft or thin skin, 3-4 for average, and 5-6 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.

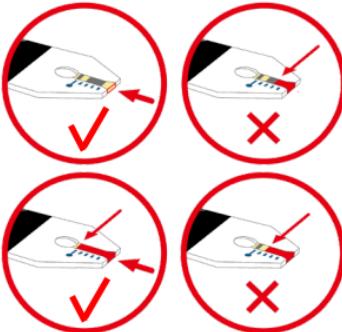
Running A Blood Glucose Test With Blood From Your Fingertip



1. Wash your hands with soap and warm water. Rinse and dry thoroughly.
2. Put a test strip into the meter in the direction of the arrow. The meter turns on.
3. When the blood drop flashes on the display, the meter is ready to obtain a drop of blood from your fingertip.



Apply blood to the edge of the test strip.



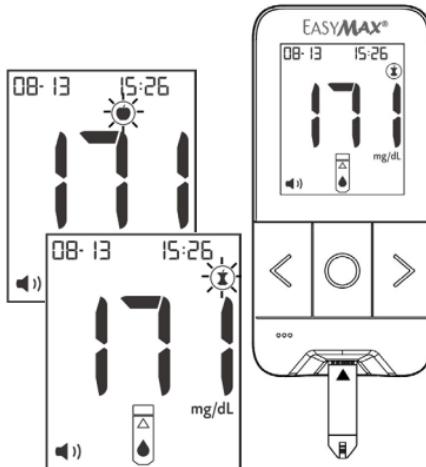
Do not apply blood on top of the test strip.

Be sure to get enough blood on strip to make it to the confirmation window.

Not enough blood on strip to get a test result.

4. Place the lancing device against the pad of your finger. Press the trigger button to activate the lancing device.
5. Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.

6. Touch the blood drop at 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.



7. The meter will beep when enough blood has entered the strip's reaction zone. The result will appear on the display after 5 seconds. Press **Left & Right** button to set or and press **Power** button to confirm.
8. Remove the test strip and the meter turns off automatically.

NOTE: please make sure to apply blood when the blood drop appears on the display.

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:

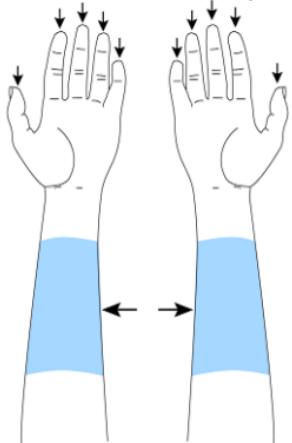
- If the blood glucose test result from the alternate site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of an alternate site result, do a fingertip test to confirm the result.
- If you often do not notice when your blood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

Caution:

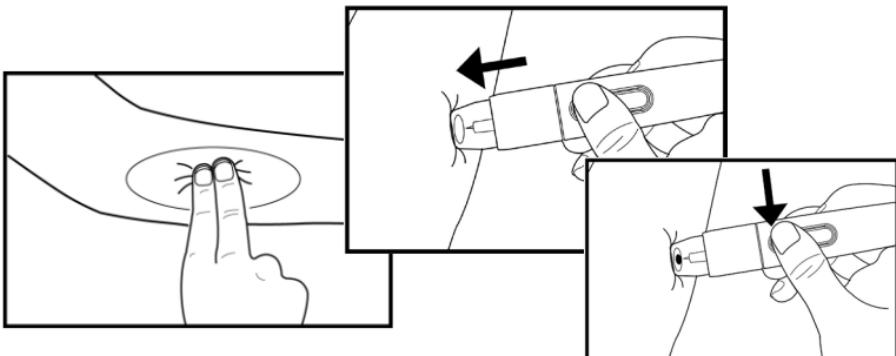
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm and palm samples.
- Measurements from alternative site testing should never be used to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

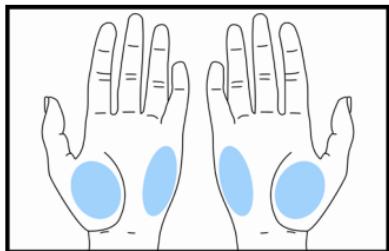


2. Massage the puncture area of forearm for a few seconds.
3. Press and hold the device with a clear adjustable tip against the forearm.
4. Press the trigger button to activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.
5. Wipe away the first drop with a tissue and use the second drop.

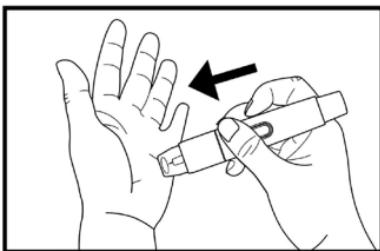
Note:

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

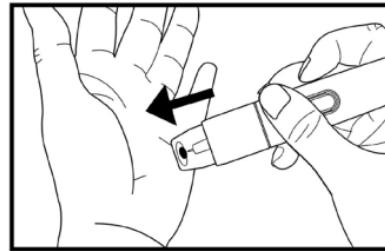
Running A Blood Glucose Test With Blood From Your Palm



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

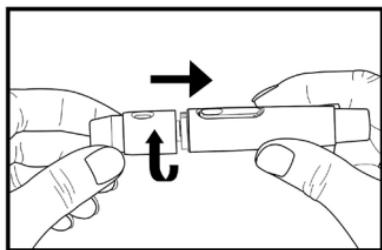


2. Press and hold the device with a clear adjustable tip against the palm

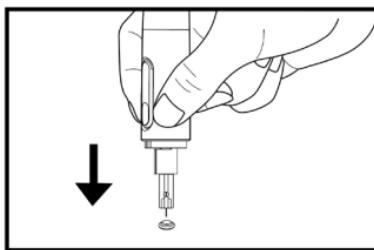


3. Press the trigger button to activate the lancing device.
4. Hold the device against palm and increase pressure until the blood sample size is sufficient.

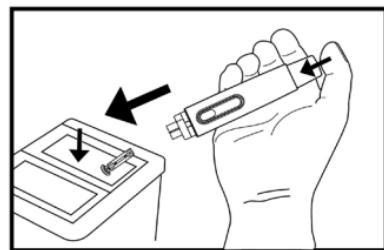
Discarding Used Lancets



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.
4. After discarding, wash hands thoroughly with soap and water. Rinse and dry thoroughly.

Understanding Your Test Results

Expected Values*

The **EASYMAX** Blood Glucose test strips are plasma-calibrated for easier comparison to lab results. The American Diabetes Association recommends for non-diabetic: post-meal <140 mg/dL, and pre-meal <100 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. *Diabetes care*. 2024; Vol. 47, Suppl. 1, S20–S42 | <https://doi.org/10.2337/dc24-S002>

NOTE:

1. **Extremely high humidity may affect the test results. A relative humidity greater than 85% 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 **EASYMAX Voice** 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 880 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.

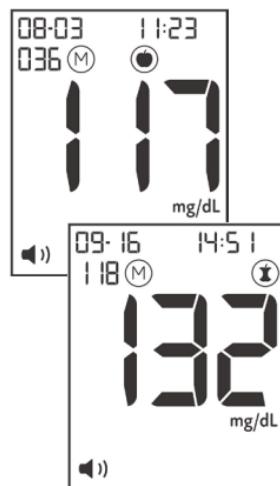
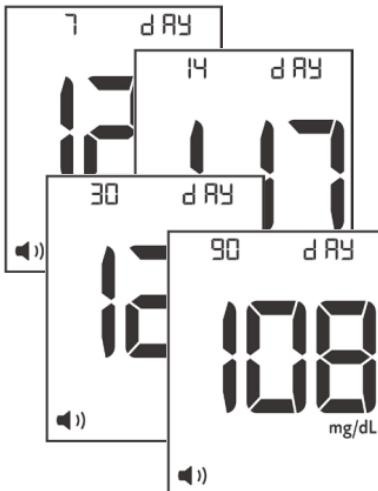
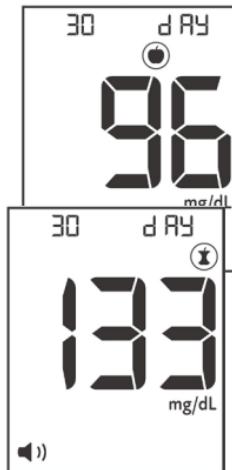
For further analysis, you can transfer test results to your personal or tablet computer etc. through NFC and then use **EzGluco** app to check your glucose value.

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 880 results are in memory, adding a new result causes the oldest one to be deleted.
4. If you don't set "  " mode, control Solution values will be included in the memory.

Viewing & Deleting Test Results

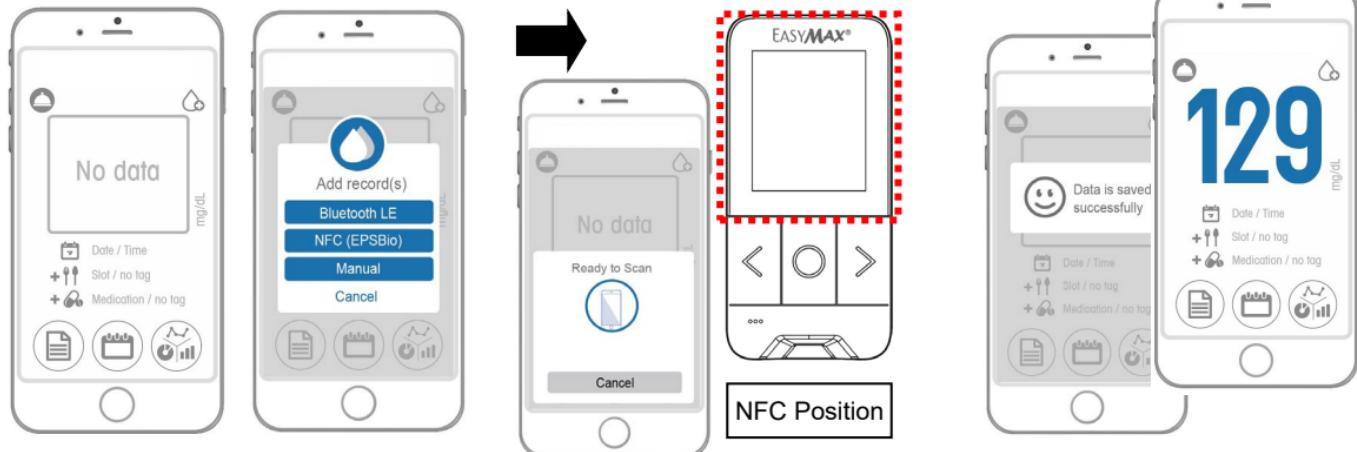
The meter provides 7, 14, 30 and 90 days averaging to help track your blood glucose trend.



1. Press **Power** button to turn on the meter.
2. Press **Right or Left** button to view averages of 30-day in / and averages for 7/14/30/90 days.
3. Repeat step 1 and press **Right or Left button** to view individual test results.
4. To delete all test results, press **Right & Left** button for more than 3 seconds and display shows "dEL". Then press **Power** button to confirm the deletion.
5. Press **Right or Left** button to keep reviewing the results, or press **Power** button for more than 3 seconds to go back to testing mode.

Running With Your Smartphone

Test results can be transferred to your mobile with NFC. To Transfer data, the meter can be turned on or off.



1. Open the **EzGluco** app of your phone and tap  and choose NFC to get ready to scan data.

NOTE:

1. Assure your personal smartphone comes with NFC function before you activate the data transmission.

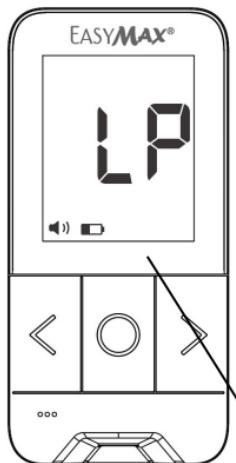
Please check where your smartphone's NFC antenna is located. While transmitting, make sure the position of NFC from your smartphone Ecos the button parts of your glucose meter.

2. Make sure you only use a personal smartphone to transmit the data from your personal glucose meter.

2. Let your mobile be close to the meter buttons, in order to make transactions of glucose data with **EzGluco** app.
3. After transferring all data, the glucose meter shows "data is saved successfully" and the glucose meter shows "nFC OK" on the screen.

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries are also acceptable, but the capacity of test times may differ. 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.

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. 1.5V (AAA) battery is 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

Use **only** The recommended EPA-registered disinfected product: **PDI® Super SANI-CLOTH® Germicidal disposable wipe (EPA Reg. No.:9480-4)**, which has been proven to be safe to use with the **EASYMAX Voice** Blood Glucose Meter and lancing device. **It is effective against HIV, Hepatitis C virus (HCV), and Hepatitis B virus (HBV).**

Please purchase in retail stores like Walmart and Office Depot. You could also purchase on the PDI website: <http://www.wearepdi.com/> or online retail sites like amazon.com, medline.com, and ebay.com.

The meter and lancing device has been tested to withstand cleaning and disinfection up to **6 times daily for 5 years** and up to **1 times per week in 5 years**, respectively.

What's the difference between Cleaning and disinfection?

Cleaning is the removal of the visible dirt and debris from the meter and lancing device, but does not reduce the risk for transmission of infectious diseases.

Disinfection (if performed properly) reduces the risk of transmitting infectious diseases (bloodborne pathogens from your meter and lancing device).

Warning: If the devices are being operated by another person who is providing testing assistance to the user, the meter should be disinfected prior to use.

The following parts should be cleaned and disinfected:

Meter

- The area around slots and openings (do not get any moisture in slots or openings)
- The meter display
- The entire meter surface

Lancing device

- The entire lancing device surface
- The cap

Cleaning Instruction:

1. After each use, open and unfold the germicidal wipe to remove heavy soil. Ensure all blood and other body fluids are thoroughly cleaned from surfaces and objects before disinfection.
2. Dry the device as needed with a clean paper towel.

Disinfection Instruction:

1. Before disinfecting, follow the cleaning instructions mentioned above.
2. Use a new wipe and ensure the treated area remains visibly wet for a full 2 minutes. Allow the devices to air dry for 30 seconds.
3. Unfold a fresh wipe and thoroughly wet all surfaces of the meter, including the strip port and other connection ports.
4. Similarly, wet all surfaces of the lancing device, including the cap or AST cap if applicable.
5. If necessary, dry all meter surfaces and the test strip port using a clean paper towel.

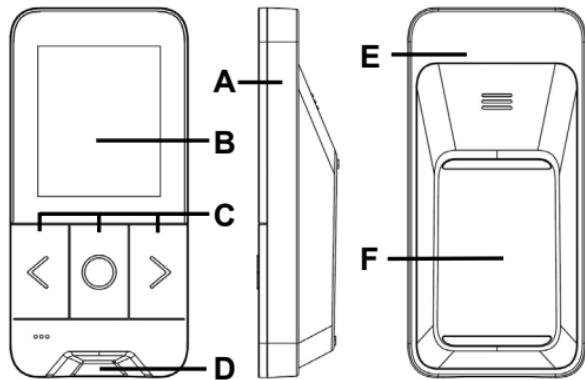
Do:

- 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 [42 to 45](#).

Do Not:

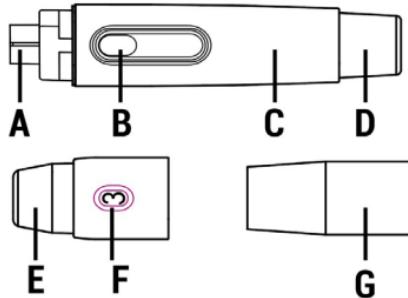
- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

1. Meter cleaning/disinfection area



Code	Name	Possibility of contact with blood
A	Side Case	High
B	Front Case	High
C	Button	High
D	Strip Slot	High
E	Back Case	High
F	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
<i>After each cleaning</i>		
1. Press and hold Power button for 3 sec.	Is meter powered on?	Yes
	Did the meter beep?	Yes
2. Press and release Right or Left 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 Power button for 3 sec.	Is meter powered on?	Yes
	Did the meter beep?	Yes
5. Press and release Right or Left 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.

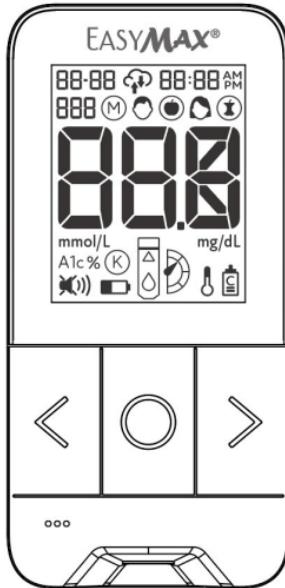
Physical Appearance check of the lancing device after each cleaning or disinfection

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
<i>After each cleaning</i>		
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
<i>After each disinfection</i>		
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.		

Maintenance and Testing

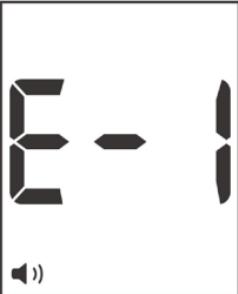
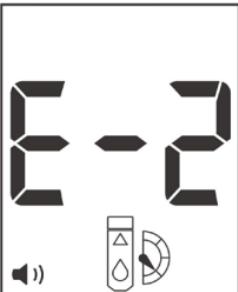


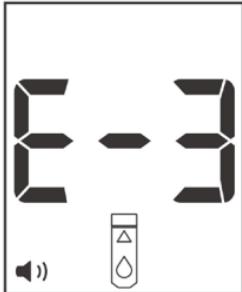
Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

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).

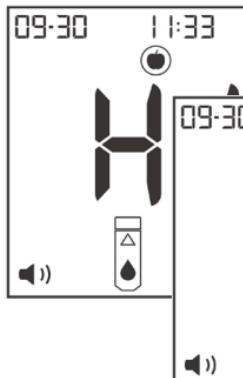
Message	What it means?	What to do?
	<p>System error There may be a problem with the meter.</p>	<p>Replace the batteries first. Refer to pages 13-20. If this error message appears again, please contact your local dealer.</p>
	<p>Volume detector error The volume of blood or control solution is NOT enough.</p>	<p>Repeat the test with a new strip. If Err appears again, please contact your local dealer.</p>

Message	What it means?	What to do?
 The display shows the error code 'E-3' in large digits. Below the digits is a small speaker icon with a double exclamation mark, indicating an audio warning. At the bottom right is a small icon of a test strip with a triangle and a drop of liquid.	Humidified / Used strips The meter has detected a problem with the test strip.	Repeat the test with a new strip. Refer to pages 26-27 for information on sample application.
 The display shows the error code 'E-S' in large digits. Below the digits is a small speaker icon with a double exclamation mark, indicating an audio warning.	Memory Error	Replace the batteries first. If ERROR 005 appears again, please contact your local dealer.

Message

What it means?

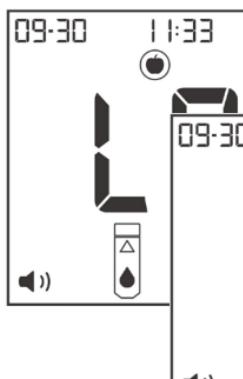
What to do?



Test result is higher than 600 mg/dL (35 mmol/L).

Re-check your glucose level.

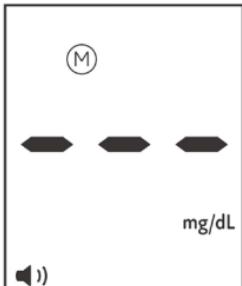
If the result is HI again, obtain and follow instructions from your healthcare professional without delay.



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?
 HF  	<p>The “HF” 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.</p>	<p>Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).</p>
 LF  	<p>The “LF” 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.</p>	<p>Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).</p>

Message	What it means?	What to do?
	<p data-bbox="573 144 729 172">Low power</p> <p data-bbox="573 180 979 246">The meter batteries do not have enough power to perform a test.</p>	<p data-bbox="1014 144 1326 172">Replace new batteries.</p>
	<p data-bbox="573 566 854 593">No result in memory</p> <p data-bbox="573 602 979 676">The meter doesn't run any test yet.</p>	<p data-bbox="1014 566 1404 676">You can still perform a blood glucose test and get an accurate test result.</p>

Chapter 6: Technical Information

Limitations

See the instructions packaged with the test strips and control solutions for the latest information on product specifications and limitations.

Measuring range		
Responsive time		
Blood volume		
Sample type	Refer to the test strip instructions	
Test strip storage conditions		
System operating conditions		
Meter storage conditions	Temperature	36°F- 86°F (2°C ~ 30°C)
	Humidity	40% - 85% R.H.
Operating environment	for Home Healthcare Environment Use	
Pollution degree	2*	
Memory capacity	880 sets	
Power supply	1.5V (AAA) battery * 2 pcs	
Battery life	Over 2000 continuous tests	
Display dimension	42 (L) x 34 (W) mm	
Device dimension H x W x D (mm)	105 x 50 x 23 mm (\pm 0.5mm)	
Weight	60 grams w/o a battery	
Control solution storage conditions	Refer to the control solution instructions	
Test principle	Electrochemistry	

Near-field communication (NFC) Technology

This blood glucose meter utilizes Near Field Communication (NFC) wireless technology for data sharing. NFC operates at 13.56 MHz with a data rate of up to 53 Kbit/s, allowing communication when the meter and smartphone are within 1 cm proximity. Only one device can connect at a time, minimizing data transmission interference.

NFC communication involves two components: an initiator that generates an RF field, and a target that utilizes this field. For the meter to function with a device, the device must support NFC technology and have compatible software to read the meter's data.

The device complies with United States Federal Communication Commission (FCC) regulations, specifically FCC Part 15, ensuring:

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

Adhering to these rules ensures proper functionality without disrupting other devices. If interference occurs, relocating the meter or other devices, such as turning them off, can resolve issues. Common sources of interference include environmental factors and cross-interference.

While NFC offers versatility, maintaining privacy and security is crucial. Users should use passwords, install antivirus software, and deactivate Bluetooth discoverable mode when not in use.

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 equipment 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.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. The equipment complies with FCC and IC radiation exposure limits for uncontrolled environments, designed for direct contact with the user's body under normal operation. It should not be co-located or operated with other antennas or transmitters.

Additionally, ensure a minimum distance of 20 cm between the radiator and your body during installation and operation.

Electromagnetic Compatibility

This meter complies with the electromagnetic immunity requirements specified by EN ISO 15197. Electrostatic discharge immunity testing was based on the standard IEC 61000-4-2. Additionally, the meter meets electromagnetic emission requirements according to EN 60601-1-2, ensuring low electromagnetic emissions. It is not expected to interfere with other electrically-driven equipment.

Performance Analysis

Please refer to the test strip instructions.

Additional Supplies

EASYMAX X Blood Glucose Test Strip

EASYMAX Control Solution,

Article	Manufacturer
Blood Glucose Monitoring System Meets the requirements of K number	EPS Bio Technology Corp. No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30076 www.epsbio.com
Lancet Meets the requirements of MDR 2017/745 & K222472	Shandong Lianfa Medical Plastic Products Co., Ltd. No.1, Shuangshan Sanjian Road, 250200 Zhangqiu City, Jinan, Shandong, China www.sdlianfa.com
Lancing Device Meets the requirements of MDR 2017/745 & K231797	Medifun Corporation 4F-1, 4F-9, 4F-10, No. 99, Jingke S. Rd., Nantun Dist., Taichung City 408, Taiwan www.medifuncorp.com