

# EASYMAX<sup>®</sup>

**Tag** Self-Monitoring Blood Glucose System

## User's Manual



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

## Dear **EASYMAX® Tag SMBG System User,**

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

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

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

## Intended Use

The **EASYMAX® Tag Self-Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh venous blood or capillary whole blood from fingertip, palm and forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for self-testing (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, is not for the diagnosis of or screening for diabetes mellitus, and that alternate site testing can only be used during steady-state blood glucose conditions.

## Standard Accessories

Your new **EASYMAX® Tag** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood.

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

## Additional Optional Accessories

- **AST Lancing Device Cap**
- **Blood Glucose Test Strip (25 pcs.)**
- **Level 1 (Low) Control Solution**
- **Level 2 (Normal) Control Solution**
- **Level 3 (High) Control Solution**



1. Level 2 (Normal) control solution is included with the system kit.
2. Level 1 (Low) and Level 3 (High) control solution are available. For purchase, please contact your local dealer.

## **Why is it so important to test blood glucose regularly?**

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

## **Do you need Help?**

If you have questions or need assistance, please contact your healthcare professional.



**Although the EASYMAX® Tag 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

- **EASYMAX® Tag** Blood Glucose Meter is designed and approved for testing in fresh venous blood or capillary whole blood samples from your fingertip, palm and forearm. The blood sample must be used right away. The meter is for *in vitro* use ONLY (for testing outside the body). It should not be used to diagnose diabetes.
- **EASYMAX® Tag** 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, a bathroom or a 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 your glucose results do not match how you feel, please contact your healthcare professional immediately.
- Remove batteries if the meter will not be used for one month or more.

- Please dispose device according to the local rule of the disposition of electronic device / accessory waste.
- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting a viral disease.
- Consult with your healthcare professional before testing on your palm or forearm.



- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 3,150 meters above sea level has no effect on readings.

## Health-Related Information


















- If you are very dehydrated, urinating frequently, have low blood pressure, in 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 healthcare professional right away.
- If you have followed the steps in the user's manual, but still have symptoms that do not seem to match your test results, or if you have questions, please contact your healthcare professional.
- Please read your test strip instructions carefully for additional health-related information.



### **Warning for potential biohazard**

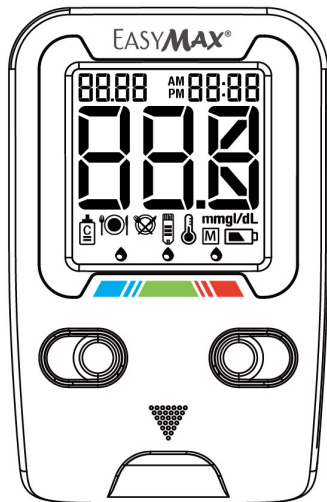
**Healthcare professionals using this system on multiple patients should handle all products or objects in contact with human blood carefully to avoid transmitting viral disease, even after cleaning.**

## Explanation of Symbols

	Consult instructions for use		Caution
	Batch code		Do not reuse
	<i>In vitro</i> diagnostic medical device		3V (CR2032) x 1-battery only
	Use by		Temperature limitation
	Manufacturer		Catalogue number
	Serial number		Control
	Sufficient for		Authorized representative in the European Community
	Blood glucose test result in mg/dL		Blood glucose test result in mmol/L
	This product meets the requirements of Directive 98/79/EC <i>in vitro</i> diagnostic medical devices		



## Explanation of Meter Symbols



	Date (on the left side)		Time (on the right side)
	AC (Before Meal)		PC (After Meal)
mmg/dL	Unit		memory
AM	AM (Before Noon)	PM	PM (After Noon )
	Insert strip		Result
	Temperature		Battery
	Apply Blood Glucose level indicator		Control solution test

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# Chapter 1: Understanding Your Meter

## The EASYMAX® Tag Blood Glucose Meter

### **Display-**

Show results, messages, and results stored in memory.

### **Right Button-**

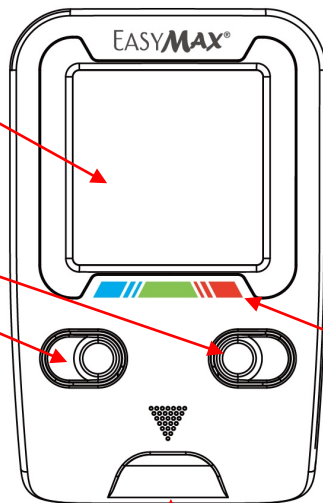
Press to confirm the setting.

### **Left Button-**

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

### **Test Strip Slot-**

Insert test strip here.



### **Battery Door-**

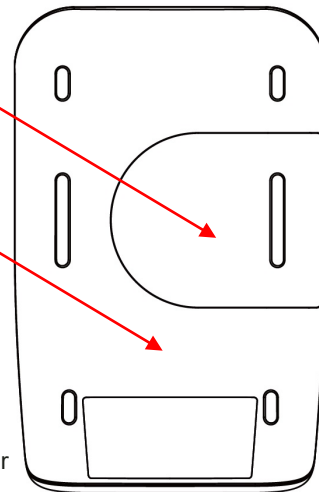
Flip open the battery door by pushing the tab in the direction of the arrow and pulling the door up.

### **NFC sensor -**

Connect to the smartphone with NFC function.

### **Glucose Level indicator -**

Blue Bar = Below Range, Green Bar = Within Range, Red Bar = Above Range

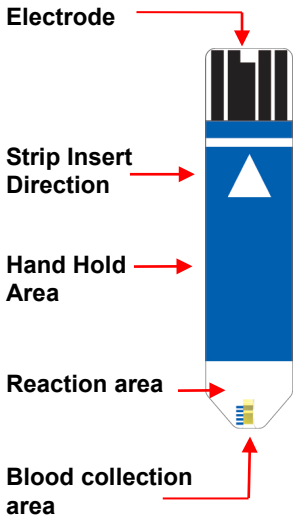


**Know whether your current glucose test result is below, within or above your range.**



# The EASYMAX® Accessories

## Blood Glucose Test Strip



## Test Strip Bottle Control Solution Bottle



Expiration  
Date

## Lancing Device

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

**Sleeve** - Hand Hold Area

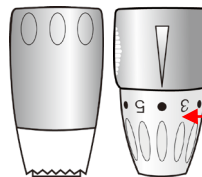
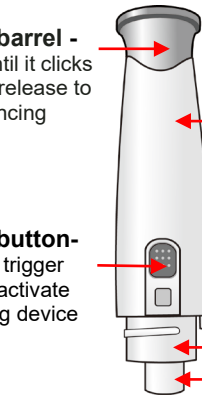
**Trigger button** - Press the trigger button to activate the lancing device

**Hub** - Unscrew or Recap the Cap.

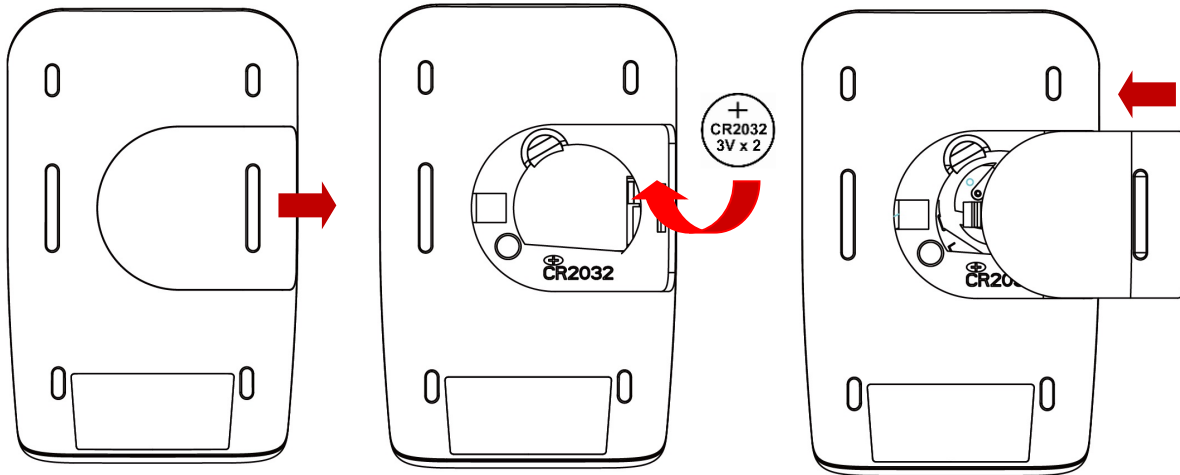
**Carrier** - Insert the lancet into the carrier

**AST Lancing Device Cap- (Optional)**  
Use this transparency cap for AST testing

**Adjustable tip** - Select the desired penetration depth



## Inserting A Battery



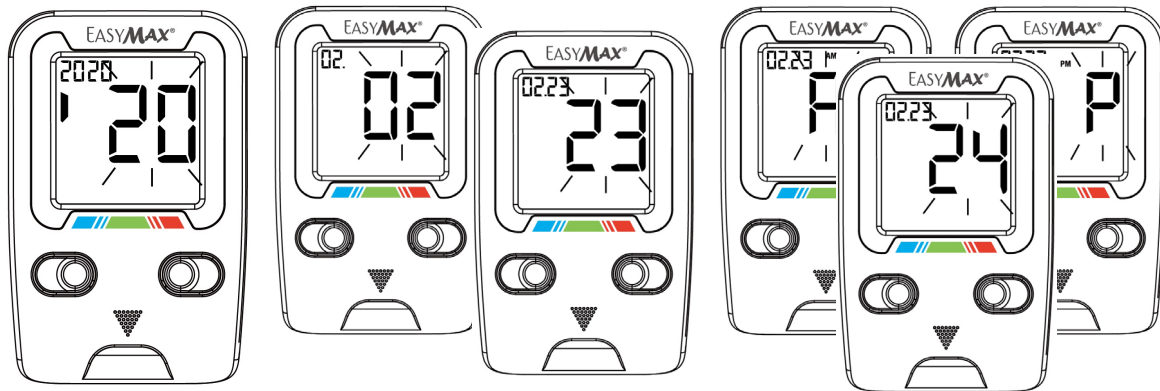
**1.** Open the battery door on the back of the meter by pushing the tab in the direction of the arrow.

**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 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 **Left** button to adjust the year and Press **Right** 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.)



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

## Why Set High Range Limit

Your low and high range limits are used by your meter to:

- Tell you when a test result is within, below or above the range limits set in the meter.
- Provide messages that let you know:
  - ◆ When you should treat a low blood glucose result.
  - ◆ Your progress staying within your blood glucose range.
  - ◆ When you have developed a pattern of blood glucose results below the low limit or above the high limit set in the meter.

### NOTE:

The low and high range limits you set apply to all glucose test results. This includes tests taken before or after mealtimes, medications and around any other activities that may affect your blood glucose.

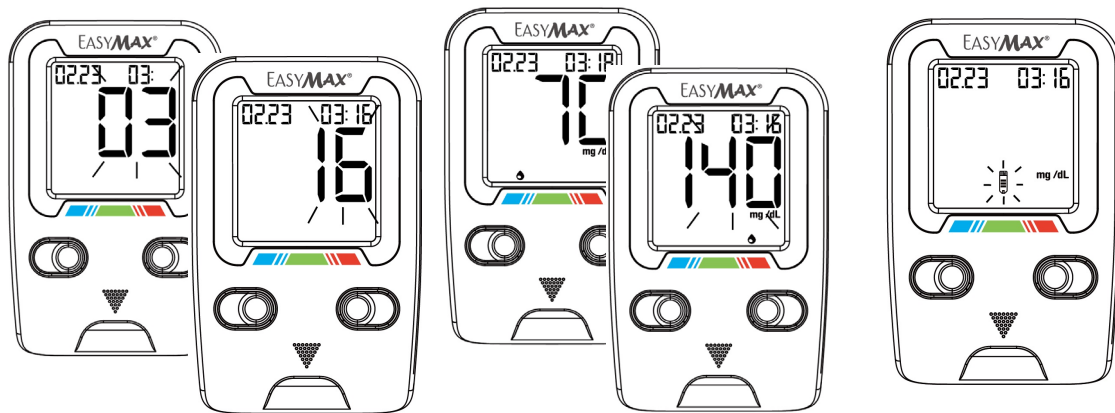


**Be sure to talk to your healthcare professional about the low and high range limits that are right for you. When selecting or changing your high limit, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your healthcare professional.**




## Setting The Date, Time and Glucose Level Alarm (High Range Limit)

Setting the testing unit and glucose level alarm in your meter is important to review your testing results.



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

5. Repeat step 2 to set the high range limit. The flashing field is the one you are currently setting.

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



The meter is pre-set with a low limit of 70 mg/dL and a high limit of 140 mg/dL. The low limit is fixed. If you need to edit the pre-set high limit, check step 5, page 17.

## Using EASYMAX® Tag Blood Glucose Test Strip

- Use only with **EASYMAX® Tag** Blood Glucose Meter.
- 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, close the bottle immediately and make sure it has been closed tightly. This keeps the test strips dry.
- Use the test strip within three minutes after you taking it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Write down the date on strip bottle when the strip bottle is first time opened. Be sure to check the expiration date on the test strip bottle. The test strip will be expired either in twelve months after the date of the bottle is opened or till the expiration date printed on the bottle.
- Store the test strip bottle and your meter in a shady and arid place.
- Store the test strips between 2°C~30°C (36°F~86°F). Do not freeze.
- Do not apply blood or control solution to the test strip until 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® Tag** Self-Monitoring Blood Glucose Test System is a “no code” system and does not require any meter calibration.

## Chapter 2: Control Solution Testing

### Why Run A Control Solution Test

We recommend that you run **EASYMAX®** Level 2 (Normal) Control Solution Tests 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® Tag** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.



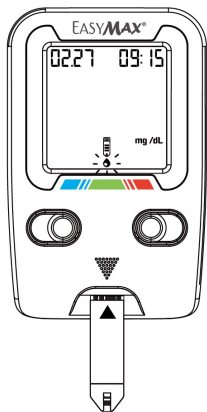
**Professional users are instructed to follow federal, state, and local guidelines.**



## About The Control Solution

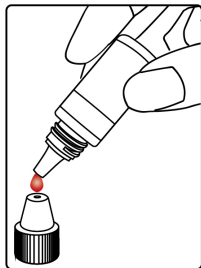
- Use only with **EASYMAX®** test strips.
- Write the date you open the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that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

## Running A Control Solution Test

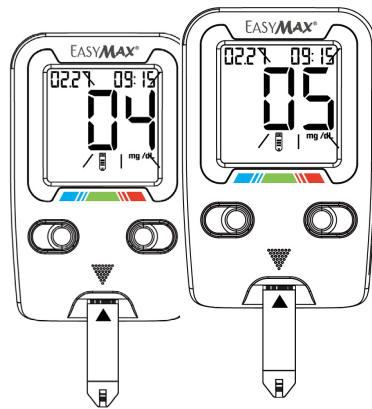
You need the meter, a test strip, and control solution.




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



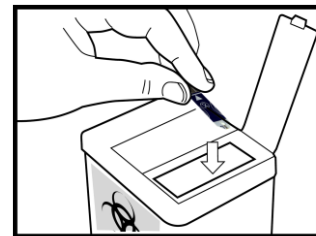
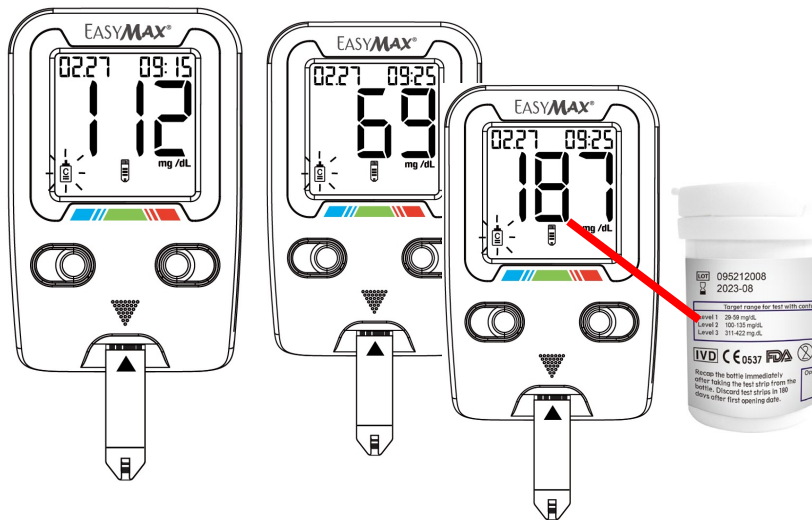
2. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip of the control solution cap.
3. Touch the drop to the collection area at the end of the test strip.




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.



- Do not put control solution on top of the test strip.
- EASYMAX® Tag 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 Solution Test Results**

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

When the control 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 Checks***

## ***Action***

✓ Was the test strip exposed to open air for a long period of time?	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?	If not, you can use control solution to verify the meter's functions. (Chapter 2)
✓ Is the control solution expired or contaminated?	Replace with new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	Repeat the control test with properly stored strips and/or control solutions.
✓ Did you follow the testing steps properly?	Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to obtain inaccurate results.



## Chapter 3: Testing Your Blood Glucose

### Using The Lancing Device

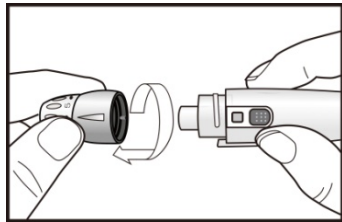
- The best depth setting is the lowest setting that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.



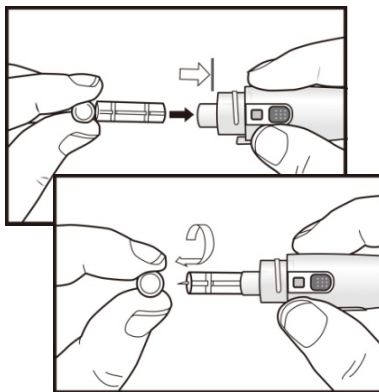
**Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. Users may discuss methods for disposing used test strips and lancets with their doctor.**

## Inserting A Lancet Into The Lancing Device

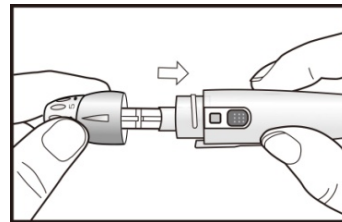
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.



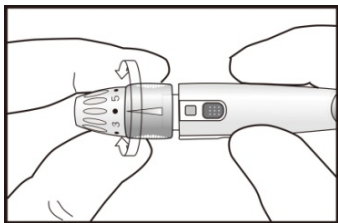
2. Insert the lancet into the lancing device firmly then twist off the protective cover.



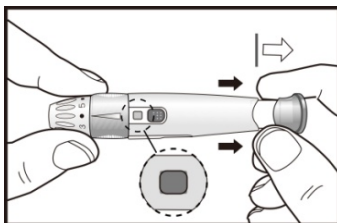
3. Recap the front cap.



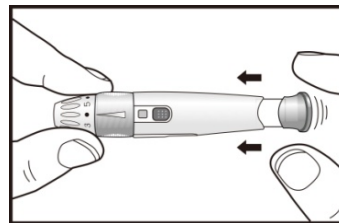
**Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.**



- 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.

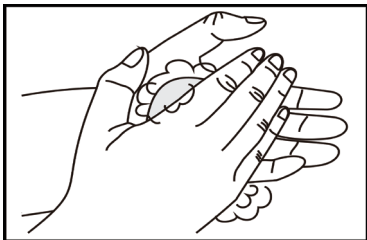


- 6.** Set the lancing device aside until later in the test.

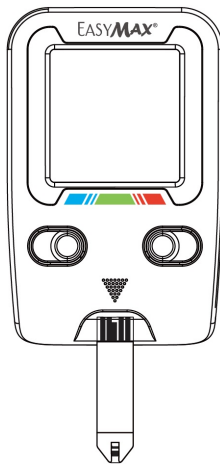


- 1.** Select 1-2 for soft or thin skin, 3-4 for average, and 5-6 for thick or calloused skin.
- 2.** Lancing device and lancets are not to be shared between users. Sharing lancing devices and lancets may transmit blood-borne pathogens, such as viral hepatitis.

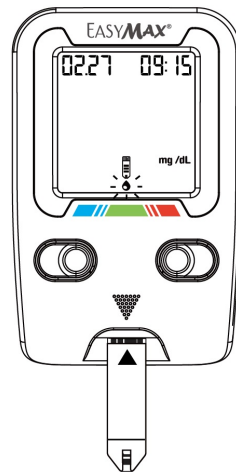
## Running A Blood Glucose Test With Blood From Your Fingertip



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




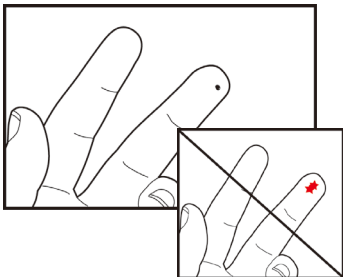
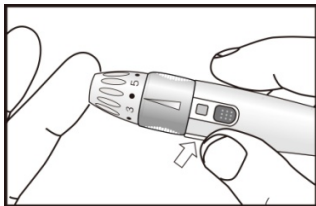
2. Put a test strip into the meter in the direction of the arrow. The meter turns on.



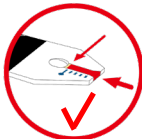
3. When the blood drop flashes on the display, the meter is ready to obtain a drop of blood from your fingertip.



**When your blood glucose result is displayed after a test, the meter will point a color-coded bar with  icon to tell you if your result is within range, below your low limit or above your high limit set in the meter. (See page 16) Blue Bar: Below Range, Green Bar: In Range, Red Bar: Above Range**



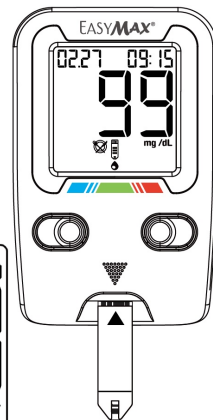
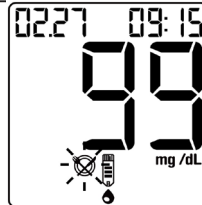
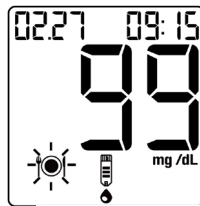
Apply blood to the edge of the test strip.



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.

Do not apply blood on top of the test strip.



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

- 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.

- 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 and confirm  or  mode.
- Remove the test strip and the meter turns off automatically.

## Alternate Site Testing (Optional)

### Understanding Alternate Site Testing (AST)

#### What is AST?

Besides the fingertip, you can test the 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 healthcare 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.

#### Fingertip test only:

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

#### **AST Results:**

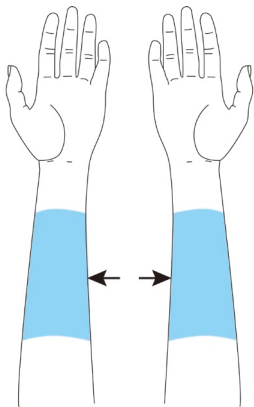
- If the blood glucose test result from the alternate site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of *an alternate site* result, do a fingertip test to confirm the result.

#### **Caution:**

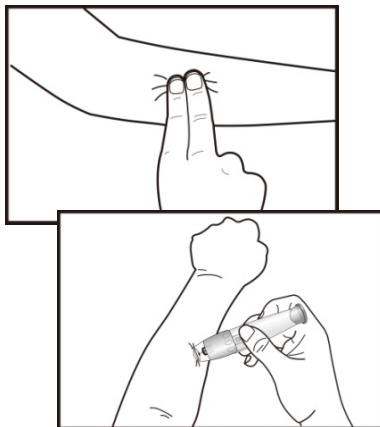
- Talk with your healthcare professional before you test with your palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertips samples are able to show the rapid change of glucose faster than forearm samples.
- Do NOT change your treatment just because of a result.

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

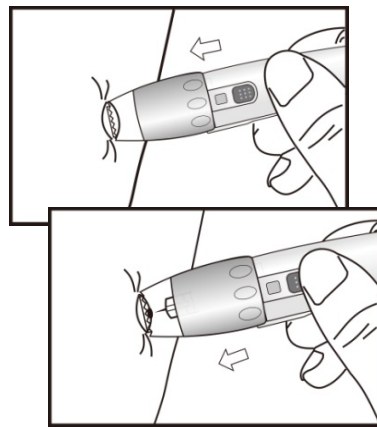
Please use the clear cap with the lancing device for AST testing



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



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

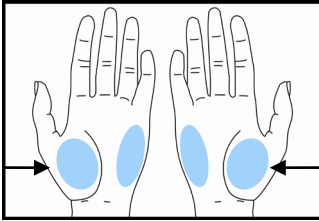


**3.** Press the trigger button to activate the lancing device.

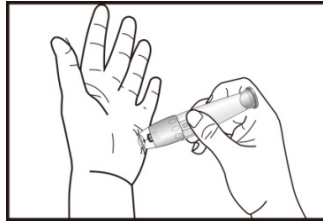
**4.** Hold the device against forearm and increase pressure until the blood sample size is sufficient.



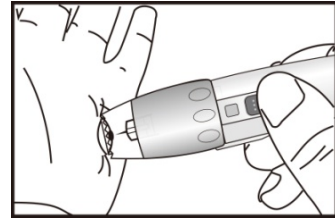
## Running A Blood Glucose Test With Blood From Your Palm (Optional)



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

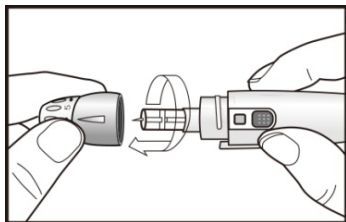


3. Press the trigger button to activate the lancing device.  
4. Hold the device against palm and increase pressure until the blood sample size is sufficient.

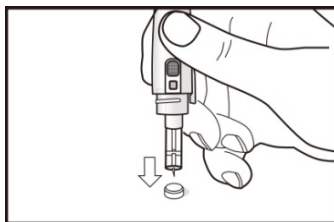


**Check with your healthcare professional before testing other sites than fingertip.**

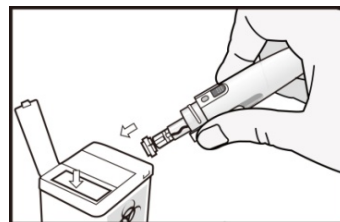
## Discarding Used Lancets



1. Unscrew and remove the cap.



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



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

## Understanding Your Test Results

### Expected Values\*

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

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

### Unusual Test Results

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

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



1. **Extremely high humidity may affect the test results. A relative humidity above 90% may cause inaccurate results.**
2. **Hematocrit: The hematocrit between 10% and 65% will not affect the results. Hematocrit below 10% may cause higher results. Hematocrit above 65% may cause lower results.**
3. **Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.**

## Symptoms Of High Or Low Blood Glucose

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

### Greater than 240 mg/dL (13.33 mmol/L)

#### **What It Means:**

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

#### **Symptoms:**

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

#### **What to Do:**

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is greater than 240 mg/dL (13.33 mmol/L) and you have symptoms of high blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

### Below 60 mg/dL (3.33 mmol/L)

#### **What It Means:**

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

#### **Symptoms:**

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

#### **What to Do:**

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is below 60 mg/dL (3.33 mmol/L) and you have symptoms of low blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

## Comparing Your Meter Result To A Lab Result

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

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by 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® Tag** Blood Glucose Meter, and that blood glucose meters for self-testing generally read somewhat lower or higher than the lab result.

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

# Chapter 4: Meter Memory, Setup

## Memory, Storing Test Results

Your meter stores a maximum of 850 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.

## Meter Setup - Using The Setting Mode

By using the set mode, you can personalize your meter to suit your needs. Here are the features you can customize —

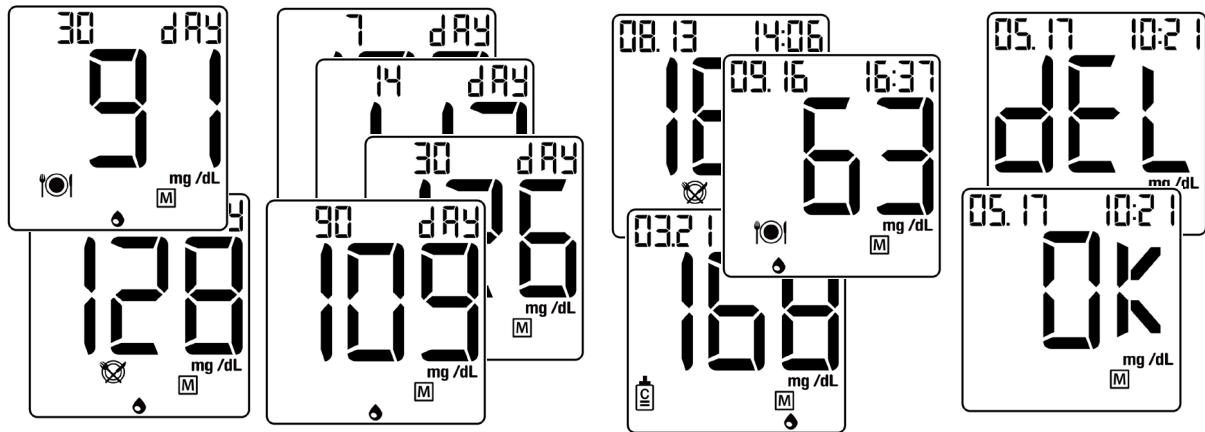
Time and Date — to set the time and date (see Chapter 1).




- 1. Do not change your therapy based on one individual result in memory.**
- 2. The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting the time and date" in Chapter 1.**
- 3. Once 850 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 and averages.**

## Viewing & Deleting Test Results

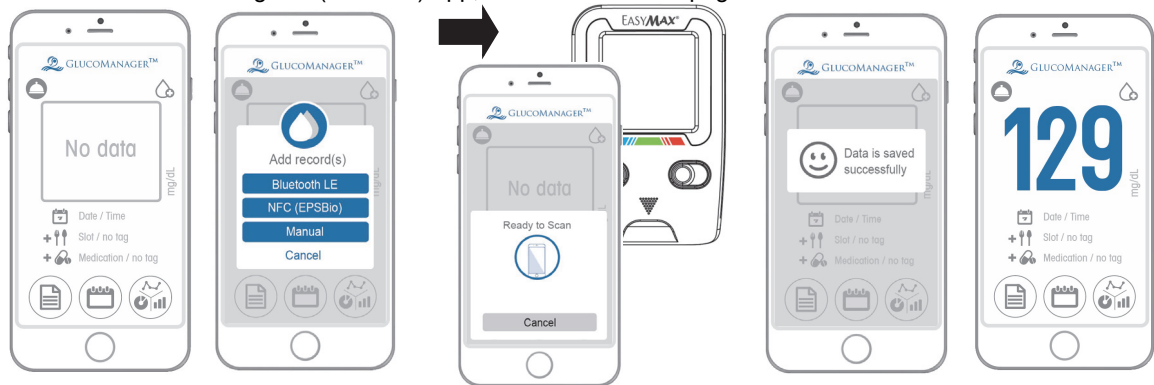
The meter provides 7, 14, 30 and 90 days averaging to help track your blood glucose trend.




1. Press **Right** button to turn on the meter.
2. Press **Left** button to view averages of 30-day in  and averages for 7/14/30/90 days.
3. Press **Right** button to view individual test results, indicated in 3 different colors of glucose levels in green, red or blue.
4. To delete a test result, press **Right & Left** button for more than 3 seconds and display shows "del". Then press **Right** button to confirm the deletion.
5. Press **Right** button to keep reviewing the results, or press **Right** 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. To download GlucoManager™ (EzGluco) App, Please refer to the page 43.



1. Open the GlucoManager™ (or EzGluco) app of your phone and tap  and choose NFC to get ready to scan data.

2. Let your mobile be close to the meter buttons, in order to make transactions of glucose data with GlucoManager™.

3. After transferring all data, the glucose meter shows "data is saved successfully".

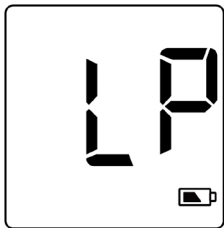


1. Assure your personal smartphone comes with NFC function before you activate the data transmission. While transmitting, make sure the position of NFC from your smartphone tags the button parts of your glucose meter.
2. Make sure you only use a personal smartphone to transmit the data from your personal glucose meter.



# Chapter 5: Maintenance and Troubleshooting

## Inserting A Battery



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

The meter will not turn on the first time a battery is inserted. 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**



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

## Cleaning Your Meter

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

### Do:

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

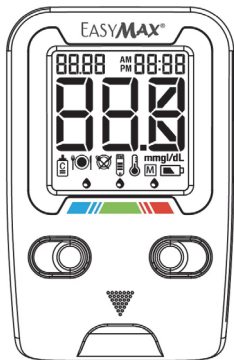
### Do Not:

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

## Cleaning Your Lancing Device

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

## Maintenance And Testing



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

To make sure the display is working properly, turn off the meter. Press and hold 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 contact your local dealer.

## **GlucoManager™ (EzGluco) App :**

**For both Android and iOS users, please scan the QR code below.**



iOS



Android

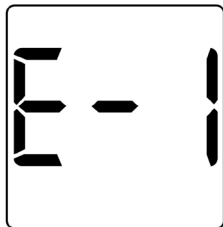
## Screen Messages And Troubleshooting

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

### *Message*

### *What it means?*

### *What to do?*

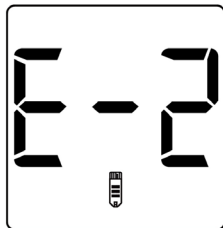


#### **System error**

There may be a problem with the meter.

#### **Replace the batteries first.**

Refer to pages 15 and 28. If this error message appears again, please contact your local dealer.



#### **Volume detector error**

The volume of blood or control solution is NOT enough.

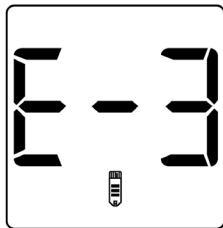
#### **Repeat the test with a new strip.**

If **Err** appears again, please contact your local dealer.

## Message

## What it means?

## What to do?

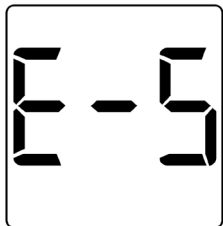


### Humidified / Used strips

The meter has detected a problem with the test strip.

### Repeat the test with a new strip.

Refer to pages 27-28 for information on sample application.

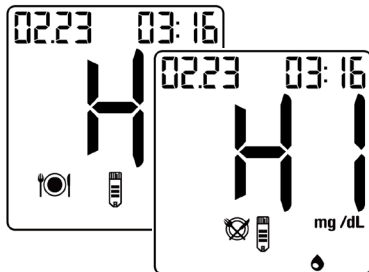


### Memory Error

### Replace the batteries first.

If **ERROR 005** appears again, please contact your local dealer.

## Message

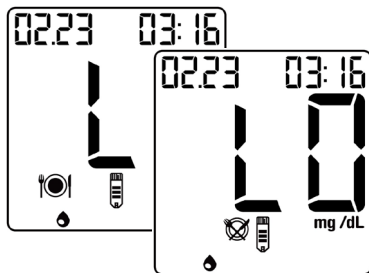


## What it means?

Test result is higher than 630 mg/dL (35 mmol/L).

## What to do?

**Re-check your glucose level.** If the result is HI again, obtain and follow instructions from your healthcare professional without delay.



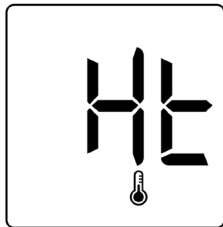
The test result is lower than 20 mg/dL (1.1 mmol/L).

This may require immediate treatment according to your healthcare professionals' recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.

## Message

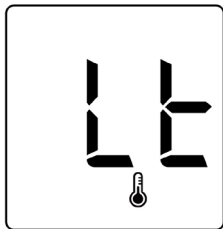
## What it means?

## 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).



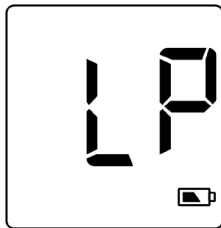
The “Lt” and thermometer icon appears. Temperature is too low, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.

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

## Message

## What it means?

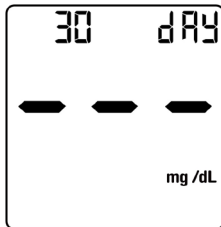
## What to do?



### Low power

The meter batteries do not have enough power to perform a test.

**Replace the new batteries.**



### 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.**



# Chapter 6: Technical Information

## Specifications

Brand name	<b>EASYMAX® Tag Blood Glucose Meter</b>	
Range	20~630 mg/dL (1.1~35 mmol/L)	
Test time	5 seconds	
Memory sets	850 test results	
Operating condition	Temp.	10°C ~40°C (50°F ~104°F)
	Relative Humidity	R.H. ≤ 90%
Storage and transportation condition	Temp.	2°C ~ 30°C (36°F ~86°F)
	Relative Humidity	R.H. ≤ 90%
Blood sample	0.6 µL	
	Fresh blood from fingertip, palm or forearm	
Hematocrit (Hct)	10-65%	
Power	CR2032 Battery * 1 ct.	
Battery life	Over 1000 tests	
Display dimension	28.0 × 29.0 mm	
Device dimension H × W × D (mm)	74 x 47 x 12 mm	
Weight	26 grams w/o batteries	
Principles	Electrochemical biosensor technology	

## Comparison of Measured Values With Laboratory Value

### Precision

Three lots of the **EASYMAX®** blood glucose test strips have been tested to assess the precision of blood glucose measuring system. This includes a repeat assessment using venous blood and a laboratory precision assessment using the control material. The blood glucose content of the venous blood samples ranges from 42.7 to 418.0 mg/dL and control material from three concentrations is used.

Results of the repeat precision measurements

Sample	Venous Blood mg/dL (mmol/L)	Grand mean value mg/dL (mmol/L)	Pooled standard deviation	Pooled coefficient of variation (%)
1	43 (2.4)	36 (2.0)	2.0	5.6
2	62 (3.4)	59 (3.3)	3.5	5.9
3	121 (6.7)	127 (7.1)	4.1	3.2
4	201 (11.2)	214 (11.9)	6.7	3.1
5	317 (17.6)	330 (18.3)	10.1	3.1
6	418 (23.2)	433 (24.1)	14.5	3.3

Results of the intermediate precision measurement

Sample	Grand mean value mg/dL (mmol/L)	Pooled standard deviation	Pooled coefficient of variation (%)
1	71 (3.9)	1.0	1.4
2	136 (7.6)	1.4	1.1
3	351 (19.5)	2.8	0.8

## System Accuracy

The **EASYMAX® Tag** blood Glucose monitor in comparison with the YSI. Three lots of **EASYMAX®** blood glucose test strips have been tested to assess the system accuracy of the **EASYMAX® Tag** blood glucose measuring system and to compare it with the reference method in which capillary whole blood concentrations of 34.4 to 442.8 mg/dL have been used.

Result of the system accuracy of glucose concentrations <100 mg/dL (<5.55 mmol/L)

<b>within±5mg/dL</b> (Within ± 0.28 mmol/L)	<b>within±10mg/dL</b> (Within ± 0.56 mmol/L)	<b>within±15mg/dL</b> (Within ± 0.83 mmol/L)
<b>55 / 180</b>	<b>111 / 180</b>	<b>175 / 180</b>
30.6 %	61.7 %	97.2 %

Result of the system accuracy of glucose concentrations ≥ 100 mg/dL (≥5.55 mmol/L)

<b>within±5%</b>	<b>within±10%</b>	<b>within±15%</b>
<b>220 / 438</b>	<b>357 / 438</b>	<b>422 / 438</b>
50.2 %	81.5 %	96.3 %

Results of the system accuracy for combined glucose concentrations between 34.4 mg/dL (1.91 mmol/L) and 442.8 mg/dL (24.60 mmol/L)

<b>Within ± 15 mg/dL or ±15% (Within ± 0.83 mmol/L or ±15%)</b>
597 / 618 (96.6%)

In comparison to the YSI, the **EASYMAX® Tag** met the ISO 15197:2013 (EN ISO 15197:2015) standard, whereby 95% of the blood glucose values measured have to fall within the following zones: either  $\pm 0.83$  mmol/L ( $\pm 15$  mg/dL) of the measured average value when using the reference measuring procedure for blood glucose concentrations  $< 100$  mg/dL ( $< 5.55$  mmol/L) or  $\pm 15\%$  for blood glucose concentrations of  $\geq 100$  mg/dL ( $\geq 5.55$  mmol/L). 99% of the individual measured blood glucose values must fall within zones A and B of the Consensus Error Grid (CEG) for diabetes type 1.

## **Performance evaluation by the user**

A study to assess the glucose values of blood samples of capillary blood from the fingertips, which were obtained from 103 individuals that had no special training, produced the following results: 96.7% within  $\pm 15$  mg/dL ( $\pm 0.83$  mmol/L) and 95.9% within  $\pm 15\%$  of the values obtained in the medical laboratory with glucose concentrations of at least 100 mg/dL (5.55 mmol/L).

You will find further details and information regarding blood glucose results and various technologies in generally relevant specialist medical literature.

## Limitation

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

1. DO NOT use serum or plasma sample.
2. DO NOT use anticoagulant NaF or potassium oxalate for venous sample preparation.
3. DO NOT use neonate blood sample.
4. Extreme humidity may affect the results. A relative humidity greater than 90 % may cause incorrect results.
5. The system should be used at temperatures between 10°C and 40°C (50°F and 104°F). Outside this range, the system may get incorrect results.
6. DO NOT reuse the test strips. The test strips are for single use only.
7. Hematocrit: The hematocrit between 10% and 65% will not affect the results. Hematocrit below 10% may cause higher results. Hematocrit above 65% may cause lower results.
8. Altitude up to 3,150 meters above sea level has no effect on readings.

### Healthcare Professionals – Please note these additional Limitations

1. If the patient has the following conditions, the result may fail:
  - ◆ Severe dehydration
  - ◆ Severe hypotension (low blood pressure)
  - ◆ Shock
  - ◆ A state of hyperglycemic-hyperosmolar state (with or without ketosis)
2. Lipemic samples: Cholesterol level up to 400 mg/dL (10.32 mmol/L) and triglycerides up to 800 mg/dL (9.04 mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with **EASYMAX® Tag** glucose meters.

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

Concentrations of the interference tested	Bias		50-100 mg/dL (2.8-5.6 mmol/L)	250-350 mg/dL (13.9-19.4 mmol/L)
	Glucose Level			
Acetaminophen	7 mg/dL	(0.46 mmol/L)	8.1	5.3%
Ascorbic Acid	4 mg/dL	(0.26 mmol/L)	6.6	5.8%
Bilirubin-unconjugated	3.3 mg/dL	(0.056 mmol/L)	0.2	5.2%
Cholesterol	400 mg/dL	(10.32 mmol/L)	9.6	7.2%
Creatinine	30 mg/dL	( 2.7 mmol/L)	1.3	1.6%
Dopamine	2.2 mg/dL	(0.14 mmol/L)	8.0	3.2%
Galactose	20 mg/dL	(1.11 mmol/L)	6.2	2.5%
Gentisic Acid	7 mg/dL	(0.45 mmol/L)	9.8	3.6%
Glutathione	1 mg/dL	(0.03 mmol/L)	3.7	6.5%
Haemoglobin	300 mg/dL	(0.05 mmol/L)	3.8	5.2%
Ibuprofen	50 mg/dL	(2.43 mmol/L)	3.9	2.7%
Icodextrin	1094 mg/dL	(0.66 mmol/L)	5.4	4.8%
L-Dopa	2 mg/dL	(0.10 mmol/L)	10.0	8.7%
Maltose	278 mg/dL	(7.78 mmol/L)	2.7	4.4%

Methyldopa	4 mg/dL	(0.19 mmol/L)	9.0	3.7%
Pralidoxime Iodide	5 mg/dL	(0.14 mmol/L)	2.8	3.3%
Sodium Salicylate	40 mg/dL	(2.5 mmol/L)	4.3	2.2%
Tolbutamide	100 mg/dL	(3.70 mmol/L)	1.4	2.3%
Tolazamide	2.5 mg/dL	(0.08 mmol/L)	2.5	3.6%
Triglycerides	800 mg/dL	(9.04 mmol/L)	9.3	5.6%
Uric acid	16.5 mg/dL	(0.99 mmol/L)	7.2	4.0%
Xylose	9.5 mg/dL	(0.63 mmol/L)	7.0	7.5%

## Device Information

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**EASYMAX® Tag** SMBG System

**EASYMAX® Tag** Blood Glucose Meter

**EASYMAX® Tag** Blood Glucose Test Strips

**EASYMAX® Tag** Level 3 (High) Control Solution

**EASYMAX® Tag** Level 2 (Normal) Control Solution

**EASYMAX® Tag** Level 1 (Low) Control Solution

## EASYMAX Headquarter



Hsinchu Science Park, Hsinchu, Taiwan 30077

[www.easymax-diabetescare.com](http://www.easymax-diabetescare.com)



EPS BIO TECHNOLOGY CORP.

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



**Lancet:** Meets the requirements of MDD 93/42/EEC  
Shandong Lianfa Medical Plastic Products Co.,Ltd  
No.1,Shuangshan Sanjian road,zhangqiu,Jinan city,

China



**Lancing Device:** Meets the requirements of MDD  
93/42/EEC

Global Medical Market Corporation  
Room 1112, Ace Tower 9<sup>th</sup> Bldg, 130, digital-ro,  
Geumcheon-gu, Seoul, Korea



**Obelis s.a.**

Boulevard Brand Whitlock  
30, B-1200 Brussels, Belgium



**Shanghai International Holding Corp.  
GmbH (Europe)**

Eiffestrasse 80, 20537 Hamburg, Germany



**GMMC S.L**

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