

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 Owner,

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

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

Thanks again for choosing the **EASYMAX® Tag** SMBG System.

Intended Use

The **EASYMAX®** Tag **SMBG** 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

EASYMAX® Tag Lancet is single use and **EASYMAX®** Tag blood glucose meter is for one person use only. A new, sterile lancet should be used one time you perform a test. The lancing device, lancets and meter CANNOT be shared between users or other family members. Do NOT use on multiple individuals. Sharing a lancing device and lancets may transmit blood borne pathogens, such as viral hepatitis.

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

This device type is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because they have not been evaluated for use in these professional healthcare settings, including for routine assisted testing or as part of glycemic control procedures. Use of these devices 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:

- Sharon, M.G. (2014). Infection Transmission Associated with Point of Care Testing and the Laboratory's Role in Risk Reduction. EJIFCC, 25(2), 188–194. http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
- Centers for Disease Control and Prevention, National Center for HIV Viral Hepatitis STD and TB
 Prevention (2011, March 2) Infection Prevention during Blood Glucose Monitoring and Insulin
 Administration (.html). Retrieved from https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Standard Set Includes

- EASYMAX® Tag Blood Glucose Meter
- CR2032 Cell Battery (1 pc)
- EASYMAX® Tag Blood Glucose Test Strips X 10 pcs
- EASYMAX® Lancets X 10 pcs
- EASYMAX® Lancing device
- EASYMAX® AST Lancing Device Cap
- EASYMAX® Tag Self-Test Log Book
- EASYMAX® Tag Level 2 Control Solution
- EASYMAX® Tag User's Manual
- EASYMAX® Tag Test Strip Instructions
- EASYMAX® Tag Glucose Control Solution Instructions
- EASYMAX® Carrying Case
- EASYMAX® Tag Blood Glucose Test Strips

Optional Accessories You Can Purchase

X 25 / 50 pcs

EASYMAX® Tag Level 2 / 3 Control Solution

Note:

Please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) to make sure the accessories are available for purchasing.

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 **EASYMAX® Tag SMBG** SMBG system as simple as possible to help you use it regularly. Your **EASYMAX® Tag** blood glucose 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® 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 EASYMAX® Tag Blood Glucose Meter

- EASYMAX® Tag 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® Tag blood glucose meter can only be used with EASYMAX® Tag 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 battery if the meter will not be used for one month or more.

- It is not necessary to require servicing, and maintenance while in use.
- It is 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 marked on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 10,000 feet above sea level will not affect the reading.
- It should not be used to diagnose or screen for diabetes.

Health-Related Information

- If you are experiencing dehydration, frequent urination, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your doctor right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, contact your Healthcare Professional or physician immediately. If you have questions regarding the use of EASYMAX® Tag blood glucose 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.

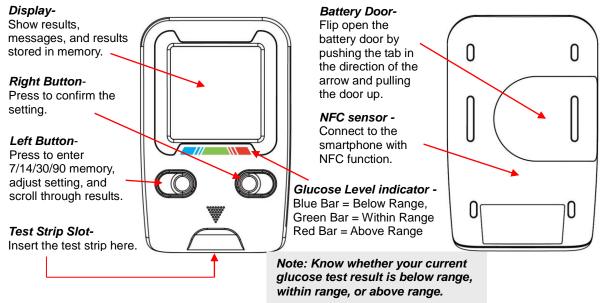
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Chapter 1: Understanding Your Meter

The EASYMAX® Tag Blood Glucose Meter

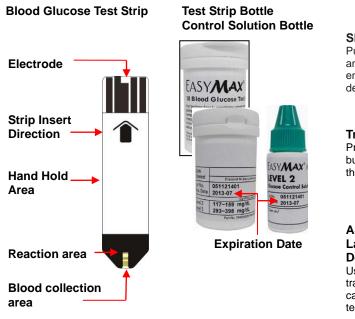


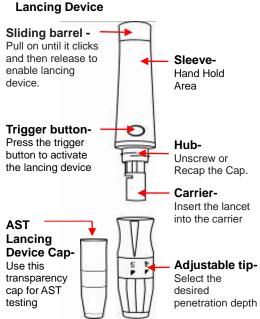
Explanation of EASYMAX® Tag SMBG Meter Symbols



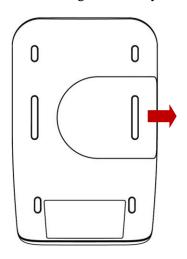
88.88	Date (in the upper left corner)	88:88	Time (in the upper right corner)
AM	AM (Before Noon)	PM	PM (Afternoon)
	Result		Control solution test
	Before Meal		After Meal
	Insert strip		Temperature
mg /dL	Unit	M	memory
	Power	•	Blood Glucose level indicator

The EASYMAX® Tag Accessories

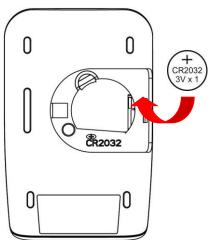




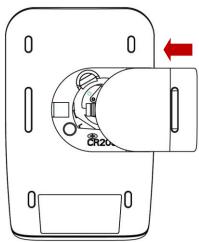
Inserting The Battery



 Push the tab in the direction of the arrow to open the battery cover on the back of the meter.



Insert a battery. The meter will beep to confirm the battery is inserted correctly.



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

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

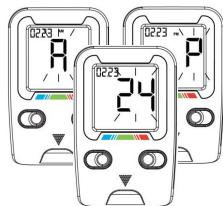
Setting the current time and date in your meter is important if you intend to use the meter memory.



1. After inserting a battery, the meter turns on automatically.



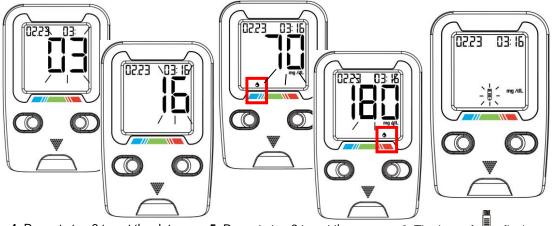
 The last 2-digits of the year flashes at the center of the display. Press Left button to adjust the year and Press Right button to confirm the setting.



3. Repeat step 2 to select A, P or 24 mode and then set the time. (A=AM, P=PM, 24=24 hr. mode.)

Note: If the display shows the wrong setting, please press the Right and Left buttons at the same time for 2 seconds to reset.

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



- Repeat step 2 to set the date. The flashing field is the one you are currently setting.
- Repeat step 2 to set the high/ low range limits. 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.

Note: The meter is pre-set with a low range limit of 70 mg/dL (adjustable from 60 to 110 mg/dL) and a high range limit of 180 mg/dL (adjustable from 90 to 300 mg/dL).

Why Set High/ Low 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.

Note: 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/ low 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.

Using EASYMAX® Tag Blood Glucose Test Strips

- Use only with **EASYMAX**® **Tag** Blood Glucose Meters.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 " EASYMAX® Tag 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® Tag Self-Monitoring Blood Glucose Test System is a "no code" system and does not require any test strip calibration.

Chapter 2: EASYMAX® Tag Control Solution Testing

Why Run a Control Solution Test

We recommend that you run the **EASYMAX®** Tag 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**® **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.

About The Control Solutions

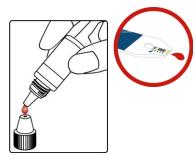
- Use with **EASYMAX**[®] **Tag** Blood Glucose test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use 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**® **Tag** level 2 and level 3 Control Solutions, please contact your local dealer.

Running a EASYMAX® Tag Control Solution Test

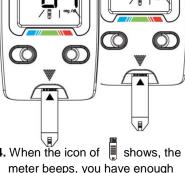
You need the meter, a test strip, and control solution of EASYMAX® Tag.



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



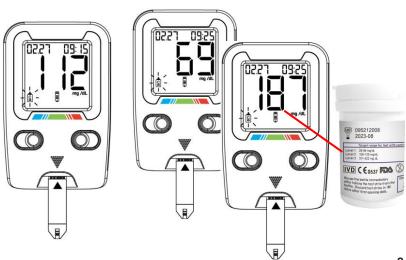
- 2. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a 4. When the icon of tiny drop forms at the tip of the control solution cap.
- 3. Touch the drop to the collection area at the end of the test strip.

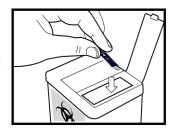


- control solution for the test.
- 5. The meter starts to count down from 5 seconds.

■ Do not put control solution on top of the test strip. Note:

■ EASYMAX® Tag Blood Glucose Meter will automatically identify your control solution test, so that results will NOT be included in the memory of blood test.





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

Don't remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle. 8. Remove the test strip and throw it away after you have compared the reading to the range printed on the test strip bottle.

Understanding EASYMAX® Tag Control Solution Test Results

The label on your **EASYMAX® Tag** 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 **EASYMAX®** Tag 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 **EASYMAX® Tag** test strip bottle), here are some things you can do to solve the problem:

Troubleshooting Check

- Was the test strip exposed to open air for a long period of time?
- Does test strip cap close tightly? Or was test strip cap left open?
- ✓ Is the meter functioning well?
- ✓ Is the control solution expired or contaminated?
- Were test strips and control solutions stored in cool, dry places?
- ✓ Did you follow the testing steps properly?

Action

If yes, repeat the control solution test with properly stored strips.

If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.

You can use the control solution to verify the meter's functions.

If yes, replace with a new control solution to check the performance of SMBG system.

If no, repeat the control solution test with properly stored strips or control solutions.

If you have followed the steps properly, contact physician. If you still have questions, please contact Customer Support at 1-866-994-3345

Chapter 3: Testing Your Blood Glucose Using the EASYMAX® Tag Lancing Device

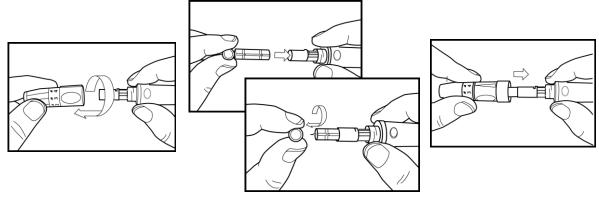
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your **EASYMAX® Tag** lancing device with anyone. And always use a new, sterile lancet. Lancets are for single use only.
- If the EASYMAX®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

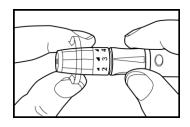


1. Unscrew the Cap.

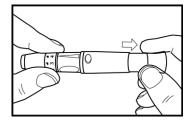
2. Insert the lancet into the lancing device firmly then twist off the protective cover.

3. Recap the front cap.

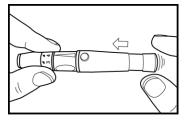
Note: Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.



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



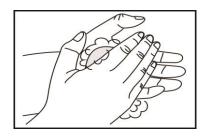
6. Set the lancing device aside until later in the test.

Note: 1. Select 1-2 for soft or thin skin, 3 for average, and 4-5 for thick or calloused skin.

strip are prepared.

2. Lancing device and lancets can not to be shared between users. Sharing lancing devices and lancets may transmit blood borne pathogens, such as viral hepatitis.

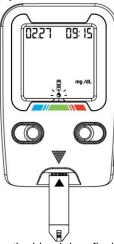
Running A Blood Glucose Test With Blood From Your Fingertip



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

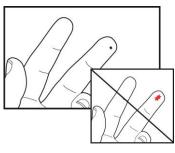


Put a test strip into the meter in the direction of the arrow. The meter turns on automatically.



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

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



4. Place the lancing device

5. Gently squeeze and/or

fingertip.

against the pad of your finger.

massage your fingertip until a

round drop of blood on your

Press the trigger button to

activate the lancing device.

Apply blood to the edge of the test strip.

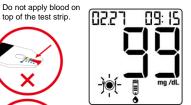


Be sure to get enough blood on strip to make it to the confirmation window.

Not enough blood on strip to get a test result.

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.

6. Touch the blood drop at the tip of





- 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 and confirm
 Or mode.
- **8.** Remove the test strip and the meter turns off automatically.

Note: When your blood glucose result is displayed after a test, the meter will point a color-coded bar with

con 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.

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:

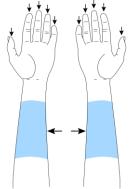
- If the test result from the alternate site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of an alternate site result, do a fingertip test to confirm the result.
- If you often do not notice when your blood glucose is low,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

Caution:

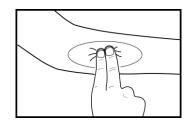
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm and palm samples.
- Measurements from alternative site testing should never be used to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

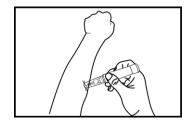
Please use the clear cap with the lancing device for AST testing



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

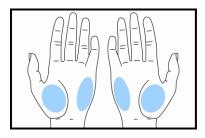


- 2. Massage the puncture area of forearm for a few seconds.
- Press and hold the device with a clear adjustable tip against the forearm.



- 4. Press the trigger button to activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.
- **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 that the fingertip.
 - 2. Please do NOT use the first drop of blood sample.

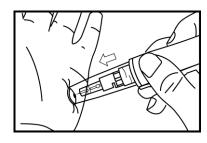
Running A Blood Glucose Test With Blood From Your Palm



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

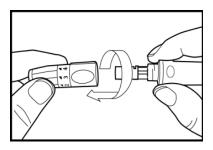


2. Press and hold the device with a clear adjustable tip against the palm

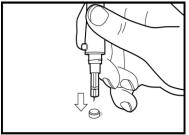


- **3.** Press the trigger button to activate the lancing device.
- Hold the device against palm and increase pressure until the blood sample size is sufficient.

Discarding Used Lancets



Unscrew and remove the cap.



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



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

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 American Diabetes Association recommends a post-meal glucose level of less than 180 mg/dL and a pre-meal glucose of 80–130 mg/dL*. For people with diabetes: please consult with your doctor for the appropriate blood glucose range.

Unusual Test Results

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

- 1. Run a control solution test, Chapter 2, " EASYMAX® Tag Control Solution Testing."
- 2. Repeat a blood glucose test, Chapter 3, "Testing Your Blood glucose."
- 3. If your test results still do not reflect the way you feel, call your doctor immediately.
- * Reference: American Diabetes Association. Standards of medical care in diabetes-Table 6.3 Summary of glycemic recommendation for many nonpregnant adults with diabetes. 2020; Vol. 43, Suppl. 1, S72.

Note:

- 1. Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.
- 2. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.

Comparing Your EASYMAX® Tag Blood Glucose 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, Transfer

Memory, Transferring Test Results

Your **EASYMAX®** Tag 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.

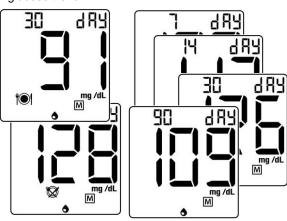
For further analysis, you can transfer test results to your personal or tablet computer etc. through NFC and then use **EzGluco Tag** app to check your glucose value.

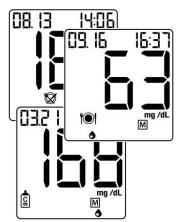
Note:

- 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 "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.

Viewing & Deleting Test Results

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



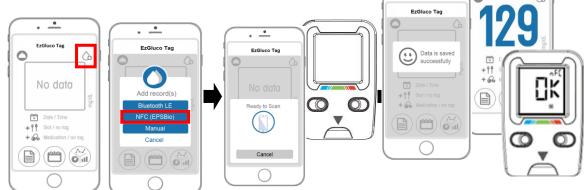




- Press Right button for more than 3 seconds to turn on the meter.
- 2. Press Left button to view averages of 30-day in and averages for 7/14/30/90 days.
- Press Right button to view individual test results, indicated in 3 different colors of glucose levels in green, red or blue.
- 4. To delete a test result, press Right & Left button for more than 3 seconds and display shows "dt". Then press Right button to confirm the deletion.
- 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

To transfer data, the meter can be turned on or off.



- 1. Open the **EzGluco Tag** app of your phone and tap **()**, choose NFC to get ready to scan data.
- Bring you mobile phone close to the meter buttons to transfer blood glucose data by using the EzGluco Tag app.
- After transferring all data, the mobile phone shows "Data is saved successfully" and the glucose meter shows "nFC OK" on the screen.

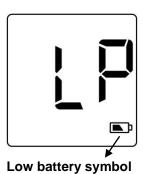
EzGluco Tag

Note:

- Assure your personal smartphone comes with NFC function before you activate the data transmission. You need to know the NFC position of the smartphone. While transmitting, make sure the NFC position from smartphone tags the button parts of your blood glucose meter. Otherwise, please move your smartphone slowly around the button parts of meter.
- 2. Make sure you only use a smartphone to transmit the data from your blood glucose meter.

Chapter 5: Maintenance and Troubleshooting

Installing The Battery



EASYMAX® Tag blood glucose meter uses one CR2032 battery. The battery can usually be tested more than 1000 times. Other types of CR2032 batteries are also acceptable, but the capacity of test times may differ. Install the battery when you first use the meter or replace with new battery when the "LP" (low power) message and the low battery symbol appear on the display.

The meter will not turn on automatically when installing the battery first time. Please press right button for more than 3 seconds or insert **EASYMAX®** Tag test strip to turn on your meter. The meter will turn off automatically. Alternatively, you can press right button for more than 3 seconds to turn off your meter.

Note:

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

Cleaning and Disinfecting Your EASYMAX® Tag Blood Glucose Meter and Lancing Device

Choosing the disinfectant

The recommended EPA-registered disinfected product is as follow:

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

Super Sani-Cloth germicidal wipe contains active ingredients: n-Alkyl (60% C14, 30%C16, 5%C12, 5%C18) dimethyl benzyl ammonium chlorides and n-Alkyl (68%C12, 32%C14) dimethyl ethylbenzyl ammonium chlorides and they have been shown to be safe for use with the **EASYMAX®** Tag Blood Glucose Meter, but any other disinfectant product with the EPA registration number may be used on this device.

Please purchase in retail stores like Walmart and Office Depot. You could also purchase online retail sites like Walmart: https://www.walmart.com/, Office Depot: https://www.officedepot.com/, Amazon:

https://www.amazon.com/ and Express medical supply: https://www.exmed.net/.

Cleaning and Disinfection Instruction

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

The meter and lancing device have been validated so that they can withstand cleaning for up to 6 times per day. After every use, follow the cleaning instruction to prevent the growth of any microorganism and also to help improving the effectiveness of disinfection. Then follow disinfection instruction once per week, which could effectively kill blood borne pathogens, such as viral hepatitis and prevent cross-contamination. If a

second person who is providing testing assistance to the user is operating the devices, the meter and lancing device should be disinfected prior to use by the second person.

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

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

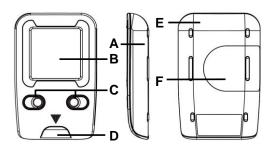
Do:

- Make sure the meter turns 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 43 to 47.

Do Not:

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

1. Meter clearing/disinfection area



Code	Name	Possibility of contact with blood
Α	Side Case	High
В	Front Case	High
С	Front Buttons	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
Α	Lancet holder	High
В	Trigger button	High
С	Body	High
D	Sliding barrel	High
Е	Cap	High
F	Depth adjust ring	High
G	AST Cap	High

Physical Appearance check of EASYMAX® Tag blood glucose 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 EASYMAX® Tag blood glucose meter

Steps	Check item Accor	
After each cleaning		
1. Insert test strip.	Is meter powered on?	Yes
	Did the meter beep?	Yes
2. Press and release Left or	Is the testing result correctly stored in the memory?	Yes
Right button.	Can the result be clearly read?	Yes
After each disinfection		
Insert test strip	Is the meter powered on?	Yes

2. Apply Level 2 control	Any reading?	Yes
solution	Is the reading within control range?	Yes
3. Remove test strip	Is meter powered off?	
Insert test strip	Is meter powered on?	Yes
	Did the meter beep?	Yes
5. Press and release Left or	Is the testing result correctly stored in the memory?	Yes
Right button.	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

Check item	Accept Result		
After each cleaning			
Can the cap be screwed on the lancing device?	Yes		
Can the lancing device click?	Yes		
Can the lancet be fired?	Yes		
After each disinfection			
Can the lancet be fixed on the lancet holder?	Yes		
Can the AST cap be screwed on the lancing device?	Yes		
Can the cap be screwed on the lancing device?	Yes		
Can the penetration depth ring be adjusted?	Yes		
Can the lancing device click?	Yes		
Can the lancet be fired?	Yes		
	can the cap be screwed on the lancing device? Can the lancing device click? Can the lancet be fired? Can the lancet be fixed on the lancet holder? Can the lancet be fixed on the lancet holder? Can the AST cap be screwed on the lancing device? Can the cap be screwed on the lancing device? Can the penetration depth ring be adjusted? Can the lancing device click?		

Action: If any of the results is "No", please call the Customer Care Service toll-free at 866-994-3345(Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for replacement with a new device.

Cleaning and Disinfection Frequency

EASYMAX® Tag blood glucose meter and **EASYMAX® Tag** lancing device can sustain 8,760 cleaning times and 208 disinfection times which represents cleaning 6 times per day and disinfecting (with a pre-clean step) once per week over the 4 year use life of the device.

4 year product life is for properly cleaning and disinfection. After 4 years, EASYMAX® Tag blood glucose meter must be replaced with a new meter.

Maintenance and Testing



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

To make sure the display is working properly, turn off the meter. Press and hold right button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please 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	age What it means?	
	System error There may be a problem with EASYMAX® Tag blood glucose meter.	Replace the batteries first. 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 EASYMAX® Tag test strip. If E-2 (Error 002) appears again, please contact your local dealer.



Humidified / Used strips EASYMAX® Tag blood glucose meter has detected a problem with the test strip. Repeat the test with a new EASYMAX® Tag test strip.

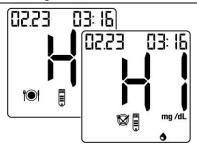
Refer to pages 28-29 for information on sample application.



Memory Error

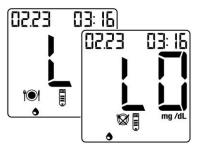
Replace the batteries first.

If E-5 (ERROR 005) appears
again, please contact your local
dealer.



Test result is higher than 600 mg/dL.

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.

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.



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

Relocate **EASYMAX®** Tag blood glucose meter to a location with temperature between 10°C - 40°C (50°F - 104°F).



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

Relocate **EASYMAX®** Tag blood glucose meter to a location with temperature between 10°C - 40°C (50°F - 104°F).



Low power

The battery do not have enough power to perform a test.

Replace a new battery.



No result in memory EASYMAX® Tag blood glucose 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		EASYMAX® Tag Blood Glucose Meter	
Range		20~600 mg/dL	
Response time		5 seconds	
Memory sets		880 test results	
Operating condition	Temp.	50°F -104°F (10°C-40°C)	
	Relative Humidity	R.H. ≦ 90%	
Storage and	Temp.	36°F -86°F (2°C -30°C)	
transportation condition	Relative Humidity	40-85 % RH	
Blood sample		0.6 μL	
		Fresh blood from fingertip, palm, or forearm	
Hematocrit (Hct)		20~60%	
Power		CR2032 Battery (1 pc)	
Battery life		Around 1000 tests	
Display dimension		28.0 x 29.0 mm	
Device dimension H x W x D		74 x 47 x 12 mm	
Weight		26 grams (without battery)	
Principles		Electrochemical biosensor technology	

Limitations

EASYMAX® Tag test strips are used for fresh capillary whole blood samples.

- 1. DO NOT use neonate blood sample.
- 2. The EASYMAX® Tag Blood Glucose Monitoring System is intended to be used at home by a single patient and should not be shared and not to be used for diagnosis or screening of diabetes.
- 3. Alternate site testing with this system can be used only during steady-state blood glucose conditions.
- 4. Extreme humidity may affect the results. A relative humidity greater than 90 % may cause incorrect results.
- 5. The system should be used at a temperature between 50°F and 104°F (10°C and 40°C). Out of 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 hematocrits between 20% and 60% will not significantly affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
- 8. Altitude up to 10,000 feet above sea level will not affect the reading.
- 9. Xylose: Do not use during xylose absorption testing, Xylose in the blood will cause an interference.
- 10. If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations > 7 mg/dL) you may get inaccurate results with this system.
- 11. If you have a disease or condition in which uric acid levels in your blood may be elevated (>11.9 mg/dL), such as gout, you may get inaccurate results with this system.
- 12. If you are taking Vitamin C (ascorbic acid) (for example Vitamin C containing supplement; at blood concentrations > 4 mg/dL) you may get inaccurate results with this system.

Technical Information

Near Field Communication (NFC) Technology

EASYMAX® Tag blood glucose meter uses Near Field Communication (NFC) wireless technology to communicate and transfer information. NFC is a set of short-range wireless technologies. According to the Quality of Service (QoS) request, the information associated with data rates, latency, and communications reliability is described as below.

NFC used in this meter operates at 13.56 MHz on ISO/IEC 15693 Type 5 air interface and at data rate maximum to 53 Kbit/s. The distance between meter and smart phone is suggested be less than 1cm. And, only one device can be connected at a time. There will be very low probability to have the interferences in data transmitting. NFC always involves an initiator and a target; the initiator actively generates an RF field that can power a passive target. The meter can only communicate with the device that:

- 1. utilizes NFC technology
- 2. has an application that can accept the meter's data.

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

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

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

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

The frequent causes of RFID interference problems are environmental factors and cross interference. If you experience meter interference problem, try moving your meter away the source of interference. You can also move the electronic device or its antenna to another location to solve the problem.

However, NFC is a versatile technology, privacy and security will be major issues. User is suggested to use passwords or keypad locks, install anti-virus software, and turn off the Bluetooth "discoverable" status when the phone is not in use.

Electromagnetic Compatibility – EASYMAX® Tag blood glucose meter meets the electromagnetic immunity requirements. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, the meter meets the electromagnetic emission requirements as per EN 60601-1-2. The meter's electromagnetic mission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.

The device complies with Part 15 of the FCC Rules. Operation is subjective to the following two conditions:

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

This equipment complies with FCC and IC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating condition. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

NOTE:

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

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

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

CAUTION:

To assure continued FCC compliance:

- 1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator & your body.

Device Information

EASYMAX® Tag SMBG System
EASYMAX® Tag Blood Glucose Test Strips
EASYMAX® Tag Blood Glucose Meter
EASYMAX® Tag Level 2 Control Solution
EASYMAX® Tag Level 3 Control Solution

Reference:

* American Diabetes Association. Standards of medical care in diabetes- Table 6.3 Summary of glycemic recommendation for many nonpregnant adults with diabetes. 2020; Vol. 43, Suppl. 1, S72.

Manufacturer: EPS BIO TECHNOLOGY CORP.

No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30076

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

Warranty

EPS warrants the original purchaser for a period of 4 years from the date of purchase. This means during the warranty period if the Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.

Please read EASYMAX® Tag User's Manual before operation. If you have any questions and/or need

assistance, please contact us as follows:

- Within the USA, call toll-free: 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.
- Outside the USA, call your authorized representative or write to: Customer Service E-mail: info@epsbio.com.tw

EASYMAX® Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

No. 32 Xinlian RD. Pingjiang Suzhou P.R. China 215031

TEL: 0086 (512) 67217661 FAX: 0086 (512) 67217663 E-mail: guopings@xinda-medical.com

EASYMAX® Lancet

Meets the requirements of MDD 93/42/EEC

Manufacturer:

SAE HAN MEDICAL CORP.

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

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