

USER'S MANUAL

EasyMax V Self-Monitoring Blood Glucose System

User's Manual

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

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Dear EasyMax V SMBG System Owner,

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

Thanks again for choosing the EasyMax V SMBG System.

Intended Use

The **EasyMax V Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (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. In addition, this device is not intended for the diagnosis of or screening for diabetes and not intended to be used in visually impaired users and neonates.

Standard Accessories

Your new **EasyMax V** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- Blood Glucose Meter
- 10 Test Strips
- Carrying Case
- 2 Alkaline Batteries
- 10 Lancets
- Lancing Device

- AST Lancing Device Cap
- User's Manual
- Quick Reference Guide
- Log Book
- Normal Control Solution
- Control Solution Instructions

Optional Accessories

• High Control Solution

Note: 1. Normal control solution is included with the system. 2.High control solutions are available. For purchase, please call Customer Service toll-free 866-994-3345.

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 the meter regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

Do you need Help?

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

Note:

Although the EasyMax V SMBG System is easy to use, you may need to consult 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 V** blood glucose meter is designed and approved for testing fresh capillary blood from fingertip, forearm. The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- Only use EasyMax V blood glucose meter with EasyMax V Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimen.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect reading. 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.
- Elevated levels of acetaminophen, uric acid, gentisic acid, L-Dopa, dopamine, ascorbic acid (vitamin C) and methyldopa may affect the test results.
- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.

- Remove batteries if the meter will not be used for one month or more.
- 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 viral disease.
- Consult with your healthcare professional before testing on your forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 10,000 feet above sea level has no effect on readings.

Health-Related Information

- If you are very dehydrated, urinating frequently, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNK), 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, or if you have questions, please talk to your doctor.
- 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



+	Left button	→	Right button
88-88	Date	Ð	Memory
88:88	Time		Insert a test strip
888	Result amount		Battery
mg/dL	Unit	ıll	Volume
En	English		Temperature
65	Espańol	\otimes	ERROR
	Blood apply		

Note: When) shows up in any sections of use's manual, the meter sounds and tells you the instructions.

Description of Sound

WHEN the meter will speak	WHAT the meter will say	
Tune on.	Turn-on music and greeting Tone.	
Setting Language / Setting Volume.	English (En) / Spanish (Es).	
Prompt user to insert test strip.	Please apply blood into the strip.	
Blood Glucose test is completed and the result is shown on screen.	Blood glucose is (number) milligram per deciliter.	
Blood Glucose test result is ABOVE the measurement range of 600 mg/dL.	Test result is higher than 600 milligram per deciliter. Please test again and if you get the same result, please contact your healthcare professional immediately.	
Blood Glucose test result is BELOW the measurement range of 20 mg/dL.	Test result is lower than 20 milligram per deciliter. Please test again and if you get the same result, please contact your healthcare professional immediately.	
Mumidified / Used strips.	Humidified or used strip. Please replace with a new strip.	
Low Power.	Low power. Please replace with new batteries.	
System error.	System error. Please replace the batteries.	
Temperature is too high.	Temperature is too high.	
Temperature is too low.	Temperature is too low.	
When the meter is turned off.	Good bye and turn-off music.	

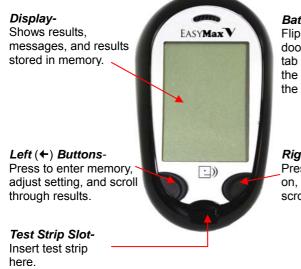
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Chapter 1: Understanding Your Meter

The EasyMax V Blood Glucose Meter



Battery Door-

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

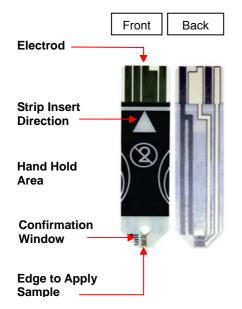
Right (→) Buttons-

Press to turn the meter on, confirm setting, and scroll through results.

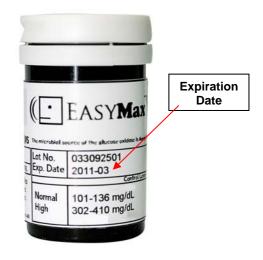


The EasyMax V Accessories

Blood Glucose Test Strip



Test Strip Bottle



Installing Batteries



 Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.



2 Insert two batteries. You will hear opening music. .



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

Setting The Time and Date—First Time Use

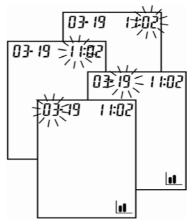
Setting the current time and date in your meter is important if you intend to use the meter memory.



1. \bigcirc ss \rightarrow to turn the meter on.

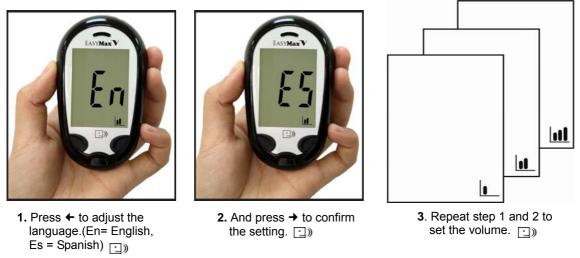


 The last 2-digit of the year flashes at the top of the display. Press ← to adjust the year and press → to confirm the setting.



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

Setting The Language and Volume—First Time Use



Note:

- 1. The priority language of the blood glucose meter is set in English.
- 2. The unit of blood glucose meter is set at mg/dL without any modification function. If the display shows mmol/L, please call Customer Service toll-free 866-994-3345.

Using EasyMax V Blood Glucose Test Strip

- Use only with EasyMax V 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.
- Close the bottle tightly right away, after you take a test strip out. This keeps the test strip dry.
- Use the test strip within three minutes after you take it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the "Expiration date" on the test strip bottle. The test strip is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 35.6°F 86°F(2°C 30°C). Do not freeze.
- Do not apply blood or control solution to the test strip 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.

Chapter 2: Control Solution Testing

Why Run A Control Solution Test

We recommend that you run the **EasyMax V** Normal control test because it lets you know that your meter and test strips are working properly to give you reliable results. You should run the control solution test when:

- You use the **EasyMax V** 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.

Note:

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

About The Control Solution

- Use only with EasyMax V test strips.
- Write the date you opened the bottle on the bottle label. The control solution is 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 35.6°F 86°F (2°C- 30°C). Do not freeze.

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.



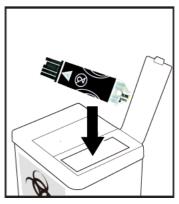
2. The meter turns on automatically ⊡) and the icons _____ of ____ and show themselves.



- **3.** Place the meter on a flat surface, like a table.
- 4. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.
- **5.** Squeeze the bottle until a tiny drop forms at the tip of the bottle.



- **6.** Touch the drop at the tip of the test strip.
- The meter starts to count down from 5 seconds and then shows the result. (1)
- 8. Do not 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.

Note: Please check if the result on the display is the same as audible result.

Understanding Control Solution Test Results

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

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:

Note:

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

Troubleshooting Checks

Was the test strip exposed to open air for a long Repeat the control test with properly stored strips. ✓ period of time? If the bottle was not capped tightly, the strips could Was the test strip bottle capped tightly? ~ be humidified. Replace the test strips. Was the meter functioning well? You can use control solution to verify the meter's functions. (Chapter 2) Replace with new control solution to check the Is the control solution expired or contaminated? ~ performance of SMBG system. Repeat the control test with properly stored strips Were test strips and control solutions stored in cool, dry places? or control solutions. Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to Did you follow the testing steps properly? ~ obtain the inaccurate results. Call Consumer Services Toll-Free: 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.

Action

Chapter 3: Testing Your Blood Glucose

Using The Lancing Device

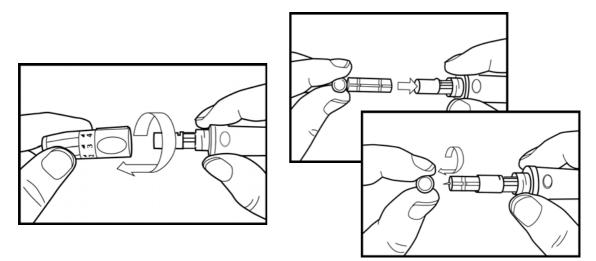
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.

Note:

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

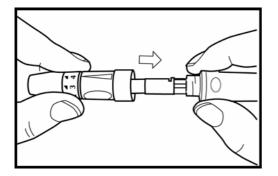
Inserting A Lancet Into The Lancing Device

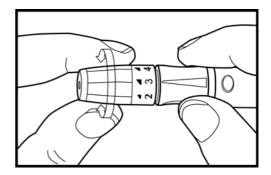
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.

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



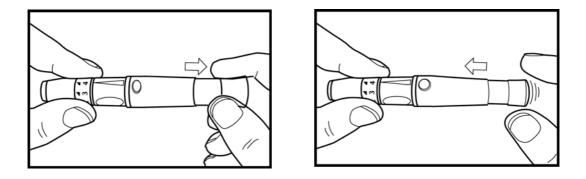


3. Recap the front cap.

4. Select the desired penetration depth.

Note:

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



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.

Running A Blood Glucose Test With Blood From Your Fingertip



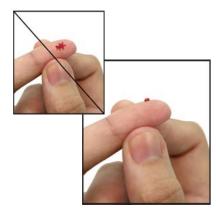
 Wash your hands with soap and warm water. Rinse and dry thoroughly.



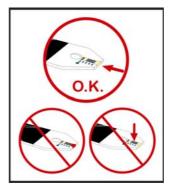
- Put a test strip into the meter in the direction of the arrow. The meter turns on automatically.⊡) The icons. and ▲ show themselves.
- When the blood drop flashes on the display, the meter will tell the instruction. ⊡



4. Using the lancing device. Hold the lancing device firmly against the side of your finger. Press the trigger button. Then remove the lancing device from your finger.



5. Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.



6. Touch the blood drop at the tip of the transparent window of the test strip. Do not put blood on top of the strip. Be sure to get enough blood in the strip's confirmation window. Otherwise, an inaccurate reading may result.



- The meter starts to count down from 5 seconds and shows the result. 3
- Remove the test strip and the meter turns off automatically. (*))

Note: Please check if the result on the display is the same as audible result.

Alternate Site Testing (AST)

Understanding Alternate Site Testing

What is AST? Besides the fingertip, you can test the 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 forearm for testing. AST that should be used with this device is the forearm only. Blood glucose test results obtained from your 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 often do not notice when your blood glucose is low.
- Your AST results do not match the way you feel.
- You think your blood glucose is high.
- 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
- After injecting rapid-acting insulin (two hours or less)
- When you have just taken insulin
- If the blood glucose test result does not match how you feel, do a fingertip test to confirm the result again.
- If you often do not notice when your blood glucose is low, do a fingertip test.

Running A Blood Glucose Test With Blood From Your Forearm

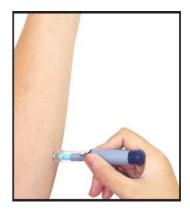
Please use the clear cap with the lancing device for AST testing.



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

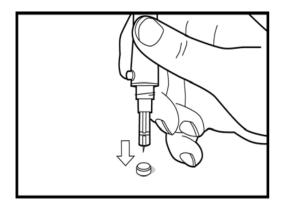


2. Press and hold the device with clear adjustable tip against the forearm.



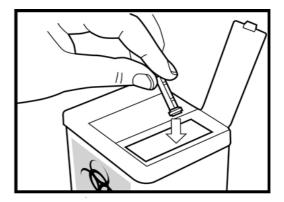
3. Press the trigger button to activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

Discarding Used Lancets



1. Unscrew and remove the adjustable cap. Without touching the used lancet, stick the lancet tip into its protective cover.

Grip the lancet carrier firmly and pull the lancet safely out.



2. Please discard used disposable lancets according to the recommendations of your healthcare professional.

Understanding Your Test Results

The **EasyMax V** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult without diabetes is 70-110 mg/dL. Two hours after meals, the blood glucose range for an adult without diabetes is less than 120 mg/dL. For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.

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.

Note:

- 1. Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.
- 2. A red blood cell count (Hematocrit) that is either very high (above 55%) or very low (below 30%) may not provide accurate results. If you do not know your hematocrit level, please consult your healthcare professional.
- 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

What It Means:

The test result is higher than reference normal range. (70-110mg/dL)

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 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

What It Means:

The test result is lower than reference normal range. (70-110mg/dL)

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 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 V** blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

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

Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

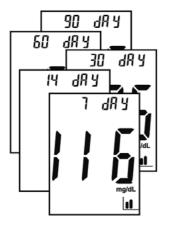
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

Note:

- 1. Do not change your therapy based on one individual result in memory.
- 2. The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting the time and date" in Chapter 1.
- 3. Once 480 results are in memory, adding a new result causes the oldest one to be deleted.
- 4. Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.

Viewing & Deleting Test Results

The meter provides 7, 14, 30, 60 and 90 days averaging to help track your blood glucose trend soundlessly.







- Press → until turning the meter on.
- 2. Press ← to view averages for 7/14/30/60/90 days.

Note: Press \rightarrow for 3 seconds to turn off the meter, or the meter turns off automatically in 90 seconds.

- To delete a test result, press ← for more than 3 seconds and display shows "dEL".
- 5. Press ← to keep reviewing the results.
- 6. Press → to go back to averages for 7/14/30/60/90 38 days.

Meter Setup

Using The Set Mode

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

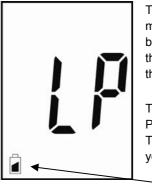
Time and Date — to set the time and date (see Chapter 1).

Language — to set the language (see Chapter 1).

Volume – to set the volume (see Chapter 1)

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries are also acceptable, but the capacity of test times may differ. Install the batteries when you first use the meter or replace with new batteries when the "LP" (low power) message and the low battery symbol appear on the display.

The meter will not turn on the first time batteries are installed. Please press and hold " \rightarrow " button or insert the test strip to turn your meter on. The meter will turn off automatically. Or you can press and hold " \rightarrow " button to turn your meter off.

Low battery symbol

Note:

- 1. The meter won't delete earlier records after you replace batteries.
- 2. You should reset the time and date again after you replace the batteries.
- 3. 1.5V (AAA) x 2 batteries are available at most stores. You may take the old batteries with you for replacement.
- 4. Remove batteries when you will not be using the meter for one month or more.

Cleaning Your Meter

Caring for your **EasyMax V** 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:

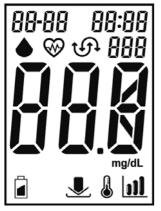
Do:

- Make sure the meter is turned off.
- Gently wipe the meter's surface with a soft cloth slightly dampened.

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.

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 " \rightarrow " to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, call the Customer Service Center toll-free: 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider

Cleaning Your Lancing Device

- To clean the lancing device, wipe 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.

Screen Messages And Troubleshooting

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



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



Low power Action: Replace with new batteries.



System fault

Action: Replace the batteries first. If **ERROR 001** appears again, please call Customer Service toll-free **866-994-3345**.

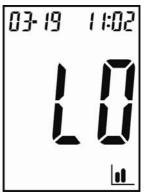


System fault Action: Replace the batteries first. If Err appears again, please call Customer Service toll-free 866-994-3345.



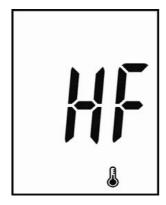
Test result is higher than 600 mg/dL.

Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please contact your healthcare professional.

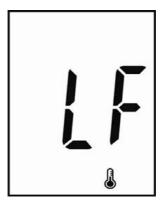


The test result is lower than 20 mg/dL.

Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please contact your healthcare professional.



The "HF" and thermometer icon appears. Temperature is too high, outside the required range of $50^{\circ}F - 104^{\circ}F (10^{\circ}C - 40^{\circ}C)$. Action: Relocate the meter to a location with temperature between $50^{\circ}F - 104^{\circ}F (10^{\circ}C - 40^{\circ}C)$.



The "LF" and thermometer icon appears. Temperature is too low, outside the required range of $50^{\circ}F - 104^{\circ}F (10^{\circ}C - 40^{\circ}C)$. Action: Relocate the meter to a location with temperature between $50^{\circ}F - 104^{\circ}F (10^{\circ}C - 40^{\circ}C)$.

Chapter 6: Technical Information

Specifications

Brand name		EasyMax V Blood Glucose Meter	
Range		20 - 600 mg/dL	
Test time		5 seconds	
Memory sets		480 test results	
Operating condition	Temp.	50°F - 104°F (10°C - 40°C)	
	Relative Humidity	$R.H.~\leq~90\%$	
Pland comple		0.6 µL	
Blood sample		Fresh blood from fingertip or forearm	
Hematocrit (Hct)		30-55%	
Power		2 Alkaline 1.5V (AAA)	
Battery life		Over 2000 tests	
Display dimension		1.57" x 1.30" (40.0 × 33.0 mm)	
Device dimension H × W × D (mm)		3.6" x 2.1" x 0.8" (92.9 × 54 × 21.65 mm)	
Weight		1.48 oz (42.04 grams) w/o batteries	
Principles		Electrochemical biosensor technology	

Limitation

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

- 1. DO NOT use neonate blood sample.
- 2. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
- 3. The system should be used at a temperature between 50°F 104°F (10°C 40°C). Outside this range, the system halts.
- 4. DO NOT reuse the test strips. The test strips are for single use only.
- Red blood cell count (Hematocrit); Hematocrit levels between 30% and 55% will not significantly affect the results, Hematocrit levels below 30% may cause higher results, Hematocrit levels above 55% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
- 6. Altitude up to 10000 feet above sea level has no effect on readings.

Healthcare Professionals – Please note these additional Limitations

- 7. Patients undergoing oxygen therapy may have inaccurate results.
- 8. If the patient has the following conditions, the result may fail:
 - Severe dehydration
 - Severe hypotension (low blood pressure)
 - Shock
 - A state of hypoglycemic-hyperosmolar state (with or without ketosis)
- Lipemic samples: Cholesterol level up to 500 mg/dL and triglycerides up to 3,000 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with EasyMax V Glucose Meter.

10. Critically ill patients should not be tested with home-use blood glucose meters.

11. Interfering Substances depend on the concentration. Elevated levels of acetaminophen, uric acid, gentisic acid, L-Dopa, dopamine, ascorbic acid (vitamin C) and methyldopa may affect the test results.

Interfering , Substance	Test Concentration mg/dL	Bias at 50±5 mg/dL	% Bias at 250±5 mg/dL	% Bias at 500±5 mg/dL
Acetaminophen	8	10.2	6.5	3.8
Ascorbic Acid	2.5	11.8	-6.8	5.3
Dopamine	2	4.3	12.9	6.3
Gentisic Acid	6	7.8	2.8	-4.3
L-Dopa	2	3.8	-1.2	-1.8
Methyldopa	2	5.2	-2.3	4.1
Uric Acid	13	7.6	3.9	3.8

Device Information

EasyMax V SMBG System, EasyMax V Blood Glucose Test Strips, EasyMax V Blood Glucose Meter, EasyMax V Normal Control Solution, EasyMax V High Control Solution.

Reference:

* American Diabetes Association: Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p.S37

Manufacturer:

2F, No.49-2, Lane 2, Guang-Fu Rd., Sec. 2, Hsinchu City, Taiwan

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

Suzhou SPR Medical Devices Development CO., Ltd

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

Lancet

Meets the requirements of MDD 93/42/EEC

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

Warranty

EPS warrants the original purchaser for a period of 3 years from the date of purchase. This means during the warranty period if your 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.

P/N. 718035300 Rev.A01-103009