EGV1.1

Self-Monitoring Blood Glucose System

User's Manual

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

Dear EGV1.1 SMBG System Owner,

Thank you for using the **EGV1.1** 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 **EGV1.1** Self-Monitoring Blood Glucose System. To start testing quickly, you can also refer to the Quick Reference Guide.

Thanks again for choosing the **EGV1.1** SMBG.

Intended Use

The **EGV1.1 Self Monitoring Blood Glucose 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. Alternative site testing can be only used during steady-state blood glucose conditions.

Important Safety Instructions

Lancing devices and meters are for single patient use only. A new, sterile lancet should be used each time you perform a test. The lancing device, lancets and meter are NOT to be shared between users or other family members. Do NOT use on multiple individuals. Sharing a lancing device and lancets may transmit blood borne pathogens, such as viral hepatitis.
All parts of the kit are considered biohazardous and may transmit infection, even if you have performed cleaning and disinfection. Wash hands thoroughly with soap and water after handling the meter or lancing device.

For further information, please see: *"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication"* (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Standard Accessories

The **EGV1.1** Blood Glucose meter and accessories are working together to measure the amount of glucose in your blood. The system includes:

- **EGV1.1 Blood Glucose Meter**
- **Alkaline Battery (2 ct)**
- **EGV1.1 Blood Glucose Test Strips (10 pcs)**
- **Test Strip Instructions**
- **Lancets (10 pcs)**
- **Lancing device**
- **AST Lancing Device Cap**
- **User's Manual**
- **Quick Reference Guide**
- **Self-Test Log Book**
- **EGV1.1 Level 2 Control Solution**
- **Control Solution Instructions**
- **Carrying Case**

Optional Accessories

- **EGV1.1 Level 3 Control Solution**

Note:
1. EGV1.1 Level 2 Control Solution is included with the system.
2. EGV1.1 Level 3 Control Solution are available. For purchase, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).

Why is it so important to test blood glucose regularly?

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

Do you need help?

If you have questions or need assistance, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.

Please complete your warranty card and mail it, so you receive the best customer service possible and news about product update.

Note:
Although the EGV1.1 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

- **EGV1.1** 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.
- **EGV1.1** blood glucose meter can only be used with **EGV1.1** 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 freezer.
- Keep the meter, test strips and lancing device away from children and pets.
- Critically ill patients should not be tested with this meter.
- 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.

Note:

- Consult with your healthcare professional before testing on your fingertip, palm or forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 10,000 feet above sea level has no effect on readings.
- It should not be used to diagnose or screen for diabetes.

Health-Related Information

- If you are experiencing dehydration, frequent urination, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get an inaccurate glucose result. If you think you have any of these conditions, contact your healthcare provider immediately.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, contact your Healthcare Professional or physician immediately. If you have questions regarding the use of the meter, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.
- Please read your test strip instructions carefully for additional health-related information.

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Chapter 1: Understanding Your Meter

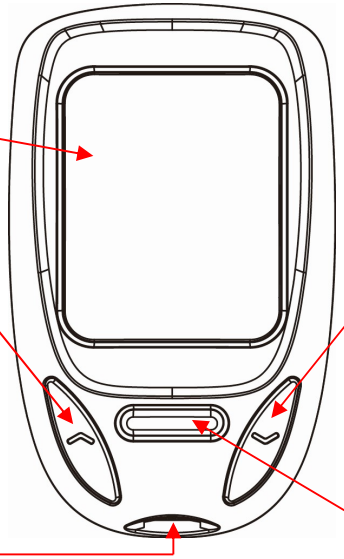
The EGV1.1 Blood Glucose Meter

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

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

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

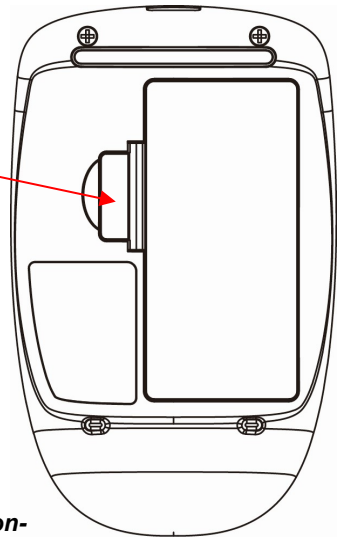
Test Strip Slot-
Insert test strip here.



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

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

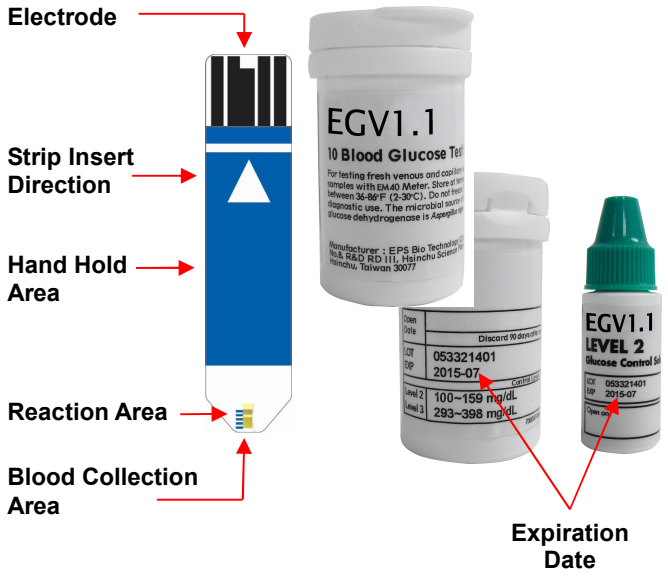
Middle (▬) Button-
Press to turn on and off the meter, confirm the setting.



The EGV1.1 Accessories

Blood Glucose Test Strip

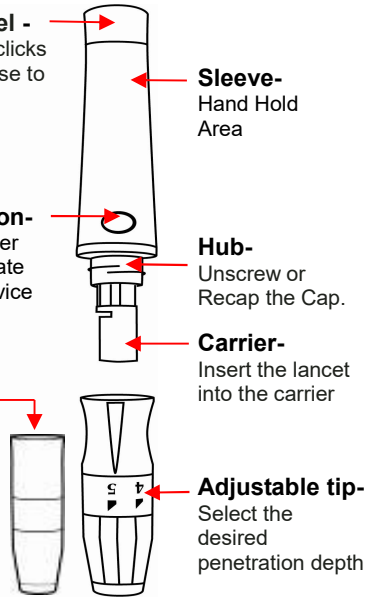
Test Strip Bottle
Control Solution Bottle



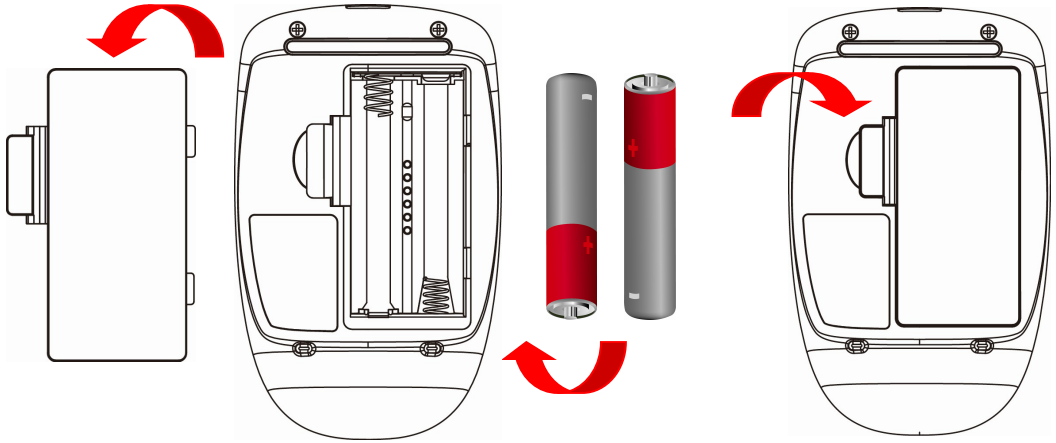
Lancing Device

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

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



Inserting Batteries



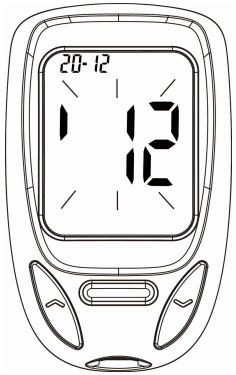
1. Open the battery door on the back of the meter by pushing the tab in the direction of the arrow.

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

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

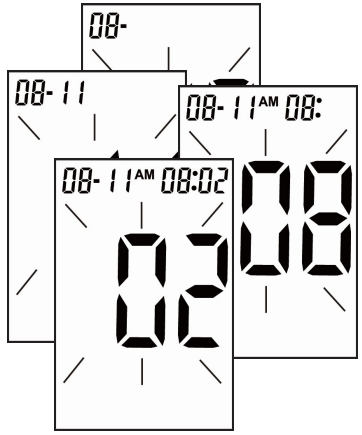
Setting The Time and Date—First Time Use

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

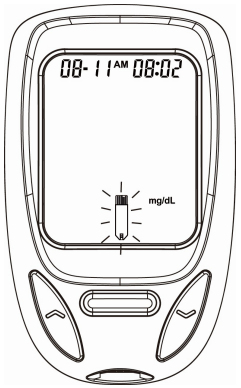


1. After inserting batteries, the meter turns on automatically.

2. The last 2-digits of the year flash at the center of the display. Press ◀ and ▶ 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.



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

Using EGV1.1 Blood Glucose Test Strips

- Use only with **EGV1.1** 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 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 test 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 36°F - 86°F (2°C ~30°C) and 40%-85% RH. 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.
- **EGV1.1** Self-Monitoring Blood Glucose Test System is a “no code” system and does not require any test strip calibration.

Chapter 2: Control Solution Testing

Why Run a Control Solution Test

We recommend that you run the **EGV1.1** level 2 and level 3 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:

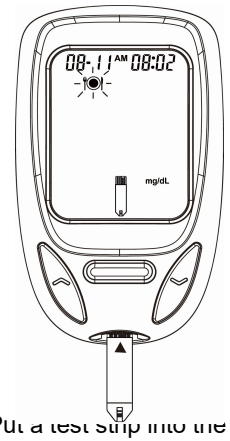
- You use the **EGV1.1** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.

About The Control Solutions

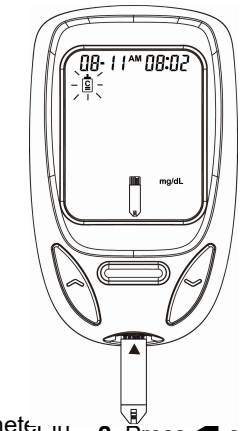
- Use with **EGV1.1** test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is 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 **EGV1.1** Control Solutions**,** please contact Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).

Running a Control Solution Test

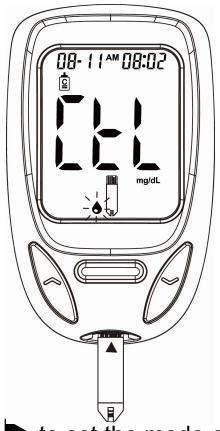
You need the meter, a test strip, and control solution.

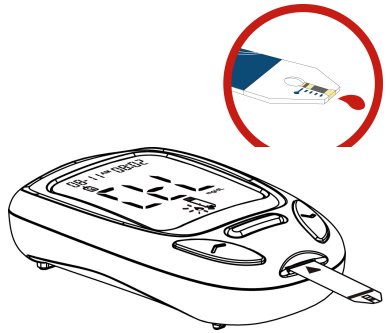


1. Put a test strip into the meter in the direction of the arrow and the icon of shows itself.



2. Press ◀ or ▶ to set the mode of control solution " ". Press to confirm the setting.



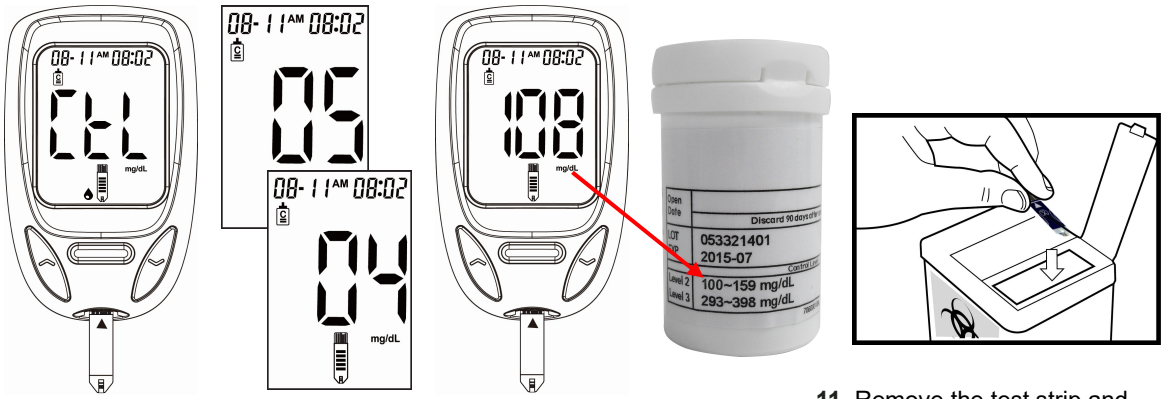


3. Place the meter on a flat surface, like a table.

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

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

Note: Setting the meter in control solution mode "CTL" will prevent the control solution reading from being added to your memory.



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

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

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

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

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

11. Remove the test strip and dispose of it according to your healthcare provider's instructions after you have compared the reading to the range printed on the test strip bottle.

Note: 1. The ranges appearing on this picture are examples only and not the ranges that the user should refer to when determining if their control solution test is acceptable.

2. Level 2 and Level 3 ranges listed on your test strip bottle are the two different control solutions. Please be sure that you are looking at the correct range.

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 the acceptable range for the appropriate control solution level. Make sure you compare the result to the correct level of control.

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

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

Note: Control Solution values will be included in the memory and averages, if the meter is not set in control solution mode “CTL”.

Troubleshooting Check	*Action*
✓ Was the test strip exposed to open air for a long period of time?	If yes, repeat the control test with properly stored strips.
✓ Does test strip cap close tightly? Or was test strip cap left open?	If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.
✓ Is the control solution expired or contaminated?	If yes, replace with a new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	If no, repeat the control test with properly stored strips or control solutions.
✓ Did you follow the testing steps properly?	Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to obtain the inaccurate results. If you continue to have problems please contact Customer Support at 866-994-3345.

Chapter 3: Testing Your Blood Glucose

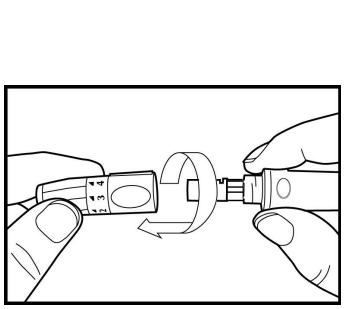
Using the Lancing Device

- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.
- If the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person. For cleaning and disinfection instruction, please refer to Chapter 5: Maintenance And Troubleshooting "Cleaning and disinfect your meter and lancing device".

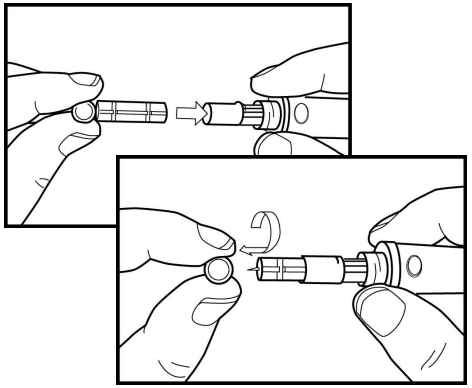
Note:
Used test strips and lancets are considered bio-hazardous waste in accordance with U.S. local regulations and should be handled as if capable of transmitting infection. The users may discuss methods for disposing used test strips and lancets with their doctor.

Inserting a Lancet into the Lancing Device

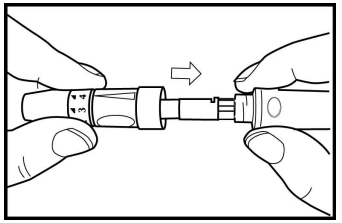
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.

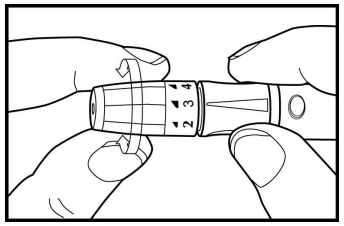


2. Insert the lancet into the lancing device firmly then twist off the protective cover.

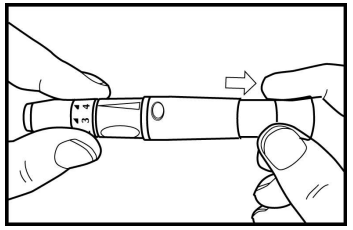


3. Recap the front cap.

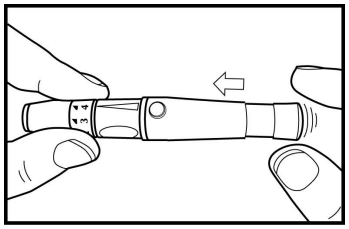
Note:
Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.



4. Select the desired penetration depth.



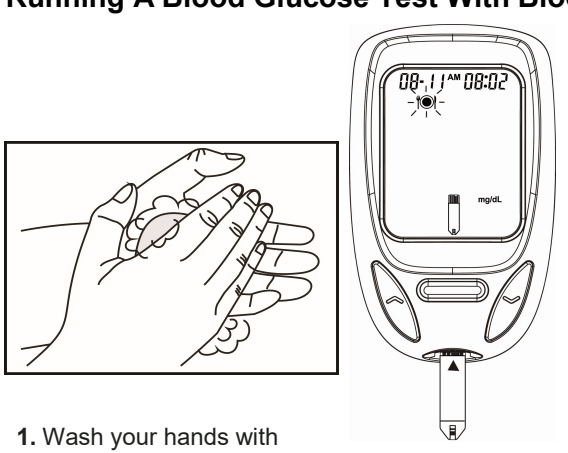
5. Pull on the sliding barrel of the lancing device until it clicks and then release.
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.

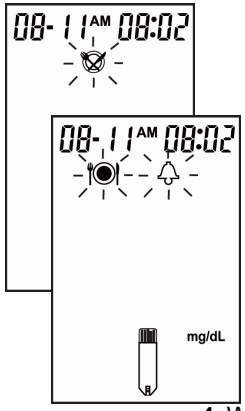


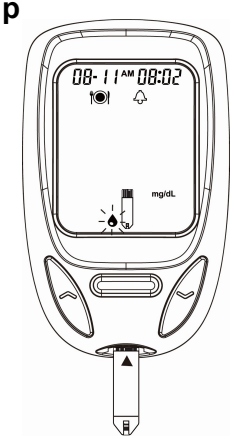
6. Set the lancing device aside until later in the test.

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

Running A Blood Glucose Test With Blood From Your Fingertip







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

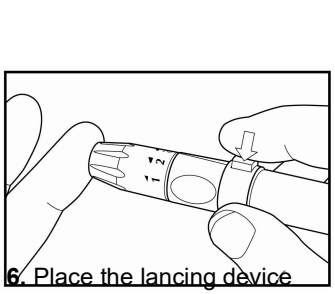
Note: **Please make sure to apply blood when the blood drop appears on the display.**

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

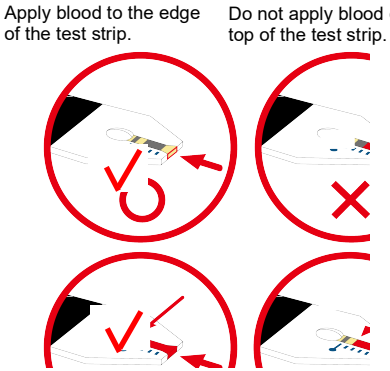
3. Press ◀ or ▶ to set , or and press to confirm the setting.

4. When the blood drop flashes on the display, swab the blood collection area on your finger with an alcohol swab. Please wait at least 5 seconds until the intended area is dry and clean before sampling the blood.

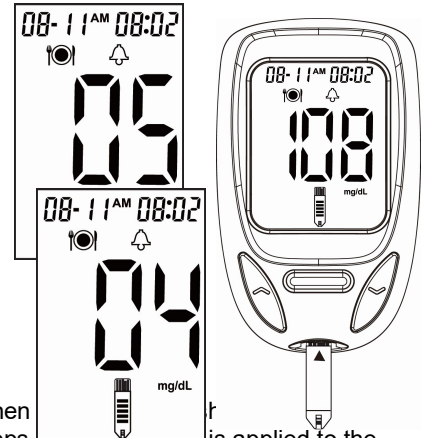
5. Gently squeeze your finger to assist the flow of blood.



6. Place the lancing device against the tip or side of your finger; press the trigger button to activate the lancing device.
7. Wipe away the first drop with a tissue and use the second drop.
8. Gently squeeze your finger to assist the flow of blood. This helps you get a blood drop.



9. Touch the blood drop to 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.



10. When beeps, is applied to the strip's reaction zone.
11. The meter starts to count down from 5 seconds. A result will appear on the display afterwards.
12. Wash hands thoroughly with soap and water after handling the meter, lancing device and test strips.

Alternative Site Testing (AST)

Understanding Alternative 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.
- You are ill.

Fingertip test only:

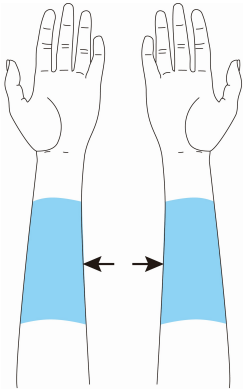
- If sick
- If blood glucose is low
- After exercising

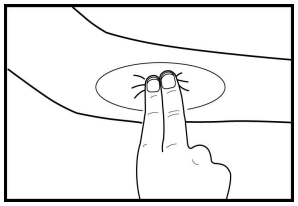
Caution:

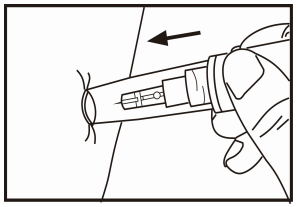
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm and palm samples.
- Measurements from alternative site testing should never be used to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

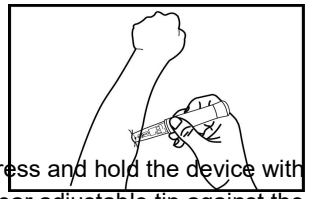
Please use the AST cap with the lancing device for alternative site testing (AST). This graphic shows where the meter was cleared for AST.



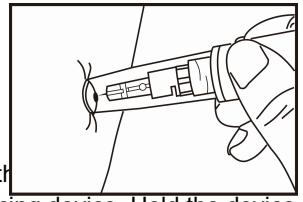




1. Massage the puncture area of forearm for a few seconds.



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

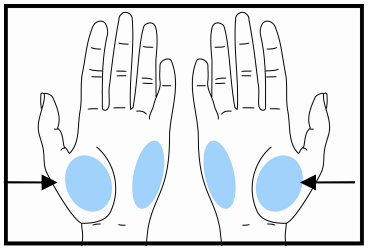


3. Press th the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

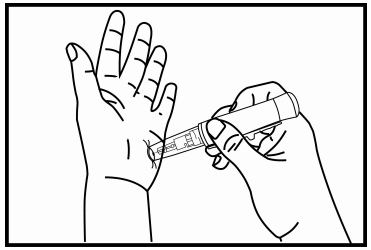
4. Wipe away the first drop with a tissue and use the second drop.

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.

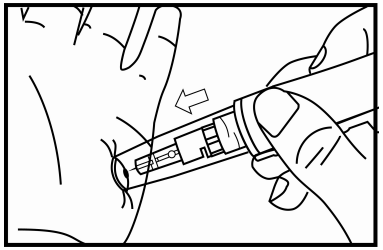
Running A Blood Glucose Test With Blood From Your Palm



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.

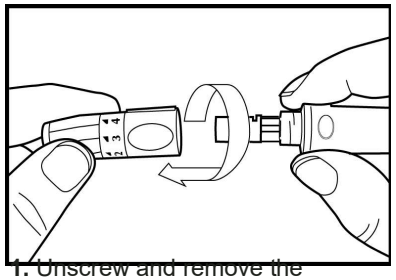


3. Press the trigger button to activate the lancing device.

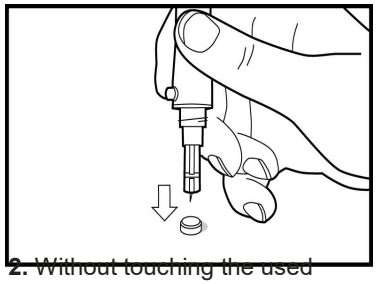
4. Hold the device against palm and increase pressure until the blood sample size is sufficient.

Caution: 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.

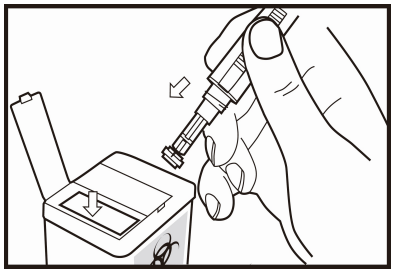
Discarding Used Lancets



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.

4. Wash hands thoroughly with soap and water after handling the meter, lancing device and test strips.

Understanding Your Test Results

Expected Values*

The **EGV1.1 Pro** Blood Glucose test strips are whole-blood referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult without diabetes is 70-100 mg/dL*. Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL. For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.

＊Reference: American Diabetes Association. Standards of medical care in diabetes. Diabetes care. 2013; Vol. 36, Suppl 1:S11-66

Unusual Test Results

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

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

Note:

1. **Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results. Operate your system between 30%-90% RH.**
2. **Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.**

Comparing Your Meter Result To A Lab Result

A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to your healthcare provider's office for a blood glucose test, your 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 **EGV1.1** 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

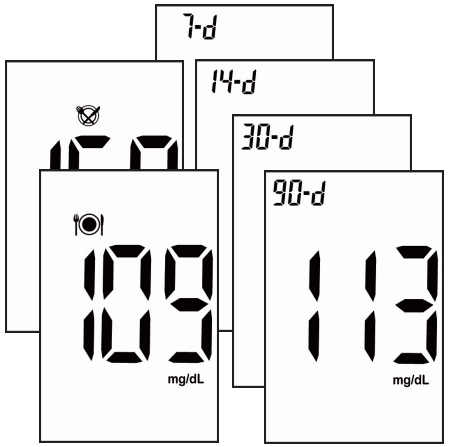
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

Note:

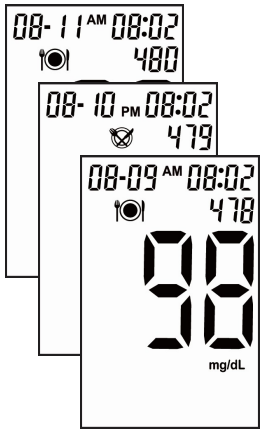
1. **Do not change your therapy based on one individual result in memory.**
2. **The memory is not lost when you replace the battery. You do need to check that the time and date are still correct for future readings. See Section "Setting the time and date" in Chapter 1.**
3. **Once 480 results are in memory, adding a new result causes the oldest one to be deleted.**
4. **If you don't set "C" mode, control solution values will be included in the memory.**

Viewing & Deleting Test Results

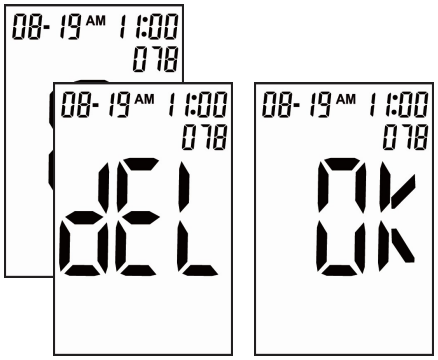
You can review them at any time without inserting a test strip when the display flashes the icon of .
Each review requires the user to go back to the main screen (testing mode) by pressing pressing ▶ and ◀ for 2 seconds.



1. Press ▶ and ◀ meanwhile to review AC & PC average values under and , the average value of 7/14/30/90-day.



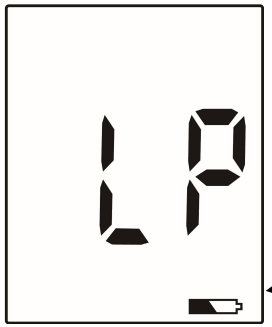
2. Press ▶ or ◀ to review all results in order from records of 480 to 001.



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

Chapter 5: Maintenance and Troubleshooting

Inserting 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. Insert 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.

Low battery symbol

Note:

1. **The meter won’t delete earlier records after you replace batteries.**
2. **You should reset the time and date again after you replace the batteries. See Section "Setting the time and date" in Chapter 1.**
3. **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 and Disinfecting Your Meter and Lancing Device

Choosing the disinfectant

The recommended EPA-registered disinfected product is as follow:

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

Super Sani-Cloth germicidal wipe contains active ingredients: n-Alkyl (60% C_{14}, 30%C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chlorides and n-Alkyl (68%C_{12}, 32%C_{14}) dimethyl ethylbenzyl ammonium chlorides and they have been shown to be safe for use with the **EGV1.1** meter, but any other disinfectant product with the EPA registration number may be used on this device.

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

Cleaning and Disinfection Instruction

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

Cleaning and disinfection are both required, but are different. Cleaning is the removal of visible dust, dirt or blood, but cleaning does not kill blood-borne pathogens. Disinfection kills blood-borne pathogens and helps prevent their spread. The disinfection step is always preceded by a cleaning step.

The EG V1.1meter should be cleaned and disinfected a minimum of once per week. The EG V1.1 meter has been validated to withstand up to 6 cleanings per day and cleaning and disinfection once per week over the 4 year use life of the device. EG V1.1 blood glucose meter and lancing device should be used only on one

patient and not shared. If the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

Cleaning Instruction: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold and use first germicidal wipe to clean before each disinfecting step.

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

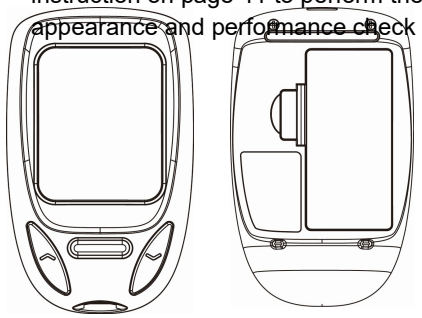
Do:

- Make sure the meter is turned off during cleaning and disinfection.
- Keep the test strip vials tightly closed when performing the cleaning and disinfection procedures because the fumes from the disinfectant may affect the performance of the strip
- After cleaning or disinfection, please follow the instruction on page 41 to perform the physical appearance and performance check of devices.

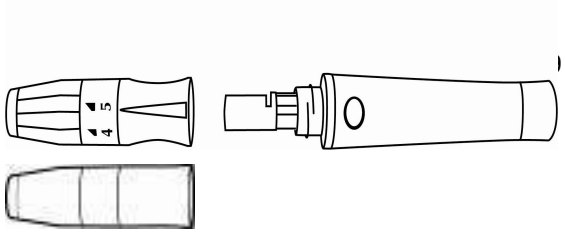
Do Not:

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

1. Meter cleaning/disinfection area



2. Lancing device cleaning/disinfection area



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

If you notice any of the following, immediately stop using the meter and call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance:

- The symbols, letters, or numbers on the display are blurry or obscured
- The lancing device or meter is scratched or cracked
- Any part of the lancing device or meter has started to erode or deteriorate
- Any printing on the lancing device, meter, or meter buttons is not legible

Performance check of the meter and lancing device after cleaning and disinfection

If you notice any of the following, immediately stop using the meter and call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon- Fri 8:00AM~6:00PM) for assistance:

- The meter does not power on or off, does not beep, or does not display symbols, letters, or numbers correctly
- Results are not stored correctly in the meter memory
- Control solution values are out of range
- The lancing device does not cock or fire correctly
- The AST clear cap cannot be screwed on
- The penetration depth ring cannot be adjusted

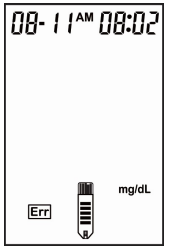
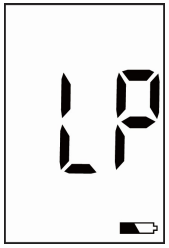
Maintenance and Testing

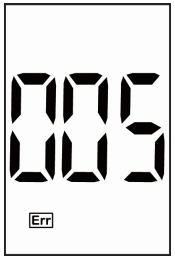
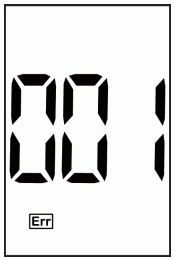
Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

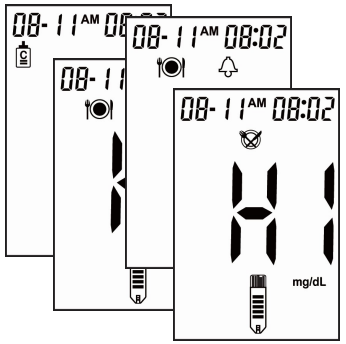
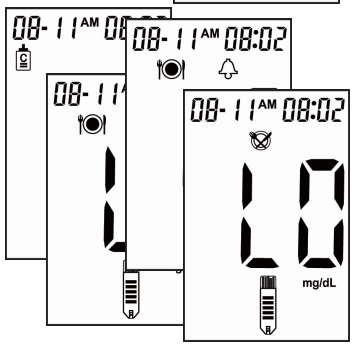
To make sure the display is working properly, turn off the meter. Press and hold power button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time,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

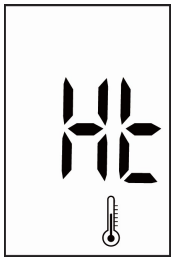
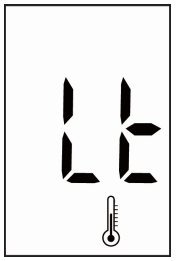
Screen Messages and Troubleshooting

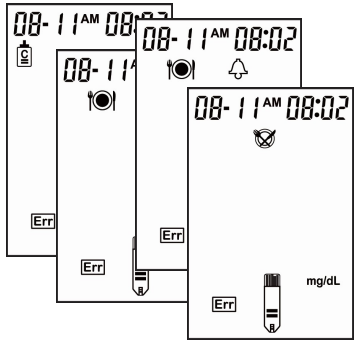
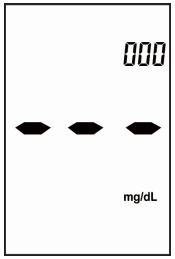
Never make treatment decisions based on an error message. If you have any concerns, please contact your healthcare professional.

Message	*What it means?*	*What to do?*
	**Humidified / Used strips** The meter has detected a problem with the test strip.	**Repeat the test with a new strip.** Refer to pages 26-27 for information on sample application.
	**Low power** The meter batteries do not have enough power to perform a test.	**Replace with the new batteries.**

Message	*What it means?*	*What to do?*
	**Memory Error**	**Replace the batteries first.** If ERROR 005 appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).
	**System error** There may be a problem with the meter.	**Replace the batteries first.** Refer to pages 14 and 38. If this error message appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).

Message	*What it means?*	*What to do?*
	**Test result is higher than 600 mg/dL.**	**Re-check your glucose level.** If the result is still “HI”, try a control solution test and if the control solution test falls within the correct range, 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.
	**The test result is lower than 20 mg/dL.**	**Re-check your glucose level.** If the result is still “LO”, try a control solution test and if the control solution test falls within the correct range, 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.

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?*
	**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 call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).
	**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		EGV1.1 Blood Glucose Meter
Range		20~600 mg/dL
Response time		5 seconds
Memory sets		480 test results
Operating condition	Temp.	50°F -104°F (10°C-40°C)
	Relative Humidity	30% - 90% R.H.
Storage and transportation condition	Temp.	36°F ~86°F (2°C ~30°C)
	Relative Humidity	40-85 % RH
Blood sample		0.6 μL
		Fresh blood from fingertips, palm or forearm
Hematocrit (Hct)		20~60%
Power		2 x Alkaline Battery
Battery life		Over 2000 tests
Display dimension		1.27” x 1.59” (32.3 × 40.4 mm)
Device dimension H × W × D (mm)		3.23” x 1.97” x 0.87” (82.0 × 50.0 × 22.0 mm)
Weight		1.41 oz (40 ±1 grams) w/o batteries
Principles		Electrochemical biosensor technology

Limitations

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

1. DO NOT use neonate blood sample.
2. Not to be used for diagnosis or screening of diabetes.
3. Alternative site testing with this system can be used only during steady-state blood glucose conditions.
4. 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.
5. Extreme humidity may affect the results. A relative humidity greater than 90 % may cause incorrect results. Operate your system between 30%-90% RH.
6. The system should be used at a temperature between 50°F and 104°F (10°C and 40°C). Outside this range, the system may get incorrect results.
7. DO NOT reuse the test strips. The test strips are for single use only.
8. Hematocrit: The hematocrits between 20% and 60% will not significantly affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
9. Altitude up to 10,000 feet above sea level has no effect on readings.

10. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Exogenous Interference data				
Exogenous Substances	**highest Conc. tested**	**interference or no**	**Bias @ blood glucose Conc.**	**Note**
Acetaminophen	8 mg/dL	Yes	14.2%@80 mg/dL 14.9%@120 mg/dL	The highest no interference concentration is 7 mg/dL
Ascorbic Acid	4 mg/dL	No	NA	
Dopamine	5.2 mg/dL	Yes	31.0%@80 mg/dL 18.2%@120 mg/dL	The highest no interference concentration is 2.6 mg/dL
Gentisic Acid	6 mg/dL	No	NA	
Ibuprofen	50 mg/dL	No	NA	
L-Dopa	4 mg/dL	Yes	16.3%@80 mg/dL 11.4%@120 mg/dL	The highest no interference concentration is 2 mg/dL
Methyldopa	2 mg/dL	No	NA	
Sodium Salicylate	50 mg/dL	No	NA	
Tetracycline	1.5 mg/dL	No	NA	
Tolbutamide	100 mg/dL	No	NA	
Galactose	20 mg/dL	No	NA	
Maltose	20 mg/dL	No	NA	
Xylose	8 mg/dL	Yes	10.1%@80 mg/dL	The highest no interference concentration is 6 mg/dL
Fructose	30 mg/dL	No	NA	
Manose	10 mg/dL	No	NA	
Sucrose	50 mg/dL	No	NA	
Xylitol	200 mg/dL	No	NA	
Glipizide	8 mg/dL	No	NA	

Endogenous Interference data				
Endogenous Substances	**highest Conc. tested**	**interference or no**	**Bias @ blood glucose Conc.**	**Note**
Bilirubin- unconjugated	25 mg/dL	No	NA	
Cholesterol	500 mg/dL	No	NA	
Creatinine	30 mg/dL	No	NA	
Triglycerides	1000 mg/dL	No	NA	
Uric Acid	15.9 mg/dL	Yes	14.3%@80 mg/dL 17.5%@120 mg/dL	The highest no interference concentration is 11.9 mg/dL

ACCURACY STUDY

The accuracy of the SMBG System was assessed by comparing to laboratory results. The following results were obtained by 153 subjects with diabetes at three independent clinical sites.
The regression statistics are derived from a plot of the capillary of fingerstick data versus YSI plasma data.

Slope	1.0100	**Intercept**	-0.9679 mg/dL
Number of subject	153	**R-square**	0.9696
Range tested	58.5– 433.5 mg/dL		

Glucose level ≦75mg/dL

within±5mg/dL	within±10mg/dL	within±15mg/dL
14/19 (73.68%)	19/19 (100%)	19/19 (100%)

Glucose level >75mg/dL

within±5%	within±10%	within±15%	within±20%
83/134(61.94%)	115/134(85.82%)	129/134(96.27%)	131/134(97.76%)

The accuracy of the SMBG System was assessed by comparing to laboratory results. The following results were obtained by 153 subjects with diabetes at three independent clinical sites.
The regression statistics are derived from a plot of the AST data versus YSI plasma data.

Thenar testing-			
Slope	0.9688	**Intercept**	4.8241 mg/dL
Number of subject	153	**R-square**	0.9481
Range tested	55– 459 mg/dL		

Glucose level ≦75mg/dL

within±5mg/dL	within±10mg/dL	within±15mg/dL
12/19 (63.16%)	17/19 (89.47%)	19/19 (100%)

Glucose level >75mg/dL

within±5%	within±10%	within±15%	within±20%
63/134(47.01%)	99/134(73.88%)	121/134(90.30%)	129/134(96.27%)

Hypothenar testing-

Slope 1.0896 **Intercept** -11.7596 mg/dL

Number of subject 153 **R-square** 0.9584

Range tested 53– 517 mg/dL

Glucose level ≦75mg/dL

within±5mg/dL	within±10mg/dL	within±15mg/dL
9/19 (47.37%)	16/19 (84.21%)	18/19 (94.74%)

Glucose level >75mg/dL

within±5%	within±10%	within±15%	within±20%
66/134(49.25%)	95/134(70.90%)	113/134(84.33%)	129/134(96.27%)

Arm testing-

Slope 1.0263 **Intercept** -4.6425 mg/dL

Number of subject 153 **R-square** 0.9503

Range tested 50– 514 mg/dL

Glucose level ≦75mg/dL

within±5mg/dL	within±10mg/dL	within±15mg/dL
8/19 (42.11%)	14/19 (73.68%)	19/19 (100%)

Glucose level >75mg/dL

within±5%	within±10%	within±15%	within±20%
59/134(44.03%)	97/134(72.39%)	112/134(83.58%)	128/134(95.52%)

EGV1.1 SMBG System,
EGV1.1 Blood Glucose Test Strips,
EGV1.1 Blood Glucose Meter,
EGV1.1 Level 2 Control Solution,
EGV1.1 Level 3 Control Solution

Manufacturer:
EPS BIO TECHNOLOGY CORP.
No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30077
TEL：+886-3-6686868 FAX：+886-3-6686866
E-mail：info@epsbio.com.tw Website：http://www.epsbio.com

Warranty

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

Please read **EGV1.1** User's Manual before operation. If you have any questions and/or need assistance, please contact us as follows:

- Within the USA, call toll-free: 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.

- Outside the USA, call your authorized representative or write to:
  Customer Service E-mail: info@epsbio.com.tw

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

68# LiTangHe RD, XiangCheng, Suzhou, China 215131
Tel: +86 512 65799308 Fax: +86 512 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

P/N: 71800528A_0077A_01