

EasyPlus mini R13N

Self-Monitoring Blood Glucose System

User's Manual

Dear EasyPlus mini R13N SMBG System Owner,

Thank you for using the **EasyPlus mini R13N** Self-Monitoring Blood Glucose (SMBG) System. We design this system for medical care on diabetes. The test results can help you determine the effects of food, exercise and diabetes medications. We design 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 will help you get the most from your EasyPlus mini R13N SMBG System. It provides you and your diabetes care team with important information and step-by-step direction to use the EasyPlus mini R13N Self-Monitoring Blood Glucose System. To start testing quickly, you can also refer to the Quick Reference Guide.

If you have questions, please contact your healthcare professional to get our help. You can also visit www.epsbio.com for diabetes management tools and product demonstrations.

Thanks again for choosing the EasyPlus mini R13N blood glucose meter.

Standard Accessories

Your new EasyPlus mini R13N Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- **EasyPlus mini R13N Blood Glucose Meter**
- **EasyPlus mini R13N Blood Glucose Test Strips (10 pcs)**
- **Lancing device**
- **AST Cap**
- **User's Manual**
- **Quick Reference Guide**
- **Wallet**
- **Check Strip**
- **CR2032 Lithium Battery (1 pcs)**
- **Lancets (10 pcs)**
- **Alcohol Pad (5 pcs)**
- **Test Strip Instructions**

Optional Accessories

- **EasyPlus mini R13N Glucose Normal Control Solution**

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 and 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, please contact your healthcare professional. You can also visit www.epsbio.com for diabetes management tools and product demonstrations.



Although the EasyPlus mini R13N 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

- EasyPlus mini R13N blood glucose meter is designed and approved for testing fresh whole blood from fingertip, palm or forearm. The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- EasyPlus mini R13N blood glucose meter only use with EasyPlus mini R13N 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, levodopa, dopamine, ascorbic acid and methyldopa may affect results.
- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.
- Remove the battery 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.



- Do not touch the strip with a wet hand.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strip.

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 instruction carefully for additional health-related information.



Warning for potential biohazard:

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

Explanation of Symbols

	Consult instructions for use		Caution, consult accompanying documents
	Batch code		Do not re-use
	In vitro diagnostic medical device		CR2032 lithium battery
	Use by		Temperature limitation
	Manufacturer		Catalog number
	Serial number		Control solution
	Contains sufficient for <n> tests		Authorized representative in the European Community

	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices		
	Left button		Right button
	System fault		AC, before meals
	PC, after meals		Morning, from 4:00 am to 10:00 am
	Noon, from 10:00 am to 04:00 pm		Evening, from 04:00 pm to 10:00 pm
	Night: from 10:00 pm to 04:00 am		Hypoglycemia 20~60 mg/dL

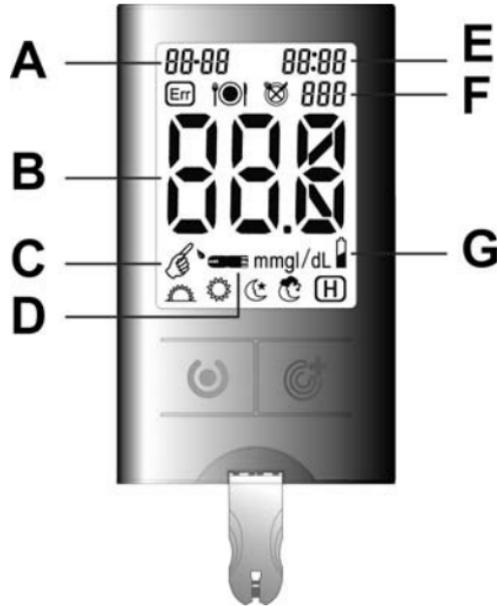
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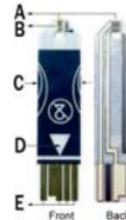
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Chapter 1: Understanding Your Meter

EasyPlus mini R13N Blood Glucose Meter



	The Overview of the Display	Meaning
A	month and date	Show the moment of month and date.
B	Test result	Show the test result.
C	Application of blood or control solution	Test your level of blood glucose.
D	Insert test strip	Insert the test strips to start testing blood glucose.
E	Time	Show the moment of time.
F	Test records	The meter will memory automatically all of test results.
G	Battery status	When the battery symbol appears, prepare other battery for installation.

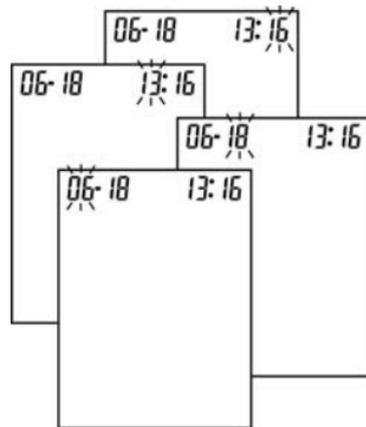
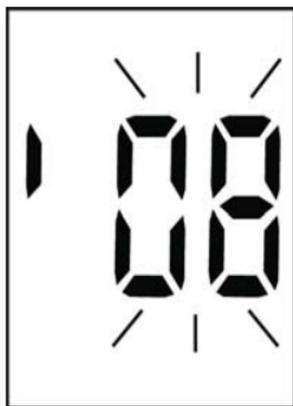


The Overview of the Test Strip:

- A.** Blood collection area
- B.** Reaction area
- C.** Hand hold area
- D.** Strip insert direction
- E.** Electrode

Setting The Time and Date—First Time Use

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



1. Put a battery into the slot and the meter turns on automatically.
2. The last 2-digits of the year flash at the center 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.

Checking Your Meter

A new check strip is included with your meter.



1. Make sure your check strip is inserted. The meter will turn on automatically.



2. The screen displays "OK".



3. Remove the check strip and the meter will turn off automatically. Store the check strip in a safe place.



When the display shows "FAL", re-insert the check strip. If FAL appears again, contact your local dealer for repair.

Using EasyPlus mini R13N Blood Glucose Test Strip

- Use only with EasyPlus mini R13N Blood Glucose Meter.
- 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 before you insert it into the meter.
- Do not touch the test strip with a wet hand. Do not bend, cut, or twist the test strips.

Chapter 2: Control Solution Testing

Why Run A Control Solution Test

Running a control test lets you know that your meter and test strips are working properly to give reliable results. You should run a control test when:

- You use the EasyPlus mini R13N Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.



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

About The Control Solution

- Use only with EasyPlus mini R13N 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 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 and the icon of  shows itself.

2. Press  twice to set "CtL" and press  to confirm the setting.

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

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



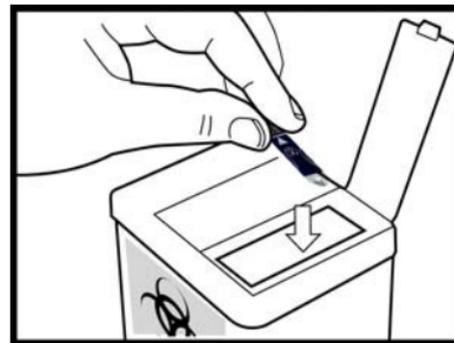
- If display stays at  or  and no any setting is made, the test results will be always in  or .
- If no choose "CtL", the test results will be included in the memory of blood test.



6. Squeeze the bottle until a tiny drop forms at the tip of the bottle.
7. Touch the drop to the Blood collection area at the end of the test strip.
8. Do not put control solution on top of the test strip.



9. When you hear the beeper, you have enough control solution in the test strip. The meter starts to count down from 5 seconds and will show the results.
10. A result appears on the display. 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 throw it away after you have compared the reading to the range printed on the test strip bottle.

Understanding Control 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 result is inside the range on the test strip bottle, your test strips and your meter is working properly.

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

Troubleshooting Checks

- ✓ Was the test strip exposing to open air for a long period of time?
- ✓ Was the test strip bottle capped tightly?
- ✓ Was 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

Repeat the control test with properly stored strips.

This will humidify strips inside. Replace the test strips.

You can use the check strip to verify the meter's functions.

Replace with new control solution to check the performance of SMBG system.

Repeat the control test with properly stored strips or control solutions.

Read Chapter 2 "Control Solution Testing" and test again. If you still have problems, please contact your local dealer for repair.

Chapter 3: Testing Your Blood Glucose

Using The Lancing Device

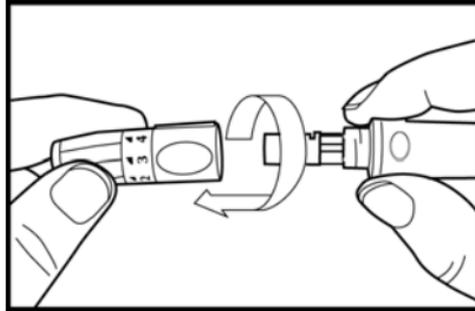
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.



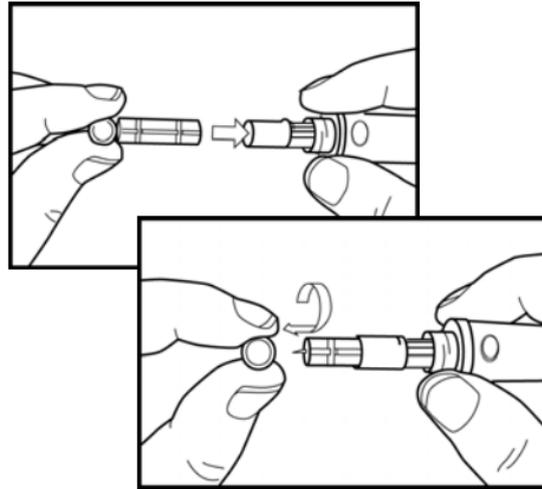
Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. The users may discuss methods for disposing of used test strips and lancets with their doctor.

Inserting A Lancet Into The Lancing Device

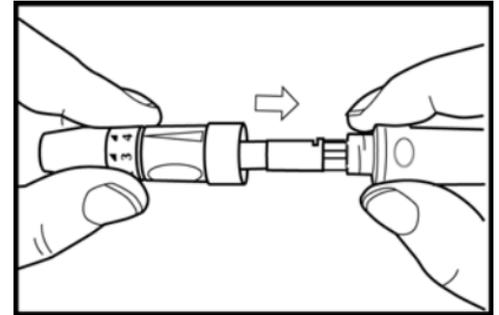
You must first load the lancet into the lancing device to get it ready for use.



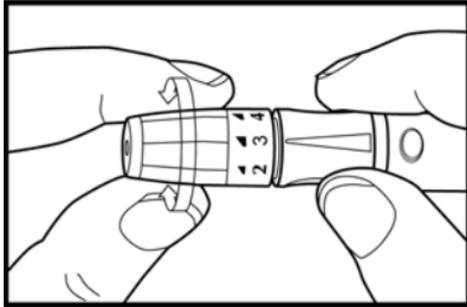
1. Unscrew the cap.



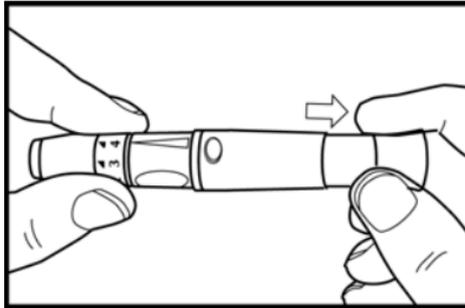
2. Insert the lancet into the lancing device firmly then twist off the protective cover.



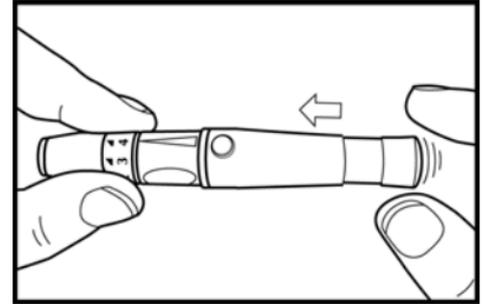
3. Recap the front cap.



4. Select the desired penetration depth.



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



6. Now the lancing device is ready. Do not prick your finger until your meter and strip are prepared. Set the lancing device aside until later in the test.



Note:

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

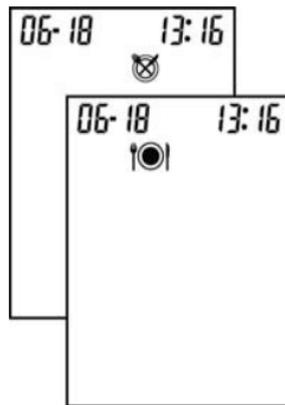
Running A Blood Glucose Test With Blood From Your Fingertip



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



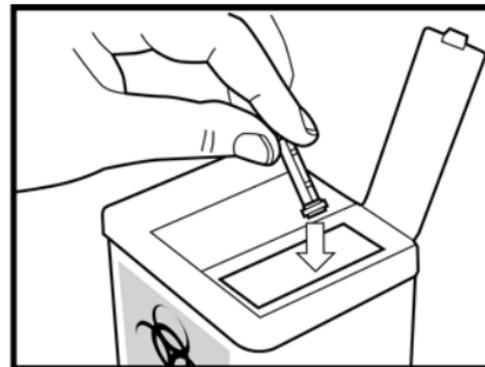
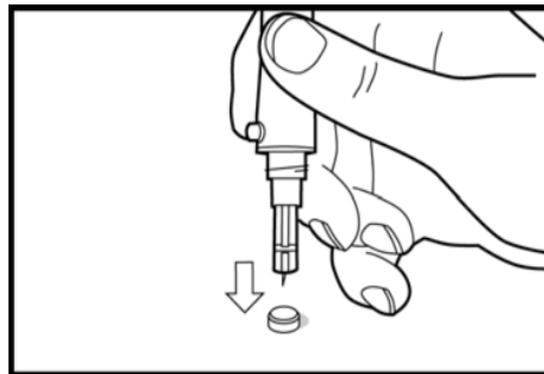
2. Put a test strip into the meter in the direction of the arrow and the icon of  shows itself.



3. Press  to set  or  and press  to confirm the setting



5. When the blood drop flashes on the display, obtain a drop of blood from your fingertip.
6. Gently squeeze your finger to assist the flow of blood.

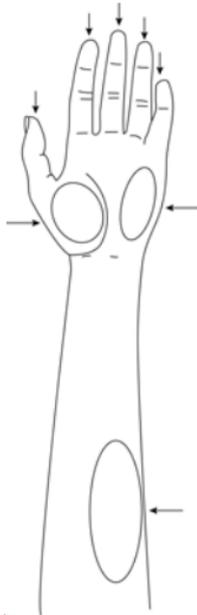


7. The meter will beep when enough blood has entered the strip's reaction zone. The result will appear on the display after 5 seconds.

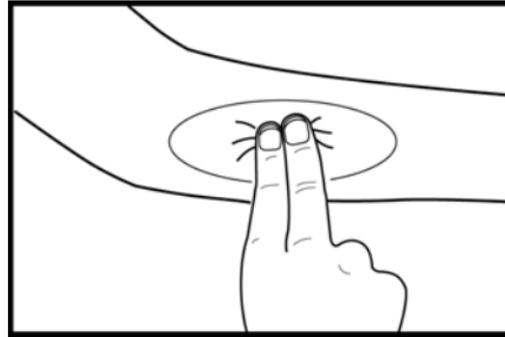
8. Without touching the used lancet, stick the lancet tip into its protective cover. Grip the lancet carrier firmly and pull the lancet safely out.

9. Discard the used disposable lancet into an appropriate sharps or biohazard container.

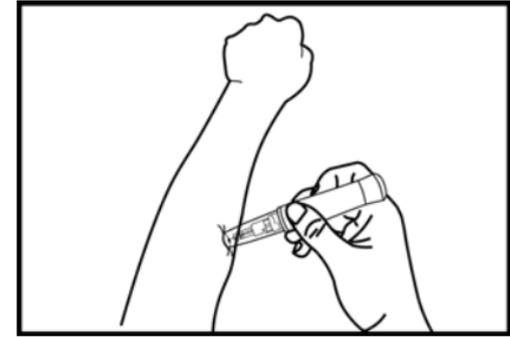
Alternative Site Testing



1. This graphic shows where the meter cleared for alternative site testing.



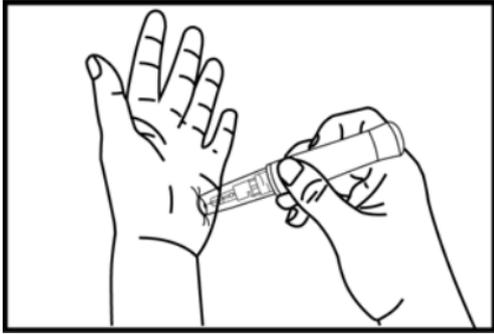
2. Massage the puncture area of forearm or palm for a few seconds.



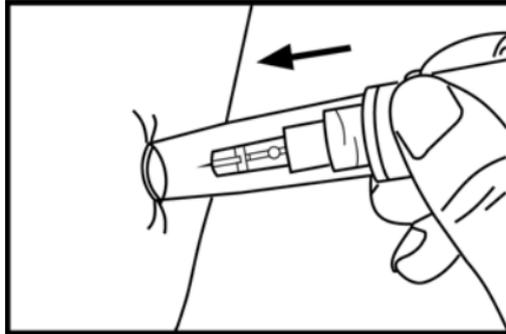
3. Press and hold the device with one clear adjustable tip against the forearm.



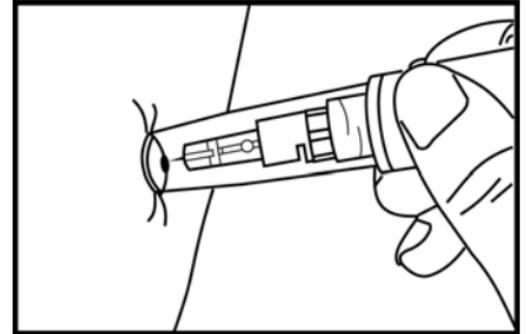
- Check with your healthcare professional before test other sites that not fingertip.
- Please do NOT use the first drop of blood sample.



4. If you choose the palm, repeat step 1-3 to obtain a drop of blood sample.

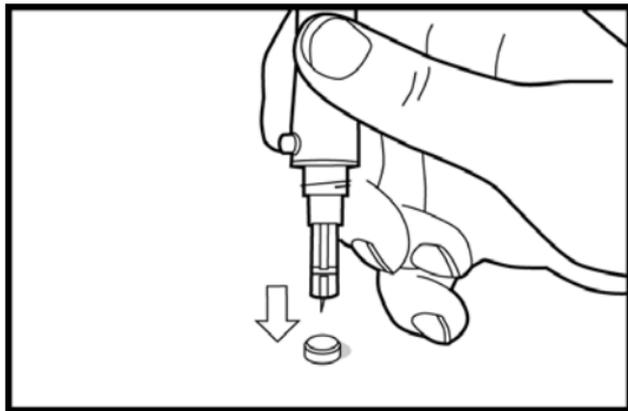


5. Press the trigger button to activate the lancing device.

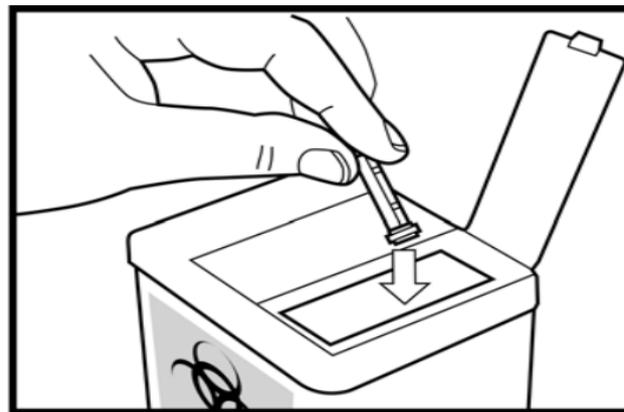


6. Hold the device against forearm or palm and increase pressure until the blood sample size is sufficient

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. Discard the used disposable lancet into an appropriate sharps or biohazard container.

Understanding Your Test Results

The EasyPlus mini R13N 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 70~120 mg/dL (3.9~6.7 mmol/L). Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL (7.8 mmol/L). 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 test, Chapter 2 "Control Solution Testing."
2. Repeat a blood glucose test, Chapter 3 "Testing Your Blood glucose."
3. If your test results still don't reflect the way you feel, call your doctor immediately.



1. **Extremely high humidity may affect the test results. A relative humidity 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.**
3. **Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.**

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 EasyPlus mini R13N 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

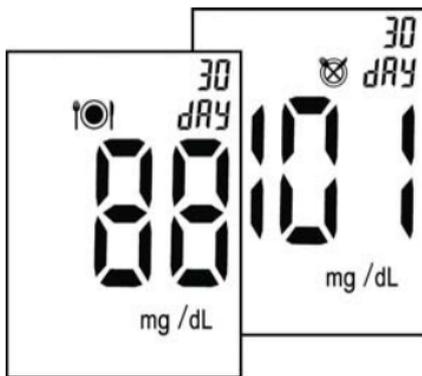
Your meter stores a maximum of 360 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.



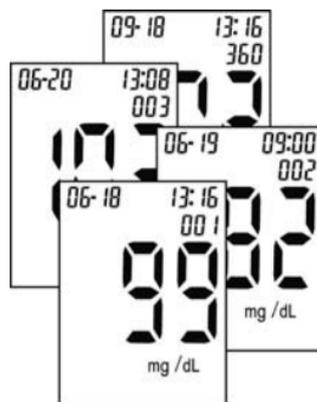
- 1. Do not change your therapy based on one individual result in memory.**
- 2. The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting the time and date" in Chapter 1.**
- 3. Once 480 results are in memory, adding a new result causes the oldest one to be deleted.**
- 4. Average function:**
From the latest test result (001) to the earliest one, the meter executes average function of all test results in 7-, 14-, 30-, 60-, and 90-day and all test results of AC and PC in 30-day.

Viewing & Deleting Test Results

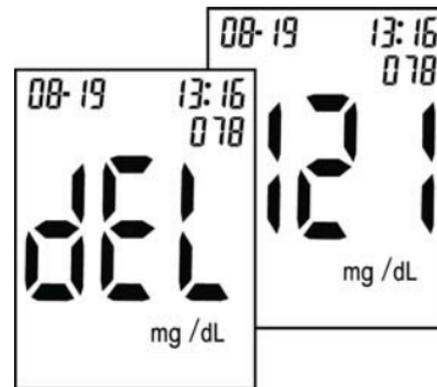
You can review them at any time **without inserting a test strip**.



1. Press  to review test results of 30 days in  or .



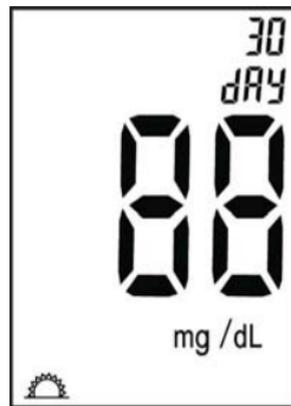
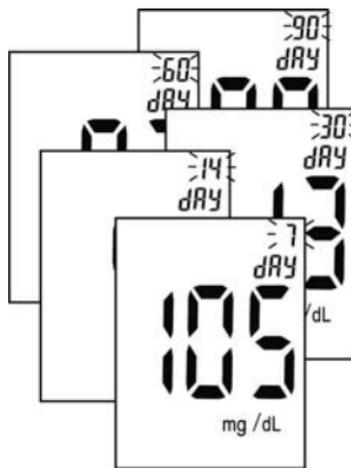
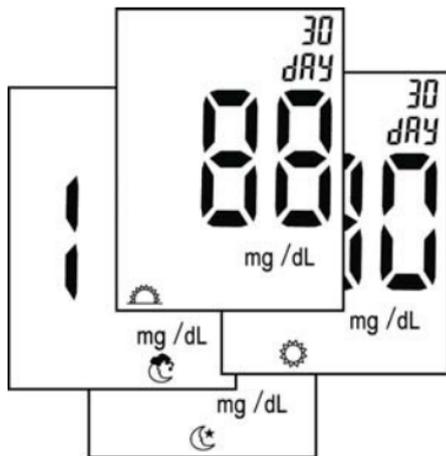
2. Press  to review all results in order from records of 001 to 360.



3. To delete a test result, press  for 3 seconds and display shows "dEL".
4. press  to keep to review the following results.
5. The meter will turn off in 1 minute automatically.

Meter Memory

You can review them at any time **without inserting a test strip.**



1. Press  to review test results of 30 days in , , , or .

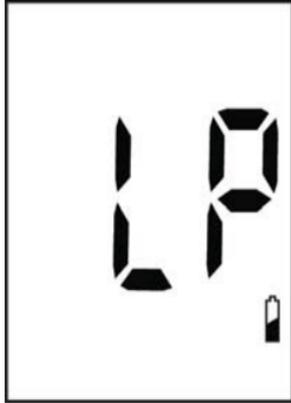
2. Press  to review results of 7, 14, 30, 60 or 90 days.

3. Press  to go back the display of .

4. Meter will turn off in 1 minute automatically.

Chapter 5: Maintenance and Troubleshooting

Installing A Battery



The meter uses one CR2032 lithium battery. One battery will normally last for over 1000 tests. Other types of CR2032 lithium batteries are also acceptable, yet the capacity of test times may differ. Install the battery when you first use the meter or replace with a new battery when the "LP" message and the low battery symbol appear on the display.

← Low battery symbol



1. The meter won't delete earlier records after you replace batteries.
2. You should reset the time and date again after you replace a battery.
3. CR2032 lithium batteries are available in shops. 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 EasyPlus mini R13N 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  to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please contact your local dealer.

Cleaning Your Lancing Device

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

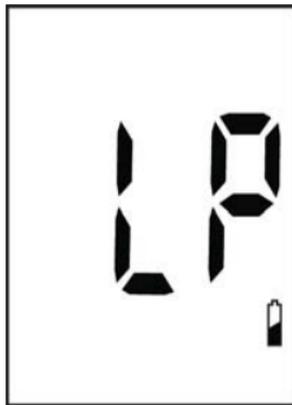
Screen Messages And Troubleshooting

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



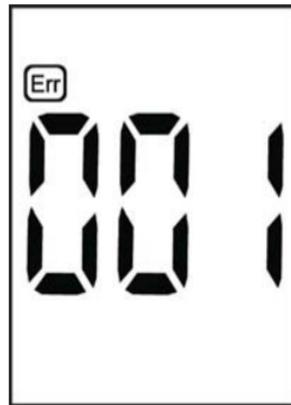
Humidified/Used strips

Action: Replace with a new strip.



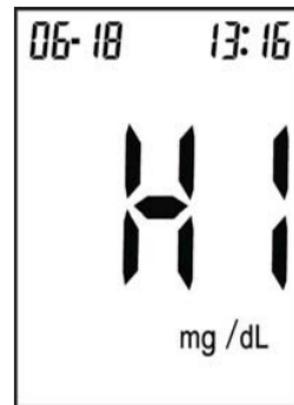
Low power

Action: Replace with one new battery.



System fault

Action: Replace the batteries first. If 001 ERROR appears again, contact your local dealer for repair.



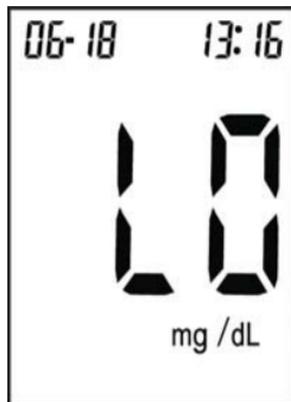
Test result is higher than 630 mg/dL.

Action: Test again. If the result is still the same, please contact your healthcare professional.



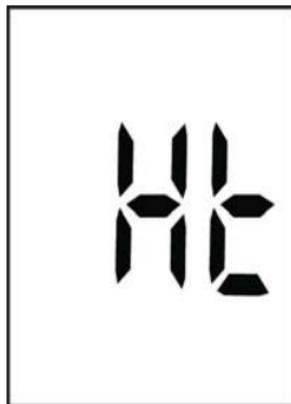
The test result is among 20~60 mg/dL.

Action: Please contact your healthcare professional.



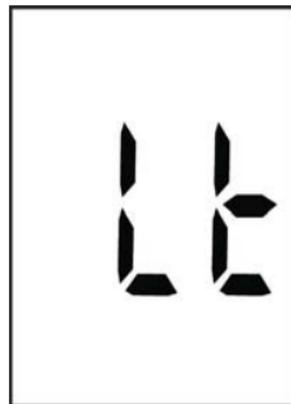
The test result is lower than 20 mg/dL.

Action: Test again. If the result is still the same, please contact your healthcare professional.



The "Ht" icon appears. Temperature is too high, outside the required range of 50°F ~104°F (10°C ~40°C). This alerts users that an incorrect result may occur if the test continues.

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



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

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

Chapter 6: Technical Information

Specifications

Brand name	EasyPlus mini R13N Blood Glucose Meter	
Range	20~630 mg/dL	
Response time	5 seconds	
Memory sets	480 test results	
Operating condition	Temp.	50°F ~104°F (10°C ~40°C)
	Relative Humidity	R.H. ≤ 90%
Storage and transportation condition	Temp.	39°F ~104°F (4°C ~40°C)
	Relative Humidity	R.H. ≤ 90%
Blood sample	0.6 µL	
	Fresh blood from fingertip, palm or arm	
Hematocrit (Hct)	30~55%	
Power	CR2032 Lithium Battery	
Battery life	Over 1000 tests	
Display dimension	42.0 × 32.0 (mm)	
Device dimension H × W × D (mm)	75.0 × 44.0 × 10.0 (mm)	
Weight	30.0 grams w/o battery	
Principles	Electrochemical biosensor technology	

Device Information

**EasyPlus mini R13N SMBG System,
EasyPlus mini R13N Blood Glucose Test Strips,
EasyPlus mini R13N Blood Glucose Meter.**

EMC

This monitor conforms to European Standard EN 61326 and is subject to particular precautions with regard to electromagnetic compatibility (EMC). Please note that portable and mobile HF communication systems may interfere with this instrument. For more details, please contact customer service at the address indicated.

Disposal:

When disposing of monitor components, strictly observe the generally applicable precautions for working with working with blood and follow the national requirement to dispose unit.



Manufacturer:

EPS BIO TECHNOLOGY CORP.

2F, No.49-2, Lane 2, Guang-Fu Rd., Sec. 2, Hsinchu City, Taiwan 300

TEL : +886-3-5752522 FAX : +886-3-5752552

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



Obelis s.a.

34, Av. de Tervuren, bte 44, B-1040 Brussels, Belgium

TEL : (32) 2.732.59 54 FAX : (32) 2.732.60 03

E-mail: mail@obelis.net

Warranty

EPS warrants the original purchaser for a period of 5 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.

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:



Global Medical Market Corp.(GMMC)

Rm # 1112, Ace Tower 9th Bldg., 345-30, Kasan-Dong

Kumchon-Ku, Seoul, Korea (Zip:153-782)

E-mail : danny@gmmc-inc.com

Lancet

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

Alcohol Pad

Manufacturer:



China Surgical Dressings Center Co., Ltd.

No.21, Lane 424, Sec. 6, Changnan Rd., Fu-Tien Li, Changhwa City, Taiwan 500

TEL : 886-4-7321239

E-mail : info@csdmedic.com.tw

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