

# OMRON

BASIC  
AUTO



## BLOOD GLUCOSE MONITORING SYSTEM HGM-112

**All for Healthcare**

INSTRUCTION MANUAL

## **IMPORTANT SAFETY PRECAUTIONS**

### **READ BEFORE USE**

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. Do **NOT** use the equipment in places where aerosol sprays are being used or where oxygen is being administered.
5. Do **NOT** use under any circumstances the device on neonates or infants.
6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. User should not take any decision of medical relevance without first consultation of medical practitioner. Always consult your doctor to have the results interpreted.
7. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
8. Use this instrument in a dry environment, if synthetic materials are present (synthetic clothing, carpets etc.) it may cause damaging static discharges that may cause erroneous results.
9. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitter, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
11. The device for self-testing is used for the monitoring of an existing disease (eg., diabetes), before changing treatment patients should refer to a medical professional.

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## Chapter 1 HGM-112 Blood Glucose System


### 1.1 Introduction


The HGM-112 system measures the small electrical current and displays the blood glucose results. The current is produced from the blood glucose mixing well with chemicals on the test strip.

User needs to apply 1 $\mu$ L of fresh capillary whole blood for one test, and the test result will be displayed in 5 seconds. Besides that, HGM-112 also has unique strip technology with auto coding system. Users don't need to code the glucose meter.


### 1.2 Intended Use

Only the HGM-STP1A blood glucose test strips are used with HGM-112 meter. They are designed for users to measure the glucose concentration in fresh capillary whole blood obtained from fingertips and palm. HGM-112 system is intended to be used by people with diabetes at home.

 **Warning: HGM-112 system should not be used for screening, diagnosis of diabetes or testing neonates.**

 **Warning: Do not change the therapy according to HGM-112 meter test result without consulting healthcare professional. If you have any question about the test results, please discuss with your healthcare professionals.**

 **Warning: Only for in-vitro diagnostic test.**

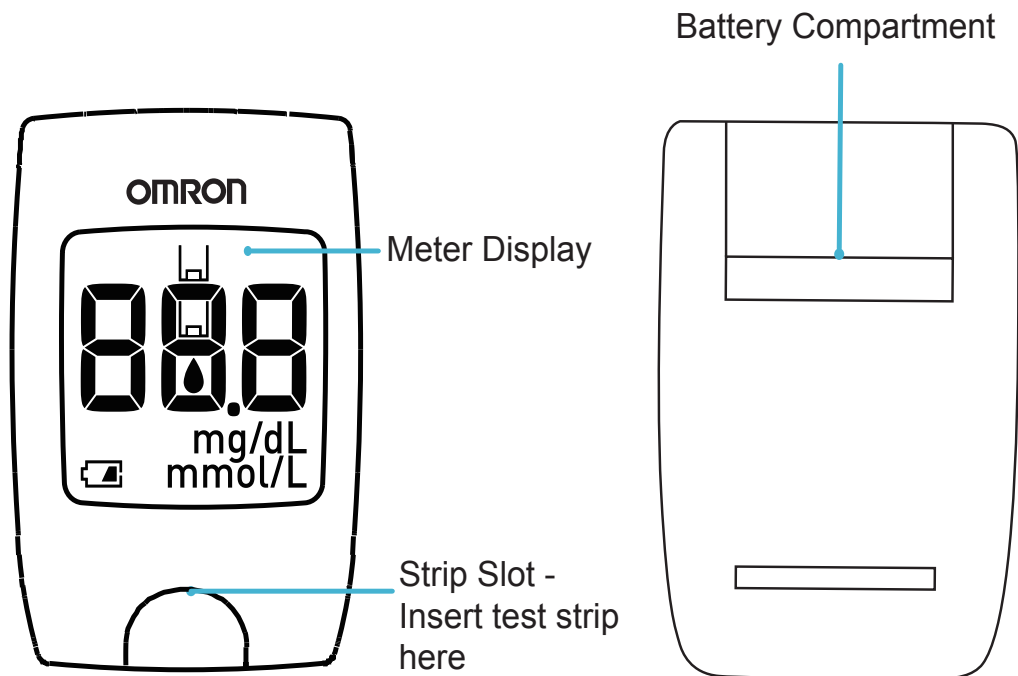
 **Warning: Please read system instruction manual and strip manual carefully**

## 1.3 List of Box Contents

1. HGM-112 Glucose Meter
2. Lancing Device
3. AST Cap
4. 10 pcs Lancets
5. Carrying Case
6. Instruction Manual
7. Log Book
8. CR2032 x 1

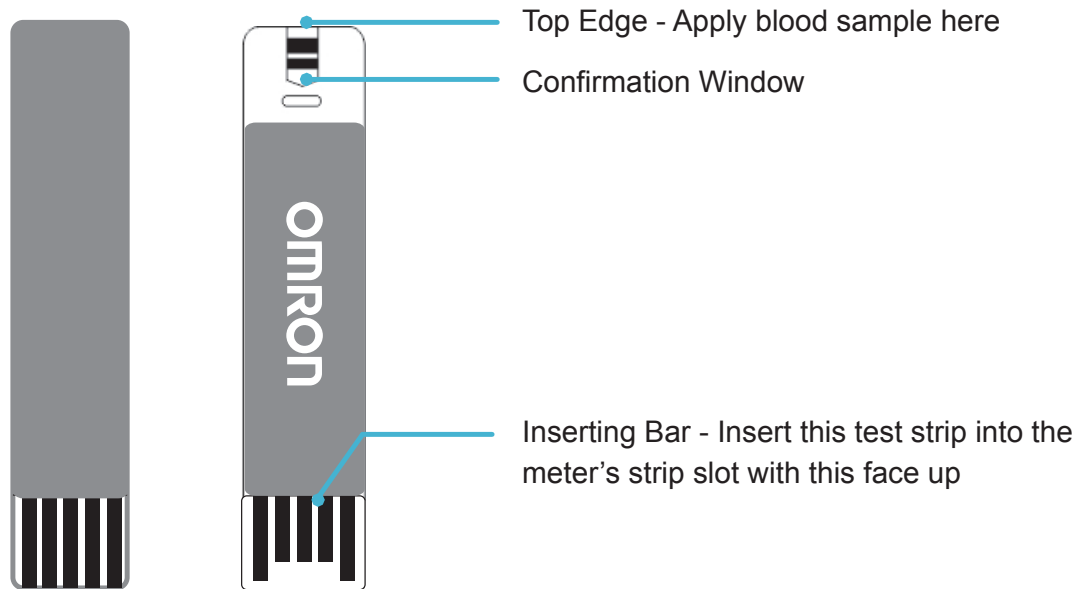
## 1.4 Product and Meter Display

### A.HGM-112 Blood Glucose Meter Display



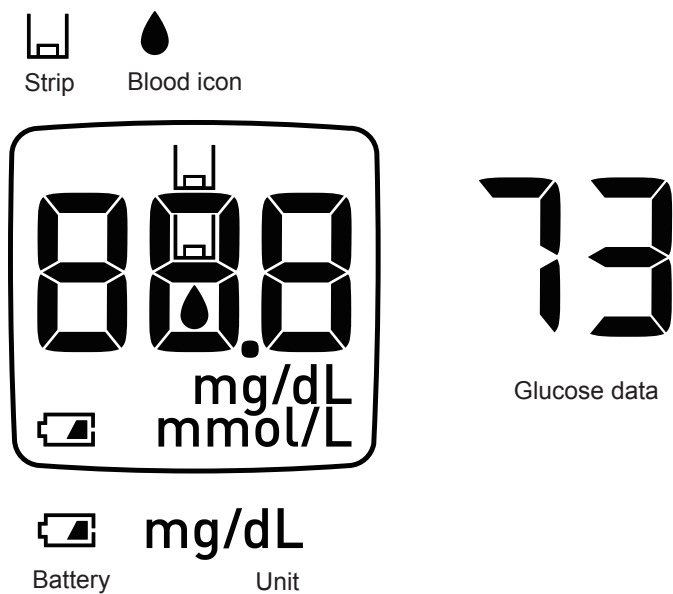
**⚠ Caution: This meter will not display mmol/L.**

## B.HGM-STP1A Blood Glucose Test Strip






**Warning:** Touch the drop of sample to the top edge of the confirmation window of the test strip. Do not smear sample on the strip.

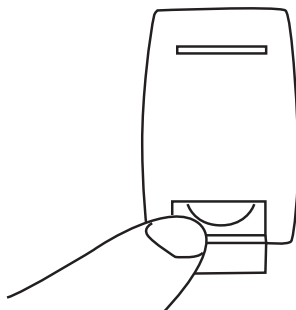
## C. Function Display



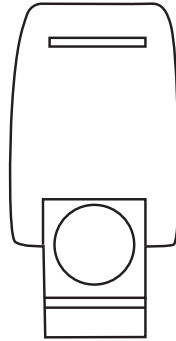
## Chapter 2 Installing and Setting up the HGM-112 Meter

### 2.1 Inserting/replacing battery

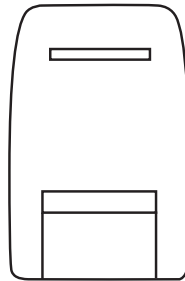
- When should users change the battery?
  1. When the symbol  shows on the display, it means the battery power is low and need to replace a battery as soon as possible. Even the battery power is low, HGM-112 meter still can work well: You still can use HGM-112 and the test results will still be accurate, but we strongly suggest you replace the battery as soon as possible.
  2. There is not enough power to support HGM-112 to operate when the symbol  is shown on display after powering on. Thus, the meter will shut down after 20 seconds when the symbol  is shown on display after powering on. It represents that the battery power is too low to perform a test. You have to replace the battery to continue using the HGM-112 meter.
- **How to replace HGM-112's battery**
  1. Turn HGM-112 to the back side and open the battery compartment.
  2. Take out the battery and insert one CR2032 battery with the (+) sign facing up.
  3. Push back the battery compartment until hearing a "click" sound.
  4. After a new battery is inserted and the cover is shut, the device is powered on automatically for 2 seconds. If not, please check the above steps.



a. Open battery compartment



b. Take out and insert a new battery



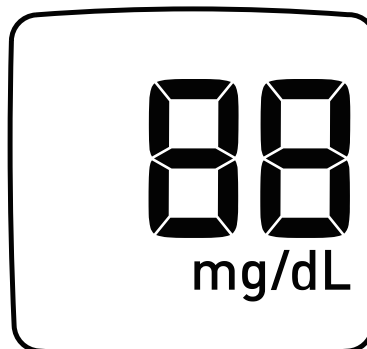
c. Push back the battery compartment

**!** Warning: Dispose of old battery according to your local environmental regulations.

## 2.2 Performing a blood glucose test

### A. Inserting a test strip

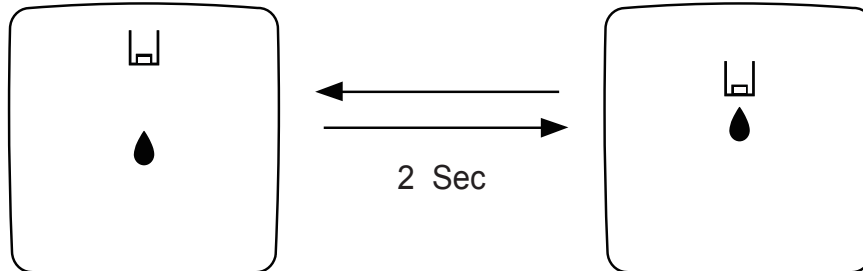
1. Insert the test strip into strip slot correctly; the HGM-112 meter will turn on. All LCD segments will display for 1 second.
2. Then the display will show the latest test result for 2 seconds.





## B. Apply sample

3. The strip symbol flashes alternatively with blood symbol as the following pictures, and users can apply blood sample now.



## C. Test blood glucose

4. After apply sample, the test result will show on display after 5 seconds.

- There is mg/dL test unit showing on display.



## Chapter 3 Finger Blood Glucose Testing

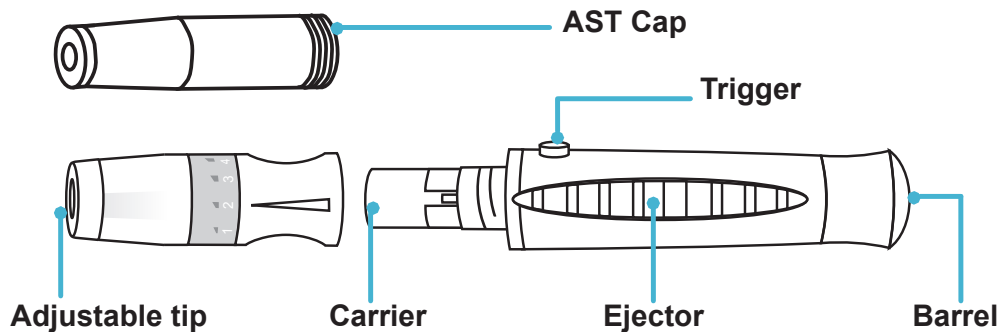
### 3.1 Preparation before glucose testing

Please prepare materials you need as listed below and read this instruction manual or test strip manual to ensure the correct measuring process and results.

- HGM-112 Blood Glucose Meter
- HGM-STP1A Blood Glucose Test Strip
- Antiseptic wipes or alcohol wipes
- Lancing Device
- Lancet

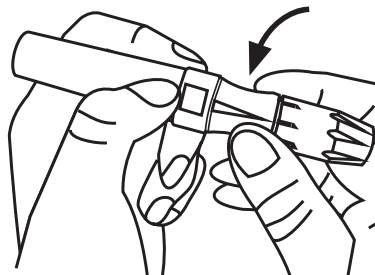
## 3.2 Fingertip blood measurement

### Structure:

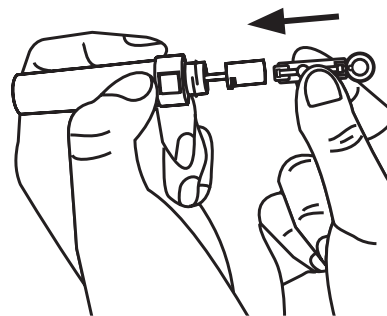


### A. Install the Lancet

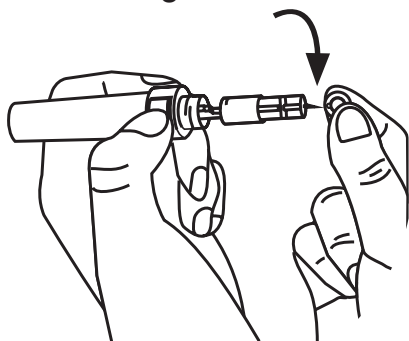
1. Unscrew the adjustable tip of the lancing device. Install a new lancet into the carrier correctly and make sure it is fully seated. Then remove the protective cap and replace the adjustable tip.
2. Adjust the puncture depth by the selection dial (Normally at the 2nd level), twist to a suitable number. (Smaller numbers are for shallower punctures and larger numbers are for deeper puncture)



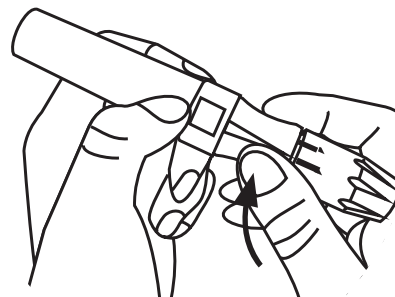
a. Unscrew the adjustable tip of lancing device



b. Install the lancet.



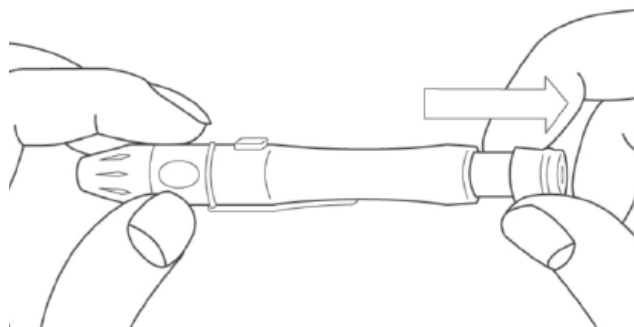
c. Twist off the protective cap from the lancet.



d. Replace the adjustable tip of lancing device and adjust the puncture depth.

## B. Preparing your Lancing Device

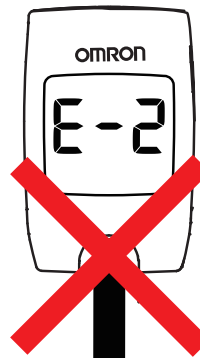
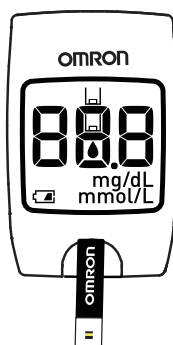
- Slide the barrel control back until it clicks. The lancing device is now ready for use.





**Warning: Sterile lancet is single use only, cannot reuse.**

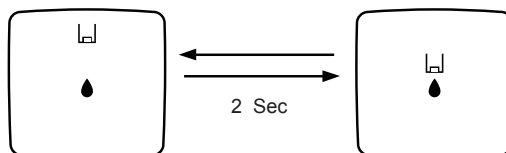
## C. Preparation of test strip

- Insert the test strip into the strip slot and the HGM-112 meter will turn on. All LCD segments will display for 1 second.



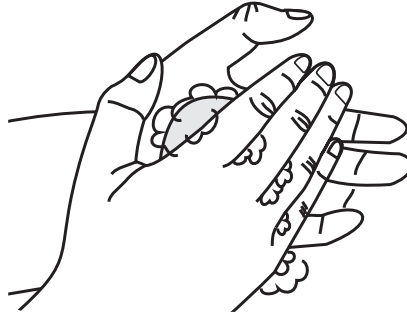
**\* Insert the test strip (Correctly) \*Do not insert the strip from reverse side.**

- The display will show the latest test result and then strip symbol  and drop symbol  will appear.



## D. Wash your hands and the puncture site

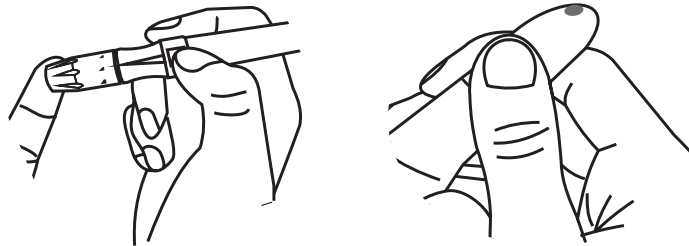
6. Wash hands with soap and warm water. Rinse and dry thoroughly.



## E. Fingertip blood sampling

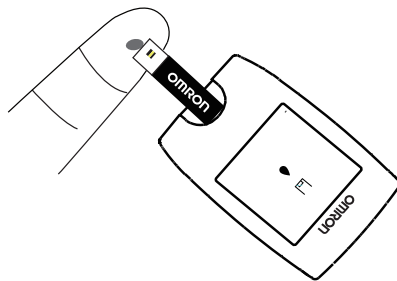
7. Please massage your fingertip gently to help you obtain blood. (We suggest that you puncture different areas each time. Repeated punctures in the same area may cause soreness. The blood sample requires only 1 $\mu$ L, do not squeeze excessively at the puncture site.)

8. Hold the lancing device firmly against the side of your fingertip. Press the release button gently and squeeze your finger to assist the flow of blood.



## F. Blood glucose test

9. Touch the blood drop to the tip of the confirmation window of test strip.

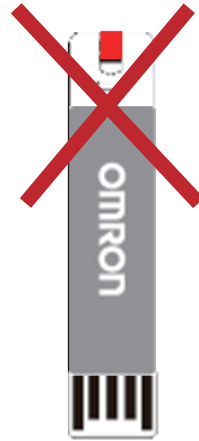


**Caution: Do not smear blood on the strip, only touch blood to the tip of the strip.**

**Touch the blood drop on fingertip to the reaction zone.**



Sample filled



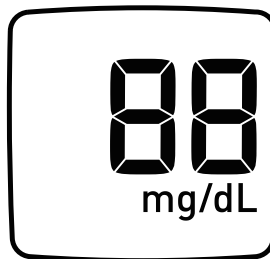
Sample too small

The following items will cause inaccurate results:

- The reaction zone does not fill completely.
- Applying blood more than once.
- Applying blood to test strip after a period of time.
- Sudden or Huge variation of environment during measurment.
- Using a false test strip.

### G. Blood glucose value display:

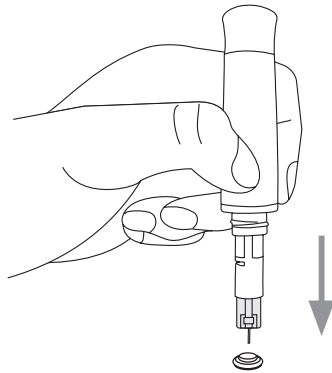
10. The blood glucose test will be completed in 5 seconds from the time the blood drops into the test strip. The last test result will automatically be stored in the meter memory.



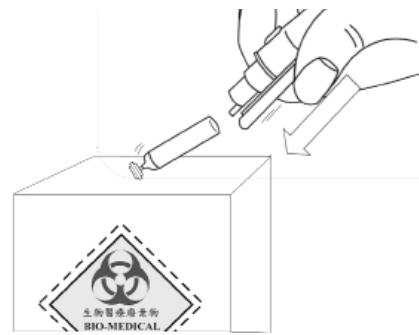
### H. Dispose of used strip and lancet properly:



**Warning:** Please follow proper precautions in accordance with local regulation when disposing of all materials.



\* After use, press the lancet needle point into the protective cap.



\* Push forward the ejector to dispose.

### Important

- Do not use test strips more than once.
- It should not be used for testing newborns.
- It should be used only for testing fresh capillary whole blood.
- It should not be used for venous whole blood or plasma.
- A red blood cell count (hematocrit) that is higher than 55% or lower than 30% can cause false test results.

### 3.3 Alternate Site Testing (AST)

You have the option of testing other places on your body besides the fingertip. You can test the palm. While fingertip blood can be tested at any time during the day, there are times when testing from any other approved site is not ideal—usually when your blood glucose is rapidly changing. Please read the following section before you try testing from other areas.

#### Caution:

1. Talk to your healthcare professional about Alternate Site Testing.
2. Do not change your treatment because of just one result.
3. NEVER ignore symptoms of high or low blood glucose.
4. If your blood glucose does not match how you are feeling, perform a fingertip test to confirm your result. If the fingertip result still does not match how you feel, please refer to the following several items:

Alternate site testing may be done:

- Immediately before a meal
- Fasting

DO NOT test from an alternate site:

- Two hours or less after eating
- After exercising
- If you are sick
- If you think your blood glucose is low
- If you often don't notice when your blood glucose is low
- When basal insulin is most active
- After injecting rapid-acting insulin (two hours or less)

### How to do AST :

You need the meter, a test strip, a lancing device designed for AST, and the clear AST cap.

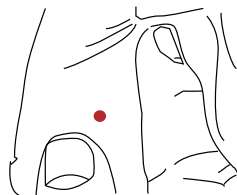
1. Unscrew the adjustable tip, insert a new lancet firmly into the carrier. Twist off lancet protective cap and replace the AST Cap. Sliding barrel signals readiness with a soft click.
2. Insert a test strip into the meter in the correct direction. The meter turns on.
3. A test strip and flashing blood drop symbol appear on the display.
4. Gently massage the alternative site (palm) that you would like to draw blood from.




5. Clean your hands and the alternative site you will puncture. Press the lancing device firmly against a fleshy area on the alternative site. Press the lancing device up and down in a slow pumping motion to assist the flow of blood.
6. Trigger the lancing device will be keeping steady pressure on the puncture site. Immediately lift the lancing device off of the site.




7. Squeeze the puncture site with appropriate pressure slowly to get enough blood.




8. Slightly touch the top of strip with the blood to make enough blood filled in strip; you can get the test result after 5 seconds.

 **Warning: The AST function of HGM-112 meter only can be used for palm, not for other sites such as upper arm, forearm.....etc.**

 **Warning: Please follow the lancing device manual to execute AST blood sampling from palm.**

## Chapter 4 Glucose Control Solution Testing (Optional)

 **Warning: If you will like to perform control solution test or have any question, please contact your local authorized distributor for more information.**

### 4.1 HGM-112 system testing

In order to provide you with an accurate test result, we suggest running a control test to check if the meter and test strips are working properly. When the control result is within the range on the test strip container, the test strips and meter are working properly.

#### ◆ **Important:**

- Use Only the OMRON glucose control solution with the HGM-112 meter and HGM-STP1A strips.
- Mark the newly opened bottle of control solution with the date opened; discard any unused control solution which is over three months after opening.
- Store the bottle at 4°C~30°C (39°F~86°F) temperature. Do not refrigerate it.
- Shake the bottle of the control solution before you use it. Please replace new control solution if control solution deteriorates or coagulates.
- We suggest you use OMRON glucose control solution for glucose control testing between 15°C~25°C (58°F~77°F).

\* **Before running the test, place the HGM-112 meter, test strips and glucose control solution at room temperature for 30 minutes to allow them to reach the new temperature before use.**



**◆ When to run the glucose control solution test :**

- The test strip vial is opened for long time or you think the test strips have been damaged.
- When the meter could be damage or not working properly.
- When you want to double check on the meter's performance.

**◆ Running a Control Test:****1. Preparing a Test Strip**

- 1) Insert the test strip into the meter. The meter will display the last measurement data.
- 2) Then the screen shows the drop blood symbol.

**2. Running the Glucose Control Solution Test**

- 3) Before using the control solution, gently shake the control bottle to mix well.
- 4) Remove the control 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 and put this drop on a clean surface.
- 6) Touch the drop to the tip of the confirmation window of the test strip. When the confirmation window is filled with control solution completely, the meter will automatically start to run the measurement.
- 7) After 5 seconds, the screen will display test result. The meter will automatically turn off after the test strip is removed. Discard the used test strip in accordance with local regulations.

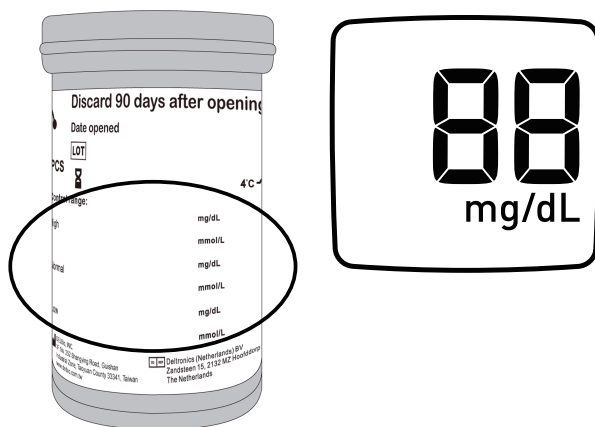
\* Write the date you first open the bottle on the bottle label. The control solution must be discarded after three months from the date the bottle was opened, on the "discard" date or on the "expired" date on the bottle label, whichever comes first. Do not use control solution that is past the "expired" or discard date.



**Warning: Before running test glucose control solution test, always check the expiration date. DO NOT use control solution if expired over three months of first opened day.**

### 3. Understanding Control Test Results

- 8) When the control result is within the range on the test strip container , the test strips and meter are working properly.



**Warning:** If the control result is not within the acceptable range (printed on your test strip container), do not use your meter until you solve the problem. Repeat the control solution test again.

**Warning:** If the result continues to be outside of the expected range, here are some points that have to be checked:

- Did you follow all of the testing instructions?
- Are the test strips or control solution past the “expired ” date or discard date?
- Is there a HGM-112 meter defect in materials or workmanship?

Repeat the control test with a new test strip. If you still have any problem, please contact your local authorized distributors for more information.

## Chapter 5 Caring for Your Strips and Meter

### 5.1 Caring for the strips

- \*Wash hands before testing.
- \*Do not use strips that have expired. Check the expiration date that is printed on the package.
- \*Record the day opened on the test strip bottle label when you first open it.
- \*Discard the bottle and any remaining test strips after 90 days from the opening date.
- \*Keep the strip bottle away from direct sunlight and heat, and store between 4°C -30°C. (39 °F~ 86 °F)
- \*Do not refrigerate the test strip.
- \*The strip bottle should be stored in a dry place at room temperature.
- \*Do not transfer the test strips into other containers.
- \*Always close the container tightly immediately after taking a test strip out.
- \* Keep the test strip from getting dirty during storage.


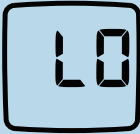
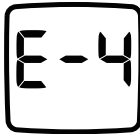
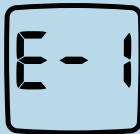
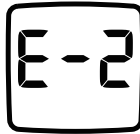
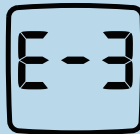
### 5.2 Caring for the meter

- \* If the meter's surface gets dirty, gently wipe with a cloth slightly dampened or use a mild detergent.
- \* For medical staff, you may use a 10% bleach, 70% alcohol (ethanol), or 10% ammonia scouring reagent.
- \* Do not clean the test strip slot.
- \* Do not put any liquid into the test strip slot or on the buttons of the meter.
- \* Do not put the meter under water or any liquid.
- \* The meter must be stored at room temperature.

## Chapter 6 Troubleshooting

When the meter is used incorrectly, in poor condition, or other unexpected events happen, the screen will show the error message to remind the user should notice the problem or show how to resolve them.

The following messages may mean you have obtained a result that requires immediate attention or there may be a problem with the meter.

Message	Symbol	Mean	Action
<b>HI</b>		You may have a very high blood glucose level. ( > 600 mg/dL)	<ol style="list-style-type: none"> <li>1. Do control solution test.</li> <li>2. Re-do your glucose test.</li> <li>3. Contact your healthcare professionals.</li> </ol>
<b>LO</b>		You may have a very low blood glucose level. ( < 20 mg/dL)	<ol style="list-style-type: none"> <li>1. Do control solution test.</li> <li>2. Re-do your glucose test.</li> <li>3. Contact your healthcare professionals.</li> </ol>
<b>Temperature Error</b>		You may have tested near the low or high end of the meter's operating temperature range. (10°C ~ 40°C/50°F ~ 104°F)	Repeat the test after the meter has reached a temperature within the operating range.
<b>Low battery warning</b>		The power is too low to perform a test.	Replace the battery.
<b>Wrong Test Strip</b>		Test strip could be expired, upside down, broken, or used again.	<ol style="list-style-type: none"> <li>1. make sure if strip inserting correctly.</li> <li>2. use an New HGM-STP1A test strip if broken, used.</li> </ol>
<b>Wrong Blood Enter Timing</b>		Obtain blood sample too soon.	Follow instruction step.

## Chapter 7 HGM-112 Performance Characteristics

### Traceability:

The test result of HGM-112 blood glucose meter is plasma calibrated by chemistry analyzer, and the analyzer was calibrated with a NIST traceable glucose standard solution.

### Measurement range:

HGM-112 meter display results between 20 ~ 600 mg/dL.

### Accuracy:

The accuracy of the HGM-112 meter was assessed by comparing blood glucose results obtained by patients with those obtained using clinical analyzer. The following results were obtained by (200) test numbers.

Slope	0.9713
y-intercept mg/dL	-0.3191 mg/dL
Correlation factor (R2)	0.9795
Test number (n)	200
Test range mg/dL	27-527 mg/dL

Number and % of results within reference (for values were < 75 mg/dL)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
14/34 (41.2%)	33/34 (97.1%)	34/34 (100%)

Number and % of results within reference (for values were ≥ 75 mg/dL)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
76/166 (45.8%)	121/166 (72.9%)	153/166 (92.2%)	162/166 (97.6%)

## Precision:


This study shows the variability from strip to strip in sample tests. The results are shown in the following table.


Within Run Precision:		
Samples	Mean glucose concentration	measured CV
Sample 1	41.01 mg/dL	SD= 4.02 mg/dL
Sample 2	83.49 mg/dL	4.26%
Sample 3	116.82mg/dL	4.85%
Sample 4	177.52mg/dL	4.66%
Sample 5	341.61mg/dL	4.05%
Between Day Precision:		
Control solution 1	42.83 mg/dL	3.61 mg/dL
Control solution 2	134.36 mg/dL	4.20%
Control solution 3	334.93 mg/dL	3.44%



















## Chapter 8 Specifications

### 8.1 Specification of HGM-112 meter

- ◆ Measuring range: 20~600mg/dL
- ◆ Calibration: Plasma-calibration
- ◆ Measuring unit: mg/dL
- ◆ Measuring time: 5 seconds
- ◆ Sample type: Capillary whole blood samples drawn from the fingertips or palm
- ◆ Blood Sample size: 1μL
- ◆ Operating temperature: (10°C ~ 40°C) / (50 °F ~ 104°F)
- ◆ Relative operating humidity: Below 90%RH
- ◆ Memory capacity: one memory for the latest memory
- ◆ Dimension: 63.2 mm x 40.6 mm x 18.0 mm (L×W×H)
- ◆ Weight: 25.5 g with battery
- ◆ Power Supply: one CR2032 battery
- ◆ Storage temperature: -20°C ~ 50°C (-4°F ~ 122°F)
- ◆ Please protect the HGM-112 from impact
- ◆ Please do not disassemble the HGM-112

 **Note:** The measurement unit either mg/dL or mmol/L is fixed in the meter according to the country demand. You are not able to change the unit in the meter.

 **Warning:** Disposing of Your Meter When no longer needed, remove the battery and dispose of the meter according to your local regulations.

	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE
	DO NOT USE IF PACKAGE IS DAMAGED		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	IN VITRO DIAGNOSTIC MEDICAL DEVICE		Council Directive 98/79/EEC on in vitro diagnostic medical devices
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	PAPER RECYCLE		CAUTION
	TEMPERATURE LIMITATION		BATCH CODE
	DATE OF MANUFACTURE		USE BY
	STERILIZED USING IRRADIATION		DO NOT REUSE
	SEPARATE COLLECTION FOR ELECTRICAL AND ELECTRONIC EQUIPMENT CONSISTS OF THE CROSSED-OUT WHEELED BIN		SERIAL NUMBER

**For self -testing**



### Lancing Device and Lancets:



SteriLance Medical(Suzhou) Inc.  
No. 68, Litanghe Road, Xiangcheng, Suzhou, 215133, China



Emergo Europe  
Molenstraat 15, 2513 BH The Hague, The Netherlands  
TEL:(31)(0) 70 345-8570 FAX:(31)(0) 70 346-7299



### Blood Glucose Meter, Test Strip and Control Solution:



DELBio, INC.  
3F, No. 252 Shangying Road, Guishan Industrial  
Zone, Taoyuan County 33341, Taiwan  
www.delbio.com.tw



Deltronics (Netherlands) BV,  
Zandsteen 15, 2132 MZ Hoofddorp, The Netherlands





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Taiwan



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