Blood Glucose Monitoring System
HEA-230
Instruction Manual
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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 use 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 electronical 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) the patient should only adapt the treatment if he has received the appropriate training to do so.
Chapter 1 Blood Glucose Monitoring System

1.1 Introduction

The blood glucose monitoring system, model HEA-230 uses the state-of-art bio-electrochemistry detecting technology, it only needs approximately 1 μL fresh capillary blood for one testing. Blood glucose concentration result will be showed in 5 seconds after you apply a blood sample into the test zone. It could help diabetics monitoring their glucose level, and is intended for blood glucose monitoring by people with diabetics and healthcare professionals. Please read instruction manual carefully before using.

HEA-230 is an in vitro diagnostic medical device for self-testing. By capillary action, test sample will automatically fill up the reaction zone by inhalation from the front channel.

Intended Use

The Blood Glucose Monitoring System, model HEA-230, is an in vitro diagnostic medical device intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body. It is designed for self-testing to monitor the effectiveness of diabetes control. The device should not be used for screening or diagnosis of diabetes or for testing neonates.Principle of the method

Principle of the method

By auto-filled mechanism, the volume of the sample can be precisely controlled. The blood glucose test strip is a kind of electrochemical biosensor. When the blood sample reacts with the strip, the glucose meter provides a voltage and the number of electrons produced by the reaction is detected. The current obtained from the blood glucose meter can be calculated by the internal conversion formula and be translated to the concentration of the sample.

⚠️ Warning: The glucose results provided by this system are only for the reference; never make significant changes in your diabetes treatment program without consulting physicians.
1.2 List of kit contents
1. Blood Glucose Meter
2. Sterile Lancets
3. Lancing device
4. Instructions for the lancing device
5. Carrying Case
6. Instruction Manual
7. Log Book
8. 2 x AAA Batteries

1.3 Product and meter display
A. Meter appearance

Caution: 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. The unit exchange ratio is as the followings: $1 \text{ mmol/L} = 18.02 \text{ mg/dL}$. 
B. Strip appearance

- **Top Edge**
  - Apply blood sample here.

- **Inserting Bar**
  - Insert this test strip into the meters’ strip port with this side facing up.

C. Function display

- **20-09 06-06 13:30**
  - Year
  - Date
  - Time

- **Temperature**

- **Error Message**

- **Test Result**
  - 10.6
Chapter 2 Installing and Setting up the Meter

2.1 Inserting / replacing batteries

◆ When to change the batteries
When the battery sign appears on the display, the battery power is low and replacing the battery as soon as possible is required for the meter.

◆ There are two conditions might occur depending on battery power status
1. When the battery sign flashes on the display after powered on, it represents the power of the batteries are low. However, you can still perform glucose measurements and the results will still be accurate, but it is recommended replacing the batteries as soon as possible.
2. The meter will shut down automatically after 120 seconds when only battery sign flashing on the display after powered on. It represents the battery power is too low to perform a measurement. You have to replace the batteries in order to continue using this meter. Time and date is required to be reset after replacing the batteries, however the past results is still recorded.

◆ How to replace batteries for Meter
1. Turn meter to the back side and open the battery compartment.
2. Replace two new AAA batteries and please take notice of (+) and (-) signs.
3. Install battery cover back to the battery compartment until hearing a “click” sound.
4. Try to turn on the device to see whether the meter is powered on. If not, please reexamine batteryies replacing procedures.
5. After turning on the meter, it will enter into time and date setting mode directly. (Please refer to setting up your meter of 2.2 for relative settings.)
6. Please dispose the used batteries according to the regulation.
2.2 Setting up your meter

1. Setting the date
   ◆ How to enter the date setting mode
   Press right button to turn on. The display will show the most recent test result. Press and hold down the left button until data sign stop flashing. Then press right button three times to display the date. To enter the date setting mode, press and hold down the left button until calendar sign flashes.
   ◆ How to set up the date
   Setting year
   Once you entered the date setting mode, the last two digits of the year will flash.
   (1) Press the right button once to increase a year.
   (2) Press the left button once to decrease a year.
   (3) Then press and hold down the left button to save your year. The display will now enter the month setting mode.
Setting month
Once you enter the month setting mode, the month field will flash.
(1) Press the right button once to increase a month
(2) Press the left button once to decrease a month
(3) Then press and hold down the left button to save your month. The display will now enter the date setting mode.

Setting date
Once you enter the day setting mode, the day field will flash.
(1) Press the right button once to increase a day
(2) Press the left button once to decrease a day
(3) Then press and hold down the left button to save your setting. The display will now show your new setting.
2. Setting the time

◆ How to enter the time setting mode
Press right button to turn on. The display will show the most recent test result. Press and hold down the left button until data sign stop flashing. Then press right button four times to display the time. To enter the time setting mode, press and hold down the left button until time sign flashes.

◆ How to set up the time
Setting Hour
Once you entered the time setting mode, the hour field will flash. The time display is by 12 hour-format, AM is before noon and, PM is afternoon or by 24 hour-format.
(1) Press the right button once to increase an hour
(2) Press the left button once to decrease an hour
(3) Then press and hold down the left button to save your setting. The display will now enter the minutes setting mode.
Setting Minute
Once you entered the minutes setting mode, the minute field flashes
(1) Press the right button once to increase a minute.
(2) Press the left button once to decrease a minute.
(3) Then press and hold down the left button to save your setting. The display will now show the time of your new setting.

2.3 Performing a blood glucose measurement

1. Inserting a test strip
   After inserting the test strip, the meter will turn on automatically and all icons on the display will appear for 1 second. Then the display will show the most recent test result. (For first time use or after battery changing, it will enter into setting mode directly)
2. Entering the code number
   The display will now show a locker sign and previous selected code number.
   Press the right or left buttons to increase or decrease the code number. Adjust the code number on display to match the code number on the test strip vial, then wait for 5 seconds to enter next screen display.

3. Applying blood
   After entering the code number, apply blood sign will appear on display. Gently touch the blood drop to the tip of the test strip within 2 minutes, then glucose level will show on the display after sign flashing for 5 seconds. If the warning sign appears, please see chapter 8.
4. Measuring blood glucose concentration

After the blood glucose measurement, \( \checkmark \) sign flashes. Then you can also press left or right button to review past results or hold down the left button to quit this mode.

\[ \text{mg/dL} \]

⚠️ Caution: 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. The unit exchange ratio is as the followings: 1 mmol/L = 18.02 mg/dL.

Chapter 3 Glucose Testing

3.1 Preparation before glucose testing

Please prepare materials you need as listed below, and read this manual carefully, to ensure the correct measuring process and results.

- blood glucose meter, model HEA-230
- blood glucose test strip, model HEA-STP30
- Lancing device
- Lancet
3.2 Fingertip blood measurement

Appearance of the lancing device:

A. Install the lancet
Check if you use a new lancet or not; unscrew the tip of lancing device; install the lancet into the lancet holder correctly and make sure it is fully seated, then remove the protective cap.
Adjust the puncture depth by selection dial, please twist case to suitable number. (The smaller number for the shallower puncture, and the larger number for the deeper puncture.)

a. Twist the cap to remove it.  

b. Install the lancet.

c. Twist the protective cap from lancet.

d. Install the tip of lancing device and adjust the puncture depth.
B. Cock the sampler
Slide the barrel control back until it clicks. The lancing device is now ready for use.

⚠️ Warning
Always use a new lancet.
Do not use the same lancet to obtain blood samples from different people.

C. Wash your hand and the puncture site
Wash hand with soap and warm water. Rinse and dry thoroughly.

D. Fingertip blood sampling
Please massage your finger tip gently and it will help you to obtain blood smoothly. We suggest that you could puncture different area each time. Repeated punctures in the same area may cause soreness. The blood sample for OMRON blood glucose test strip, model HEA-SP30, is just need approximately 1μL. Do not squeeze excessively at puncture area.
E. Preparation of test strip
To get a new blood glucose test strip from vial, then insert test strip into the meter. The strip code number will appear on meter display, check the code number on strip vial. If it does not match, please select the correct code number according to chapter 2.3. The symbol of blood drop with finger symbol will appear after selecting.

⚠️ Warning: To protect test strips from exposure to air, please press the cap of the vial till it “clicks”.

F. Blood glucose measurement
Hold the lancing device firmly against the side of your fingertip. Press the release button, gently squeeze your finger to assist the flow of blood. Touch the blood drop to the tip of the reaction zone of test strip after the symbol of blood drop flashes on the meter display. The test result will appear on display after the meter counts down from 5 to 1 (5 seconds).

Touch the blood drop of fingertip to the reaction zone.
The following items will cause inaccurate results:
• The reaction zone does not fill completely
• Apply blood over once.
• Do not apply blood to test strip after a period of time.
• Avoid violent variation of environment when you measure.
• Using a false test strip.

G. Blood glucose value display
The blood glucose test will perform in 5 seconds when the blood drop is drawn into the test strip. The test result will automatically be stored in the meter memory.
* Please dispose of used test strip and lancet to a sealed container to avoid environment pollution.

Important:
• Do not use single use test strip more than once.
• It should not be used for testing arterial, venous, or neonatal blood.
• It should be used for testing fresh capillary whole blood only.
• It should not be used for plasma.
• If red blood cell count (hematocrit) is higher than 55% or lower than 30%, it can cause false test results.
Chapter 4 Glucose Control Solution Testing (Optional)

4.1 Control test

In order to provide you a precise blood glucose value, we suggest the user to run a control test to let you know if the meter and test strips are working properly or not. When the result is within the range of the control solution value written on the test strip vial, the test strips and meter are working properly.

◆ When to run the glucose control solution test:
  • You think your test strips have been damaged.
  • Test result is not compatible with how you feel.
  • You think your glucose meter could be broken.

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

Important:
  • Use only the OMRON glucose control solution HEA-CTR30 with HEA-230 meter and HEA-STP30 strips.
  • Mark the newly opened bottle of control solution with the date opened; discard any unfinished control solution over three months after opening.
  • Store control solution at room temperature. Do not freeze.
  • Shake control solution before you use it. Please replace new control solution if the control solution deteriorate or coagulate.

* Before running the test, place the meter, test strips and glucose control solution at room temperature to reach the new temperature before use.
◆ The step of running control test:

1. Preparing a test strip

Take a test strip from strip vial and insert the test strip into the meter correctly in the front direction of the meter, in the meantime, the meter will display the code number. Make sure the code number on the display matches the code number on the test strip vial. If it does not match, please set the code number on screen to match the strip vial. When the screen shows a symbol of finger tip and drop blood, press the left button to enter glucose control solution test mode. After the symbol of finger tip disappears, system enters the glucose control solution test mode. In the glucose control solution testing mode, the results are not recorded in historical memory.

2. Running the glucose control solution test

Before running the glucose control solution test, always check the expiration date. DO NOT use control solutions if expired. Before using the control solution, gently shake the solution bottle to make the solution well mixed. Remove the bottle cap and wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip of the bottle. Put this drop on the clean surface. Touch the drop of control solution to the tip of the reaction zone of the test strip. accordance with local regulations.
Write the date you first open the bottle on the bottle label. The control solution must be discarded over three months from the date the bottle was opened (“discard” date) or on the “expired” date on the bottle label, whichever comes first. Do not use control solution that is “expired” or after discard date.

3. Understanding control test results

When the control solution result is within the range on the test strip vial, the test strips and meter are working properly.

If the result is not within the acceptable range (printed on your test strip vial), do not use your meter until you solve the problem. Repeat the control solution test again. If the result continues to be outside of the expected range, here are some things you can check:

• Did you follow all of the testing instructions?
• Are the test strips or control solution past the “expired” date or discard date?
• Is HEA-230 meter defective in material or workmanship?
• Does the code number on the meter display match the code number on the test strip vial?

Repeat the control test with a new test strip. If you still have problems, please contact your local authorized distributor for more information.
Chapter 5 Memory Function

5.1 Reviewing past results

* The code number will not show on the display when reviewing the past results.

1. Checking single result

◆ Press right button to turn on the HEA-230 System, then all icons will appear on the display for 1 seconds. After the sign flashes and the display will show second the most recent test result

◆ Then you can press left button to review previous test results. (In this mode, time and date display alternately.)

◆ HEA-230 system is able to store up to 512 test results together with date and time.
2. Average the results

◆ How to enter the result averaging mode

Press right button to turn on the HEA-230 system, then all segments will appear on the display for 1 second. The $\begin{matrix} \text{ 笔} \end{matrix}$ sign will appear and the display will show the most recent test result. Press and hold down left key will display the most test recent result.

Press right button once to display result averaging sign.

◆ How to check average Information

□ Press and hold down the left button to enter result average mode, then result averaging sign $\begin{matrix} \text{ 笔} \end{matrix}$ flashes.

□ Press left or right button to calculate the average result based on the test results stored for the past 7, 14 or 28 days.
Press and hold down left button to exit result averaging mode, then the display will return to the past 7 day average screen.

◆ How to read average measurement
Average information displays the current day selection for average, how many test results being recorded and glucose unit.
When test result exceeds 99 records, it will represent.
Chapter 6 Instructions on Caring and Storing for Your Strips and Meter

6.1 Caring for the strip

□ Wash hands before testing.
□ Do not use the expired strip.
□ Check the expired date printed on the package.
□ Record the opened day on the test strip bottle label when you first open it.
□ Discard the bottle and any remaining test strips after 90 days.
□ Keep the strip vial away from direct sunlight and high heat.
□ Store the test strips at ambient temperature between 4°C~30°C (39°F~86°F).
□ Do not refrigerate.
□ Humidity should be below 75% RH.
□ The strip vial should be stored in a dry place.
□ Do not put the test strip into other containers.
□ Always close strip vial tightly after taking a test strip out.
□ Keep the test strip from getting dirty or polluted during the storage.

6.2 Caring for the meter

□ If the meter’s surface gets dirty, gently wipe it with a cloth slightly dampened or one with mild detergent.
□ For those medical staff, you may use 10% bleach, 70% alcohol(ethanol), or 10% ammonia scouring reagent.
□ Do not clean the test strip slot.
□ Do not get any liquid into the test strip slot or on the button of the meter.
□ Do not put the meter under water or any liquid.
□ The meter must be stored at room temperature.
Chapter 7 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 problems or 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. If the result appears to be questionable to you, please contact contact your distributor.

<table>
<thead>
<tr>
<th>Message</th>
<th>Symbol</th>
<th>Means</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI</td>
<td>![Hi Symbol]</td>
<td>You may have a very high blood glucose level (&gt;33.3 mmol/L, 600 mg/dL)</td>
<td>Recheck your glucose level and contact your healthcare professionals</td>
</tr>
<tr>
<td>LO</td>
<td>![Lo Symbol]</td>
<td>You may have a very low blood glucose level (&lt;1.1 mmol/L, 20 mg/dL)</td>
<td>Recheck your glucose level and contact your healthcare professionals</td>
</tr>
<tr>
<td>Temperature symbol continuously flash</td>
<td>![Temperature Symbol]</td>
<td>You may have tested in an environment near the low or high end of the system's operating temperature range (10 ℃-40 ℃/50 ℉-104 ℉)</td>
<td>Repeat the test after the meter have reached a temperature within the operating range</td>
</tr>
<tr>
<td>Battery symbol continuously flash</td>
<td>![Battery Symbol]</td>
<td>The power is too low to perform a test</td>
<td>Replace the battery at once</td>
</tr>
<tr>
<td>Wrong test strip</td>
<td>![Wrong Test Symbol]</td>
<td>Test strip is over expiration data, broken, or used again.</td>
<td>Use other new Premium test strip</td>
</tr>
<tr>
<td>Wrong blood enter timing</td>
<td>![Wrong Blood Symbol]</td>
<td>Obtain blood sample too soon</td>
<td>Follow instruction step</td>
</tr>
<tr>
<td>Display freezes over two minutes or button can't be operated</td>
<td>![Display Symbol]</td>
<td>Reset the meter system</td>
<td>Reinstall the battery or change battery</td>
</tr>
</tbody>
</table>
Chapter 8 HEA-230 Performance Characteristics

The test result of Premium glucose monitoring system is plasma calibrated by chemistry analyzer, and the analyzer was calibrated with a NIST traceable glucose standard solution.

Measurement range:
The HEA-230 display results between 20 and 600 mg/dL (1.1 ~ 33.3 mmol/L).

Accuracy:
The accuracy of the HEA-230 was assessed by comparing blood glucose results obtained by patients with those obtained using clinical analyzer. The following results were obtained 120 subjects at 2 clinical centers.

<table>
<thead>
<tr>
<th>Slope</th>
<th>1.0384</th>
</tr>
</thead>
<tbody>
<tr>
<td>y-intercept</td>
<td>1.6664 mg/dL (0.0925 mmol/L)</td>
</tr>
<tr>
<td>Correlation factor (n)</td>
<td>0.9827</td>
</tr>
<tr>
<td>Patient number (n)</td>
<td>240</td>
</tr>
<tr>
<td>Test range</td>
<td>40<del>443 mg/dL (2.2</del>24.6 mmol/L)</td>
</tr>
</tbody>
</table>

Number and % of results within reference (for values were < 75 mg/dL(4.2 mmol/L))

<table>
<thead>
<tr>
<th>Within ± 5 mg/dL (0.3mmol/L)</th>
<th>Within ± 10 mg/dL (0.6mmol/L)</th>
<th>Within ± 15 mg/dL (0.8mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>26/40 (65 %)</td>
<td>34/40 (85 %)</td>
<td>39/40 (97.5 %)</td>
</tr>
</tbody>
</table>

Number and % of results within reference (for values were ≥ 75 mg/dL(4.2 mmol/L))

<table>
<thead>
<tr>
<th>Within ± 5 %</th>
<th>Within ± 10 %</th>
<th>Within ± 15 %</th>
<th>Within ± 20 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>67/200 (33.5 %)</td>
<td>135/200 (67.5 %)</td>
<td>178/200 (89 %)</td>
<td>197/200 (98.5 %)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Within Run Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples</td>
</tr>
<tr>
<td>Sample 1</td>
</tr>
<tr>
<td>Sample 2</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Sample 3</td>
</tr>
<tr>
<td>Sample 4</td>
</tr>
<tr>
<td>Sample 5</td>
</tr>
</tbody>
</table>

Between Day Precision

<table>
<thead>
<tr>
<th>Control solution 1</th>
<th>56.2 mg/dL (3.1 mmol/L)</th>
<th>SD=4.2 mg/dL (0.2 mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control solution 2</td>
<td>104.1 mg/dL (5.8 mmol/L)</td>
<td>3.2%</td>
</tr>
<tr>
<td>Control solution 3</td>
<td>306.1 mg/dL (17.0 mmol/L)</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

**Chapter 9 Specification and Maintenance**

- Measuring range: 20~600 mg/dL or 1.1~33.3 mmol/L
- Measuring unit: mg/dL or mmol/L
- Measuring time: Approximately 5 seconds
- Blood Sample size: Approximately 1μL
- Operating temperature: (10℃~40℃) (50 ℉~104 ℉)
- Store the test strips at ambient temperature between 4~30℃ (39 ℉~86 ℉). Do not refrigerate.
- Relative operating humidity: Below 90% RH
- Relative storage humidity: Below 75% RH
- Memory capacity: Up to 512 test results (together with date, time and unit) include average results for the last 7, 14 and 28 days
- Dimension: 9.0 x 6.0 x 2.5 cm (L x W x H)
- Weight: Approximately 90g with batteries
- Power supply: Two 1.5V AAA batteries
- Recommend to store in room temperature environment.
- Please do not store in high temperature or high humidity.
- Please prevent the HEA-230 system against from impact.
- Please do not disassemble the HEA-230 system.

**Warning:** 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.

**Caution:** Any further service and product information, please contact OMRON distributors.
For self-testing

Lancing Device and Lancets:
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