尺寸:100*140mm
材质:封面128g铜版,
内页80g双胶骑马钉,
黑白打印

# Blood Glucose Meter

## User Manual


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Issue Date: 2024.01.23 Version: A0.0

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CONTENT

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Dear Users,

Thank you for purchasing our CGH200/CGH210 Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

CGH200/CGH210 Blood Glucose Meter should only be used with CGH200/CGH210 Blood Glucose Test Strips respectively. Using other test strips with the meter can produce inaccurate results. The Blood Glucose Monitoring System is used to monitor the concentration of glucose in the human body's capillary blood in vitro (usually collected from the fingertip blood) and venous whole blood in vitro. It is easy to use with less blood sample volume, which can help you to control the glucose level better. For further details about this product, please call the after-sales service department.

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**IMPORTANT SAFETY INFORMATION**

1. DO NOT use for diabetes diagnosis or blood glucose monitoring of newborns.
2. Must be performed under the guidance and assistance of professional medical personnel.
3. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.
4. Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
5. Use this device ONLY for the intended use described in this manual.
6. Only use compatible blood glucose test strips provided or recommended by the manufacturer. Using other test strips with this meter can produce inaccurate results.
7. DO NOT use the device if it is not working properly or damaged.
8. When blood samples contain lipids (triglycerides with a concentration not exceeding 500 mg/dL or cholesterol not exceeding 25 mg/dL) and sugars (maltose concentration not exceeding 200 mg/dL), they have no significant impact on blood glucose test results; When the concentration of ascorbic acid is ≥4.2mg/dL and the concentration of xylose is ≥10mg/dL, it may affect the blood glucose test results. Therefore, do not use this product in the xylose absorption test.
9. Test strips have limitations such as expiration date, storage temperature and humidity, etc. Please use and store the test strips in accordance with the instructions for use.

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10. The system is intended to be used by a single person and should not be shared, due to the risk of infection from bloodborne pathogens.
11. Please properly dispose of used test strips and lancets according to the relevant local laws and regulations to avoid cross infection and disease transmission.
12. Please dispose of replaced batteries properly in accordance with local laws and regulations to avoid pollution to the environment.
13. Do NOT use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the correct operation.
14. Remove the battery when the meter is not used for a long time.
15. DO NOT put the meter into any liquid.
16. DO NOT use the expired test strips.
17. Avoid bumping as much as possible when using the meter to avoid affecting the meter’s measurement performance.
18. During testing, the meter may come into contact with blood. Therefore there is a risk that used meter may carry infectious materials. When this meter is used in a medical setting, health care workers should follow your facility's appropriate infection control procedures for sanitation equipment, such as wearing gloves or other personal protection.
19. When receive the glucose monitoring system, please check if the package is damage. If any items are missing from your kit or opened before use, please contact local customer service or place of purchase for assistance.

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# I. PRODUCT OVERVIEW

## 1.1 Intended Use

The Blood Glucose Monitoring System CGH200/CGH210 is comprised of the meter and the test strips. It is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip and venous whole blood in vitro as an aid in monitoring the effectiveness of glucose control. It can be used by professionals in clinics, hospital, or non-professionals with diabetes at home. This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use. Do not change your therapy based on a test result that does not match how you feel or if you believe that your test result could be incorrect.

## 1.2 Test Principle

The reaction area of the blood glucose test strip is fixed with special chemicals, the glucose in the blood sample comes into contact with it and a chemical reaction occurs to produce a micro-current, which is detected by the blood glucose meter and converted into a blood glucose concentration result that is displayed.

## 1.3 Contents of System

| Item | Quantity |
|---|---|
| Blood glucose meter CGH200/CGH210 | 1PCS |
| Instruction manual | 1PCS |
| 2* CR2032 3.0V coin cell battery | 2PCS |
| Carry Case | 1PCS |

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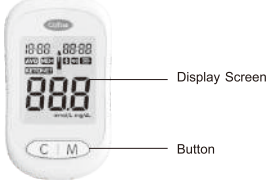
| | |
|---|---|
| Lancing device (CE-marked, optional) | 1PCS |
| Lancet (CE-marked, optional) | 10PCS |
| Blood glucose test strip CGH200/CGH210 | 10PCS |

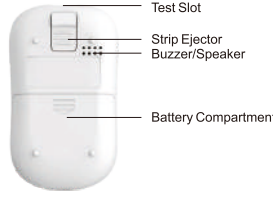
Battery, lancing device, and lancets may not be included in the kit (please check the contents on your product box). They may be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

### 1.4 Monitor Overview

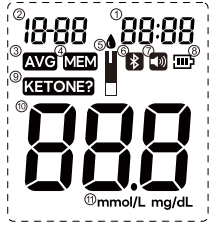
**Front**




**Back**




### 1.5 Screen Display



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① Time

② Date

③ Day Average

④ Memory Record

⑤ Blood Drop Symbol

⑥ Bluetooth Symbol

⑦ Voice Prompt Symbol

⑧ Battery Symbol

⑨ Ketone Warning (Appears when your result is equal to or higher than 240mg/dL (13.3 mmol/L))

⑩ Glucose Level

⑪ Measurement Unit: mmol/L and mg/dL (1mmol/L=18mg/dL)

After you install the battery or replace the battery, the full display interface will be displayed for about 2 seconds.

## II. SETTING THE MONITOR

**Entering the Setting Mode**

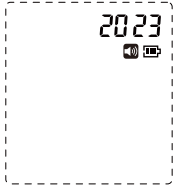
Start with the monitor off (no test strip inserted). Long press the **"C"** button for 3 seconds at least to enter the setting mode.

### Step 1

**Setting the YEAR/MONTH/DAY/HOUR/MINUTE**

The sequence of the date setting is: YEAR → MONTH → DAY → HOUR → MINUTE. With the YEAR / MONTH / DAY/HOUR/MINUTE flashing in sequence, press **"M"** to change the digit and press **"M"** until the correct YEAR/MONTH/DATE/HOUR/MINUTE appears. The number will be incremented continually while long pressing . When the YEAR reaches

2050, it will automatically return to 2023.




### Step 2

**Setting the unit of measurement**

After the time setting, press **"C"** to enter the unit of measurement setting mode. Press **"M"** to select mmol/L or mg/dL (the default setting is mg/dL), press **"C"** to save the settings and enter the broadcast setting mode.

### Step 3

**Setting the broadcast**

Long press **"M"** for about 3 seconds to select "ON" or "OFF". Then press the **"C"** button to turn off the device.


**Sound On**


**Sound Off**

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**Step 4**

**Deleting the memory**

In standby mode, press **“M”**, your 7-day average of glucose test result will be displayed. Press **“M”** again, you will review your 14-, 28-, 60-, 90-day average. After 90-day average displayed, Long-press the **"M"** to the earliest test result, press **“M”**, the display will show “END”. Press “M” another time, **“MEM”** will be flashing, **“dEL”** will come up. Finally long press **“M”** to delete all memory. After deleting, the display will show **"---"** and shut down after 1 minute. Or you can press **“M”** to turn off the device.

## III. BLOOD GLUCOSE TESTING

### 3.1 Performing a Blood Glucose Test with Blood from Your Fingertip

**Step 1**

**Installing batteries**

The blood glucose meter requires 2* CR2032 3.0V coin cell battery , and the two batteries can support 1000 times of testing. After inserted the test strip, the meter is waiting for blood sample with blood drop symbol flashing, the meter will automatically shut down if there is no operation for about 3 minutes. When the meter is in other mode, it will automatically shut down if there is no operation for about 1 minute.

**WARNING**

- When the screen displays **"E-b"** warning reminder, it means that the battery is low, please replace the battery as soon as possible;
- If the meter will not be used for a long time, please take out the battery.

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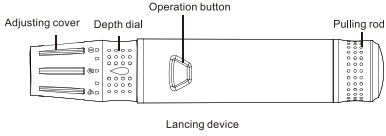
- DO NOT use inferior or expired batteries to avoid measurement errors.
- Waste batteries should be disposed in accordance with local environmental regulations.

## Step 2

**Preparing the lancing device**




① Screw off the removable cap of lancing device.

② Insert a new, unused lancet into the Holder. Firmly press lancet until it stops and fits securely within the holder.

③ Twist off the protective cap of lancet, then screw the removable cap on tightly.

④ Select the skin penetration depth by twisting the selector. The device offers 5 different levels of skin penetration.

⑤ Pull back the arming mechanism until you hear a clicking noise.

## Step 3

**Insert the test strip**

Insert the test strip, and a flashing symbol will be shown in the screen to remind you to apply the drop of blood to the absorbent hole of the test strip at a tilted angle.

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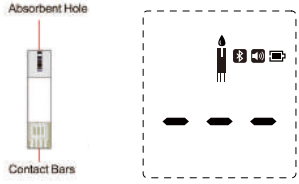


**WARNING**

- After taking out the test strip, immediately close the vial cap tightly to avoid moisture and light from affecting the unused test strip.
- If the test strip is taken out from the vial for a long time, an error message will be displayed after the test strip is inserted into the meter, please take it out and discard it properly, and use a new test strip for testing.
- Test strips are disposable, please do not reuse them.

## Step 4

**Obtaining a blood sample**

Please follow the suggestions below before obtaining a drop of blood:

① Wash and dry your hands before starting.

② Select a puncture site.

③ Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.

④ Use the pre-set lancing device to puncture your fingertip.

⑤ Rub the puncture site for about 20 seconds before penetration.

⑥ After penetration, discard the first drop of blood with a clean tissue or cotton. Gently squeeze the punctured area to obtain another drop of blood

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(do not squeeze too hard). The volume of blood sample must be at least 0.8 microliter (μL) of volume.

**NOTE**

- If the first sample you provided is not sufficient, second-chance sampling is not allowed. You have to discard the used test strip and retest with a new one.
- Discard the used lancet after the test.

### Step 5

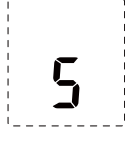
**Applying the sample**

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle.

### Step 6

**Reading your result**

After applied the blood drop to the strip, the screen will display the countdown interface. The result of your blood glucose test will appear after the meter counts down from 5 to 0.




The result displayed is as follows:

The blood glucose test result at 09:20 on July 18th was 15.3mmol/L and

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ketone warning symbol appeared.


The blood glucose test result at 08:12 on July 28th was 5.8mmol/L.


**Step 7**

**Discard the used test strip**

Remove the used test strips with the ejector and throw into a disposal container. When the meter is turned off, the test result will be automatically saved. (Note: If the test strip is removed during the countdown process, the test will be canceled and the test results will not be saved.)

**Step 8**

**Review test results**

Your monitor stores the 500 most recent glucose test results along with respective dates and times in its memory. To recall the memory, start with the monitor off.

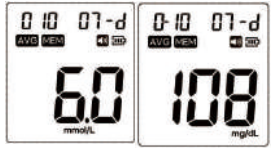
In the standby state, press **"M"** to enter the memory mode. Your 7-day average of the blood glucose test results will appear. Press **"M"** again to

review 14-, 28-, 60-, 90-day average.

When the screen displays the 90-day average of blood glucose, press **"M"** again, and the latest result with date and time will be displayed. Press **"M"** to scroll up or press **“C”** to scroll down until the desired test result appears.

If the meter is used for the first time or the user has deleted the memory, **"---"** will be shown and it means that there is no measurement result in the memory.

The following figure shows that the average value of 10 measurements in the last 7 days is 6 mmol/L or 108mg/dL.




Keep pressing **"M"** to exit the memory mode.

### 3.2 Performing a Blood Glucose Test with Blood from Your Palm, Forearm, or Upper Arm (Alternate Site Testing)

When users want to test blood sugar, they usually take a blood sample from their fingertips. However, there are many nerve endings in the fingertips, so the pain may be greater. Therefore, you can choose different parts of the body, such as the forearm, upper arm, palm, thigh, calf and abdomen, to reduce the pain of blood collection.

Although AST can reduce the pain of blood collection, it may not be simple for everyone. The following principles should be adhered to during the test:

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① Choose a clean and soft fleshy part without visible veins and hair, away from bones;

② Wash the area with soapy water and dry thoroughly;

③ Gently massage the blood collection site with clean fingers to help blood circulation and minimize the difference in measurement results between the fingertips and the blood collection site;

④ Diet, medical treatment, illness, stress and exercise all affect blood sugar levels, and capillaries in fingertips respond to these changes faster than capillaries in other parts of the body. Therefore, users who need to perform blood glucose measurements within two hours of eating, exercising, experiencing stress, or injecting insulin can only collect blood samples from their fingertips;

⑤ When your blood sugar level is unstable, please do not use blood samples from other parts except fingertips;

⑥ Pregnant women should not use blood samples from other parts except fingertips.

## IV. DATA TRANSMISSION VIA BLUETOOTH

When you choose the CGH200 glucose meters, the meters have the ability to transmit your various test results to your mobile device via Bluetooth (your mobile device will need to have the Blood Glucose Management app installed).

| Steps and Descriptions | Illustrations |
|---|---|

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1. Pair your mobile device with the blood glucose meter (The first time you use the Bluetooth function)

a) When the meter is turned on, the Bluetooth function is turned on and the Bluetooth icon will flash to remind the user to pair with the meter.

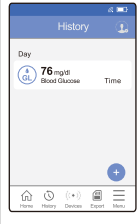
b) the Bluetooth icon is always on if the connection is successful.

Note: The Bluetooth would automatically turn off and the icon would disappear when the mobile device fails to connected with the meter in one minute.

**2. Upload the results**

When the glucose meter and the mobile device are successfully connected, the glucose meter will actively upload the results of each test to the mobile device.

Note: the meter will also automatically upload historical results that have not been uploaded before to the currently paired mobile device.




**NOTE**

The glucose meter can only be paired with one mobile device at a time; when you pair a new device, new data will only be transferred to the new device, and old data can only be viewed on the old device.

## V. CONTROL SOLUTION TESTING

Glucose control solution is used as a test for control of the blood glucose

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testing system to ensure that the blood glucose meter and blood glucose test strips are working properly. Regular system checks will ensure that the meter provides accurate test results.

You can contact customer service through your local distributor or by calling the hotline to obtain the quality control solution.

**NOTE**

Use only blood glucose control solution manufactured by our company.

### 5.1 When to Perform a Control Test?

- You open a new bottle of blood glucose test strips.
- You left the test strip container open.
- You think the test strips are damaged.
- You want to check the meter and test strips.
- The test strips were stored in extreme temperatures, humidity, or both.
- You dropped the meter.
- Your test result does not match how you feel.
- You want to check if you are performing the test correctly.

### 5.2 Performing a Control Test

**NOTE**

- Please read the instruction manual of the control solution carefully and know the precautions for using the control solution.
- It is recommended that the control solution test should be done at room temperature (68°F to 77°F / 20°C to 25°C). Make sure your control solution, monitor, and test strips are at this specified temperature range before testing.

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**Step 1**

**Insert the test strip**

Insert the test strip into the monitor. Wait for the monitor to display the test strip and blood drop symbol.

**Step 2**

**Apply control solution**

Shake the control solution bottle thoroughly and squeeze out the first drop and discard it. Then squeeze another drop and place it on the tip of the vial cap.

Hold the monitor to move the absorbent hole of test strip to touch the drop. Once the confirmation window fills completely, the monitor will begin counting down.

**Step 3**

**Read and compare the result**

After counting down to 0, the test result of control solution will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

When the test is finished, push the test strip ejector to discard the test strip.

**NOTE**

Please dispose of the used test strips and control solution according to the medical waste.

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## VI. SYSTEM TROUBLE SHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair by yourself and never try to disassemble the monitor under any circumstances.

**6.1 Error Messages**

| MESSAGE | CAUSE | WHAT TO DO |
|---|---|---|
|  | Test strip is used, or expired, or getting damp. | Use a new test strip |
|  | Blood glucose result is above 33.3 mmol/L (600 mg/dL) | Please test again. If the result is same, please contact distributor or customer service. |
|  | Blood glucose result is below 1.1 mmol/L (20 mg/dL) | Please test again. If the result is same, please contact distributor or customer service. |

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|---|---|---|
|  | Low battery | Please replace the batteries |
|  | Abnormal room temperature | The test should be carried out at a temperature of 5°C~40°C |
|  | Insufficient sample size | Please use a new test strip and provide sufficient blood samples to retest. |
|  | Abnormal sample | Please use a new test strip and re-test. If the results are the same, please contact the dealer or customer service center. |

**6.2 Troubleshooting**

- After inserting the test strip, the blood glucose meter does not start:

| POSSIBLE CAUSE | SOLUTION |
|---|---|
| Test strip is not inserted correctly | Reinsert it correctly. |
| Test strip is not fully inserted | Fully insert the strip. |

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|---|---|
| Damaged test strips | Insert with a new test strip. |
| Low battery | Replace the battery in time. |
| Defective meter or strips | Please call customer service for assistance. |

- The blood glucose meter does not start counting down after blood sampling:

| POSSIBLE CAUSE | SOLUTION |
|---|---|
| Insufficient blood sample | Repeat the test using a new test strip with larger volume of blood sample. |
| Sample applied after automatic switch-off (3 minutes after last user action). | Repeat the test with a new test strip. Apply sample only when flashing " 💧 " appears on the display. |
| Defective strip | Replace with new test strips. |
| Defective meter | Please call customer service for assistance. |

- If the control solution testing result is out of range:

| POSSIBLE CAUSE | SOLUTION |
|---|---|
| Error in performing the test. | Read instructions thoroughly and repeat the test again. |
| Control solution vial was poorly shaken. | Shake the control solution vigorously and repeat the test again. |

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|---|---|
| Use the first drop of control solution after opening the bottle | Repeat the test with a new test strip. |
| Expired or contaminated control solution. | Change a bottle of well-stored control solution within the expiration date and repeat the test again. |
| Defective test strip. | Replace the test strip with a new bottle (box) and measure again. |
| Temperature of meter, test strip, control solution is too high or too low. | Control solution, monitor, and test strips should be at room temperature (68°F to 77°F / 20°C to 25°C) for 30 minutes before testing |
| Meter malfunction | Please contact your distributor or customer service center |

**NOTE**

After doing the analysis of the reasons as above and taking the measures as above, If the test results are still outside the control range, the test system may not work properly, please contact your local distributor or customer service center.

## VII. MAINTENANCE

The blood glucose meter may be contaminated by blood samples and other substances during use, you can clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with a soft cloth.

**WARNNING**

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DO NOT get any moisture in slots or openings.

DO NOT disassemble, repair or modify your blood glucose meter.

STORE the meter in a protective case or box after use to avoid damage

## VIII. ELECTROMAGNETIC COMPATIBILITY

**PRECAUTION**

- Blood Glucose Meter meets the emission and immunity requirements specified by IEC61326-1 and IEC61326-2-6.
- It is recommended to evaluate the electromagnetic environment before using the equipment.

**NOTE**

- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$, where d is the minimum separation distance in meters, P is the maximum power in watts, and E is the immunity test level in V/m.

**WARNING**

- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.
- Do not use this instrument in proximity to sources of strong

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electromagnetic radiation, as these may interfere with the proper operation.

- This equipment is designed for use in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

## IX. EXPLANATION OF SYMBOLS

The following symbols will appear on the blood glucose meter and its packaging, and the meanings of these symbols are as follows：

| | |
|---|---|
|   | In vitro diagnostic *medical device* |
|  | Caution |
|   | *Serial number* |
|  | Keep away from sunlight |
|  | Consult *instructions for use* |
|   | Temperature limit |

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| | |
|---|---|
|  | Direct Current |
|  | *Manufacturer* |
|  | CE marking |
|  | Fragile, handle with care |
|  | Keep dry |
|  | Symbol for the marking of electrical and electronics devices according to Directive 2012 /19 / EU . The device, accessories and packaging have to be disposed of waste correctly at the end of the usage, please follow Local Ordinance or Regulatory for disposal. |

## X. SPECIFICATION

| Model | CGH200 | CGH210 |
|---|---|---|
| Display | LCD | |
| Voice Prompt | Buzzer alert | |

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|---|---|
| Power Supply | 2* CR2032 3.0V coin cell battery |
| Dimension | 53.8mm*92.1mm*19.6mm |
| Memory Capacity | 500 |
| Temperature | During testing: 5℃～40℃<br>During storage: -20℃～+55℃ |
| Atmospheric Humidity | During testing: 10%～80%RH<br>During storage: 10%～90%RH |
| Measuring Range | 1.1mmol/L～33.3mmol/L(20mg/dL～600mg/dL) |
| Measuring Time | 5 seconds |
| Accuracy | Allowable deviation does not exceed ± 0.83 mmol/L (±15 mg/dL) at glucose concentrations < 5.55 mmol/L (<100 mg/dL), or;<br>Allowable deviation does not exceed ± 15 % at glucose concentrations ≥ 5.55 mmol/L (≥100 mg/dL). |
| Precision | Standard deviation SD< 0.42 mmol/L (7.7 mg/dL) for glucose concentration <5.55 mmol/L (<100mg/dL).<br>Coefficient of variation CV< 7.5% for glucose concentration ≥ 5.55 mmol/L ( ≥ 100 mg/dL). |
| Hematocrit Range | 10%～70% |
| Ketone Warning | Glucose value is over 13.3 mmol/L (240 mg/dL) |
| Date of Production | See body nameplate or outer packing |
| Service life | 5 years |

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## XI. REFERENCE VALUES

Blood Glucose Test Strip are used to detect blood glucose levels in whole blood and the results obtained are automatically displayed as plasma glucose values.

Blood glucose test results may vary depending on food intake, medication dosage, health conditions, stress or exercise. Plasma glucose values in non-diabetic patients usually remain within a relatively narrow range, with fasting glucose values ranging from approximately 3.9 to 6.1 mmol/L, and within 2 hours after a meal, glucose values <7.8 mmol/L.

Please consult with your physician about your ideal blood glucose range.

**References:**

1. American Diabetes Association. Glycemic Targets. Diabetes Care 2017 Jan; 40 (Supplement 1): S11-S24.

2. EN ISO 15197:2015 In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus