

Operation Manual

Dear IGM-1001D Blood Glucose Monitoring System Owner,

Thank you for choosing the IGM-1001D Blood Glucose Monitoring System. This manual contains everything you need to know about your new glucometer and how it works. Please take a moment to read the instructions carefully.

We understand that self-testing of blood glucose level provides a way to control your diabetes and may give you peace of mind by testing regularly. As a result, IGM-1001D has been developed to provide you with a fast and accurate reading in a convenient and simple process. Our goal for the IGM-1001D Blood Glucose Monitoring System is to provide you with the best quality healthcare products coupled with superior customer service. Always consult with your healthcare professional, before making any changes to your diabetes management. The IGM-1001D Blood Glucose Monitoring System is for in-vitro diagnostic use only.

Customer Service is available 24 hours a day, 7 days a week, and 365 days a year. Please call customer support center in your local area.

Important Information

The IGM-1001D Blood Glucose Monitoring System is intended for use outside the body (in-vitro diagnostic use only). It should be used only for testing blood glucose and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes.

Consult with your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer.

Please pay close attention when handling blood. Improper procedures may cause serious hazards to your health.

The IGM-1001D Blood Glucose Monitoring System contains small parts, which could be a choking hazard for children if swallowed.

Test Principle

IGM-1001D blood glucose test strip is the bio-sensor which has been made by the FAD-dependent glucose dehydrogenase(enzyme). FAD-GDH(enzyme) quantitatively reacts with the glucose in the whole blood and the mediator. At this moment, mediator $\text{Fe}(\text{CN})_6^{3-}$ is reduced to $\text{Fe}(\text{CN})_6^{4-}$. This $\text{Fe}(\text{CN})_6^{4-}$ generated by the reaction is re-oxidized on carbon electrode, for which the method is called amperometry. The measured oxidation current exists in proportion to the glucose concentration in the whole blood.

WARNING:

1. All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have taken cleaning and disinfection measures.
2. Always use a new, sterile lancet. Lancets are for single use only.
3. Avoid getting hands lotions, oil, dirt or debris in and/or on the lancets and reusable lancing device.
4. Please refer to page 12 for cleaning and disinfecting IGM-1001D Blood Glucose Monitoring System.
5. Do not change your medication based on the IGM-1001D meter test results without contacting your physician or healthcare professional first.
6. Do not assemble or disassemble the blood glucose test meter
7. Keep out of direct sunlight.

CAUTION:

Following list of **IMPORTANT SAFETY INSTRUCTIONS** provided:

1. Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.
2. Do not place the equipment in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, remove the batteries and dry the device.
3. Use the equipment only for the purpose described in the instructions for use.
4. Do not use accessories which are not supplied or recommended by the manufacturer.
5. Do not place anything on top of the equipment.

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Learning the System

Intended use of Blood Glucose Test Meter

The IGM-1001D Blood Glucose Monitoring System is intended for use outside the body only (in-vitro diagnostic use) and self-testing. Recorded results make it easier for your doctor to access your metabolic control. However, the self-testing should not take the place of overall diabetes management assessment from your doctor. It should be used for testing blood glucose (sugar) only with fresh capillary whole blood samples. IGM-1001D Blood Glucose Monitoring System is intended for use in places like home and in professional setting to monitor blood glucose levels.

CAUTION

- Do not use system for any other purpose than blood glucose test.
- Cholesterol concentrations > 500 mg/dL or triglyceride concentrations > 3,000 mg/dL may produce elevated reading.
- Icodextrin does not interfere with this version of IGM-1001D test strips.
- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.
- Before using any product, please read all instructions.
- Consult with your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer. If you have any questions about the IGM-1001D product, please contact your local representative.

WARNING

- Before using IGM-1001D system, read all instructions in this manual, and practice for accurate and safe test. You should have commentary recommendation from your diabetes care professional for the proper use of the meter and daily management of your diabetes.
- If you think your blood glucose results are too low or too high, or if the results are doubtful, please contact your doctor.
- If your blood glucose result is unusually low or high, or you do not feel the result is correct, repeat the test again with a new test strip.
- If the results are still inconsistent, please consult with your physician before making any decision in controlling your diabetes.

IGM-1001D Kit Components

- | | |
|----------------------------|------------------------------------|
| 1. IGM-1001D Meter | 6. Warranty Registration Card |
| 2. IGM-1001D Test Strip | 7. Carrying Case |
| 3. Reusable Lancing Device | 8. Patient Logbook |
| 4. Lancets | 9. 2EA of 3V Coin Battery (CR2032) |
| 5. Operation Manual | |

Your IGM-1001D Blood Glucose Monitoring System has been sealed to protect the contents. If you find your seal has been broken, please return it to the place of purchase.

IGM-1001D meter



<Front>

- **Test Strip Port:**
Insert the IGM-1001D test strip
- **Display Screen:**
Displays your test results, symbols and messages.
- **Power/Enter Button:**
Power the meter on/off, prompts memory data and acts as an "Enter" button during setup and after tests.
- **Up/Down Arrow Buttons:**
Scroll up or down to adjust settings or retrieve memory.



<Rear>

- **Test Strip Ejector:**
Releases and discards test strip
- **Serial Number:**
- **Battery Cover:**

CAUTION

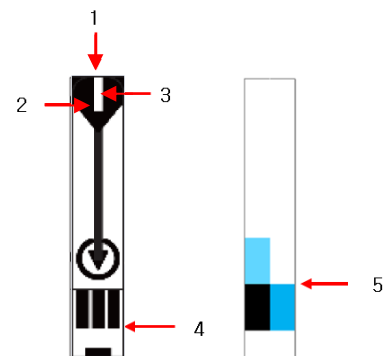
- Do not use IGM-1001D glucose test meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharge in a dry environment.
- Do not use IGM-1001D glucose test meter near cellular or cordless telephones, walkie-talkies, garage door openers, radio transmitters, or other electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the glucose test meter.

IGM-1001D meter display



- Low Battery Warning Symbol
- Alarm Symbol
- CHK Troubleshooting Symbol
- ALL DEL Delete Results
- AVG Average Test Result System
- Before Having a Meal
- After Having a Meal
- After Taking Medication
- After Sport Activity
- Control Solution Symbol
- Blood Drop Symbol for Test Strip Code Symbol
- CODE Test Result Unit Symbol
- mg/dL Temperature / Date
- YR DAY, MON AM PM Time / Test Result Amount

IGM-1001D test strip



Number	Name	Function
1	Entrance	Blood goes into this area.
2	Air exit	As blood enters, air exits thru this area
3	Confirmation Window	Able to see through this window whether blood is fully filled.
4	Connector	Connect between the electrodes and meter
5	Auto-coding label	Automatic coding recognition

CAUTION

1. Store the IGM-1001D test strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
2. Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
3. Immediately replace the vial cap and close tightly after removing any test strips from the vial.
4. Make a note of the expiry date, which is three months from the date you first open a new vial of strips. Throw IGM-1001D test strips and vial away after the expiry date.
5. Do not use the test strips after the expiration date printed on the package or vial, since it may cause inaccurate results.
6. IGM-1001D test strips should be single use only. DO NOT RE-USE.
7. Do not test at temperatures below 10°C (33.8°F) or above 40°C (104°F).
8. Do not test in the condition that humidity is below 10% or above 90%.
9. Do not bend, cut, or alter the test strip.
10. Avoid getting dirt, food, and water on the test strip with wet hands.
11. Avoid getting dirt, food, and water on the color-coding label (backside of test strip)
12. Refer to additional information in the IGM-1001D test strip package.

Before Testing

WARNING

To reduce the chance of infection:

1. Lancing device and lancets should NOT be shared with others.
2. Always use a new lancet and a new blood glucose test strip.
3. Practice using the lancing device and become accustomed with its use.
4. Lancets and blood glucose test strips should be single use only.
5. Wash your hands in warm clean running water using soap before testing.
6. Avoid getting hand lotion, oils, dirt or debris on the lancets or on the lancing device.
7. Dry your hands completely before testing.

Setting Your Meter

The IGM-1001D meter has a wide variety of functions to choose from. From the setup mode you have the ability to turn activity/meal flags, set the date/time, designate three unique averages and set up to five daily alarms.



Power On

Press \odot for 3 seconds at least



User Activity Option

After pressing and releasing either \blacktriangle or \blacktriangledown buttons to turn the User Activity Option on/off, confirm with \odot



Year

After pressing and releasing either \blacktriangle or \blacktriangledown buttons to set the year, confirm with \odot



Date / Time

After pressing and releasing either \blacktriangle or \blacktriangledown buttons to set the date and time, confirm each with \odot



Number of days for average

After pressing and releasing either \blacktriangle or \blacktriangledown buttons to set the number of days for average calculation (3 different possible), confirm with \odot



Alarm on/off

After pressing and releasing either \blacktriangle or \blacktriangledown buttons to turn the alarm on/off, confirm with \odot



Alarm time

After pressing and releasing either \blacktriangle or \blacktriangledown buttons to set the alarm hour and minute, confirm with \odot



Alarm

After programming the number of desired alarms (5 alarms possible), confirm with \odot

CAUTION

1. **VERY IMPORTANT:** Set the right test unit. Your IGM-1001D Meter is pre-set to mg/dL as test unit. A wrong test unit will read to wrong test result display. Please consult your healthcare professional if you're not sure which test unit to use. Without setting the date properly, the average glucose level and the results in memory will not show proper values. It is recommended to set the glucose test meter before use and also when new batteries are installed.
2. You cannot test your blood glucose in the setting mode.
3. To turn the meter off during the setup, press \odot for at least 3 seconds.

Auto-coding Function



1. IGM-1001D has automatic code recognition function (e.g. C26)



2. It recognizes the code number automatically. This is a very convenient function preventing the inconvenience of setting the code number on the glucose test meter every time. Check the code on the vial to see if the codes match each other

CAUTION

1. Do not bend the glucose test strip to prevent the automatic code recognition failure.
2. If the code recognition label is damaged, code recognition may fail. Please check the code number on the LCD window together with the code number on the glucose test strip vial to see if code numbers match each other.

Backlight Function



When inserting IGM-1001D glucose test strip (starting measuring process), backlight will turn on for 10 seconds.

After the test result displays, backlight will last for 10 seconds.

By pressing the power button (moving into memory mode), backlight will turn on for 10 seconds.

When pressing the power button for 3 seconds (entering the setting mode), backlight will turn on for 10 seconds.

When inserting the PC cable into the USB port, backlight will turn on for 10 seconds.

Performing a Control Solution Test

IGM-1001D control solutions contain a known amount of glucose that reacts with IGM-1001D test strip. By comparing your control solution test results with the expected range printed on the test strip vial, it is able to check the meter and test strips are working properly and that you are performing the test correctly. It is very important that you perform the check routinely to make sure you get accurate results.

The Glucose control solution should be used

- Before using a new box of strips
- Whenever you suspect the blood glucose test meter or blood glucose test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the blood glucose test meter.
- For quality control in the point of care usage.
- For teaching or learning the system.
- When using the meter for blood glucose tests after any disinfection procedure.



Firmly insert the test strip into the meter test port. Insert down firmly in direction of arrow on test strip (arrow up). Please do not insert the glucose test strip upside down.

When you insert the glucose test strip into the glucose test meter, the power automatically adjusts the meter accordingly.



Before inserting blood, Scroll through the icons with the ▲ or ▼ button until the control solution bottle is blinking, press



1. Check the expiration date before performing a control solution test. Do not use if expired. Please note the expiration date on the control solution bottle.



2. Gently shake the control solution before use.



3. Discard the 1st drop of control solution, this will eliminate any residue.

Place a drop of control solution on a clean dry surface (e.g. the lid of the test strip vial)



4. Dip the test strip into the control solution.
Results will appear in 5 seconds.
Compare the result to the range printed on the test strip vial, the result should fall within that range

CAUTION

1. Control solutions is for in-vitro diagnostic use only. This means that it is only used for testing outside the body.
2. Control solution is exclusively made for the IGM-1001D Blood Glucose Monitoring System. Do not use other brand control solutions made by other manufacturers.
3. Check the expiration date on the vial. Do not use, if expired.
4. Once opened, use it for the next three months only. Record the discard date on the control solution bottle. Discard after three months.
5. Do not swallow. This is NOT for human or animal consumption.
6. The control solution bottle icon contains letter 'C,' so as not to be confused with the medication bottle.
This will allow you to understand differences between a control solution test and an actual blood test.

For example only :

If you are using the normal control solution, according to this particular vial of strips, your meter should show a number between 80 and 120.



Please note that the control values shown in the picture are not control ranges.

NOTE:

- It is recommended that glucose control solution is stored at room temperature 20~25°C (68~77°F) before testing.
- Check the expiration date before performing a glucose control solution test.
- Do not use if it expired. Once opened, the control solution expires after 3 months.

If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiration dates on all the products you are using. Be sure you are using IGM-1001D control solution.
- Try another control solution test.
If this test falls out of range, try another control solution test with a new unopened bottle of strips.
- After following the appropriate steps and the control test still falls out of range, do not perform a glucose test.

Please call customer support toll: 82-31-460-0300

Follow-up Action

1. Check your meter and strip with the glucose control solution.
2. Perform your test again.

CAUTION

1. If your glucose control solution falls out of range, do not perform a glucose test and please contact your local distributor.
2. The glucose control solution's measurement range has nothing to do with individual's blood glucose level, as its own purpose is to check the status of strip and meter. Discard the used control solution and test strips carefully, according to the local regulation.

Performing Your Test

Testing Blood - Preparation

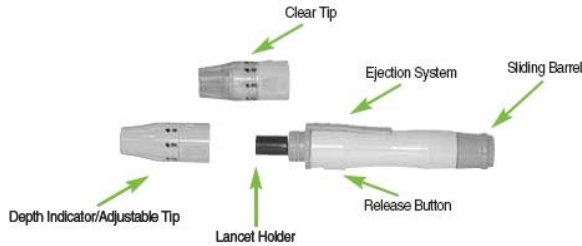
Lancing device is a convenient medical tool for collecting capillary blood samples for glucose monitoring or other tests which require one or two drops of blood.

Being a more advanced lancing device, it provides ultimate safety and comfort for obtaining blood samples. An adjustable tip offers 5 different strength levels of skin penetration for individual user's comfort, while a lancet ejector enables the safe disposal of the used lancet. As an added bonus, this also comes with a transparent tip for AST (Alternative Site Testing).

CAUTION

1. Never use a lancet that has been used by someone else. This could lead to contamination.
2. If the lancing device is to be used by another person, the unit must use a new tip or properly disinfected
3. Do not leave the lancet in the device after use.
4. A new lancet must only be placed into the lancing device directly before testing.
5. This device has many small parts and could be a choking hazard for children if swallowed.
6. In the case of hospital use, hospitals need to observe their own infection control protocols in order to avoid any contamination.
7. Always dispose of the used lancet in a biohazard garbage container.

Components



Using the Clear Tip(AST)

1. Place the lancing device and lancet on the skin in the chosen area, press and hold it continuously for a few seconds, then push the release button to take a blood sample.
2. Watch through the clear tip until a sufficient blood sample is taken. If there is not enough blood, gently massage the area until a sufficient sample is collected.

STORAGE

Products must be stored at room temperature protected from sunlight or moisture.

CLEANING AND DISINFECTION

- Clean and wipe the outer part of lancing device once a week at the minimum with a soft cloth dampened with mild soap and water. Wash the adjustable tip and clear tip, once a week with mild soap.
- DO NOT immerse the lancing device in water or liquid.

WARRANTY

Lancing device has a 2-year warranty from the date of purchase.
A malfunctioning device should be returned to the following address:

Manufacturer :

GMMC

Room No. 1112, Ace Tower 9th Bldg., 345-30, Gasandong, Geumcheon-gu, Seoul, South Korea
Tel : +82 2 2104 0470
Fax : +82 2 2104 0472

EU Authorized Representative :

GMMC, S.L.

C/Vinalopo' 4 - 1° - Pta 4 Valencia, Spain
Tel : +34 963 691 484
Fax: +34 961 125 949

Performing a blood test with your fingertip

Step 1



1. Firmly insert the test strip into the meter test port. Insert down firmly in direction of arrow on test strip (arrow up). Please do not insert the glucose test strip upside down. When you insert the glucose test strip into the glucose test meter, the power automatically turns on with the code and temperature.



2. Make sure the code number matches on the strip bottle its code (e.g. C26). The IGM-1001D automatically recognizes the test strip code number and adjusts the meter accordingly.



- A blinking test strip will appear at the top of the screen indicating the meter is ready for testing

CAUTION

1. If the code is not displayed after for a while, pull the glucose test strip out of the port, and re-start the procedure from the beginning.
2. If the code on the LCD display window as well as on the glucose test strip vial does not match, try another new glucose test strip. If the mismatch persists, please contact your local representative for assistance.
3. Avoid testing under direct sunlight, for a more accurate test result.
4. If you apply your blood sample too early, Er5 message will appear on LCD. Please refer to Page 12.

Step 2

To obtain a suitable blood samples

- Before obtains a blood sample, wash your hands with warm, clean water and soap. Dry hands completely before testing.

WARNING

1. All parts of the kit are considered bio hazardous and can potentially transmit infectious disease, even after you have conducted cleaning and disinfection measures.
2. To reduce the chances of getting infection: The test strips are for single use only. Do not reuse.
3. Avoid getting hands lotion, oil, dirt or debris in or on the lancets (single use only) and the lancing device.
4. Wash your hands thoroughly with soap and clean water after handling the meter, lancing device and/or test strip.



1. Unscrew the lancing device cap.



2. Insert a sterile lancet into the lancing device.



3. Twist the protective cover off. Do not discard.



4. Put the lancing cap back and twist it tightly.



5. To adjust the depth setting:
Use strength level 1-2 for soft skin, 3 for average skin, 4-5 for thick or calloused skin.



6. Pull the end of the lancet device back.



7. To prick your finger, push the center button.

CAUTION

1. If the blood smears or runs, do not use such blood sample. Dry the area and gently squeeze another drop or puncture a new area of the finger.
Do not share reusable lancing device with anyone

Step 3

● **Correct**



● **Applying Blood**



● **Incorrect**



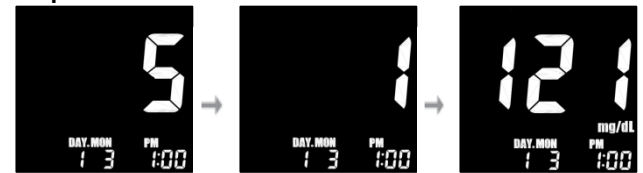
IGM-1001D test meter only requires 0.5 ul sample volume.

- Place the edge of the test strip to the drop of blood.
- The blood will automatically be 'drawn' into the test strip channel.
- When your sample blood is enough, your meter will automatically count down

CAUTION

1. If the countdown does not start, do not add more blood to the glucose test strip. Discard the glucose test strip and re-start testing.
2. If you do not conduct the test within 3 minutes, the glucose test meter will automatically power off to save battery life. In this case, test procedure should start again from the beginning.
3. You may get an inaccurate result if the blood sample is not completely filled.
4. You must inject the blood sample until beep sounds.

Step 4



- After the beeping sound, the test will begin automatically and your results will appear in 5 seconds. It should begin counting down from 5 to 1 second on the LCD display window. The LCD window will display the result of your blood glucose level. Temperature and time.
- After results displayed, you choose to use the activity/meal flags (🍏 🍷 🍷 🍷), press and release ▲ or ▼ button to select the activity, then press and release the power button ⏻



- Record the result value in your logbook. When glucose test strip is removed, the glucose test meter turns off automatically.

CAUTION

1. If the test result is out of the test range, "Hi/Lo" message will be shown on the LCD window.
2. Safely discard used glucose test strips and lancets in the proper place, according to the local regulation.

Test Strip Ejector Function

Disposing of your test strip



Once the test is complete, push the strip forward to remove the test strip from the meter



Used test strips may be considered bio hazardous waste in your area. Be sure to contact your local representative for proper disposal

Disposing of your lancet



Push the needle into the protective cover.

Pull the lancet out and discard accordingly.

CAUTION

1. If you push the ejector button forward too much, it may be part of the failure.
2. Do not give strong impact to blood glucose test meter.
3. Please follow the waste disposal regulations on the used lancets and strips imposed by your local authorities.

Reviewing Your Results

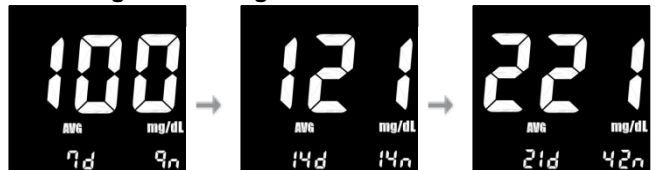
The IGM-1001D meter stores up to 365 test results in its built-in memory, along with the average sugar level for the number of days, which you had preset the glucose test meter to calculate.

Reviewing Your blood sugar

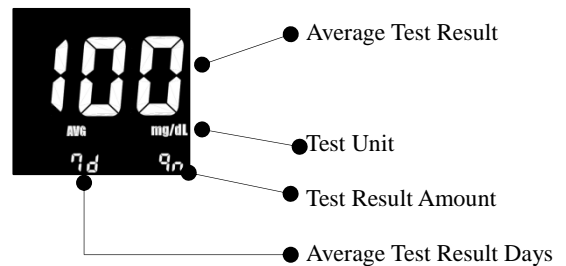


Press and release \odot button. The most recent result appears first. Note the time and day of your blood sugar result. Press and release the ∇ button and your previous result will appear on the display

Reviewing Your averages



Press and release the \blacktriangle button and your average result will appear on the display.



Deleting Test Results



Deleting individual test result

To delete any individual test result in the memory press \blacktriangle or ∇ button for 3 seconds, while the test result is to delete, displayed **DEL** blinking. After the third beep sound you may hear, the test result is deleted.



Deleting all test results
To delete all test results in the memory press ▲ and ▼ button for 3 seconds, while the test result is to delete, displayed **ALL DEL** blinking. After the third beep sound you may hear, the test results are deleted.

CAUTION

The deleted test results cannot be recovered. Please be careful in deleting the test results.

Alternate Site Test



The IGM-1001D Blood Glucose Monitoring System gives you the ability to obtain a blood sample for testing your sugar from different areas of your body. The figure shown above displays the areas where you can test using your IGM-1001D meter. You may test you blood sugar from your forearm, upper arm, palm (ventral palm or dorsal hand), fingertips, thigh, or calf.

IMPORTANT

It is recommended that alternate site testing be used when sugars are stable: before meals and before bedtime. However, when sugars are changing, blood from the fingertip may show these changes sooner than blood from other sites.

LIMITATION

1. Alternative site testing results should never be used to calibrate continuous glucose monitoring systems.
2. Alternative sampling results should never be used in insulin dosing calculations.

Lancing and sampling form an alternate site area

Sampling from your upper arm, forearm, dorsal hand, ventral palm, thigh, or calf allows you to use your fingertips less often. You may find that obtaining a blood sample from an

alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertip.

Ventral palm/Dorsal hand



Choose a fleshy area on the palm, below your thumb or pinky finger. Select a spot without any visible veins and away from any deep lines. This may cause your blood sample to smear.

Forearm



Upper arm



Calf



Thigh



Choose a fleshy area of the forearm, upper arm, thigh, or calf away from bone, visible veins and/or hair. Sometimes there is less blood flow to these areas than to the fingertip. To help you get a large enough drop of blood, you may gently massage or apply a heating pad to the site to increase blood flow.

IMPORTANT

We recommend that you test on your fingertips if you are testing for hypoglycemia (low blood glucose) or if you are suffering from hypoglycemia unawareness

To ensure accurate results when lancing your arm (forearm or upper arm), leg (calf or thigh), or palm (ventral palm or dorsal hand), clean the test site with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

WARNING

To reduce the chances of getting infection: never share a lancet or reusable lancing device with anyone.

The lancing device clear cap is used for alternate site testing

Lance the test site with the lancing device



1. Remove the lancing cap by twisting off.



2. Insert lancet and replace with the clear cap.



3. To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm. Applying heat may be helpful.



4. Adjust clear cap to the highest setting. Hold the clear cap down against a fleshy area on the alternative site. Press the release button. Do not lift up.



5. Continue to hold the lancing device and gradually increase pressure for several seconds.



6. While holding the lancing device on your test site, look through the clear cap; until a round drop of blood appears



7. Lift the lancing device straight up; be careful not to smear the blood on your testing site.

8. Place the edge of the test strip to the drop of blood. The blood will automatically be drawn up.

REMEMBER

1. Consult with your healthcare professional before using alternate site testing.
2. Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.
3. If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.
4. Do not share reusable lancing device with anyone including other family members.

CAUTION

Do not test on you forearm or palm when

1. You think you blood glucose is rapidly falling. For example within two hours of exercise, rapid-action insulin injection, or an insulin pump bolus.
2. Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.

Caring for your IGM-1001D System

Cleaning your meter and maintenance

Blood glucose test meter :

Your blood glucose test meter does not require special maintenance or cleaning. Avoid getting dirt, dust, blood, glucose control solution, or liquids on the blood glucose test meter, the test port, or data port. Your blood glucose test meter's operation temperature is 10~40°C(50~104°F). It is recommended that you store the blood glucose test meter in the portable pouch after each use.

A cloth dampened with water and mild detergent can be used to wipe down the outer part of the blood glucose test meter. Your **IGM-1001D** blood glucose test meter is a precision instrument. Please handle it with care.

Lancing device :

Clean the lancing device and caps with soap and tepid water. To disinfect the lancing device, prepare a disinfectant solution household bleach and water in 1(bleach) : 9(water) ratio. Dampen a cloth with this solution and wipe the lancing device thoroughly. Soak only the cap for at least 30 minutes in the disinfectant solution. Do not soak the lancing device in liquid. Rinse the lancing device and cap with water, and dry thoroughly.

1. For detailed instructions concerning **IGM-1001D** blood glucose test strips, refer to the blood glucose test strip package inserted and found in the blood glucose test strip box.
2. Please store the **IGM-1001D** blood glucose measuring system in a cool and dry area, out of reach of children. Do not freeze. For a more accurate test result, avoid testing under direct sunlight.
3. Do not soak the blood glucose test meter or blood glucose test strips in water or liquid.
4. Do not subject the meter or blood glucose test strips to excessive heat.
5. Use your meter according to the instructions in the manual.
6. If you need to purchase the lancing device, lancets or blood glucose test strips, contact your local representative.
7. Discard the used lancets carefully, to prevent any infection.

Storage of your IGM-1001D System

To prevent the meter and test strips from getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use

Meter Storage

- Storage condition: 10~40 °C or 50~104 °F (Temperature) / 10 ~ 90% (Humidity)
- Always store and transport the meter in its original storage case.
- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

Strip Storage

- Storage condition: 2~30 °C or 36~86 °F (Temperature) / 10 ~ 90% (Humidity)
- Store your test strips in their original vial only. Do not store the strips in other containers.
- Store test strip packages in a cool and dry place. Keep

away from direct sunlight and heat.

- Do not freeze.
- After removing a test strip from the vial, immediately close it tightly.
- Record the discarded date (date vial opened, plus 3 months) on the strip label.
- Do not use if it is expired(2 years) after manufacturing.
- Touch the test strip with clean and dry hands.
- Do not use if 3 months have been passed, since the opening of the vial cap for strips.

Control Solution Storage

- Storage condition: Store in a cool, dry place at between 8~30 °C or 46~86 °F (Temperature)
- After use, close cap tightly.
- Make sure the control solution bottle is tightly closed
- Record the discarded date (date vial opened, plus 3 months) on the control solution on the bottle.
- Do not use if expiry date has passed.
- It expires 24 months after manufacturing date.
- It expires 3 months after opening the vial cap.

CAUTION

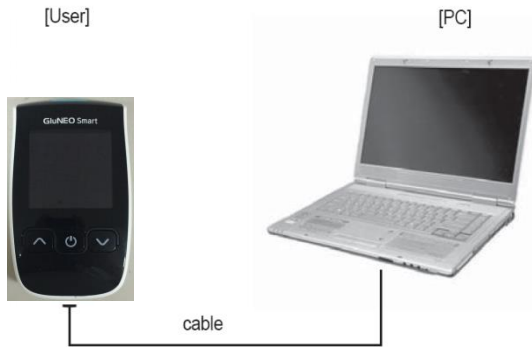
1. Store the IGM-1001D test strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
2. Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
3. Immediately replace the vial cap and close tightly after removing any test strips from the vial.
4. Make a note of the discard date, which is three months from the date you first open a new vial of strips. Throw IGM-1001D test strips and vial away after the discard date.
5. Do not use the test strips after the expiration date printed on the package or vial, since it may cause inaccurate results.
6. Do not test at temperatures below 10°C(50°F) or above 40°C(104°F).
7. Do not test with humidity below 10% or above 90%.
8. Do not bend, cut, or alter the test strip.
9. Avoid getting dirt, food, and water on the test strip with wet hands.
10. Avoid getting dirt, food, and water on the color-coding label (backside of test strip)

Transferring your results

USE to Data Transfer CABLE(Optional)

You can transfer test results from the IGM-1001D meter to a computer.

You will need to download to software from the following web site (<http://www.infopia21.com>) and purchase the computer cable from your local representative. This is sold separately.




USE to Bluetooth Unit

1. Press the 'Up' button of the IGM-1001 meter, running pairing mode. LCD Screen displayed 'P' and start count from 0.
2. run to application on mobile phone.
3. Operating search mode on mobile phone.
4. select the operating meter in search list.
5. if pairing is succeeded, meter LCD screen displayed 'P' -> 'C' and re-start count from 0.
6. 'Data Update' command from the mobile phone to meter.
7. Glucose data sent from meter to mobile phone. LCD screen displayed re-start count to 0.
8. connection termination : Press 'Power' button or application exit on mobile phone.
8. if connection is fail, LCD screen displayed 'C' -> 'P'. After some seconds meter is power off automatically.
9. if pairing is incomplected, re-start to list 1.

Download application

Use apple app store or google play.

Battery Installation

The low battery icon.  will appear in the upper left corner of the LCD display to alert you when the battery power is running low, indication a new battery are needed.



Your IGM-1001D blood glucose test meter uses only two 3V

lithium batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent lithium battery should be used.

Follow-up Action

1. Check your meter with the glucose control solution
2. Perform your test again.
3. If you are experiencing symptoms that are not consistent with your blood glucose test results, call you healthcare professional.

NOTE:

1. Make sure your date and time are correct after changing your battery.
2. Remove both batteries from the battery compartment and dispose of them, according to your institution's guidelines..

CAUTION

1. Risk of explosion if battery is replaced by an incorrect type.
2. Dispose of used batteries according to the instructions.

Dispose of meter :

The meter must be disposed of according to the local regulations concerning the disposal of electrical and electronic equipment. The Waste Electrical and Electronic Equipment(WEEE) regulation implement provisions of the European Parliament and Council Directive 2012/19/EU aimed to reducing the amount of EEE waste going for final disposal.

The manufacturer,has specific instructions for the recovery of the meter.






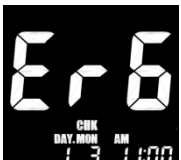


Please contact your distributor.


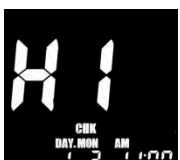
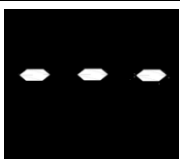
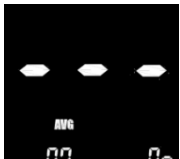
Dispose of batteries :

Please recycle or dispose of used batteries using your local battery collection systems and in compliance with your local environmental laws and regulations. Batteries contain chemicals that, if released, may affect the environment and human health. The crossed-out wheeled-bin symbol indicates the need for the separate collection for batteries.

Troubleshooting

The following chart may help you identify certain problems, but may not solve all problems that can occur. Contact your authorized representative or Infopia Co.,Ltd. customer support if the problem persists.

Message	What it means	Action required
	Problem with the blood glucose test meter	Place the battery again, and set the blood glucose test meter. If the problem persists, Please contact your authorized representative or customer support.
	Caused by either used or wet blood glucose test strip	Please, insert a new glucose test strip and perform your test again
	Problem with the test strip	Please insert a new glucose test strip and apply the blood sample until confirming the window is completely filled.
	Blood glucose test strip is damaged	Please insert a new glucose test strip and perform your test again
	User applied the blood sample before the LCD display was blinking	Wait for the meter to display the blinking icon before applying your blood sample.
	Color bar of the strip is dirty or not good or there is too much light. Action required.	Please insert a new glucose test strip and perform your test again. If blink with "Sun", avoid to the direct sunlight and retest. Contact your local representative or customer support if the problem persists.
	The ambient temperature is less than 10°C (50°F)	Place the meter at a temperature between 10 ~ 40°C (50 ~ 104 °F) for more than 10 minutes or more and test again.
	The ambient temperature is over 40°C (104°F)	Place the meter at a temperature between 10 ~ 40°C (50 ~ 104 °F) for more than 10 minutes or more and test again.
	The test result is lower than 10mg/dl	Check the accuracy of your blood glucose test strip by

Message	What it means	Action required
		performing a glucose control solution test. If the test results in a normal reading, re-test your blood sample two or three times. If "Lo" persists, consult your doctor immediately.
	The test result is higher than 700mg/dl	Check the accuracy of your blood glucose test strip by performing a glucose control solution test. If the test results in a normal reading, re-test your blood sample two or three times. If "Hi" persists, consult your doctor immediately.
	There are no reading stored in the meter	-
	Not enough reading in the memory to display designated average	-
The glucose test meter does not power its ON	Battery is dead or there is a problem with the meter	Change the battery and if the problem persists, contact your local representative.
The glucose test meter does not start after applied blood sample.	Insufficient amount of blood.	Please insert a new test strip and perform your test again.
The results are inconsistent	There may be a problem with the glucose test strip	Please insert a new test strip and perform your test again.

Inconsistent or Unexpected Test Results

If you continue to get unexpected results, check your system with control solution. If you experience symptoms that are not consistent with your glucose results, review and follow all instruction in this manual. Never ignore symptoms or make significant changes to you diabetes control program. Inform health care professional of symptoms and/or concerns.

CAUTION

1. Low Glucose Results: if your result is lower than 70mg/dL, it may mean hypoglycemia (low blood sugar). This may require immediate treatment according to your healthcare profession's recommendations. Although this result could be due to a test error, it is safer to treat first and you may test another.
2. High Glucose Results: if your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood sugar). If you are uncertain about your test results, consider with re-test. Your health care profession will help you to decide how it action. If the meter displays HI all the time, please re-check your blood sugar but still it's higher, please find your healthcare profession immediately.

Warranty

Manufacturer's Warranty

Infopia Co.,Ltd. warrants to the original purchaser that this instrument will be free from defects in workmanship for 3 years from the date of original purchase.

Limitations of Warranty

This warranty is subject to the following exceptions and limitations.

1. Infopia Co.,Ltd. shall not be required to replace any units which are damaged or malfunction due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than Infopia Co.,Ltd. or failure to operate in accordance with the instructions.
2. Infopia Co.,Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
3. Infopia Co.,Ltd. has no knowledge of the performance of the instrument when the test strip is altered or modified in any manner.

For Warranty Service

Purchaser must contact the customer service department of Infopia Co.,Ltd. by calling toll 82-31-460-0300, for assistance and/or instructions for obtaining service of this instrument.

Service Information

Infopia Co.,Ltd. has trained specialists to help you 24 hours a day, 7 days a week, and 365 days a year.

IMPORTANT

Confirming to Infopia Co.,Ltd. representative before returning your meter for any reason. You will be given the information needed to get your problem handled correctly and efficiently. Remaining your meter, test strip and control solution nearby when you call.

Declaration of Conformity

FCC

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES.

Operation is subject to the following two conditions; (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE:


















This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:


- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Specifications

Sample Type	Capillary, venous, arterial whole blood
Sample Volume	0.5 μ l
Test Range	10 ~ 600 mg/dL
Reading Time	5 seconds
Hematocrit	20 ~ 60%
Altitude	3048 meter Up to (10,000 feet)
Operating Temperature	10 ~ 40 °C (50 ~ 104 °F)
Operating Humidity	10 ~ 90%
Strip Storage Temperature	Store 2~30 °C or 36~86 °F and no direct sunlight. Do not Freeze
Display Type	LCD (Including backlight model)
Dimension(HxDxT)	96 X 56 X 23.5 (mm)
Weight	66±1g (Including batteries)
Power Source	3V (Coin Battery, CR2032 X 2EA)
Batter Life	IGM-1001D: Running 1,000 Tests

Symbol Reference

Symbol	Description
	Consult Instructions for use
	Use By date
	This product fulfills the requirements of Directive 98/79/EC on in-vitro diagnostic medical devices
	Attention, See Instructions for use
	For in-vitro diagnostic use
	Batch code
	Do not reuse
	Serial number
	Date of Manufacture
	Manufacturer
	Keep away from sunlight
	Waste electrical and electronic equipment symbol
	Temperature limitation
	Catalogue number
	Self-testing used
	Authorized representative in the European Community
	Biohazard

	Separate collection of batteries
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