

OSANG Healthcare

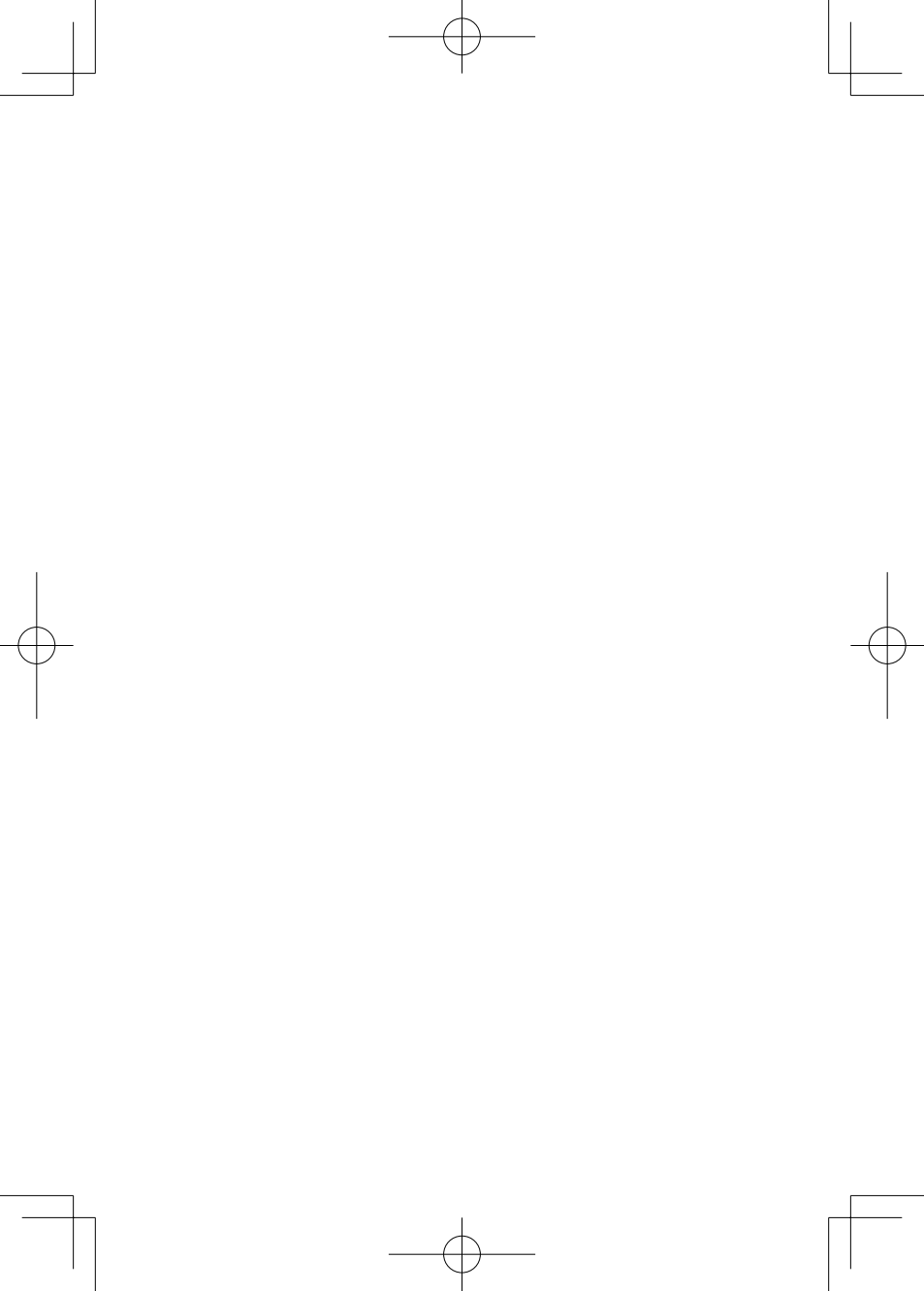
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GluNEO[®] Smart

Blood Glucose Monitoring System for self-testing

Instructions for Use





Test Principle

GluNEO® Smart 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. Glucose in the whole blood sample reacts with the reagent of the test strip and generates an electrical. The amount of current, which is related with glucose concentration, is measured by the meter, for which the method is called amperometry. The measured current exists in proportion to the glucose concentration in the whole blood.

WARNING :

- All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have taken cleaning and disinfection measures.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hands lotions, oil, dirt or debris in and/or on the lancets and reusable lancing device.
- Please refer to page 27 for cleaning and disinfecting GluNEO® Smart Blood Glucose Monitoring System.
- Do not change your medication based on the GluNEO® Smart meter test results without contacting your physician or healthcare professional first.
- Do not assemble or disassemble the blood glucose test meter
- Keep out of direct sunlight.

CAUTION :

- Please keep your monitoring system out of reach of children.
- Make sure it does not come in contact with water and moisture.
- Avoid getting dirt and moisture.

NOTE :

- Blood Glucose Monitoring System may also be called as Blood Glucose Test Meter, the Meter, Test Meter in this manual, for which they have equal meaning to each other.
- Blood Glucose Test Strip may also be called as the Test Strip, Strip, for which they have equal meaning to each other.

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Learning the System

Intended use of Blood Glucose test meter

The GluNEO® SmartTest meter is used with GluNEO® SmartTest Strip for the measurement of glucose in fresh whole blood sample (Capillary and/or venous). It should not be used for the diagnosis or screening of diabetes or for the testing of new born babies.

GluNEO® Smart Blood Glucose Monitoring System is intended for use outside the body only (in-vitro diagnostic use).

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.

CAUTION :

- Do not use system for any other purpose than blood glucose test.
- Cholesterol concentrations > 510 mg/dL or triglyceride concentrations > 3,400 mg/Dl may produce elevated reading.
- Icodextrin does not interfere with this version of GluNEO® Smart 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 GluNEO® Smart product, please contact your local representative.

WARNING :

- Before using GluNEO® Smart 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.

GluNEO® Smart Kit contents



The sterile lancet may vary from the image above.

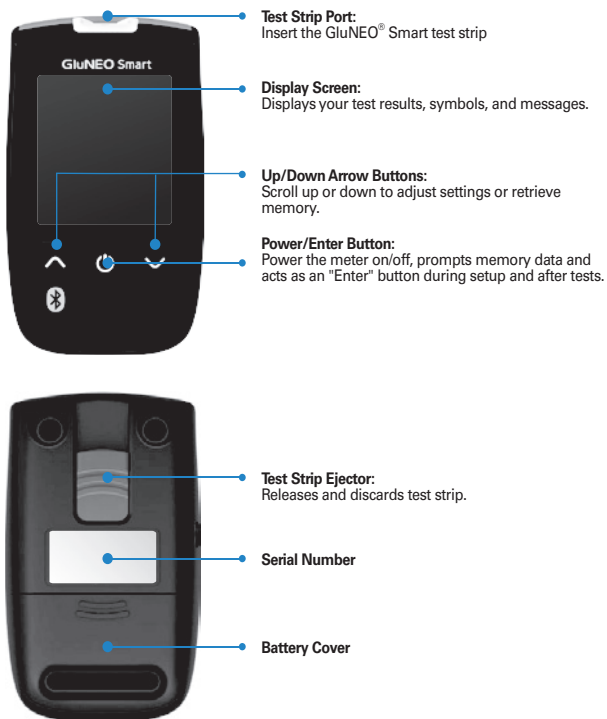
The following items are included:

- GluNEO® Smart Meter
- Reusable Lancing Device
- Carrying Case
- 2EA 3V Coin Battery (CR2032)-2
- User's Manual
- Quick Start Guide

Your GluNEO® Smart 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.

*GluNEO® SmartTest Strips, GluNEO® Smart Control Solution and Lancets are required but not included and must be purchased separately.

GluNEO[®] Smart meter



CAUTION :

- Do not use the GluNEO[®] Smart 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 the GluNEO[®] Smart 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.

GluNEO® Smart Meter display



Low battery warning symbol



Alarm symbol

CHK

Troubleshooting symbol

**ALL
DEL**

Delete results

AVR

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

ID

User ID Symbol

CODE

Test strip code symbol

mmol/L

Test result unit symbol

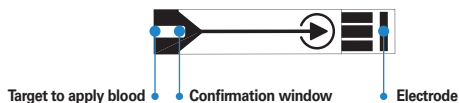
YR DATE
88.88

Temperature / Date

88.88

Time / Test Result Amount

GluNEO[®] Smart blood glucose test strip



1. Store the GluNEO[®] Smart 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 six months from the date you first open a new vial of test strips. Throw all GluNEO[®] Smart 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. GluNEO[®] Smart test strips are for single use only. DO NOT RE-USE.
7. Do not test at temperatures below 10°C(50°F) or above 40°C(104°F).
8. Do not test with humidity 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. Do not handle test strips with wet hands.
11. Avoid getting dirt, food, and water on the color-coding label (backside of the test strip).
12. Refer to additional information in the GluNEO[®] Smart test strip package.
13. The GluNEO[®] Smart meter should be used with GluNEO[®] Smart test strips.

Before your testing

WARNING :

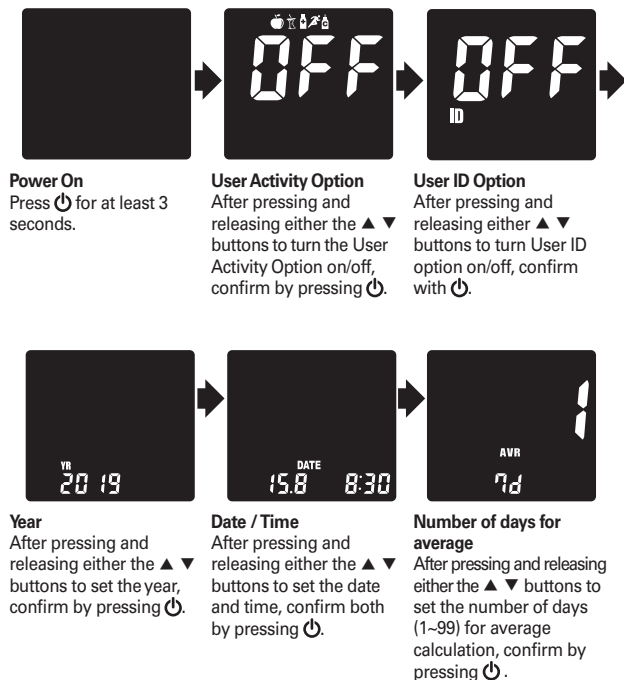
To reduce the chance of infection:

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

Setting your meter

The GluNEO® Smart meter has a wide variety of functions.

The setup mode you can turn activity/meal flags, set the date/time, designate three unique average, and set up to five daily alarms.





Alarm on/off

After pressing and releasing either the ▲ ▼ buttons to turn the alarm on/off, confirm by pressing

Alarm time

After pressing and releasing either the ▲ ▼ buttons to set the alarm hour and minute, confirm by pressing

Alarm

After programming the number of desired alarms (5 alarms are available), confirm by pressing

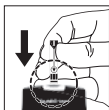
Auto Send

After pressing and releasing either ▲ or ▼ buttons to turn the "Auto Send" function on/off for bluetooth data transfer which before meter turn off, push button.

CAUTION :

- VERY IMPORTANT: Set the date rightly
- Without setting the date properly, the average glucose level and the test results in the memory will not show the proper values. It is recommended to set the glucose test meter before you use it and when new batteries are installed.
- You cannot test your blood glucose while it is in the setting mode.
- To turn the meter off during the setup, press for at least 3 seconds.

Auto-coding Function



1. GluNEO® Smart Meter has automatic code recognition function.



2. The GluNEO® Smart Meter 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 :

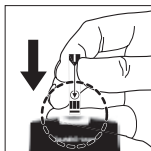
- Do not bend the glucose test strip. Bending the test strip will cause automatic code recognition failure.
- If the code recognition label is damaged, the code recognition may fail. Verify that the code number on the LCD window matches the code number on your glucose test strip vial.

Performing a glucose control solution test

The GluNEO® Smart Blood Glucose Control Solutions contain a known amount of glucose that reacts with the GluNEO® Smart Blood Glucose Test Strip. By comparing your control solution test results with the expected range printed on the test strip vial, you can verify that the meter and test strips are working properly, and you are performing the test correctly. It is very important that you perform the control solution test routinely to make sure you receive accurate results.

The Glucose control solution should be used

- Before using a new box of test strips
- Whenever you suspect the blood glucose test meter or blood glucose test strip are 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 deeply in direction of arrow on test strip (arrow up). Please do not insert the glucose test strip upside down.



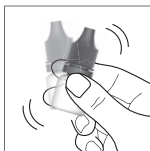
When you insert the glucose test strip into the glucose test meter, the power automatically adjusts the meter accordingly.



Press and release either the ▲ or ▼ button, then control solution bottle icon will appear, then Press ⏻.



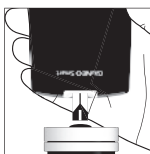
Check the expiration date before performing a control solution test. Do not use if expired. Please note the expiration date marked on the control solution bottle.



Gently shake the control solution before use.



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)



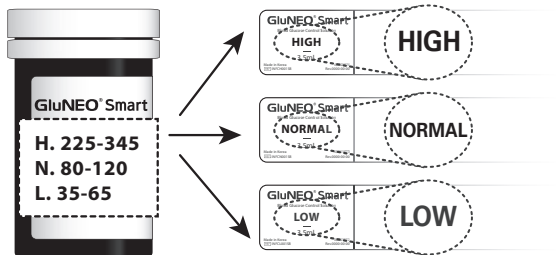
Dip the test strip into the control solution liquid. Results will appear in 5 seconds. Compare the result to the range printed on the test strip vial. Result should fall within that range.

CAUTION :

- Control solutions is for in-vitro diagnostic use only. This means that it is only used for testing outside the body.
- Control solution is exclusively made for the GluNEO Smart® Blood Glucose Monitoring System. Do not use other brand control solutions made by other manufacturers.
- Check the expiration date on the vial. Do not use, if expired.
- Once opened, use it for the next three months only. Record the discard date on the control solution bottle. Discard after three months.
- Do not swallow. This is NOT for human or animal consumption.
- 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 test 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 20–25°C (68–77°F) before testing.
- Check the expiration date before performing a glucose control solution test.
- Do not use if expired. Once opened, the control solution expires after 3 months.
- In order to perform the more accurate glucose control solution test, you can use the control solution 3 different levels – low, normal and high. You can buy each GluNEO® Smart control solutions (low, normal and high levels) separately, please consult your local distributor about control solutions.

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 GluNEO® Smart 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 test strips.

After following the appropriate steps and the control solution test still falls out of range, do not perform a glucose test. Please call customer support toll free: +82-31-460-0300. OSANG Healthcare Co.,Ltd. has trained specialists to help you 24 hours a day, 7 days a week, and 365 days a year.

Follow-up Action

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

CAUTION :

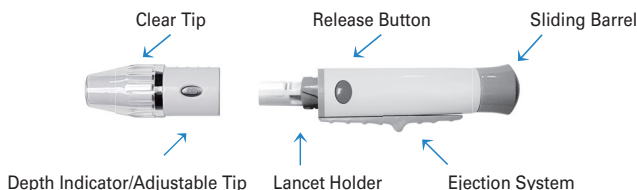
- If your glucose control solution falls out of range, do not perform a glucose test and please contact : +82-31-460-0300
- OSANG Healthcare Co.,Ltd. has trained specialists to help you 24 hours a day, 7 days a week, and 365 days a year. .
- 1. The glucose control solution measurement range has nothing to do with individual's blood glucose level, as its own purpose is to check the status of test strip and meter.
- 2. 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 6 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).

COMPONENTS



RECOMMENDED AVAILABLE LANCETS

It is recommended that the lancing device is used with sterile lancet provided by OSANG Healthcare Co.,Ltd.

NOTE :

- Some less known lancets may not work properly with the due to their dimensions.
- Please, contact your supplier to make sure you are using proper lancets

USING THE CLEAR TIP (AST)

- 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.
- 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.

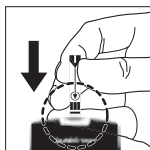
WARRANTY

Lancing device has a 2-year warranty from the date of purchase.

A malfunctioning device should be returned to the following address

Performing a blood test with your fingertip

Step 1



Firmly insert the test strip into the meter test port in the 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 displaying the code and temperature. Make sure the code number matches the one on your strip bottle. The GluNEO® Smart meter automatically recognizes the test strip code number and adjusts the meter accordingly.



A blinking test strip will appear in the top right corner indicating that the meter is ready for testing.

CAUTION :

- If the code is not displayed within a short amount of time, pull the glucose test strip out of the port and re-start the procedure from the beginning.
- If the code on the LCD display window and the one on the glucose test strip vial do not match, try another new glucose test strip. If the mismatch persists, please contact our customer support.
- If you apply your blood sample before the blood symbol blinks, an Er5 message will appear on the LCD.

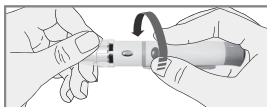
Step 2

To obtain suitable blood samples

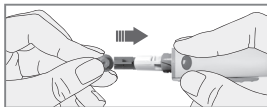
- Before obtaining a blood sample, wash your hands with warm, clean water and soap. Dry hands completely before testing.

WARNING :

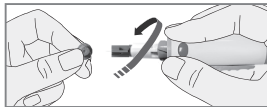
- All parts of the kit are considered to be bio-hazardous and can potentially transmit infectious disease, even after you have performed cleaning and disinfection measures.
- Avoid getting hands lotion, oil, dirt or debris in or on the lancets (single use only) and the lancet device.
- Wash your hands thoroughly with soap and clean water after handling the meter, reusable lancet device and/or test strip.



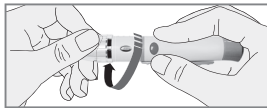
Unscrew the reusable lancet device cap.



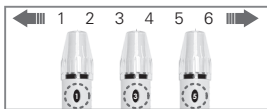
Insert a new sterile lancet into the reusable lancet device.



Twist the protective cover off. Do not discard.



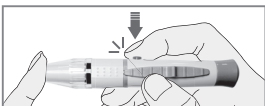
Replace the lancet cap by twisting it back on tightly.



Adjust the lancet depth by turning adjustable tip. The higher the number visible in the depth indicator, the greater the depth setting. If your skin is calloused or thick, you may need to try a higher setting.



Pull the end of the lancet device back.

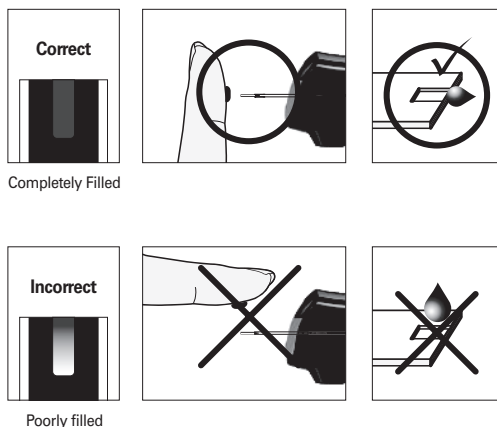


To prick your finger, push the center button.

CAUTION :

- If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop or puncture a new area of the finger.
- Do not share reusable lancet device with anyone including other family members.

Step 3

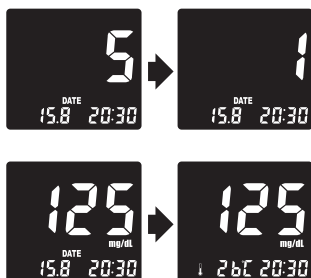


- GluNEO® Smart Meter only requires 0.5 ul sample volume.
- Stick the edge of the test strip to the drop of blood.
- The blood will be automatically 'drawn' into the test strip channel.
- When your blood sample size is enough, your meter will automatically count down.
- Apply the blood to the glucose test strip and do not take off your finger until you get the completion sound. The test will automatically start.
- Please respect recommended quantity of blood sample. Too much blood may cause malfunction of your meter by contaminating it.

CAUTION:

- 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.
- 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 the test procedure should start again from the beginning.
- You may get an inaccurate result if the blood sample is not completely filled.

Step 4



After the beeping sound, the test will start automatically and your test result will appear in 5 seconds. It will begin counting down from 5 to 1 second on the LCD display window. When finished the LCD window will display the result of your blood glucose level, temperature and time.



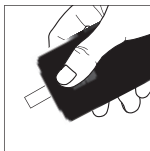
If you chose to use the activity/meal flags (  ) during the setup process, press and release ▲ and ▼ button to select the activity that will correlate with your result, then press and release the power button.

CAUTION :

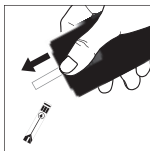
- If the test result is out of the test range, the Hi/Lo message will be shown on the LCD.
- Safety discard used glucose test strips and lancets in the proper place, according to the local regulation.

Test Strip Ejector Function

Disposing of your test strip

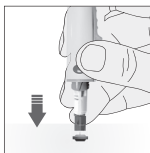


1. Once the test is complete, push the ejector button forward to remove the test strip from the meter.

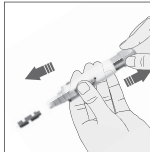


2. Used test strips may be considered bio-hazardous waste in your area. Be sure to contact your local representative for proper disposal.

Disposing of your lancet



1. Push the needle into the protective cover.



2. Pull the lancet out and discard accordingly.

CAUTION :

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

Reviewing your results

The GluNEO® Smart meter stores up to 365 test results in its built-in memory, along with the average glucose level for the number of days, which you have preset the glucose test meter to calculate.

Reviewing your blood glucose



The latest

The Second latest

The Third latest

Press and release the 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

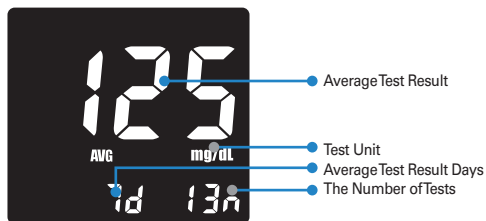


The average from 7 days worth of data from your recent test date.

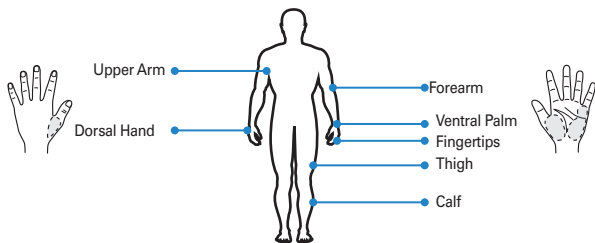
The average from 14 days worth of data from your recent test date.

The average from 21 days worth of data from your recent test date.

Press and release the ▲ button and the average test result will appear on the display.



Alternative site test



The GluNEO® Smart 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 GluNEO® Smart meter.

You may test your blood sugar from your forearm, upper arm, palm (ventral palm or dorsal hand), or fingertips.

IMPORTANT

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

LIMITATION

Alternative site testing results should never be used to calibrate continuous glucose monitoring systems.

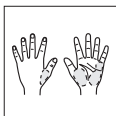
Alternative sampling results should never be used in insulin dosing calculations.

Lancing and sampling from an alternative site area

Sampling from your upper arm, forearm, dorsal hand, ventral palm, thigh, or calf allows you to use your fingertips less often.

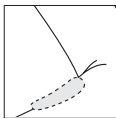
You may find that obtaining a blood sample from an alternative site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertip.

Ventral palm/Dorsal hand

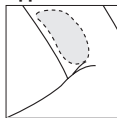


Choose a fleshy area on the palm, below your thumb or pinky finger. Select a spot without any visible veins and away from any deep lines. This may cause your blood sample to smear.

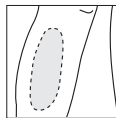
Forearm



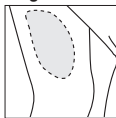
Upper arm



Calf



Thigh



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



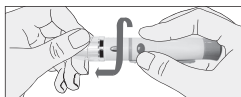
To ensure accurate results when Page 10 / 18 lancing your arm (forearm or upper arm), leg (calf or thigh), or palm (ventral palm or dorsal hand), clean the test site with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry the patient's hands and test site.

WARNING :

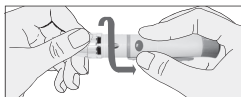
To reduce the chances of getting infection: never share a lancet or a reusable lancing device with anyone.

The reusable lancing device clear cap is used for alternative site testing

Lance the test site with the lancing device



1. Pull the adjustable Tip.



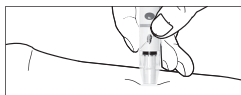
2. Insert a lancet and replace with the white cap.



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 a heating pad may be helpful.



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



8. Stick the edge of the test strip to the drop of blood. Blood will be automatically drawn up.

REMEMBER :

- Consult with your Healthcare Professional before using alternative site testing.
- Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- If bruising occurs at an alternative 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.
- Do not share your reusable lancing device with anyone including other family members.

CAUTION :

Do not use an Alternative Test Site when:

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

Caring for your GluNEO® Smart 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 GluNEO® Smart blood glucose test meter is a precision instrument. Please handle it with care.

Lancing device :

Clean the lancing device and tips 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 tip for at least 30 minutes in the disinfectant solution. Do not soak the lancing device in liquid. Rinse the lancing device and tip with water, and dry thoroughly.

- For detailed instructions concerning GluNEO® Smart blood glucose test strips, refer to the blood glucose test strip package inserted and found in the blood glucose test strip box.
- Please store the GluNEO Smart® blood glucose monitoring 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.
- Do not soak the blood glucose test meter or blood glucose test strips in water or liquid.
- Do not subject the meter or blood glucose test strips to excessive heat.
- Use your meter according to the instructions in the manual.
- If you need to purchase the lancing device, lancets or blood glucose test strips, contact your local representative.
- Discard the used lancets carefully, to prevent any infection.

Storage of your GluNEO® Smart system

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

Meter Storage

- Storage condition: 2~30°C or 36~86°F (Temperature)
- Always store or transport the meter in its original storage case.
- Avoid dropping the meter.
- Avoid direct sunlight and humidity.

Test Strip Storage

- Storage condition: 2~30°C or 36~86°F (Temperature)
- Store your test strips in their original vial only. Do not store in other types of containers.
- Store test strip package 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 replace the vial cap and close it tightly.
- Record the discard date (It expires 6 months after first opening) on the strip label.
- Do not use if expiry (2 years) after manufacturing.
- Touch the test strip with clean and dry hands.
- Do not use if 6 months have been passed, since the opening of the vial cap for test strips.

Control solution Storage

- Storage condition: Store in a cool dry place 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 discard date (It expires 3 months after first opening) on the control solution 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 :

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

Bluetooth function



GluNEO® Smart meter stores glucose test result data and can transmit it to wireless device such as a Smart Phone (android or ios) and Tablet PC via Bluetooth wireless technology.

STEP 1

Ensure you have completed one or more tests on your GluNEO® Smart Meter and your Bluetooth is switched 'ON' on your mobile device.

STEP 2

Go to your app store on your mobile device (you can find your app store at google play or the apple app store), and search for the 'mHealthgate App'. Download and launch the mHealthgate app and fill in all details required.

STEP 3

Once your mHealthgate app is ready to use, select 'Connect Device' on the mHealthgate app on your mobile device. From the drop down list shown on your mobile device, select the meter that you are using.

STEP 4

Ensure your meter is switched off, then press the left arrow button pointing upwards above the Bluetooth symbol on your meter for 3 seconds until you hear the sound of a beep. A 'bt' for Bluetooth and a flashing 'p' for pairing will appear on your screen. This indicates your meter is transferring Bluetooth signals to your mobile device. When reconnecting to a mobile device that has already been paired, simply press the left arrow button to enter data transfer mode.

STEP 5

Press 'OK' to the alert appearing on the mHealthgate app on your mobile device. A flashing 'c' for confirmed will now appear on you meter to show that the pairing between your meter and your mobile device has been successful.

STEP 6

Your meter will now transfer all glucose test result data to your mHealthgate app. When this has been completed, your meter will automatically switch to sleep mode.

NOTE

- When ejecting the test strip, this will automatically activate the Bluetooth on your meter. If you wish to transmit your results to your mHealthgate app on your mobile device, open your mHealthgate app and follow the instructions above. If you do not wish to transmit your result to your mHealthgate app at this time, simply press the middle 'OFF' button – your meter will enter sleep mode and your results can be transmitted to your mHealthgate app another time.
- Activate at the Bluetooth function at a close distance.
- Do not turn off the app whilst transmitting data via Bluetooth from your meter

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, indicating new batteries are needed.



Your GluNEO® Smart Meter uses only two 3V coin batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent coin batteries 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 your healthcare professional.

NOTE

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

Dispose of meter and batteries

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 implements provisions of the European Parliament and Council Directive 2012/19/EU aimed at 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.

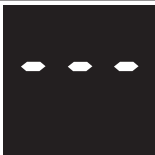
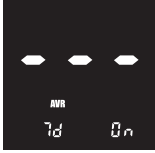
The crossed-out wheeled-bin symbol indicates the need for the separate collection for batteries.

Trouble-shooting

Do not make treatment decision based on an error message. If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact your authorized representative or customer support. Do not attempt to repair yourself and never try to disassemble the meter.

Message	What it means	Action required
	Hardware is defective.	Reboot the meter by removing and replacing the meter with new batteries. Make sure that the test strip is not inserted into the meter. If the problem persists, please contact customer support.
	Test strip may be contaminated or reused.	Please, insert a new glucose test strip and perform your test again.
	Insufficient amount of blood samples placed on the test strip.	Please insert a new glucose test strip and apply the blood sample and confirm the window is completely filled.
	Blood glucose test strip is damaged.	Please insert a new glucose test strip and perform your test again.

Message	What it means	Action required
 CHK DATE 17.7 1:30	Blood sample is placed on the test strip before the symbol for test () blinks.	Wait for the meter to display the blinking apply blood icon before applying your blood sample.
 CHK DATE 17.7 1:30	Color area of the tests trip is dirty, defective or there is too much sunlight.	Please insert a new glucose test strip and perform your test again, or if it blinks with "sun", avoid direct sunlight and retest. Contact your local representative or customer support if the problem persists
	Inserting another brand of test strip in the meter.	Please insert the correct glucose test strip.
 CHK 9°C	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 and test again.
 CHK 42°C	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 and test again.
 DATE 17.7 1:30	The test result is less than 10mg/dL (0.6mmol/L)	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 "Lo" persists, consult with your doctor immediately.

Message	What it means	Action required
	The test result is over 600mg/DL (33.3mmol/L)	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 with your doctor immediately.
	There are no readings stored in the meter.	
	Not enough readings in the memory to display designated averages.	
The glucose test meter does not turn-on.	The batteries are dead or there is a problem with the meter.	Change the batteries and if the problem persists, contact our customer support.
The glucose test meter does not start after applying the 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 strips.	Please insert a new test strip and perform your test again.

Inconsistent or Unexpected Test Results

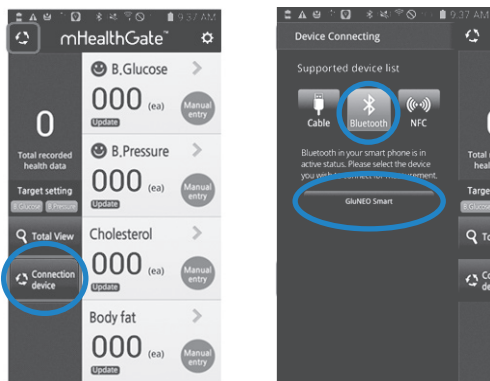
- If you continue to get unexpected test results, check your system with control solution. If you experience symptoms that are not consistent with your glucose results, review and follow all instructions in this manual. Do not ignore symptoms or make significant changes to your diabetes control program by informing healthcare professional of your symptoms and/or concerns.

CAUTION

- 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 Professional's recommendations. Although this result could be due to a test error, it is safer to treat first and you may test another.
- 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 re-testing. Your Healthcare Professional will help you decide how to take action. If the meter displays "Hi" all the time, please re-check your blood sugar, however if your test result is still high, please contact your Healthcare Professional immediately.

Connection between mHealthGate and GluNEO Smart

1. Measure your blood glucose level by using GluNEO Smart.
2. Click mHealthGate app on your smartphone
3. Click "Connection device" button as below, and then select your connecting device.



4. Once the app is ready to receive your measuring value, following message is appeared.

Turn off the power of the device, and push Bluetooth button located on the front of the device to change the mode to Bluetooth data transfer(* Refer to the user's manual).

Once it is ready, click <OK> button to start data sending.

Cancel

OK

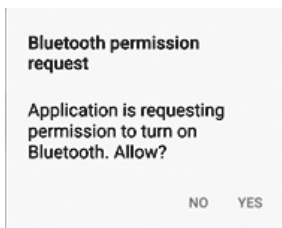
Turn off the power of the device by clicking power button, push Bluetooth button according to the message.

When Bluetooth mode is enabled, it starts counting numbers with beep sound.

※ Refer to below image to find out the location of Bluetooth mode activation button.



When mode transfer is completed, touch <OK> button to start sending data.

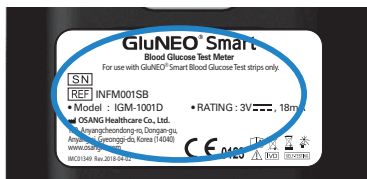


5. If Bluetooth function is off status, 'Bluetooth permission request' is appeared as below.

Push the <YES> to turn on Bluetooth to be connected with GluNEO Smart device.

6. If the connection status between app and GluNEO Smart is not set, the display of product number registration will be appeared. Register product serial number into your App.

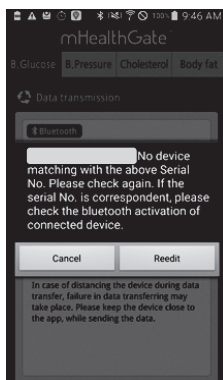
※ You can check the location of product serial number at the backside of meter as below.



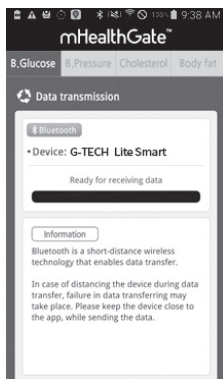
※ If product number is already registered, mHealthGate App starts connecting device without requesting the product number.



[Display of product number registration]



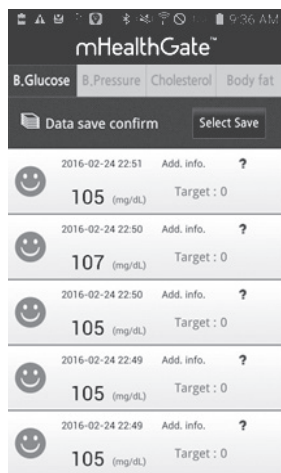
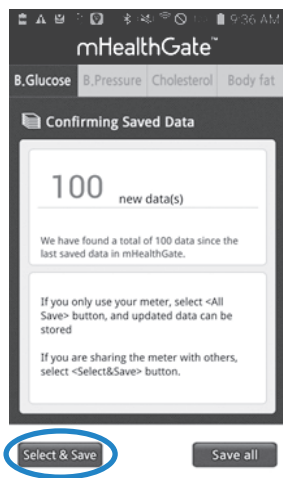
[In case that registered product number is different from the device product number]



[Display of Data transmission]

7. Once the data is completely transferred, below display will be appeared.
Select <Select & Save> button or <Save all> button, and store measuring value into your App.

※ If several people use one GluNEO Smart device together, select <Select & Save> button to select and store your measurement.



Warranty

Manufacturer's Warranty

OSANG Healthcare 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. OSANG Healthcare Co.,Ltd. shall not be required to replace any units which are damaged or malfunctioning due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than OSANG Healthcare Co.,Ltd. or failure to operate, in accordance with the instructions.
2. OSANG Healthcare Co.,Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
3. OSANG Healthcare 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 OSANG Healthcare Co.,Ltd. by calling +82-31-460-0300, for assistance and/or instructions for obtaining service of this instrument.

Alternatively, you are requested to contact your place of purchase in your country for initial warranty request.

Service Information

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

IMPORTANT NOTICE

Please confirm with the OSANG Healthcare 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. Keep your meter, test strip and control solution with you, when you call.

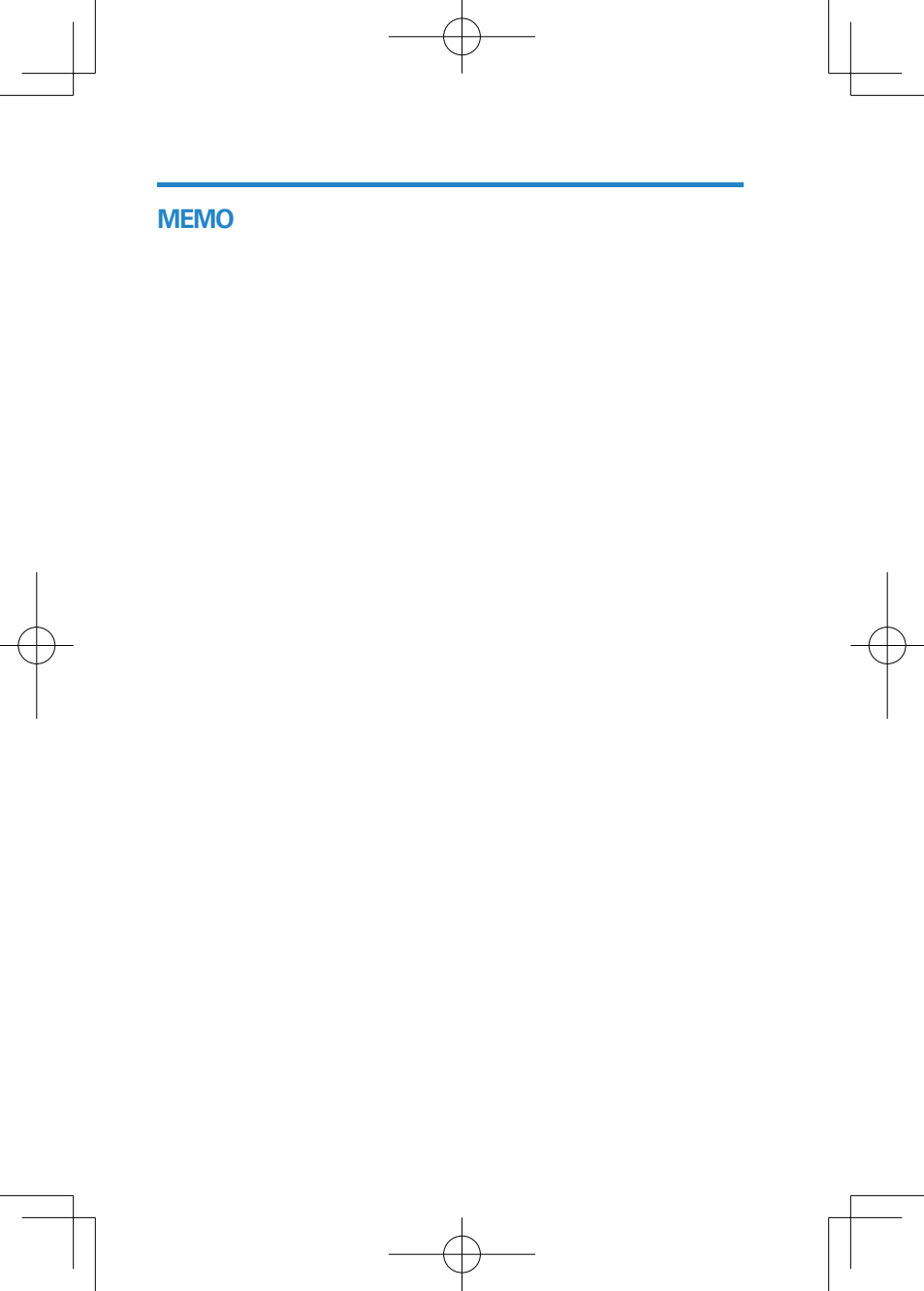
Specifications

Sample Type	Fresh Capillary Whole Blood
Sample Volume	0.5ul
Test Range	10 ~ 600 mg/dL(0.6~33.3mmol/L)
Reading Time	5 seconds
Calibration	Plasma – equivalent
Hematocrit	20 ~ 60%
Altitude	≤ 3048m(10,000 feet)
Operating Temperature	10 ~ 40°C(50 ~ 104°F)
Operating Humidity	10 ~ 90%
Strip Storage Temperature	Store 2-30°C (36 - 86 °F) and no direct sunlight. Do not Freeze.
Display Type	LCD
Dimension (H x D x T)	96 X 56 X 24 (mm)
Weight (Including Battery)	65±1g (including batteries)
Power Source	3V Li Battery (CR2032) x 2EA
Battery life	Running 1,000 times
Bluetooth	Bluetooth Smart (Bluetooth Low Energy)

Symbol reference

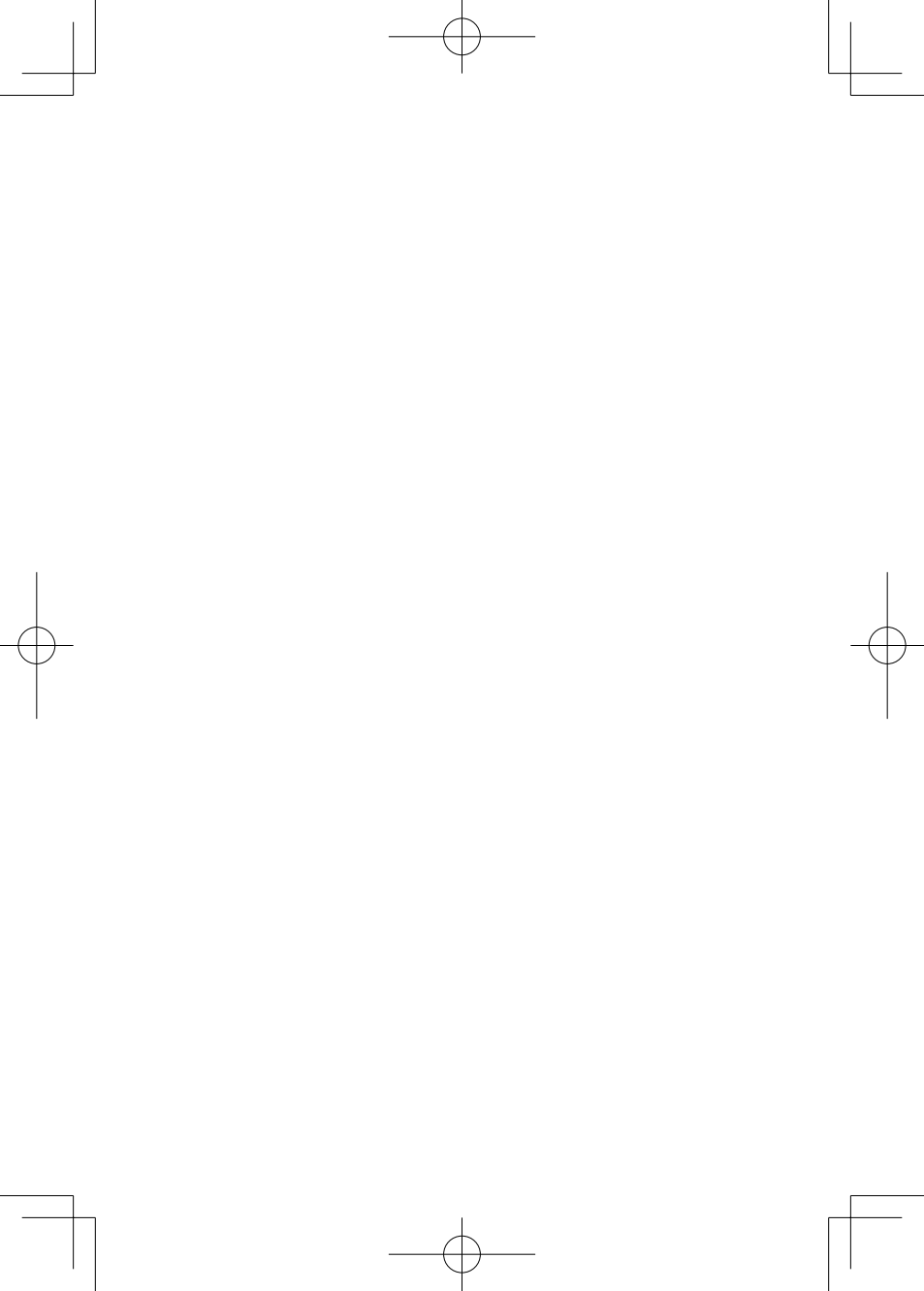
Symbol	Description
	Consult Instructions for use
	Use By date
CE 0123	This product fulfills the requirements of Directive 98/79/EC on In-Vitro Diagnostic medical devices.
	Attention, see instructions for use
IVD	For In-Vitro Diagnostic Use
LOT	Batch Code
SN	Serial number
	Date of manufacture
	Manufacturer
	Keep away from sunlight
	Waste electrical and electronic equipment symbol
	Temperature limitation
REF	Catalogue number
SELF-TESTING	Self-testing Used
EC REP	Authorized representative in the European community
	Waste batteries and accumulators
STERILE	Indicates a medical device that has been sterilized using irradiation

MEMO



MEMO

MEMO





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CE 0123

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CE 0123
STERILE

[REF] INF0015B
IMC01346 Rev.2023-02-07