

GluNEO *Lite Smart*

Blood Glucose Monitoring System for self-testing

Instructions for Use



Dear GluNEO Lite Smart Blood Glucose Monitoring System Owner,

Thank you for choosing the GluNEO Lite Smart 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. GluNEO Lite Smart has been developed to provide you with a fast and accurate reading in a convenient and simple process. Our goal for the GluNEO Lite Smart 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 GluNEO Lite Smart 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 GluNEO Lite Smart 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 with fresh whole blood samples (Capillary and/or venous). 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 GluNEO Lite Smart Blood Glucose Monitoring System contains small parts, which could be a choking hazard for children if swallowed.



Test Principle

GluNEO Lite Smart blood glucose test strip is the bio-sensor which is composed of 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 current, for which the method is called amperometry.

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 hand lotions, oil, dirt or debris in and/or on the lancets and reusable lancing device.
4. Please refer to page 33 for cleaning and disinfecting GluNEO Lite Smart Blood Glucose Monitoring System.
5. Do not change your medication based on the GluNEO Lite Smart 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

1. Please keep your monitoring system out of reach of children.
2. Make sure it does not come in contact with water and moisture.
3. Avoid getting dirt and moisture.
4. Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.
5. Do not place the equipment in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, unplug it before touching it.
6. Do not use accessories which are not supplied or recommended by the manufacturer.
7. Do not place anything on top of the equipment.

NOTE:

1. 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.
2. Blood Glucose Test Strip may also be called as the Test Strip, Strip, for which they equal meaning to each other.

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Learning the System

Intended use

The GluNEO Lite Smart test meter is used with GluNEO Lite Smart test strip for the measurement of glucose in fresh whole blood samples (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 Lite Smart Blood Glucose Monitoring System is intended for use outside the body only (in-vitro diagnostic use).

GluNEO Lite Smart Blood Glucose Monitoring System is for self-testing by people with diabetes and by healthcare professionals.

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.

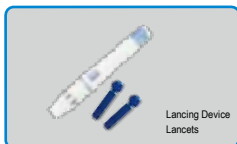
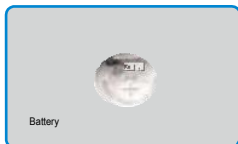
CAUTION

- 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 GluNEO Lite 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 Lite Smart product, please contact your local representative.

WARNING

- Before using GluNEO Lite 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 Lite Smart Kit Contents

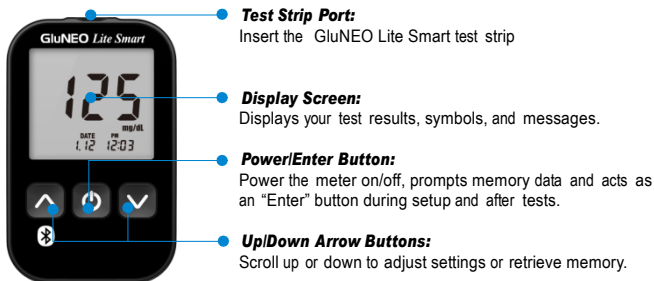


1. GluNEO Lite Smart Meter
2. GluNEO Lite Smart Test strip
3. Reusable Lancing Device
4. Lancets
5. Instructions for use
6. Warranty Registration Card
7. Carrying Case
8. Patient Logbook
9. 3V Coin (1EA) Battery (CR2032)

Your GluNEO Lite 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.



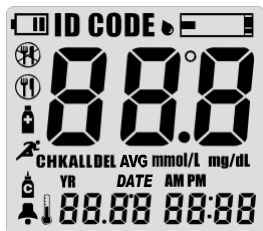
GluNEO Lite Smart Meter



CAUTION

1. Do not use GluNEO Lite 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.
2. Do not use GluNEO Lite 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 Lite Smart 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

ID User ID Symbol

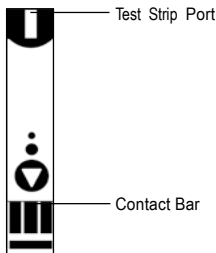
CODE Test Strip Code Symbol

mmol/L mg/dL Test Result Unit Symbol

YR DATE
 **88.88** Temperature / Date

AM PM
88:88 Time

GluNEO Lite Smart Test Strip



Caution

1. Store the GluNEO Lite 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 expiry date, which is six months from the date you first open a new vial of test strips. Throw GluNEO Lite Smart 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. GluNEO Lite Smart test strips should be 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 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 GluNEO Lite Smart 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 GluNEO Lite Smart Meter has a wide variety of functions to choose. From the setup mode you can turn activity/meal flags, set the date/time, designate three unique averages, and set up to five daily alarms.



Power On

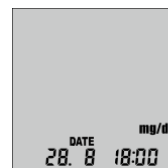
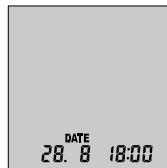
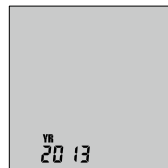
Press  for 3 seconds at least.

User Activity Option

After pressing and releasing either  or  buttons to turn the User Activity Option on/off, push  button.

User ID Option

After pressing and releasing either  or  buttons to turn the User ID option on/off, push  button.



Year

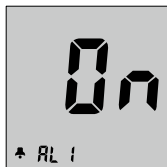
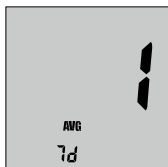
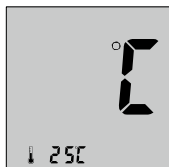
After pressing and releasing either  or  buttons to set the year, push  button.

Date / Time

After pressing and releasing either  or  buttons to set the date and time, respectively push  button.

Test Unit

After pressing and releasing either  or  buttons to set the test unit(mg/dL or mmol/L), push  button.



Temperature Unit

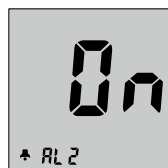
After pressing and releasing either ▲ or ▼ buttons to set °C or °F and push button.

Number of days for average

After pressing and releasing either ▲ or ▼ buttons to set the number of days for average calculation (3 different settings possible), push button.

Alarm on/off

After pressing and releasing either ▲ or ▼ buttons to turn the alarm on/off, push button.



Alarm time

After pressing and releasing either ▲ or ▼ buttons to set the alarm hour and minute, push button.

Alarm

After programming the number of desired alarms (5 alarms possible), push button.

CAUTION

1. VERY IMPORTANT: Set the right test unit.

Your GluNEO Lite Smart Meter is pre-set to mg/dL as test unit. A wrong test unit will lead 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 for at least 3 seconds.



Auto-coding Function



1. GluNEO Lite Smart has automatic code recognition function
(e.g. CODE 125)



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.

Performing a Glucose Control Solution Test

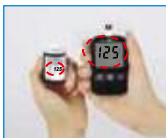
GluNEO Lite Smart control solution contains a known amount of glucose that reacts with GluNEO Lite Smart test strip. By comparing your control solution test results with the expected range printed on the test strip vial, you are able to check that the meter and test strips are working properly, and that you are performing the test correctly. It is very important that you perform routine checking to ensure accurate results.

The Glucose control solution should be used

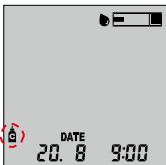
- Before using a new box of test strips.
- Whenever you suspect the blood glucose test meter or blood glucose test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms, or if you think results are not accurate.
- If you have dropped the blood glucose 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 (⏻).



1. 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.



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 liquid on a clean, dry surface (e.g. the lid of the test strip vial)



4. Dip the test strip into the control solution liquid.

Results will appear in 5 seconds.

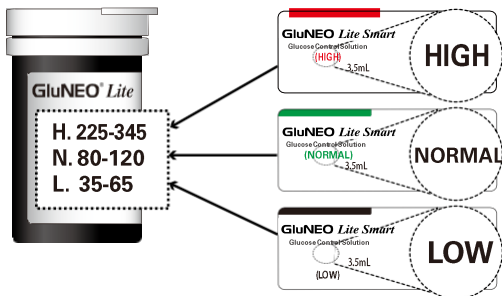
Compare the result to the range printed on the test strip vial. Result should fall within that range.

CAUTION

1. Control solution 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 GluNEO Lite Smart 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 beyond expiration date. 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 GluNEO Lite 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.

If you continue to get control solution test results that fall outside the range, do not perform a glucose test. Please call customer support in your local area.

Follow-up Action

1. Check your meter and test strips 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 representative.
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 test 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.

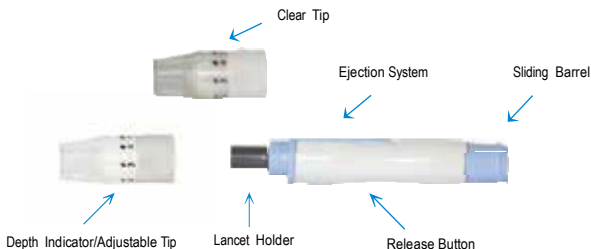
Being a more advanced lancing device, it provides ultimate safety and comfort for obtaining blood samples. An adjustable tip offers 5 different strength levels of skin penetration for individual user's comfort, while a lancet ejector enables the safe disposal of the used lancet. As an added bonus, this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

CAUTION

1. Never use a lancet that has been used by someone else. Sharing lancet could lead to contamination.
2. If the lancing device is to be used by another person, the unit must be 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.

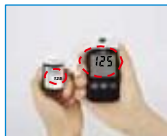
A malfunctioning device should be returned to the following address:
put address:

Performing a blood test with your fingertip

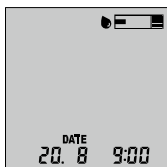
Step 1



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 with the code and temperature. Make sure the code number matches on the test strip bottle (e.g. CODE 125). GluNEO Lite Smart automatically recognizes the test strip code number and adjusts the meter accordingly.



A blinking test strip will appear at the top of the screen, which indicates that the meter is ready for testing.

CAUTION

1. If you do not see the code displayed, pull the glucose test strip out of the port, and re-start the procedure from the beginning.
2. If you do not see the code displayed match the code printed in the vial, 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 before a blinking test strip on the screen, Er5 message will appear on LCD. Please refer to Page 40.



Step 2

To obtain a suitable blood sample

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

WARNING

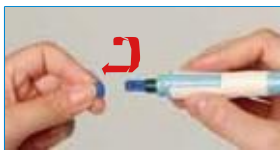
1. All parts of the kit are considered bio hazardous and can potentially transmit infectious disease, even after you have conducted cleaning and disinfection measures.
2. Avoid getting hand lotion, oil, dirt or debris in or on the lancets (single use only) and the lancing device.
3. Wash your hands thoroughly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



1. Unscrew the lancet device tip.



2. Insert a sterile lancet into the lancet device.



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



4. Put the lancing tip 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.
2. Do not share reusable lancing device with anyone including other family members.



Step 3

- Correct



Completely Filled

- Applying Blood



- Incorrect



Poorly filled



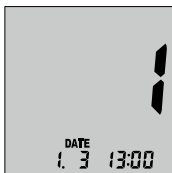
GluNEO Lite Smart Test Meter only requires 0.5 ul sample volume.

- Stick 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.
- Apply your blood to the glucose test strip and do not take off your finger until you get the beep 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.

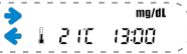
CAUTION

1. If the countdown does not start, do not add more blood to the glucose test strip. Discard the glucose test strip and restart 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.

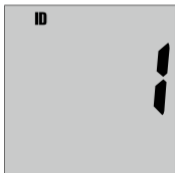
Step 4



- After the beeping sound, 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. LCD window will display the result of your blood glucose level, temperature and time.



- If you selected to use the User Activity option during set up, press and release ▲ or ▼ button to select the activity (Ⓟ, Ⓢ, Ⓣ) that correlates with your result, then press and release the power button ⏻.
- If you do not select to use User Activity option during set up, press the power button ⏻.



- If you selected to use the User ID option during set up, press ▲ and ▼ button to select the correct User ID, then press the power button ⏻.
- Record the result value in your logbook.
When glucose test strip is removed, 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



1. Once the test is complete, push the test strip 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

1. Pushing the ejector button too hard could cause a damage to the meter.
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 GluNEO Lite Smart 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

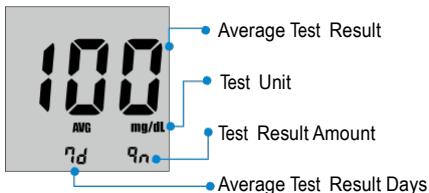


Press and release  button. The most recent result appears first. Note the time and day of your blood sugar result. Press and release the  button and your previous result will appear on the display

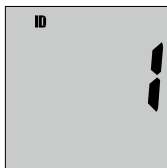
Reviewing Your averages



Press and release the  button, and your average result will be displayed.



Reviewing your results with activated user ID



Press the  button once and the User ID option will appear the LCD screen.

Use  or  buttons to scroll and choose the correct user ID, then press the .



If you choose the User ID to check the stored results, only the results of the selected user ID are displayed.

Deleting Test Results



Deleting individual test result

To delete any individual test result in the memory, press  or  button for 3 seconds. Then displayed **DEL** icon will start blinking.



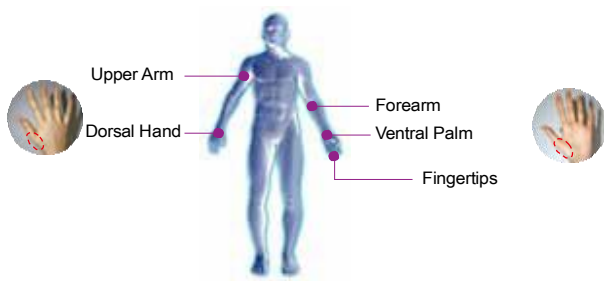
Deleting all the test results

To delete all test results in the memory press  and  button for 3 seconds. Then displayed **ALL , DEL** will start blinking.

CAUTION

Deleted test results cannot be recovered. Please be careful in deleting the test results.

Alternative Site Test



GluNEO Lite Smart blood glucose monitoring system gives you the ability to your sugar from different areas of your body.

The figure shown above displays the areas where you can test using your GluNEO® Lite 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 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 body areas.

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 from an alternative site area

Sampling from your upper arm, forearm, ventral palm, or dorsal hand 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.



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, which may cause your blood sample to smear.

Forearm



Upper arm



Choose a fleshy area of the forearm or upper arm away from bone, visible veins and thick hairs of the arm. Sometimes there is less blood flow to these areas than to the fingertip. To help you get enough drops 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), 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 lancing device with anyone.

The lancing device clear tip is used for alternate site testing

Lance the test site with the lancing device



1. Remove the lancing tip by twisting off.



2. Insert lancet and replace with the clear tip.



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 tip to the highest setting. Hold the clear tip 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 tip 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. Stick the edge of the test strip to the drop of blood. 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 your forearm or palm when

1. You think your 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 GluNEO Lite 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 Lite 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.

1. For detailed instructions concerning GluNEO Lite Smart 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 GluNEO Lite 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.

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 GluNEO Lite Smart 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: 2~30℃ or 36~86°F (Temperature)
- Always store and transport the meter in its original storage case.
- Avoid dropping and strong impact.
- 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 the test 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 discard date (date vial opened, plus 6 months) on the test 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 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 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 discard date (date vial opened, plus 3 months) on the control solution on the bottle.
- Do not use if expiry date has passed.
- It expires in 24 months after manufacturing date.
- It expires in 3 months after opening the vial cap.

CAUTION

1. Store the GluNEO Lite 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 GluNEO Lite 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, Testing with expired strips 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)



Bluetooth Function

GluNEO Lite Smart Meter stores glucose test result data and can transmit it to wireless device such as a Smart phone and Tablet PC via Bluetooth wireless technology.



STEP 1

Launch the application on your mobile phone.

If Bluetooth function or Bluetooth icon is already activated on the LCD's first screen of your mobile phone, please move on to the next step.

STEP 2

When you press UP button (Pair) at the same time as buzzer sound, the LCD window will display the "P" and the operating time count by one second units. The meter will begin to transfer Bluetooth signal to your mobile phone and to count up to 300.

STEP 3

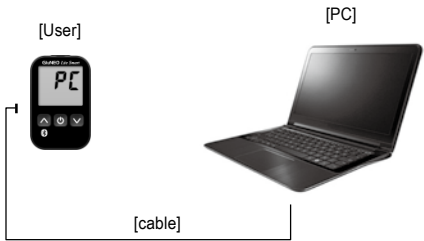
When the meter is paired with your mobile phone, the LCD window will display "C" which confirms the paired status. The meter can transfer the glucose test result data to external mobile device via Bluetooth wireless technology.

STEP 4

Pressing the center/power button, the meter enters sleep mode and LCD display will then turn off. You can then navigate to the applications to view the other features.

Transferring Your Result Data

You can transfer test results from the GluNEO Lite Smart meter to a computer. You will need to download the software from the following web site (<http://www.osanghc.com>) and purchase the computer cable from your local representative. This is sold separately.



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, which is an indication that a new battery is needed.



Your GluNEO Lite Smart blood glucose test meter uses only one 3V lithium battery (CR2032), which is included. When replacing battery, 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 your healthcare professional.

NOTE

1. Make sure your date and time are correct after changing your battery.
2. Please recycle or dispose of used batteries using your local battery collection systems and in compliance with your local environmental laws and regulations.
3. Caution risk of explosion if battery is replaced by an incorrect type.



Disposal of meter and batteries

Disposal 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.

Disposal 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.

Disposing of your Blood glucose test strips and lancets

Discard your Blood glucose test strip



Once the test is complete, push forward the discard knob to remove the Blood glucose test strip from the GluNEO® Lite Blood glucose test meter.



Dispose of used Blood glucose test strip in a sealed container with your household waste in accordance with local regulations

Discard your Blood glucose test Lancet



Push the needle into its protective cover.



Pull the lancet out and discard appropriately.

Trouble-shooting

The following chart may help you identify certain problems, but may not solve all the problems that could occur. Contact your authorized representative or customer support center of OSANG Healthcare Co., Ltd., if the problem continues.

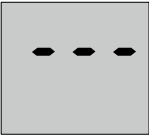
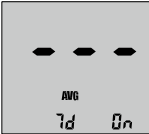
Message	What it means	Action required
	Problem with the blood glucose test meter	Place the battery again, and set the blood glucose test meter. If the problem persists, please contact your authorized representative or customer support at OSANG Healthcare Co.,Ltd.
	Caused by either used or wet blood glucose test strip	Please insert a new glucose test strip and perform your test again.
	Caused by less blood or irregular blood fill	Please insert a new glucose test strip and apply the blood sample.
	Caused by reagent damage in the test strip	Please insert a new glucose test strip and perform your test again.



Trouble-shooting

Message	What it means	Action required
	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.
	Caused by color bar contamination or foreign test strip	Please insert a new glucose test strip and perform your test again. If "Sun" is blinking, avoid direct sunlight and re-test. Contact your local representative or customer support at OSANG Healthcare Co., Ltd., 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 30 minutes 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 30 minutes or longer, and then test again.
	Test result is lower than 20 mg/dL (1.1 mmol/L)	You may have a very low blood glucose level. Treat this condition immediately according to your doctor's recommendations. Perform a control solution test to check the accuracy of your test strip.

Trouble-shooting

Message	What it means	Action required
	Test result is higher than 600 mg/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 reading stored in the meter	
	Not enough reading in the memory to display designated average	
The glucose test meter is not powered ON	Battery is dead, or there is a problem with the meter	Change the battery and if the problem persists, contact your local representative or customer support at OSANG Healthcare Co., Ltd.
Glucose test meter does not start after being applied blood sample.	Insufficient amount of blood.	Please insert a new test strip and perform your test again.
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

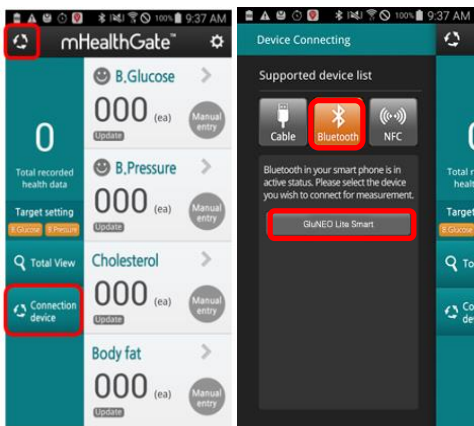
If you continue to get unexpected results, check your system with control solution. If you experience symptoms that are not consistent with your glucose results, review and follow all the instructions in this manual. Do not ignore symptoms or make significant changes to your diabetes control program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

CAUTION

1. Low Glucose Results: If your result is lower than 70mg/dL, you may have episodes of 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.
2. High Glucose Results: if your test result is higher than 180 mg/dL, you may have episodes of hyperglycemia (high blood sugar). If you are uncertain about your test results, consider re-testing. Your health care professional will help you to decide how you need to act. If the meter displays "HI" all the time, please re-check your blood sugar. If the "HI" continues, please consult with your healthcare professional immediately.

Connection between mHealthGate and GluNEO Lite Smart

- ① Measure your blood glucose level by using GluNEO Lite 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

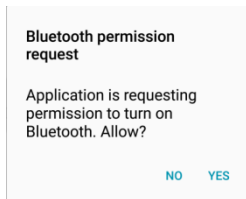
When Bluetooth mode is enabled, it starts counting numbers with beep sound

※ 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.



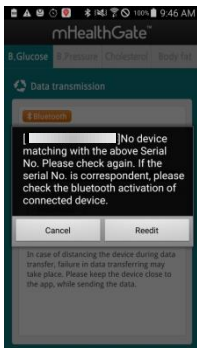
Push the <YES> to turn on Bluetooth to be connected with GluNEO Lite Smart device.



- ⑥ If the connection status between app and GluNEO Lite 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]

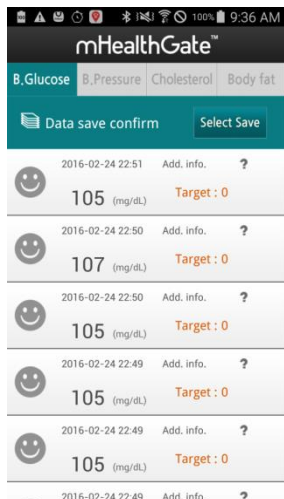
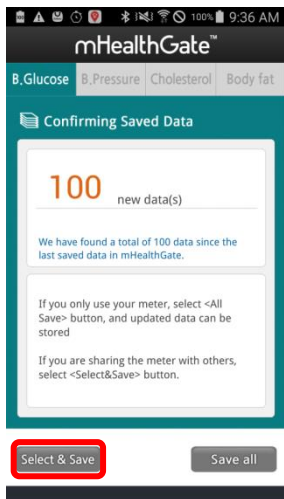


[Display of Data transmission]

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 Lite 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.

Declaration of Conformity

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.

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.

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

To comply with RF exposure compliance requirements, the antenna used for this transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.

Specifications

Sample Type	Capillary and/or venous whole blood
Sample Volume	0.5ul
Test Range	20~600mg/dL (1.1 ~ 33.3 mmol/L)
Reading Time	5 seconds
Calibration	Plasma – equivalent
Hematocrit	20~60%
Altitude	3048 meter Up to (10,000 feet)
Operating Temperature	10 ~ 40 °C (50 ~ 104 °F)
Operating Humidity	10 ~ 90%
Test Strip Storage Temperature	Store 2~30 °C (36~86 °F) and no direct sunlight. Do not Freeze
Display Type	LCD
Dimension(HxDxT)	81 X 52 X 16 ±1 (mm)
Weight	43±1g (Including Battery)
Power Source	3V Li Battery (CR2032) X 1
Battery life	One year after purchasing
Bluetooth	Bluetooth Smart (Bluetooth Low Energy)

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
	Waste batteries and accumulators



MEMO





🏢 OSANG Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu,
Anyang-si, Gyeonggi-do, Korea (14040)
www.osanghc.com

CE 0123

EC REP Obelis S.A

Bd. General Wahis 53, 1030 Brussels, Belgium
Tel : +(32) 2.732.59.54 / Fax : +(32) 2.732.60.03
E-mail : mail@obelis.net