

## GluNEOM3

## Blood Glucose Monitoring System



## Dear GluNEO<sup>®</sup> M3 blood glucose monitoring system Owner,

Thank you for choosing the GluNEO<sup>®</sup> M3 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<sup>®</sup> M3 has been developed to provide you with a fast and accurate reading in a convenient and simple process. Our goal for the GluNEO<sup>®</sup> M3 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<sup>®</sup> M3 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<sup>®</sup> M3 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<sup>®</sup> M3 Blood Glucose Monitoring System contains small parts, which could be a choking hazard for children if swallowed.

## **Test principle**

GluNEO<sup>®</sup> M3 blood glucose test strip is the bio-sensor which is composed of the FAD-dependent Glucose Dehydrogenase(enzyme). FAD-GDH(enzyme) quanitatively 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

- 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 hand lotions, oil, dirt or debris in and/or on the lancets and reusable lancing device.
- Please refer to page 29 for cleaning and disinfecting GluNEO<sup>®</sup> M3 Blood Glucose Monitoring System.
- Do not change your medication based on the GluNEO<sup>®</sup> M3 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.
- Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.
- 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.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- · Do not place anything on top of the equipment.

#### 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 equal meaning to each other.

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## Learning the system

## Intended use

The GluNEO<sup>®</sup> M3 test meter is used with GluNEO<sup>®</sup> M3 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.

GluNE0<sup>®</sup> M3 Blood Glucose Monitoring System is intended for use outside the body only (in-vitro diagnostic use).

GluNE0<sup>®</sup> M3 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 > 500 mg/dL or triglyceride concentrations > 3,000 mg/dL may produce elevated reading.
- Icodextrin does not interfere with GluNEO<sup>®</sup> M3 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® M3 product, please contact your local
  representative.

#### NOTE:

- Before using GluNE0<sup>®</sup> M3 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<sup>®</sup> M3 kit contents



- 1. GluNEO<sup>®</sup> M3 Meter
- 2. GluNEO<sup>®</sup> M3 Test strip(optional)
- 3. Reusable Lancing Device(optional)
- 4. Lancets(optional)
- 5. Instructions for use
- 6. Warranty Registration Card
- 7. Carrying Case
- 8. Patient Logbook
- 9. 2EA 3V Coin Battery (CR2032)

Your GluNEO<sup>®</sup> M3 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<sup>®</sup> M3 meter



- Do not use GluNEO<sup>®</sup> M3 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 GluNEO<sup>®</sup> M3 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<sup>®</sup> M3 meter display



$\swarrow$	Low Battery Warning
Ó	Before Having a Meal
Í	After Having a Meal
Ý)	Pasting
٥	Blood Drop Symbol for Test
MEMORY	Memory Mode
SET	Setting Mode
<b>*</b> •)	Bluetooth Function
AVG	Average Test Result
	Warning
mmol/Lmg/dL	Measurement Unit
BATE 8888	Date
8888	Time
SodE	Test Strip Code
$\heartsuit$	Alarm
Ĉ	Control Solution

## GluNEO<sup>®</sup> M3 test strip



#### CAUTION

- Store the GluNEO<sup>®</sup> M3 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 expiry date, which is six month from the date you first open a new vial of test strips. Throw
  GluNEO<sup>®</sup> M3 test strips and vial away after the expiry date.
- Do not use the test strips after the expiration date printed on the package or vial, since it may cause inaccurate
  results.
- GluNEO<sup>®</sup> M3 test strips should be single use only. DO NOT RE-USE.
- Do not test at temperatures below 10°C(50°F) or above 40°C(104°F).
- Do not test in the condition that humidity is 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)
- Refer to additional information in the GluNEO<sup>®</sup> M3 test strip package.
- Use only GluNEO<sup>®</sup> M3 test strip with your GluNEO<sup>®</sup> M3 meter.

## **Before testing**

#### WARNING

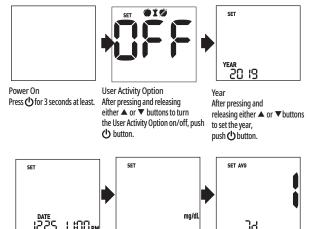
To reduce the chance of infection:

- 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 and 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<sup>®</sup> M3 Meter has a wide variety of functions to choose.

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



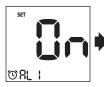
Date / Time After pressing and releasing either **A** or **V** buttons to set the date and time, respectively push 🖰 button.

1 100 ps

Test Unit After pressing and releasing either  $\blacktriangle$  or  $\blacktriangledown$ buttons to set the test unit(mg/dL or mmol/L), 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.

ЪС



Alarm on/off After pressing and releasing either  $\blacktriangle$  or  $\checkmark$  buttons to turn the alarm on/off, push button.



After pressing and releasing either

▲ or ▼ buttons to set the alarm

hour and minute, push Obutton.

Alarm time

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

- VERY IMPORTANT: Set the right test unit. Your GluNEO<sup>®</sup> M3 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.
- You cannot test your blood glucose in the setting mode.
- To turn the meter off during the setup, press I for at least 3 seconds.

## **Auto-coding function**



1. GluNEO<sup>®</sup> M3 has automatic code recognition function (e.g.125)



 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

- Do not bend the glucose test strip to prevent the automatic code recognition failure.
- 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<sup>®</sup> M3 control solution contains a known amount of glucose that reacts with GluNEO<sup>®</sup> M3 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.



1. Firmly insert the test strip into the meter test port. Insert deeply in direction of arrow on test strip.

Please do not insert the glucose test strip upside down.



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



3. Press and release either the ▲ or ▼ button, then, Control Solution bottle icon will appear. Then, press ( 小).



 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.



5. Gently shake the control solution before use.



6. 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)



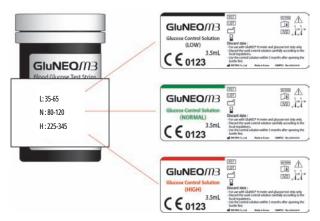
7. Dip the test strip into the control solution liquid. Results will appear in 5 seconds.

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

- 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 GluNÉO<sup>®</sup> M3 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 strips, your meter should show a number between 80 and 120.



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

#### NOTE

- It is recommended that glucose control solution is stored at room temperature 20~25°C (68~77°F) before testing.
- · Check the expiration date before performing a glucose control solution test.
- · Do not use if it expired. Once opened, the control solution expires after 6 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 GluNE0<sup>®</sup> M3 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 soulution 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

- If your glucose control solution falls out of range, do not perform a glucose test and please contact your local representative.
- 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.

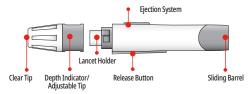
## Performing your test

#### 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).

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

## Components



## 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



1. Firmly insert the test strip into the meter test port in the direction of arrow on test strip. Please do not insert the glucose test strip upside down.



2. When you insert the glucose test strip into the glucose test meter, the power automatically turns on with the code. Make sure the code number matches on the test strip bottle (e.g. 125). GluNEO<sup>®</sup> M3 automatically recognizes the test strip code number and adjusts the meter accordingly.



3. A blinking blood drop symbol will appear at the top of the screen, which indicates that the meter is ready for testing.

- If the code is not displayed after for a while, pull the glucose test strip out of the port, and re-start the procedure from the beginning.
- If the code on the LCD display window as well as on the glucose test strip vial does not match, try another new
  glucose test strip. If the mismatch persists, please contact your local representative for assistance.
- Avoid testing under direct sunlight, for a more accurate test result.
- If you apply your blood sample too early, Er5 message will appear on LCD. Please refer to Page 35.

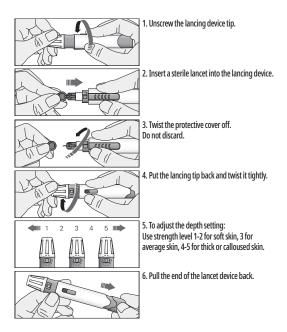
## Step 2

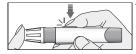
To obtain a suitable blood samples

 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 biohazardous and can potentially transmit infectious disease, even after you have conducted cleaning and disinfection measures.
- Avoid getting hands lotion, oil, dirt or debris in or on the lancets (single use only) and the lancing device.
- Wash your hands thoroughly with soap and clean water after handling the meter, lancing device and/or test strip.

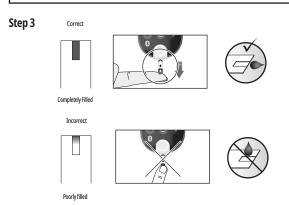




7. To prick your finger, push the center button.

#### CAUTION

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



GluNEO® M3 Test Meter only requires 0.9 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.

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

## 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 (● 1 参) 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 心.

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

- If the test result is out of the test range, "HI/Lo" message will be shown on the LCD window.
- 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 biohazardous 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.

- 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<sup>®</sup> M3 meter stores up to 1,000 test results in its built-in memory, along with the average glucose level for the number of days, which you had preset the glucose test meter to calculate.

Reviewing your blood glucose

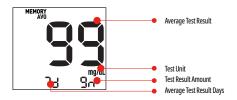


Press and release ⓓ button. The most recent result appears first. Note the time and day of your blood glucose result. Press and release the ▼ button and your previous result will appear on the display

**Reviewing your averages** 



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



## **Deleting test results**



Deleting individual test result

To delete any individual test result in the memory, press  $\blacktriangle$  or  $\checkmark$  button for 3 seconds. Then displayed dEL will start blinking. After the third beep sound, you may hear that the test result has been deleted.



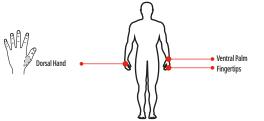
Deleting all the test results

To delete all test results in the memory press  $\blacktriangle$  and  $\checkmark$  button for 3 seconds. Then displayed  $R_{L,L}$ ,  $dE_{L}$  will start blinking. After the third beep sound you may hear that the test results have been deleted.

### CAUTION

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

## **Alternative site test**





GluNEO® M3 blood glucose monitoring system gives you the ability to obtain a blood sample for testing your blood glucose from different areas of your body.

The figure shown above displays the areas where you can test using your GluNE0<sup>®</sup> M3 meter. You may test your blood glucose from your 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

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 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. 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.

#### IMPORTANT

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

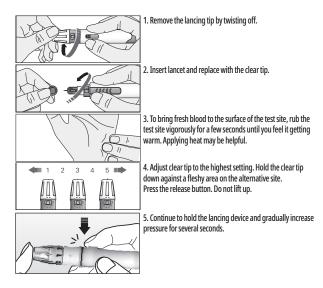
To ensure accurate results when lancing your palm (ventral palm or dorsal hand), clean the test site with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

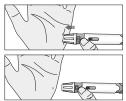
#### WARNING

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

## Lancing device clear tip is used for alternate site testing

Lance the test site with the lancing device





6

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

- · Consult with your healthcare professional before using alternate 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 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.
- Do not share reusable lancing device with anyone including other family members.

#### CAUTION

Do not test on your Alternative Site Test when

- You think you 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 palm sample.

## Caring for your GluNEO<sup>®</sup> M3 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<sup>®</sup> M3 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<sup>®</sup> M3 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<sup>®</sup> M3 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.
- 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<sup>®</sup> M3 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°C 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 discarded date (date vial opened, 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 2 ~ 30°C or 46~86°F (Temperature)
- After use, close cap tightly.
- Make sure the control solution bottle is tightly closed
- Record the discarded date (date vial opened, 6 months) on the control solution on the bottle.
- Do not use if expiry date has passed.
- It expires 24 months after manufacturing date.
- It expires 6 months after opening the vial cap.

#### CAUTION

- Store the GluNEO<sup>®</sup> M3 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<sup>®</sup> M3 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)

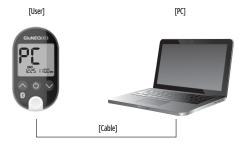
## Transferring your result data

You can transfer test results from the GluNEO<sup>®</sup> M3 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.

\* Please use the exclusive USB cable provided by OSANG Healthcare.



## **Bluetooth Function**

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.



#### Step1.

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

#### Step2.

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 'GluNEO M3 App'. Download and launch the app and fill in all details required.

### Step3.

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

#### Step4.

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 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.

### Step5.

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

### Step6.

Your meter will now transfer all glucose test result data to your 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 app on your mobile device, open your app and follow the instructions above. If you do not wish to transmit your results to your app at this time, simply press the middle 'OFF' button – your meter will enter sleep mode and your results can be transmitted to your 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, which is an indication that a new battery are needed.







Your GluNEO® M3 blood glucose test meter uses only two 3V lithium batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent lithium battery should be used.

## **Follow-up action**

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

#### NOTE

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

## **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 implement provisions of the European Parliament and Council Directive 2012/19/EU aimed to reducing the amount of EEE waste going for final disposal. The manufacturer, has specific instructions for the recovery of the meter. Please contact your distributor.

## **Dispose of batteries :**

Please recycle or dispose of used batteries using your local battery collection systems and in compliance with your local environmental laws and regulations.

Batteries contain chemicals that, if released, may affect the environment and human health. The crossedout 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® M3 Blood glucose test meter.

## **Disposing of your lancet**



1. Push the needle into the protective cover.



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



2. Pull the lancet out and discard accordingly.

## **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 bloodor irregular blood fill	Please insert a new glucose test strip and apply the blood sample completely and regularly.
	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
	Blood sample is placed on the test strip before the display for the blinking blood icon( <b>b</b> )	Wait for the meter to display the blinking blood icon(♠) before applying your blood sample.
DATE 1225 I HOOPM	Caused by color bar contamination or foreign test strip	Please insert a new glucose test strip and perform your test again. If blinking with "Sun", avoid the direct sunlight and re-test. Contact your local representative or customer support at OSANG Healthcare Co, Ltd., if the problem persists.
SE SE	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 or more and test again.
	The ambient temperature is over 40°C (104°F)	Place the meter at a temperature between 10 ~ 40°C ( $50 - 104^{\circ}F$ ) for more than 30 minutes or longer, and then test again.
	Test result is lower than 20 mg/dL(1.1mmol/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	
	Low Battery	Change the battery and if the problem persists, contact your local representative or customer support at OSANG Healthcare Co., Ltd.
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

- Low Glucose Results: If your result is lower than 60mg/dL, it may mean hypoglycemia (low blood glucose). 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 glucose). 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 glucose. If he "HI" continues, please consult with your healthcare professional immediately.

#### FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

#### NOTE:

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

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

#### **RED Compliance Statement**

This product is CE marked according to the provision of the RED (2014/53/EU). Hereby OSANG Healthcare Co., Ltd. declares that this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU

## 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.
- OSANG Healthcare Co., Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
- 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 and/or venous whole blood
Sample Volume	0.9ul
Test Range	20~600mg/dL (1.1~33.3mmol/L)
Reading Time	5 seconds
Calibration	Plasma – equivalent
Hematocrit	15~65%
Altitude	3048 meter Up to (10,000 feet)
Operating Temperature	10~40°C (50~104°F), indoor use only
Operating Humidity	10~90% RH
Storage Temperature	Store 2~30°C(36~86°F)and no direct sunlight. Do not Freeze
Display Type	LCD
Dimension(WxHxD)	89 x 51 x 17 (mm)
Weight	48±1g (Including batteries)
Power Source	3V (Coin Battery, CR2032 X 2EA)
Data Communication	USB to Serial / Bluetooth
Battery life	One year after purchasing

## Symbol reference

Symbol	Description
Ĩ	Consult Instructions for use
B	Use By date
C € 0123	This product fulfills the requirements of Directive 98/79/EC on in vitro Diagnostic medical device
$\square$	Caution, consult accompanying documents
IVD	In vitro diagnostic medical device
LOT	Batch Code
8	Do not re-use
SN	Serial number
	Date of manufacture
	Manufacturer
*	Keep away from sunlight
X	Waste electrical and electronic equipment Symbol
X	Temperature limitation
REF	Catalogue number
SELF-TESTING	Self-testing Used
EC REP	Authorisd representative in the European community
X	Waste batteries and accumulators

## MEMO

# GluNEOM3

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