GluNEO Dual

Blood Glucose / Blood β-Ketone Monitoring System

Instructions For Use

For Self-Testing
"In-vitro diagnosis medical device"

OHC OSANG HEALTHCARE

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Introduction

Intended Use

The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System is intended for self-testing outside the body (in vitro diagnostic use only) of layperson including diabetic patients, as an aid to monitor the effectiveness of diabetes management.

The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System should not be used for the diagnosis of diabetes or diabetic ketoacidosis.
The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System is used for the quantitative measurement of the glucose level/β-Ketone in fresh capillary whole blood samples drawn from fingertips.

The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System includes:
- GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter
- GluNEO H Blood Glucose Test Strip*
- KetoNEO Blood β-Ketone Test Strip*
- Lancing device*
- Disposable Lancet*

  * Purchased separately

Some components may not be included depending on the product set. Components can be found on the packaging box.

⚠ **Warning**

- The GuNEO Dual Blood Glucose/Blood β-Ketone Monitoring System is intended for self-testing use only.
- The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System should be used for in vitro diagnostics and should not be used for diagnosis of diabetes or for the diagnosis of diabetic ketoacidosis.
- Before using the GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System, you must read and understand the instructions for use. Inadequate blood glucose/Blood β-Ketone measurements and inaccurate test results can lead to adverse effects, such as the progression of the disease owing to delayed treatment
- The GluNEO Dual Blood Clucose/Blood β-Ketone Monitoring System is for self-testing and cannot be used for any purpose other than blood glucose/β-Ketone measurement.
- The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System should not be used in neonates.
- The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System is intended for self-testing outside the body.
- The GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System facilitates diabetes or diabetic ketoacidosis management, and blood glucose/Blood β-Ketone test results obtained using this system are not a substitute for medical care.
- Consult your healthcare professional if you experience

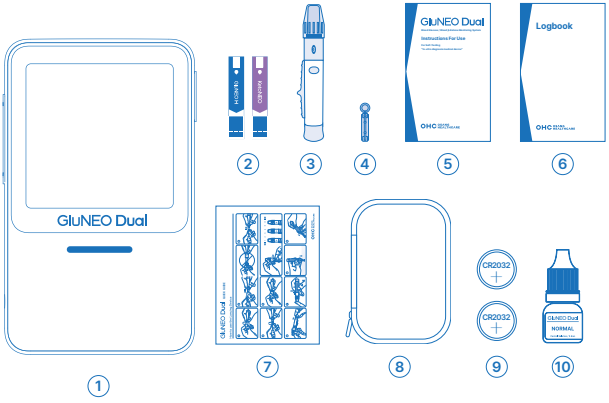
symptoms that do not match your blood glucose/β-Ketone test results. Do not ignore symptoms or change your treatment plan without consulting your healthcare professional.

- If you think your blood glucose/Blood β-Ketone test result is abnormally low or high, or if you feel that the result is inaccurate, take another blood glucose/Blood β-Ketone test with a new test stip.
- It you have followed all instructions in the instructions for use and your blood glucose/Blood β-Ketone test results contrue to be aonornal , contact your healthcare professional.
- Keep all contents of the package out of the reach of children. Swallowing small parts in the package may be a choking hazard for children.
  If you suspect that small components (including the battery) from the package have been swallowed or entered the human body, please consult a doctor immediately.
- Any part that comes into contact with human blood should be considered biohazardous and can potentially transmit infectious diseases even after washing.
  To reduce the possibility of infection, please be aware of the following:
  - The meter must be used by a single person and must not be shared by multiple people.
  - The meter and lancing device must be disinfected before use.

- Do not reuse test strips and lancets. Single use only.
- Test strips and lancets must be disposed of safely after use.
- Before the measurement, wash your hands in warm and clean water using soap, and dry thoroughly.
- Avoid getting hand lotion, oil, dirt or debris on the meter, lancing device, and lancets.

- If a serious incident occurs related to this device, contact the legal manufacturer and the Competent Authority.

Components



① GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter
② GluNEO H Blood Glucose Test Strip
KetoNEO Blood β-Ketone Test Strip
③ Lancing device (1EA)
④ Lancet (10T)
⑤ Instructions for use
⑥ Logbook
⑦ Quick Guide
⑧ Carrying Case (Pouch)
⑨ Battery (CR2032, 2EA)
⑩ Control solution*
* Sold separately

The components listed above may vary depending on the type of set. If the component is damaged, do not use it and contact your retailer/seller for a replacement.
The control solution can be purchased separately by contacting the place of purchase.

Meter

① **Display (LCD)**
Symbols, messages, and test results display

② **Mode button**
Recall test results stored in memory, enter standby (screen off) mode, enter setting mode, and save settings

③ **Up and down buttons**
Scroll through test results,change settings

④ **Color Indicator**
Display to easy range for result

⑤ **Battery cover**
A cover to open when replacing batteries

⑥ **Labeling part Meter**
information

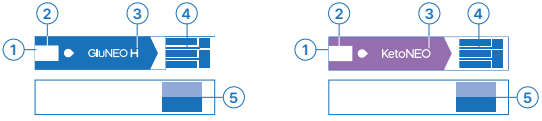
⑦ **Ejector**
Push the test strip out

⑧ **Test strip port**
Insertion port to insert a test strip

⑨ **Communication port**
(Manufacturer only use)

Test strip (sold separately)

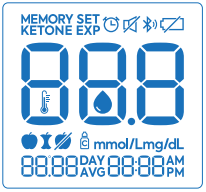
To obtain accurate blood glucose test results, you must use GluNEO H Blood Glucose/ KetoNEO Blood β-Ketone Test Strip.



[GluNEO H Blood Glucose test strip] [KetoNEO Blood β-Ketone test strip]

① Blood inlet
② Sample confirmation window
③ Cover
④ Meter contact terminal
⑤ Code label

Meter – LCD display and symbol descriptions



	Low battery
	Before meal
	After meal
	Fasting
	Control solution
	Waiting for blood
DAY AVG	Average display in memory mode
	Display Temperature Error
mmol/Lmg/dL	Display unit of measurement (mg/dL or mmol/L depending on local standards)
MEMORY	Display Result in memory mode
KETONE	Display when KetoNEO strip is inserted
SET	Display for setting mode
EXP	Strip expiration date
	Measurement date
AM PM	Measurement time
	Beep sound off
	Alarm
	Bluetooth communication

Precautions for use

- Fresh capillary whole blood should be used for accurate measurement.
- In case of severe dehydration with excessive vomiting, diarrhea, or urination, you should not use the device as the blood glucose/blood β-Ketone test results may be inaccurate.
- Be careful to not drop the meter. Strong external shocks should be avoided.
- The meter should be stored in a clean, dry place away from direct sunlight and should not be exposed to too high or too low temperatures.
- For proper operation of the meter, do not use it in an environment that may cause static electricity or near mobile phones, cordless phones, walkie-talkies, radio transmitters, or other electrical equipment that may cause electromagnetic radiation.
- If a low battery alarm turns up, the battery must be replaced with a new battery.
- For the meter, the test strip and the control solution marked exclusively for the device should only be used.
- Test strips are for a single use. Reuse is prohibited.
- An inaccurate blood glucose/blood β-Ketone test result may be obtained with a test strip after its expiry date. Check the expiry date before measuring blood glucose/ blood β-Ketone and discard expired test strips.
- The test strip should be stored in a cool and dry place and should not be exposed to heat or humidity.

- Do not replace the bottle for test strips with another bottle to preserve quality.
- For the details of the test strip, refer to the test strip instructions for use.
- Measure blood glucose/blood β-Ketone or perform a control solution test in a place where there is least influence of light, noise, temperature and humidity.
- To maintain the measurement accuracy of this product, it is recommended to compare your test result with the blood glucose/blood β-Ketone test results measured in the hospital laboratory at least once a year.
- A control solution should be used regularly to ensure that the meter and test strip are working properly.
- In case of an incident related to cyber security, please contact the customer service center.

Precautions for lancing device and lancet

- Lancets are disposable products. Do not reuse even for the same person.
- Use new, sterilized lancets.
- Do not leave lancets being inserted into the lancing device after measuring blood glucose/blood β-Ketone.
- After using a lancet, insert it firmly into the protective cap and dispose of it.
- When disposing of used lancets, dispose of them in an anticontamination disposal bag to prevent infection or according to applicable local government laws and regulations, or follow the guidance of a healthcare professional.
- Keep lancets out of the reach of children as there is a choking hazard if swallowed.
- Do not use if a protective cap of a lancet is broken or if the needle of a lancet is exposed outside the protective cap.

How to use

Description of Modes

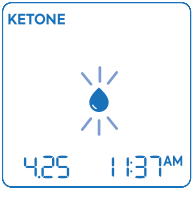
Distinguish the modes according to the LCD display.

Standby Mode

The screen is off.

Measurement Mode (Blood Glucose)

Blood glucose measurement status.
See 'Measurement Mode'



Measurement Mode (Blood β-Ketone)

Blood β-Ketone measurement status.
See 'Measurement Mode'

Memory Mode (Blood Glucose)

This is a state where you can check the stored blood glucose test results.
See 'Memory Mode'

Memory Mode (Blood β-Ketone)

This is a state where you can check the stored blood β-Ketone test results. See 'Memory Mode'

Setting Mode

This is a state where you can change the settings of the meter.
See 'Setting Mode'

Description of Buttons

Describes the mode buttons and up/down buttons of the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter.

Button	Operation	Function
 **Mode Button**	Press and release the button.	Switches from Standby Mode to Memory Mode.
		Switches from Memory Mode to Standby Mode.
	Press and hold for at least 3 seconds.	It will change to Setting Mode.
	Press and release the button.	Select an option from Setting Mode and go to the next step for Setting.
	Press and hold for at least 3 seconds.	The options are saved in Setting Mode and changes to Standby Mode.
 **Up/Down Button**	Press and release the button.	Displays blood glucose/ blood β-Ketone test results or an average measured value in Memory Mode.
		Change options in Setting Mode.

Measurement Mode

1. Preparation before measurement

- Set the meter correctly before taking a blood glucose/blood β-Ketone measurement for the first time. (See 'Setting Mode')
- Prepare a GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter, GluNEO H Blood Glucose/KetoNEO Blood β-Ketone Test strip, lancing device, and lancet.
- Before drawing blood, wash your hands in warm, clean water using soap and dry completely the area of the finger where blood will be drawn.

2. Measurement Procedure

- Use only the GluNEO H Blood Glucose/KetoNEO Blood β-Ketone Test strip.
- Do not pre-inject blood or control solution before inserting the test strip into the meter.
- Check the expiry date on the test strip bottle. Do not use if the expiry date passed.
- Take a test strip out of the bottle, close the cap, and use immediately.

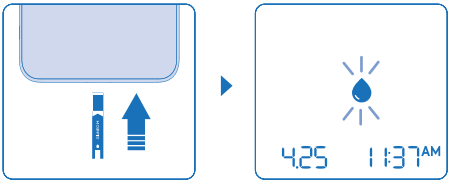
Step 1

Insert a test strip into the meter. At this time, make sure that the contact terminal of the test strip is facing upward and insert it all the way.

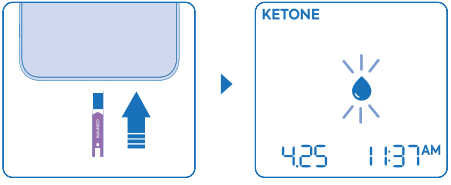
When the test strip is inserted, the screen turns on.

When the blood injection symbol (💧) flashes, draw blood from your fingertip.

'KETONE' will be displayed on the screen when you insert the KetoNEO Blood β-Ketone Test strip.



[When inserting GluNEO H Blood Glucose test strip]



[When inserting KetoNEO Blood β-Ketone test strip]

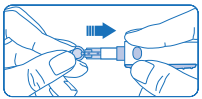
Precautions

- Do not use if the test strip is wet, bent or scratched, or if the recognition label of a calibration code (back of the test strip) is defective.
- After taking a test strip out of the storage bottle, it should be used immediately, and the cap of the bottle should be closed securely.
- Once used, test strips cannot be reused, and used test strips should be discarded immediately and do not put them back into the storage bottle.
- Do not touch or damage the “blood inlet” of the test strip with your hands.

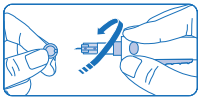
- If the calibration code displayed on the screen of the meter and the calibration code printed on the bottle of the test strip are different, do not use it and contact the customer service center. If the calibration code cannot be checked, the test strip must be removed and reinserted to check the code.
- If blood is applied to the test strip before the blood symbol appears on the screen, an error message will appear. (If an error occurs, check 'Troubleshooting')
- If blood is not injected properly into the test strip, blood glucose/blood β-Ketone measurement may not start, an error message may be displayed on the screen, or an inaccurate blood glucose/blood β-Ketone test result will be obtained. (If an error occurs, check 'Troubleshooting')
- If blood is injected from above with the meter upside down, blood may flow into the device, causing errors and device failure.

How to use a lancing device and lancet

① Turn the cap of the lancing device and take it.

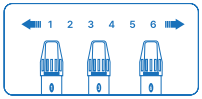


② Insert a lancet into the device so that it is securely fastened.

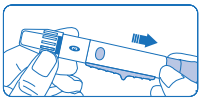


③ Turn the protective cap of the lancet to remove it.

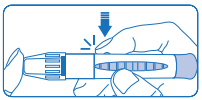
④ Close the cap of the lancing device.



⑤ Turn the depth adjustment unit printed with the numbers from 1 to 6 to adjust the piercing depth. If the depth is set at 1, the piercing depth is the shallowest, and if it is set at 6, the piercing depth is the deepest. Adjust the depth appropriately according to the amount of blood to be taken and the thickness of the user's skin.



⑥ Pull the loading handle of the lancing device until it "clicks."



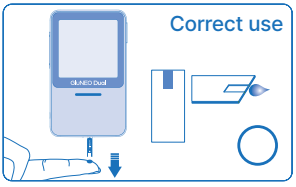
⑦ Lightly place the lancing device on the blood collection site (fingertip) and press the release button in the middle of the lancing device.

Precautions

- Blood glucose/blood β-Ketone should be measured using capillary whole blood from the fingertip.
- Avoid the use of and contact with hand cream and oil on the blood collection site before drawing blood.
- If you have cleaned the blood collection area with an alcohol swab, draw blood after alcohol has evaporated sufficiently.
- Once the sample is collected, it should be measured immediately.

Step 2

Touch the blood drop to the front edge of the test strip. When blood has been applied into the test strip, the meter will beep and begin measuring.



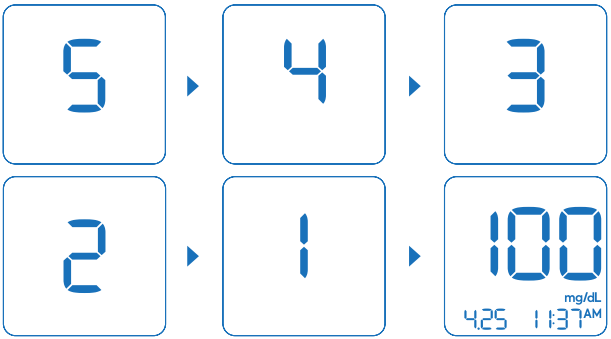
Precautions

- Observe the recommended blood sample volume of 0.5 µL. Excessive blood volume may cause malfunction.
- If the measurement does not start after the blood is applied, do not add any more blood to the test strip. Remove the test strip and insert a new one to restart the measurement procedure.
- If blood is not applied within 3 minutes after inserting the test strip, the meter screen will turn off. In this case, restart the measurement procedure.
- If the blood sample is not completely filled, inaccurate results may be obtained.

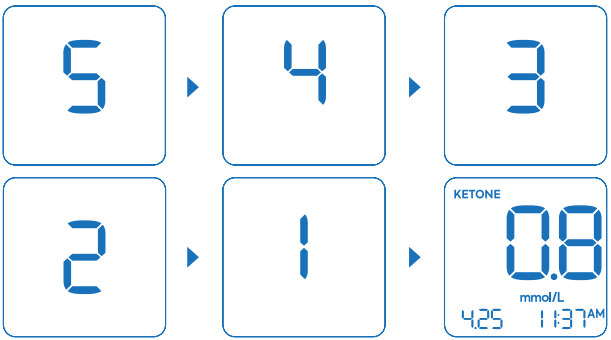
Step 3

When the blood glucose/blood β-Ketone test starts with a "beep" sound, the screen will display the blood glucose/blood β-Ketone measurement time counting down from 5 to 1. After the measurement is completed, the blood glucose/blood β-Ketone test result is displayed on the screen.

[Blood Glucose mode]



[Blood β-Ketone mode]



Set the user status after the blood glucose test result is displayed. (This function cannot be used if the screen is turned off by removing the test strip or pressing the mode button after the measurement is completed.)

Step 4

While the measured value is displayed, pressing the up and down buttons displays the user's current status ( ).
Select the user's current status with the up and down buttons, and then press the mode button.
When you press the mode button, it saves the current user status on the meter with measurement data.

- When the user's current status is before meal
- When the user's current status is after meal
- When the user's current status is fasting
- When control solution testing was performed.

Fill in the on-screen readings and user status in the Diabetes Management Logbook.
Slide the ejection slide to remove the used test strip.
After the measurement is finished, dispose of the used test strips and lancets in a safe place.

Precautions

- Discard used test strips and disposable lancets according to local government regulations or follow your doctor's guidance.

3. Result interpretation

After blood glucose/blood β-Ketone measurement, the blood glucose/blood β-Ketone test result is displayed.

[Blood Glucose mode]

[Blood β-Ketone mode]

The measuring range of the system is 10–600 mg/dL (0.6–33.3 mmol/L). It is displayed on the screen as "Lo" if the blood glucose test result is less than 10 mg/dL (0.6 mmol/L), and as "HI" if the result is higher than 600 mg/dL (33.3 mmol /L). If "Lo" or "HI" is displayed, repeat the blood glucose test.

- The normal blood glucose level is less than 100 mg/dL (5.6 mmol/L) when blood glucose is measured after fasting for 8 hours or more, and less than 140 mg/dL (7.8 mmol/L) after 2 hours after a meal.
  (Source: American Diabetes Association, STANDARDS OF MEDICAL CARE IN DIABETES -2022, Diabetes Care, Vol 45, Supplement 1)
- When hypoglycemia occurs, you may feel hungry, tremble all over, have a lack of energy, have night sweats, have heart palpitations, become anxious, and numbness around your lips or fingertips.
  (Source: Korean Diabetes Association)

After measuring blood β-Ketone, the blood β-Ketone test result is displayed on the screen of the meter.
The measuring range of the system is 0.0–8.0 mmol/L. It is displayed on the screen as "HI" if the result is higher than 8.0 mmol/L. If "HI" is displayed, take a blood β-Ketone measurement again.

⚠ **Warning**

- If the blood glucose test result is "Lo" or "HI" even after repeating the measurement, or if you have symptoms that are different from the usual, consult a healthcare professional immediately.
- If the blood β-Ketone test result is "HI" even after repeating the measurement, or if you have symptoms that are different from the usual, consult a healthcare professional immediately.
- Blood glucose test results may be displayed in mg/dL or mmol/L(depending on local standards), blood β-Ketone test results displayed in mmol/L.
  Incorrect units of measurement can mislead test results and lead to incorrect interpretations. If you are unsure of the unit of measurement, consult your healthcare professional.

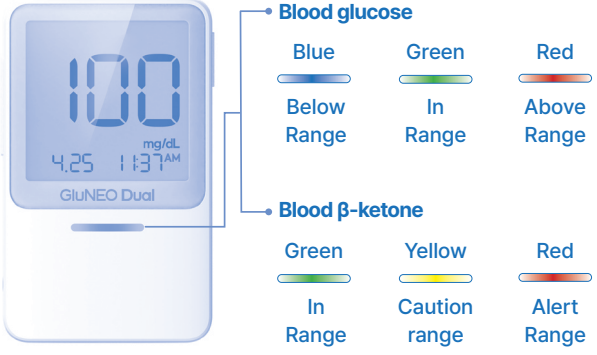
Precautions for abnormal blood glucose/blood β-Ketone test results

- If the blood glucose test result shows "LO", the blood glucose is very low.
- If the blood glucose test result shows "HI", the blood glucose or the blood β-Ketone is very high.
- If you think that an abnormal blood glucose/blood β-Ketone test result reflects your current condition, consult a healthcare professional immediately.
- Ask your healthcare professional if you experience symptoms that do not match your blood glucose/blood β-ketone test results.
- If the hematocrit is very high (exceed 70%) or very low (less than 10%), inaccurate test results may occur.
- If you think your blood glucose/blood β-ketone test result is different from your current physical condition, please confirm the check points below.
- Check the expiry date of the test strip.
- Make sure the test strip bottle has been closed tightly and stored in a cool, dry place.
- Test the system with a control solution to ensure that it is working correctly.

Color Indicator

GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter automatically displays whether the test result is below or above a predefined range, or within the range. This is done using the "Color Indicator" located below the meter display, which shows the current test result range using colors. This helps users easily recognize their test results.

The meter has pre-set values for the color indicator. In the case of blood glucose, the below range pre-set value of glucose for the color indicator is 70 mg/dL, and the above range pre-set value of glucose is 180 mg/dL. If needed, you can change these settings in the setup mode. In the case of blood β-Ketone, the caution level is set to 0.6 mmol/L and the alert level is set to 1.5 mmol/L, these values cannot be changed.



Precautions

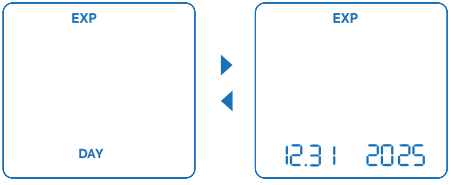
- The low and high range limits you set apply to all blood glucose/blood β-Ketone test results. This includes tests taken before or after mealtimes, medications and around any other activities that may affect your blood glucose/ blood β-Ketone.

⚠ **Warning**

- Be sure to talk to your healthcare professional about the low and high range limits that are right for you. When selecting or changing your limits, you should consider factors such as your lifestyle and diabetes or diabetic ketoacidosis therapy. Never make significant changes to your diabetes or diabetic ketoacidosis care plan without consulting your healthcare professional.

Strip expiration date (For glucose only)

If you have set the strip expiration date in the settings menu, a warning message will be displayed if you insert a strip that has expired.

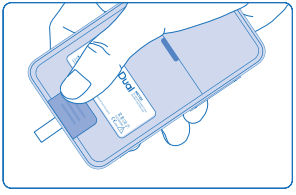


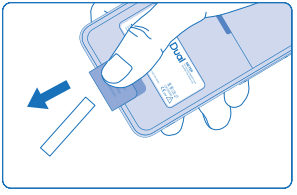
Precautions

- An inaccurate blood glucose/blood β-Ketone measurement result may be obtained with a test strip after its expiration date. Check the expiration date before measuring blood glucose/blood β-Ketone and discard expired test strips.

Function of ejecting a test strip

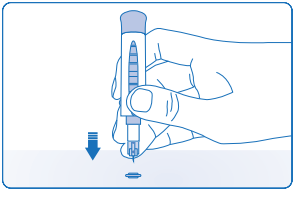
1. After checking the blood glucose/blood β-Ketone test result, push the ejection slide forward as shown in the figure to eject the use test strip. Be careful not to push the ejection slide forward too hard, as this may cause a malfunction.
2. Please dispose of the discharged test strip safe and hygienically. Used test strips may be considered biohazardous waste in your area. Consult your local representative for proper disposal methods.

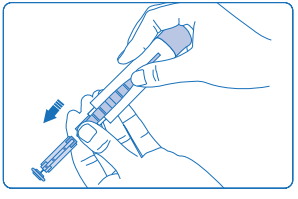




Function of discharging lancet

1. After checking the blood glucose/blood β-Ketone test result, poke the lancet being plugged into the lancing device, into the protective cap.
2. Pull back the loading handle of the lancing device and slide the removal button forward to remove the lancet.
3. Please dispose of discharged lancets hygienically safe. Used lancets may be considered biohazardous waste in your area. Consult your local representative for proper disposal.



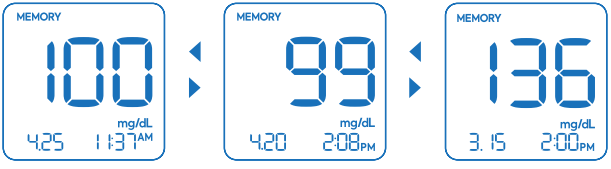


Memory Mode (Recall Stored test Results)

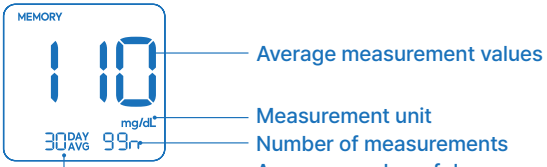
> ⚠ **Warning**
> - Do not change the treatment plan based on the blood glucose test results stored in the memory, and consult your healthcare professional.

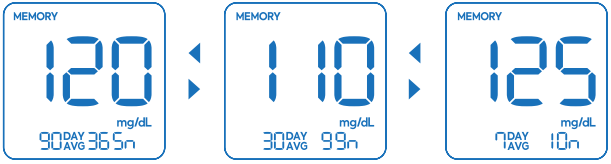
The GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter stores up to 1,000 blood glucose test results along with the measurement date, time and user status, and can recall and check the average values according to the blood glucose test results and determined period. If 1,000 blood glucose/blood β-Ketone test results are stored in the memory, older blood glucose/blood β-Ketone test results are deleted and a new one is saved as blood glucose/blood β-Ketone measurements are performed.

- Press the mode button to display the most recent blood glucose test result.
- You can check the blood glucose test results and the average measurement for the period of three measurements using the up and down buttons. The average measurement does not include the test results using a control solution and the blood β-Ketone test results.
  - Press Down Button to display the blood glucose/blood β-Ketone test results in the order from the latest to the oldest. Once you scroll through all the stored glucose measurements, you will see the average measurement.



- Press Up Button to display the average measured value. Once you scroll through all the average measurements, blood glucose test results are displayed from oldest to most recent. The blood β-Ketone test results and control solution test results are not included in the average measurement.





Average measurement for the last 90 days

Average measurement for the last 30 days

Average measurement for the last 7 days

Setting Mode

If you do not set the date and time of the meter at the time of initial purchase or battery replacement, the average measurement may not be calculated normally.

- Press and hold the mode button on the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter fo longer than 3 seconds. After a while, it will switch to Setting Mode.
- You can change the options as below in the setting mode.

Setting	Options	Functions
Beep Sound	ON	System beep sound On
	OFF	System beep sound Off
Bluetooth	ON	Bluetooth On
	OFF	Bluetooth Off
YEAR	2023 ~ 2063	set until 2063
DATE	Day - Month	set day and month
TIME	Hour, Minute	set hours and minutes
Color Indicator Below range	60~110 mg/dL	Set the below range of the color indicator. If the result value is lower than the set value, the indicator color is displayed in blue.
Color Indicator Above range	90~300 mg/dL	Set the above range of the color indicator. If the result value is higher than the set value, the indicator color is displayed in red.
KETONE Indicator	ON	Color Indicator function works for blood β-Ketone

Setting	Options	Options
KETONE Indicator	OFF	Color Indicator function don't works for blood β-Ketone test result
Strip Expiration Date	OFF	Strip Expiration Date Alarm Off
	ON	Strip Expiration Date Alarm On
	Year, Month, Day	Set the date of Strip Expiry Date.
Alarm Time 1 (Alarm1)	OFF	First alarm time not set. Pressing the mode button exits the setting mode.
	ON	You can set the first alarm time. Time setting is displayed when the mode button is pressed.
	Hour, Minute	set alarm time
Alarm Time 2 (Alarm2)	OFF	Second alarm time not set. Pressing the mode button exits the setting mode.
	ON	You can set the second alarm time. Time setting is displayed when the mode button is pressed.
	Hour, Minute	set alarm time
Alarm Time 3 (Alarm3)	OFF	Third alarm time not set. Pressing the mode button exits the setting mode.
	ON	You can set the third alarm time. Time setting is displayed when the mode button is pressed.
	Hour, Minute	set alarm time

• Guidance on the setting method and procedure

Entering Setting Mode

Press the Mode button for at least 3 seconds. After a while, the screen will change.

Beep Sound

You can set a system beep sound function. Press the up or down button to set it to ON and then press the mode button. If you select Off, the system beep sound mute of meter.

Bluetooth

You can set a Bluetooth function. Press the Up or Down Button to set ON and then press the Mode Button to use Bluetooth function. If you choose OFF, you can't use Bluetooth function.

YEAR

Press the up and down buttons to select the year, and then press the Mode button.

DATE

Press the up and down buttons to select a date, and then press the Mode button.

TIME

Press the up and down buttons to select a time, and then press the Mode button.

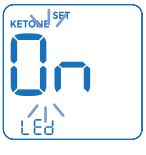
Indicator Below range

Press the up and down buttons to select a color indicator below range value (between 60 mg/dL-110 mg/dL) of color indicator, and then press the Mode button.

Indicator Above range

Press the up and down buttons to select a color indicator above range value (between 90 mg/dL-300 mg/dL) of color indicator, and then press the Mode button.

KETONE Indicator Function



You can set a "Color Indicator" function for the KETONE value. Press the up or down button to set it to ON and then press the Mode button. If you select Off, Don't work "Color Indicator" function for the KETONE value.

Strip Expiration Date (For glucose only)

You can set a strip expiration date alarm. Press the up or down button to set it to ON and then press the mode button. If you select Off, move on to the next setting menu.

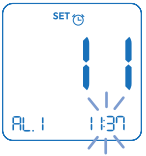
Press the up and down buttons to select a year of strip expiration date, and then press the Mode button.

Press the up and down buttons to select a date of strip expiration date, and then press the Mode button.

Alarm1 on/off

You can set 3 alarms. Press the up and down buttons to set the first alarm ON and then press the Mode button. If selecting Off exits the setting mode.

Alarm1 time



Press the up and down buttons to select the alarm time and minute, then press the Mode button.

Alarm2 on/off

Press the up and down buttons to set the second alarm ON and then press the Mode button. Time setting is the same as Alarm 1.
If selecting Off exits the setting mode.
Alarms3 settings are also the same.

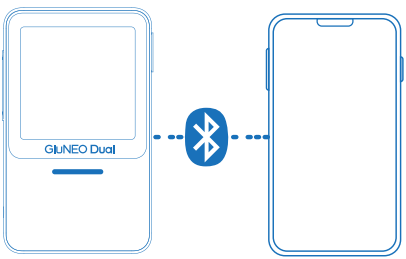
When exiting the setting mode, the "End" is displayed with a beep sound and the screen turns off after a while.

- **How to exit the setup mode**
- Press the Mode button repeatedly until the screen turns off with a beep sound.
- In the setup mode, press the Mode button for longer than 3 seconds to switch to a standby mode.
- If you do not press any button for longer than 1 minute, it will go into a standby mode.

Bluetooth Communication

GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter can be connected wirelessly to mobile devices with Bluetooth communication function. Your mobile device must have an application that can receive data.

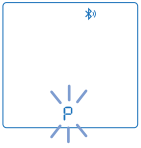
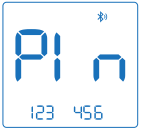
- Pairing : The connection process between GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter and a mobile device is called pairing. If you pair the device once the first time you use it, it will automatically connect thereafter.
- App(Application) : To transfer the measurement results stored in the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter, an app is required.



1. Preparation

GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter	Position yourself as close as possible to the mobile device. When pairing with another mobile device, the existing pairing information will be deleted.
Mobile Device	Turn on the Bluetooth function and run the app.

2. Pairing attempt

GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter	Press the Up button on the meter for at least 3 seconds until you hear the beep. ᛒ (Bluetooth symbol) is displayed and 'P' blinks. 
Mobile Device	Search for the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter according to the instructions in the app, select it, and attempt to pair.
GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter	A 6-digit PIN will be displayed on the screen. 
Mobile Device	Enter the PIN No.displayed on the meter screen and press Confirm.

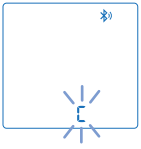
3. Pairing successful

GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter	If pairing is successful, the stored blood glucose test results will be transmitted, and when completed, a beep will sound and the screen will turn off. If pairing fails, 'PAIR FAIL' is displayed. Start again from '1.Preparation' 
Mobile Device	When the product name appears in the app, select it according to the description. Pairing is complete.

4. Data transfer

GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter

You must be paired with a mobile device, and the Bluetooth function must be turned on in 'Setting Mode'. After glucose measurement, the blood glucose test result is transmitted by removing the glucose test strip or pressing the Mode button.
The screen displays (Bluetooth symbol) and 'C' blinks.



If the transfer fails, 'SYNC FAIL' is displayed. Please retry data transfer by press the Mode Button in Memory Mode.

If the transfer continues to fail, restart with '2. Pairing attempt'.
If the transfer fails repeatedly, please contact the customer service center.

Mobile Device	Run the app after measuring blood glucose. Data is automatically received when paired with the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter. After the data is transmitted, check the blood glucose test result.

Precautions for Bluetooth communication

- The GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter can only be paired with one mobile device at a time.
- Turn off the wireless communication function in places where wireless use is not permitted, such as hospitals or airplanes.
- Some smartphones may not be able to use to app. (Please refer to the app user manual for details.)

Maintenance and troubleshooting

Quality control

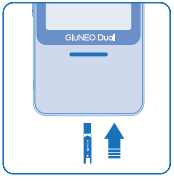
To purchase GluNEO Dual control solution, please contact your retailer/seller or customer service. By comparing the control solution test results with the range printed on the test strip bottle, you can verify that the system is working properly and that you are performing the correct blood glucose/blood β-Ketone measurement. It is very important to perform routine tests to ensure accurate results.

Control solution testing is recommended in the following cases:

- When the meter is used for the first time or the test strip is newly opened
- When the accuracy of the meter or test strips is in doubt
- If the meter is dropped and impacted
- If the test strip is considered to be damaged
- If the blood glucose test result and the physical condition do not match
- If you want to check if you are doing the test correctly
- When using the meter after cleaning and disinfection

How to use the product

Check the expiration date of the test strip and control solution.
Place the meter on a leveled surface.
Store the meter, test strip, and control solution at room temperature for at least 30 minutes before using.



Use a non-expired test strip printed on the bottle of GluNEO H Blood Glucose/KetoNEO Blood β-Ketone Test strip.
Insert the test strip firmly into the meter.
Insert it deep in the direction of the arrow on the cover of a test strip.
Do not insert the test strip upside down.

Check the expiration date before performing the control solution test. Do not use if it has expired.

Shake the control solution lightly before use. Open the cap of the bottle, remove the first drop, and wipe the tip of the bottle clean with a tissue paper.

Put a drop of the control solution on the clean, dry surface (e.g. cap of the test strip bottle).

When the dropped solution is injected into the GluNEO H Blood Glucose/KetoNEO Blood β-Ketone Test strip, the test result is displayed in 5 seconds. Check the test results and the range indicated on the bottle of control solution. The result must be within that range.

Press Up Button or Down Button to select the control solution symbol and press (Mode button).

Discard the used test strip, wipe the end of the control solution bottle with a tissue paper, and be sure to close the lid. If the control solution test result is out of the normal range, take out a new test strip, and perform the test again, and if there is still a problem, contact the customer service center.

Precautions when using the control solution

- Use only a control solution specific for the GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System.
- Be sure to close the bottle cap after using the control solution.
- Do not eat or swallow the control solution.
- Control solution can leave stains on clothes. Wash immediately with soapy water to avoid stains.
- Use only to perform an inspection of the system.

Maintenance of the meter

Whenever you replace the batteries in the meter, an error message may occur if there is a problem with the device. (See 'Troubleshooting')

Cleaning and disinfecting the meter

Keep dust, blood, control solution, and liquids away from the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter, test strip port, or communication port.

If contaminants such as blood or dust get on the surface after using the meter, remove it with a soft cloth or tissue paper.

Do not immerse the meter directly in liquid when cleaning. Be careful not to allow liquid to get inside the device. Never use highly corrosive organic solutions such as benzene or acetone as they may damage the blood glucose/blood β-Ketone meter. When using alcohol, do not pour the solution directly onto the blood glucose/blood β-Ketone meter, but use a small amount on a soft cloth or tissue paper.

Cleaning and disinfection methods

1. Make sure the meter is turned off.
2. Dampen a soft cloth with the following cleaning solution and carefully wipe the surface of the meter.
- When washing: Use a neutral detergent diluted with water.
- Cleaning or disinfection area: Around the test strip insertion port.
3. Use a soft cloth to dry the meter thoroughly.

How to store

After the blood glucose/blood β-Ketone measurement is finished, keep the components out of the reach of children in the included carrying bag to prevent the components from being lost.

GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter

- Store all components in a cool, dry place away from direct sunlight or heat.
- Store in a place safe from vibration, shock, and in not-inclined places.
- Keep out of contact with water and away from dust and moisture.
- Strong electromagnetic waves may affect normal operation. Keep away from the sources of strong electromagnetic waves. Please be especially careful when measuring blood glucose/blood β-Ketone.

GluNEO H Blood Glucose/KetoNEO Blood β-Ketone Test strip

- Store in a cool, dry place between 2-32°C (36-90°F). Store away from direct sunlight and do not freeze.
- Store only in the original bottle. Do not use different bottles or mix test strips.
- Always close the bottle cap securely after use.
- Take note of the date of disposal. This date is 6 months from the date the test strip's bottle is first opened. After the disposal date, discard the test strip and bottle.
- Open the foil test strip packet to take out a test strip for testing and use the test strip immediately. Do not use the test strip if the foil is damaged or torn.
- Do not use test strips after the expiry date printed on the bottle as they may produce inaccurate results.

- Do not bend, cut or alter the test strip.
- Do not touch the test strip with wet hands. Keep dust, food, and water away.
- Do not allow dust, food, and water on the recognition label (on the back of the test strip) of the calibration code.
- For detailed instructions on test strips, refer to the test strip manual.

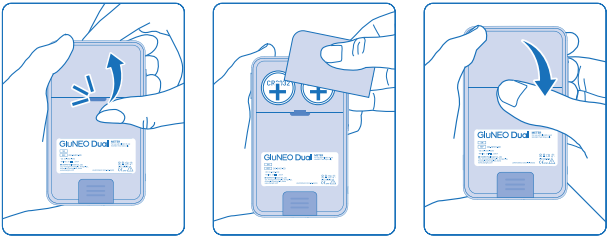
GluNEO Dual Control Solution

- Store in a cool, dry place between 8-30°C (46-86°F).
- After use, make sure to close the cap and ensure it is tightly closed.
- Record the disposal date (opening date + 3 months) on the bottle of control solution bottle.
- Do not use if the expiry date has passed.
- For detailed instructions on the control solution, see the control solution manual.

Battery Replacement

If the low battery symbol is displayed on the screen or the screen does not turn on while the meter is in use, the battery has reached the end of its life. Replace the battery.

- The GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter uses two 3V lithium batteries (CR2032).
- Even if the battery is replaced, the stored blood glucose test result will not be deleted.
- Purchase and use a batteries compatible with CR2032 type.
- Open the battery compartment cover and replace the batteries, paying attention to its (+) and (–) polarity. Insert it with the (+) side visible.
- After replacing the battery, reset the date and time of the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter.
- After replacing the battery, the GluNEO Dual Blood Glucose/ Blood β-Ketone Test Meter automatically enters the Setting Mode for the year, date and time settings.



1. To replace the battery, gently insert your fingernail or a pointed tool into the groove and open the cover by pulling it towards you.
2. Insert the batteries with the (+) side facing up.
3. Close the battery compartment cover securely.

Precautions for battery replacement

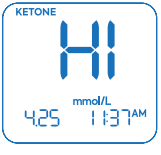
- Keep new and used batteries out of the reach of children.
- Using a battery that is not compatible with CR2032 type may cause malfunction.
- Battery life may vary depending on factors such as the temperature and battery manufacturer.
- If the low battery symbol is displayed but the battery is not replaced, there may be problems saving the test results.
- If the date and time are not set after battery replacement, there may be problems with the calculation of the average measured value.
- Dispose of used batteries according to local regulations.
- If the battery compartment does not close completely, stop using it, keep it out of reach of children, and contact customer service.
- This product contains a coin cell battery. If the coin cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death.
- If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.
- Risk of fire or explosion if the battery is replaced by an incorrect type.

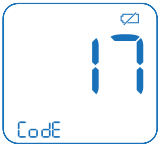
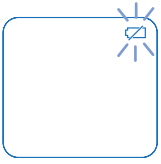
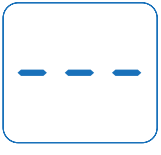
Troubleshooting

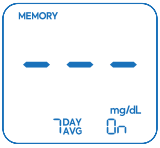
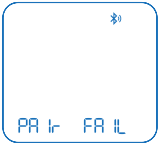
- If the below mentioned messages appear on the screen while using the GluNEO Dual Blood Glucose/Blood β-Ketone Monitoring System, please take measures according to the cause. If the problem is not resolved, please contact customer service. Do not disassemble or attempt to repair the meter on your own.
- If you have any questions about the product or in the event of an accident related to cybersecurity, please contact customer service.

LCD	Cause	Solution
	There is a problem with the meter. (e.g. H/W defect, Strip connector wear)	Remove the test strip, if inserted, and turn the meter back on after replacing the battery. If the problem persists, contact customer service.
	If you have inserted a test strip that has already been used. When a wet test strip is inserted.	Replace the test strip with a new one and take the blood glucose/ blood β-Ketone measurement again.
	Insufficient amount of injected blood or failure to inject normally.	After checking the 'Measurement Mode' replace the test strip with a new one and measure blood glucose/ blood β-Ketone again.

LCD	Cause	Solution
	Test strip is damaged	Replace the test strip with a new one and take the blood glucose/ blood β-Ketone measurement again.
	Injecting blood sample before the blood waiting symbol ( ) is displayed.	Reinsert a new test strip and wait until the blood injection symbol is displayed. When the blood injection symbol is displayed, inject blood.
	Insert the test strip with the color label on the back of the test strip dirty or damaged. Incompatible product's test strip is used.	Take out a new test strip and take the blood glucose/blood β-Ketone measurement again. Make sure the test strips are specified for the system.
	The measurement temperature is lower than 10°C or higher than 40°C.	Move to an area that is not out of the temperature limit and take the blood glucose measurement again after 30 minutes.

LCD	Cause	Solution
	Use under direct sunlight	Move to a place where you can avoid direct sunlight and take the blood glucose/blood β-Ketone measurement again.
	The blood glucose test result is less than 10 mg/dL (0.6 mmol/L)	If the message continues to appear after 2–3 repeated measurements, please consult a healthcare professional immediately. If it differs from your physical condition, perform a control solution test to check the operation of the system. If it does not work properly, contact customer service.
	The blood glucose test result exceeds 600 mg/dL (33.3 mmol/L)	If the message continues to appear after 2–3 repeated measurements, please consult a healthcare professional immediately. If it differs from your physical condition, perform a control solution test to check the operation of the system. If it continues to malfunction, contact customer service.
	The blood β-Ketone test result exceeds 8.0 mmol/L.	

LCD	Cause	Solution
	Battery Warning (Low battery icon constantly displayed)	Measurements and operation are possible, but the batteries will soon need to be replaced.
	Low battery	Replace the battery (CR2032, 2 EA) immediately.
 	Strip expiration date warning message	Check the expiration date before measuring blood glucose and discard expired test strips. Set the strip expiration year and date correctly in the setup mode before measuring.
	There is no stored blood glucose test result.	Insert a test strip to measure.

LCD	Cause	Solution
	If the average value cannot be calculated based on the current date.	Set the date and time correctly in the setup mode before measuring.
	Bluetooth pairing failed	Please refer to the instructions for Bluetooth mode and try the pairing process again. If the problem persists, contact customer service.
	Bluetooth transfer failed	In Memory Mode, you can press the mode button to retry the transfer. If the transfer continues to fail, please refer to the instructions for Bluetooth mode and try the pairing process again. If the problem persists, contact customer service.

LCD	Cause	Solution
Screen not turn on	The battery runs out. There is a problem with the meter.	Replace the batteries. If the problem persists, contact customer service.
Measurement does not start	The amount of blood injected is insufficient. The test strip is damaged.	After checking the "Measurement Mode," replace the test strip with a new one and measure blood glucose again.
Results are inconsistent	There may be a problem with the glucose test strip.	Please perform the test with a new test strip. If you still have the same problem, check the code on the bottle of test strip and the code marked on the meter. If they do not match, please contact customer service.

Technical Information

Product specifications

Meter	GluNEO Dual
Memory capacity	1,000 test results
Dimensions (mm)	58±1 X 96±1 X 18±1 mm (W X H X D)
Weight (g)	65±1g (including batteries)
Power supply	3V Lithium battery 2EA (CR2032)
Operating Temperature	10~40°C
Operating Humidity	10~90%
Altitude	Up to 10,000 ft(3,048 m)
Interface	Bluetooth Low Energy

GluNEO H Blood Glucose Test strip

Measuring substance	Blood Glucose
Sample type	Fresh capillary whole blood
Measuring range	10~600 mg/dL (0.6~33.3 mmo/L)
Measuring time	5 seconds
Sample volume	0.5 μL
Hematocrit	10~70%
Test strips storage condition	2~32°C(36~90°F)

KetoNEO Blood β-Ketone Test strip

Measuring substance	Blood β-Ketone
Sample type	Fresh capillary whole blood
Measuring range	0.0~8.0 mmol/L
Measuring time	5 seconds
Sample volume	0.5 μL
Hematocrit	10~70%
Test strips storage condition	2~32°C(36~90°F)

Measuring principle

Blood glucose monitoring system

Glucose in the blood is oxidized to gluconic acid by catalysis of glucose dehydrogenase (GDH-FAD) in the enzyme layer of the test strip, and FAD, the active site of GDH-FAD, receives electrons and is reduced to $FADH_2$. In this process, through the oxidation–reduction (redox) reaction of the electron transfer mediator and $FADH_2$, $FADH_2$ is oxidized to FAD, and the electron transfer mediator is reduced. The electron transfer mediator in the reduced state is oxidized on the electrode surface where voltage is applied through the meter, generating an electric current. Since the resultant current is proportional to the glucose concentration, the meter measures the current to determine the blood glucose concentration.

Blood β-Ketone monitoring system

β-Ketone in the blood is oxidized to acetoacetate by catalysis of 3-Hydroxybutyrate Dehydrogenase (3-HBDH) in the enzyme layer of the test strip, and Nicotinamide Adenine Dinucleotide (NAD+) receives electrons and is reduced to NADH. At the same time, NADH is oxidized to NAD+ with the reduction of the electron transfer mediator. The electron transfer mediator in the reduced state is oxidized at the surface of the electrode where a voltage is applied through the meter, producing a current. Since the current is proportional to the β-Ketone concentration, the meter measures the current to determine the blood β-Ketone concentration.

Performance Characteristics

Performance of the test strips has been evaluated in clinical trials.

Measurement Range

Measurement range of GluNEO H Blood Glucose Monitoring System is 10 to 600 mg/dL.

Measurement range of KetoNEO Blood β-Ketone Monitoring System is 0.0 to 8.0 mmol/L.

Blood Glucose Monitoring System

Please note the following interferences that may affect test results

- GluNEO H Blood Glucose Test Strip results can be used with hematocrit levels in the range of 10% to 70%, If the hematocrit range is out of the range(10%~70%), then the test results may be lower or higher than the actual value.
- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substance (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results. Samples containing Bilirubin up to 40.0 mg/dL, Ascorbic acid up to 6.0 mg/dL & Ibuprofen up to 50.0 mg/dL do not significantly affect results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 1500 mg/dL do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.
- Do not use during or soon after Sodium absorption testing. Sodium in the blood will cause interference.

Accuracy

The accuracy results obtained with the GluNEO Dual Blood Glucose/β-Ketone Monitoring System were compared to glucose results obtained with the cobas c111 analyzer, a laboratory instrument. Glucose levels were measured on 350 fresh capillary specimens.

System accuracy results for Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
(TBD)	**(TBD)**	**(TBD)**

System accuracy results for Glucose concentration ≥75 mg/dL

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
(TBD)	**(TBD)**	**(TBD)**	**(TBD)**

Regressions between GluNEO H Blood Glucose Test Strip results and the cobas c111 analyzer for the capillary whole blood samples:

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
(TBD)	**(TBD)**	**(TBD)**	**(TBD)**	**(TBD)**

Precision

Precision Results for venous whole blood samples.

Blood Conc. Level	N	46 mg/dL	101 mg/dL	142 mg/dL	220 mg/dL	346 mg/dL
Grand Mean	300	46.1	89.9	136.8	214.4	338.8
Pooled Variance	300	5.1	11.4	13.5	38.1	74.0
Pooled SD	300	2.3	3.4	3.7	6.2	8.6
95% CI		(2.24, 2.36)	(3.30, 3.50)	(3.60, 3.80)	(6.03, 6.37)	(8.37, 8.83)
Pooled CV(%)	300	5.0	3.8	2.7	2.9	2.5

Precision Results for Control solution.

Control solution Conc. Level	N	1	2	3	4	5
Grand Mean	360	40.4	76.4	126.5	226.8	370.8
Pooled Variance	360	8.5	7.8	11.2	30.5	95.0
Pooled SD	360	2.9	2.8	3.4	5.5	9.7
95% CI		(2.88, 2.94)	(2.75, 2.84)	(3.30, 3.41)	(5.44, 5.60)	(9.59, 9.90)
Pooled CV(%)	360	7.2	3.7	2.6	2.4	2.6

User Performance

(TBD)

Blood β-Ketone Monitoring System

Please note the following interferences that may affect test results

- KetoNEO Blood β-Ketone Test Strip results can be used with hematocrit levels in the range of 10% to 70%, If the hematocrit range is out of the range(10%~70%), then the test results may be lower or higher than the actual value.
- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substance (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results. Samples containing Bilirubin up to 40.0 mg/dL, Ascorbic acid up to 6.0 mg/dL & Ibuprofen up to 50.0 mg/dL do not significantly affect results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 1500 mg/dL do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Icodextrin does not interfere with KetoNEO Blood β-Ketone Test Strip.

Accuracy

The accuracy results obtained with the GluNEO Dual Blood Glucose/β-Ketone Monitoring System were compared to β -ketone results obtained with the RX Daytona+ analyzer, a laboratory instrument. Glucose levels were measured on 100 fresh capillary specimens.

System accuracy results for β-Ketone concentration <1.5 mmol/L

Within ±0.15 mmol/L	Within ±0.225 mmol/L	Within ±0.3 mmol/L
(TBD)	**(TBD)**	**(TBD)**

System accuracy results for β-Ketone concentration ≥1.5 mmol/L

Within ±10 %	Within ±15 %	Within ±20 %
(TBD)	**(TBD)**	**(TBD)**

Regressions between KetoNEO Blood β-Ketone Test Strip results and the RX Daytona+ analyzer for the capillary whole blood samples:

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
(TBD)	**(TBD)**	**(TBD)**	**(TBD)**	**(TBD)**

Precision

Precision Results for venous whole blood samples.

Blood Conc. Level	N	0.57 mmol/L	1.32 mmol/L	2.55 mmol/L	4.64 mmol/L	6.73 mmol/L
Grand Mean	300	0.5	1.0	2.3	4.3	6.7
Pooled Variance	300	0.001	0.002	0.010	0.011	0.028
Pooled SD	300	0.036	0.045	0.098	0.107	0.168
95% CI		(0.032, 0.040)	(0.040, 0.049)	(0.094, 0.101)	(0.105, 0.109)	(0.162, 0.174)
Pooled CV(%)	300	7.2	7.2	4.5	4.2	2.5

Precision Results for Control solution.

Control solution Conc. Level	N	Level 1	Level 2	Level 3	Level 4	Level 5
Grand Mean	360	0.3	1.2	2.6	4.5	7.1
Pooled Variance	360	0.002	0.003	0.007	0.014	0.015
Pooled SD	360	0.041	0.056	0.081	0.118	0.123
95% CI		(0.037, 0.044)	(0.051, 0.062)	(0.078, 0.083)	(0.114, 0.122)	(0.121, 0.126)
Pooled CV(%)	360	13.6	4.8	3.2	2.6	1.7

User Performance

(TBD)

OUR COMMITMENT TO YOU:

Our goal at OSANG Healthcare is to provide you the best quality products and superior customer service. If you have any questions or comments, please contact your local representative or visit our website at www.osanghc.com. OSANG Healthcare Co., Ltd USA is here for you 24 hours a day, 7 days a week. If you experience any difficulty call our friendly customer care representatives.

Please contact customer support toll free: 800-925-2949.

Limitations

The meter may be limited in use owing to wear and tear on the parts at the test strip port. After replacing the battery, if the screen does not turn on or an "Er1" message is displayed when the test strip is inserted, the machine can no longer be used. If the same phenomenon is repeated, contact customer service center.

Product FCC Information

Part 15.19	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.
Part 15.105	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.
Part 15.21	Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Product : GluNEO Dual
Model : OG-SH01-GDM
Rating : DC 3V ⎓, 20 mA
FCC ID : WSX-OG-SH01-GDM
Frequency : 2.4 GHz (2 402 MHz ~ 2 480 MHz)
(Bluetooth Low Energy)

Electromagnetic compatibility (EMC) information

Guidance and manufacturer's declaration – electromagnetic emissions

OG-SH01-GDM is designed for use in the electromagnetic environment specified below.
Customers or users of OG-SH01-GDM must ensure that it is used in such an environment.

Emissions test	Compliance limit	Electromagnetic environment – guidance
Mains terminal disturbance voltage CISPR 11	Group 1 Class B	OG-SH01-GDM is suitable to use in home healthcare environment. The OG-SH01-GDM uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
Radiated disturbance CISPR 11	Group1, Class B	
Harmonics IEC 61000-3-2	Class A	The OG-SH01-GDM is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/ Flicker IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

OG-SH01-GDM is designed for use in the electromagnetic environment specified below.
Customers or users of OG-SH01-GDM must ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	IEC 60601 Compliance level	Electromagnetic environment– guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	IEC 60601 test level	IEC 60601 ±0.5 kV, ±1 kV, ±2 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF Electromagnetic Field IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	OG-SH01-GDM is suitable to use in home healthcare environment.
Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	RF communication equipment is used no closer than 30 cm to any part of the OG-SH01-GDM, including cables specified by OSANG Healthcare Co., Ltd.
Electrical Fast Transient /Burst IEC 61000-4-4	100 kHz repetition frequency ± 2 kV for power supply lines ± 1 kV for input/output lines	100 kHz repetition frequency ± 2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV	Main power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	IEC 60601 Compliance level	Electromagnetic environment– guidance
Conducted Disturbances Induced by RF fields IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	The strength of RF field in the frequency range higher than 150 kHz - 80 MHz, the strength of the RF field is smaller than 3 V.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m 50 & 60 Hz	30 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11*	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OG-SH01-GDM requires continued operation during power mains interruptions, it is recommended that the OG-SH01-GDM be powered from an uninterruptible power supply or a battery be used with the system power source.
Radiated fields in close proximity IEC 61000-4-39	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	OG-SH01-GDM is suitable to use in home healthcare environment. Portable radio frequency (RF, RFID) communication devices can interfere with the medical electrical device.

Note: U_T is the AC voltage of the power before using test level

Recommended separation distances between portable and mobile RF communications equipment and the OG-SH01-GDM

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OG-SH01-GDM including cables specified by the manufacturer. If the distance is closer than 30 cm (12 inches), performance of the OG-SH01-GDM may decrease.

Immunity test	Band [a]	Service [a]	Modulation	IEC 60601 test level	Compliance level
Proximity fields from RF wireless communications equipment	380-390 MHz	TETRA 400	Pulse modulation 18 Hz	27 V/m	27 V/m
	430–470 MHz	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704-787 MHz	LTE Band 13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800-960 MHz	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28 V/m	28 V/m
	1700-1990 MHz	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28 V/m	28 V/m
	2400-2570 MHz	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28 V/m	28 V/m
	5100-5800 MHz	WLAN 802.11 a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) For some services, only the uplink frequencies are included.

Precautions

- This blood glucose meter meets the electromagnetic emission requirements according to IEC 60601. Therefore, it has low electromagnetic emissions, and interference with other electronic devices is not expected.
- Strong electromagnetic fields may interfere with the normal operation of the blood glucose meter. Do not use the meter in areas with excessively strong electromagnetic radiation.
- To prevent electrostatic discharge, do not use the blood glucose meter in excessively dry environments, especially in the presence of synthetic materials.

⚠ **Warning**

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GluNEO Dual Blood Glucose/Blood β-Ketone Test Meter, including cables specified by the manufacturer.

Description of symbols

	Instruction manual
	Expiration date
	Refer to warnings and safety related descriptions
	Temperature limit
	Batch Code
	Serial Number
	In vitro diagnostic medical device
	Catalog number
	Unique Device Identifier
	Reuse is prohibited
	Model number
	Country of manufacture
	Manufacturing year and month
	Manufacturer
	Avoid sunlight
	For self-testing
	Separate collection of electrical and electronic equipment waste
	Bluetooth® wireless technology

Consumables

- The Blood Glucose Test Strips: GluNEO H Blood Glucose Test strip
- The Blood β-Ketone Test Strips: KetoNEO Blood β-Ketone Test strip
- Disposable lancet
- Control Solution: GluNEO Dual Control Solution Please contact the place of your purchase or customer service center.

Reorder Information

- GluNEO H Blood Glucose Test Strip

Catalogue No. (Ref. No.)	Configuration
OG-SH01-GHS	50 test strips (50T x 1 bottle)
OG-SH01-GHS-3	100 test strips (50T x 2 bottles)

- KetoNEO Blood β-Ketone Test Strip

Catalogue No. (Ref. No.)	Configuration
OG-SK01-KNS	50 test strips (50T x 1 bottle)
OG-SK01-KNS-1	25 test strips (50T x 2 bottles)

- GluNEO Dual Control Solution

Catalogue No. (Ref. No.)	Configuration
OG-SH01-GDC-1	Level 1 concentration (1 bottle)
OG-SH01-GDC-2	Level 2 concentration (1 bottle)

Disposal

Dispose the used meter after removing the battery in accordance with local regulations regarding the disposal of electrical and electronic equipment. Dispose the used batteries according to local environmental regulations. Dispose of used test strips in sealed bottles according to local regulations. Always dispose of used lancets in accordance with local regulations.

MEMO

MEMO

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