REF PG310-004-25

IVD

User's Guide

Gmate® *Origin*



CE
0197

GenBody

GenBody Co., Ltd.
4F, 1-dong, 15 Jayumyeok 2-gil,Gunsan-si,
Jeonbuk-do 54001, Republic of Korea

Tel +82-63-453-1421
Fax +82-63-453-1423
Email help@genbody.co.kr

EU REP

Obelis SA
Boulevard Général
Wahis 53 1030
Brussels, Belgium

Tel +(32) 2 732-59-54
Fax +(32) 2 732-60-03
Email mail@obelis.net

[Revision History]				
No.	Slide	Summary of the revisions	Drafter	Revision date
0	-	Initial enactment	000	2026-10-01

PM310D-CE0-2100 Rev. Date 2026-10 Printed in Korea

Thank you for purchasing the Gmate® Origin Blood Glucose Monitoring System. Please read this User's Guide carefully before using to ensure correct use.
Please keep this User's Guide in a safe place for your reference.

If you are using this product for the first time, it is very helpful to practice with a control solution that can replace your blood. For more information, please refer to the user's manual of the test solution (see page 37).

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Package Contents

Contained in your package



1. Gmate® Origin Meter
2. Carrying Case
3. Lancing Device
4. Lithium Battery (CR2032)
5. Gmate® Test Strips (25 EA)
6. Lancets (10 EA)

Note

- Please call your local distributor if any items are missing.
- Gmate® Blood Glucose Test Strips, Gmate® Control Solution and Lancets are available for additional purchase at your point of purchase.
- Gmate® Control Solution is not included in this package and is supplied separately.
- Documents include this User Guide, Quick Guide and Test Strip Insert.
- A dedicated data cable(USB-to-Serial) is not included.

Before Use

Symbols

	Keep away from sunlight
	Keep Dry
	Caution, see instructions for use
	Single use only
	Expiration date
SN	Serial number
LOT	Lot number
IVD	In Vitro Diagnostic medical device
	Manufacturer
EU REP	European authorized representative
	Symbol for temperature limitation
	Consult instructions for use
	Biological risks
Σ	Contains sufficient for <n> tests
	Direct current
	Separate disposal from other household waste
REF	Reference number
UDI	Unique Device Identifier
	Do not use if package is damaged and consult instructions for use
CE 0197	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.

Intended Use

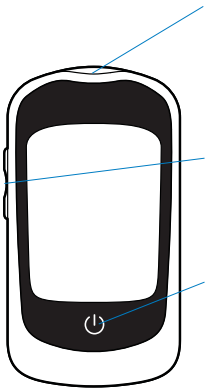
- The Gmate® Origin Blood Glucose Monitoring System is an in vitro diagnostic (outside the body) medical device intended for self-testing by a layperson for the quantitative measurement of glucose concentrations in fresh fingertip capillary whole blood.
  The system consists of the Gmate® Origin Blood Glucose Meter and the Gmate® Blood Glucose Test Strip.
  The system is intended to aid in monitoring blood glucose levels and blood glucose fluctuations in relation to physiological or pathological conditions, such as fasting, postprandial state, or physical activity.
  The system may be used by laypersons, including individuals with diabetes and individuals who need to monitor their blood glucose levels.
  The system is not intended for the diagnosis of diabetes, or for use in pregnant women or newborns. This product is not intended for use by individuals under 20 years of age.
- Disposable lancet : It is a single use disposable type instrument that is used for obtaining blood.
- Lancing device : A device used to collect a small amount of blood from the body. The lancet is excluded.

Test Principle

The Gmate® Origin Blood Glucose Monitoring System uses an electrochemical measurement method with the Gmate® Blood Glucose Test Strip, which contains a glucose oxidase (GOD)-based enzyme reagent.

When fresh fingertip capillary whole blood is applied to the test strip, glucose in the blood sample reacts with the GOD-based enzyme reagent on the test strip. This reaction generates an electrical current proportional to the glucose concentration in the sample.

The meter measures this electrical current and converts it into a quantitative blood glucose result, which is displayed on the screen.



Front View

Test Strip Port

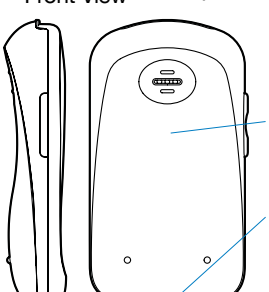
Insert the end of a Gmate® test strip port to begin a blood glucose test. The Gmate® Origin meter automatically power on when you insert the test strip.

Side Buttons(Up/Down Button)

The two side buttons are used to recall the stored results and adjust the parameters in setting mode.

Power Button

The Power button will power the Gmate® Origin meter on/off and change the meter modes.You can turn the meter off by pressing the power button for 2 seconds.



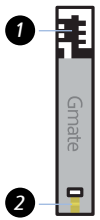
Side View Back View

Battery Cover

Open this cover to replace battery.

Data Port

Use to transfer test results to your personal computer (Software and Cable are sold separately.)



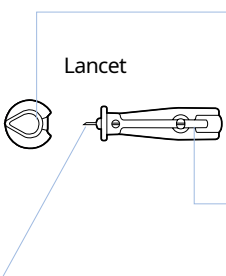
Gmate® Blood Glucose Test Strips (PS-004)

Electrodes

Insert this end facing up into the test strip port of the meter.

Yellow Filling Window

Apply your blood sample on the edge of this window.



Lancet Cap

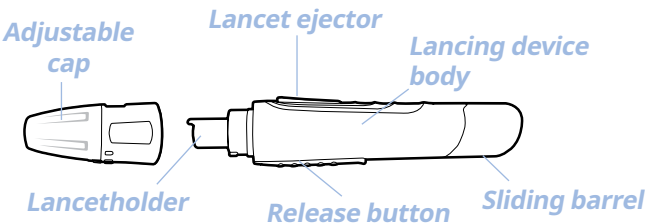
It protects the needle part of the lancet, prevents contact with foreign matter and unintentional puncture. After placing the lancet to the lancing device, remove the cap by twisting it.

Lancet Body Holder

It fixes and secures the position of the lancet when placed in the lancing device.

Needle

The only part of the lancet that comes into contact with the human body while collecting blood sample. The Needle immediately come inside the lancing device after skin puncture.



Lancing device

Adjustable cap

It adjusts the depth of puncture of the lancet.

Lancet holder

It's the part that being attached to the lancing device.

Release button

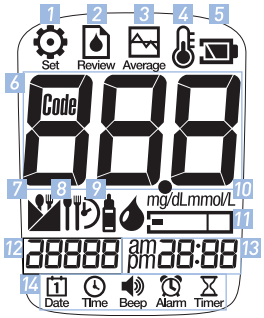
It's the button that release the lancet.

Lancet ejector

It's the part that eject the used lancet.

Sliding barrel

It's the part that need to be pulled out to prepare the lancing device to be ready for puncture.



Display

1. Set mode
2. Review mode
3. Average mode
4. Indicates abnormal temperature warning
5. Warning that the battery is low or needs to be replaced
6. Displays test results, average, and error messages
7. Indicates Pre-meal
8. Indicates Post-meal
9. Indicates control solution test
10. Measuring Unit
11. Test strip and blood drop
12. Date
13. Time
14. Features within the Set Mode: Date, Time, Beep, Alarm, Timer

Precautions when using blood glucose monitoring system

- This product is intended for self-monitoring of blood glucose levels. It is not intended for the diagnosis of diabetes.
- The System is intended for use outside the body (in vitro diagnostic use only).
- The system is not intended for use in pregnant women or newborns.
- Be aware of sudden temperature changes. If there is a sudden change in temperature, wait for 30 minutes in a room temperature before measuring.
- Do not drop the meter or apply strong impacts.
- Do not drop the meter from high place or apply strong force on it.
- If any abnormality is found, stop using the product and contact customer service or your local distributor.
- This product should be used with the Gmate® test strip and control solution, manufactured by GenBody.
- Before using this product, please read this manual carefully to ensure safe and accurate measurements.
- This product is not intended for use by individuals under 20 years of age.
- This product contains small parts that may be dangerous if swallowed.
- Keep the meter out of the reach of children. If a child swallows a battery or small part, seek immediate medical attention and consult a physician immediately.
- This product is not waterproof and should not be wiped with water or wet hands.
- Do not wipe this product with thinner or abrasive.
  The test strip should be stored in a cool, dry place at 2 ~ 32 °C.

- The test strip should be stored away from direct sunlight or heat.
- After taking a test strip out from the storage container, close the storage container lid immediately.
- Do not drop the blood sample directly on the surface of the test strip.
- The blood is sucked in automatically when you put the collected blood at the end of the test strip.
- Do not press or bend the test strip with force. This may result in inaccurate measurement results due to blood not entering the test strip in suitable amount.
- Do not use damaged or re-use test strip. The test strip is disposable.
- Keep the test strip in its original container. Do not keep it mixed with other test strips in other containers.
- Do not cut or deform the test strips.
- Take the test strip out of the container and use it within 3 minutes. If the test strip is exposed to air for a long time, incorrect measurement results may occur.
- Use all the test strips within 3 months after opening the test strip container lid.
- Do not use a test strip that is expired. Incorrect measurement results may occur.
- Touch the test strip with clean and dry hands to perform the blood glucose measurement.
- Test results may be inaccurate in users undergoing renal dialysis.
- Test results may be inaccurate in users receiving immunoglobulin treatment.
- This device complies with EMC requirements. However, avoid using or storing the meter near strong magnetic fields or electromagnetic sources (e.g., MRI, radio transmitters, mobile phones, microwave ovens), as these may affect the performance of the device.
- If a serious incident occurs related to this device, contact the legal manufacturer and the Competent Authority.
- Do not make any treatment decisions or change your medication based only on the test result.
- Do not change your medication, diet, or diabetes management plan based only on the test result. If your test result is unexpected or does not match how you feel, repeat the test with a new test strip. If the result is still unexpected, follow the diabetes management guidance provided to you.

- This device is intended for self-testing by laypersons. Do not make treatment decisions or change your medication or diabetes management plan based only on the test result.
- If the blood glucose test result is unexpectedly low or high, or does not match how you feel, repeat the test with a new test strip. If repeated results remain unexpectedly low or high, seek advice from your healthcare professional.

Precautions while using blood glucose test strip

- This test strip should only be used for in vitro diagnostics.
- This test strip should only be used with our approved Gmate® Blood Glucose Meter.
- This test strip is intended to aid in monitoring blood glucose levels and is not intended for the diagnosis of diabetes.
- Be careful of sudden temperature changes. If there is a sudden change in temperature, wait for 30 minutes in room temperature before measuring.
- Blood glucose test strips used for testing newborn and pregnant women blood specimens are not validated.
- Test results may be inaccurate if the hematocrit level is outside the range of 20–60%. Hematocrit means the percentage of red blood cells in your blood.
- The test strip should be used within 3 months after opening the container lid.
- Operating conditions: Temperature 10–32 °C, relative humidity 90% or less, altitude up to 3,048 m.
- The test strip is disposable. Do not re-use.

Precautions when using the lancet

- Insert the lancet into the lancet holder without removing the protective cap. After the lancet is inserted, remove the protective cap and attach the adjustable cap.
- Do not use products that have damaged or no protective cap.
- The lancet is a disposable, sterilized product, so reuse and re-sterilization are prohibited.
- Do not apply excessive force to the product during use.
- Be sure to only press the button on the lancing device to obtain blood sample. Be careful not to make any mistakes or other damage due to careless use of the button.

Precautions when using the lancing device

- A non-standard lancet cannot be used with this lancing device, so be sure to use the appropriate lancet.
- Use only for specified purpose, and do not use it for other purposes.
- If there is any problem in storing and using, please inform us immediately so that the manufacturer can take action.

Precautions for wired communication

- Ensure that the security patches for the PC are updated to keep your cyber assets safe.
- Measurement cannot be made in PC mode.
- Data received from the meter do not include personal information other than the blood glucose test result.
- If a dedicated data cable(USB-to-Serial) is not used, the communication may be affected by the electromagnetic field and cause malfunction.
- In case of an incident related to cybersecurity, please contact the customer service center

The Gmate® Origin Blood Glucose Monitoring System has five user settings: Date, Time, Beep, Alarm, and Timer.



To enter the Set mode, press and hold the power button for 2 seconds when the meter is off. The Date, Time, Beep, Alarm, and Timer settings will appear on the bottom of the screen.

Press either side button to scroll through the setting selections. Once you have reached your desired setting, press and release the power button to confirm your setting selection.

Important:

- Press and release up or down button to make your setting selection.
- Press and release power button to confirm your setting selection.
- Press and release power button for 2 seconds to exit the Set mode.

Tip:

- By pressing on either the up or down buttons, it will allow you to scroll through the different features within each setting.
- By pressing the power button, this will confirm your entry or desired feature.
- Within each feature, the up button will scroll the numbers up.
- Within each feature, the down button will scroll the numbers down.

Setting the Date



STEP 1

The meter is in the Set mode and the "Set" symbol appears at the top of the screen with the different setting appearing below.

STEP 2

Use either the up or down button to scroll through settings. Once you see that the Date setting is blinking, quickly press and release the power button. You are now in the Date setting.



STEP 3

Setting the Year: The Year will be flashing. Use the up or down button to adjust the year. The up button will increase the number and the down button will decrease the number. Once the desired year has been selected, quickly press and release the power button to confirm your entry and advance to the Month setting.



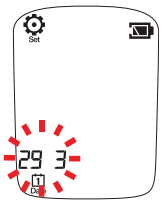
STEP 4

Setting the Month: The Month will be flashing. Use the up or down button to adjust the month. Once the desired month has been selected, quickly press and release the power button to confirm your entry and advance to the Day setting.



STEP 5

Setting the Day: The Day will be flashing. Use the up or down button to adjust the day. Once the desired day has been selected, quickly press and release the power button to confirm your entry and advance to the Date Format setting.



STEP 6

Setting the Date Format: The Date will be flashing. Use the up or down button to adjust "month-day" or "day month". Once the desired date format has been selected, quickly press and release the power button to confirm your entry and exit the Date setting.

Setting the Time



STEP 1

The meter is in the Set mode and the "Set" symbol appears at the top of the screen with the different setting appearing below.

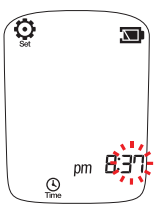
STEP 2

Use either the up or down button to scroll through settings. Once you see that the Time setting is blinking, quickly press and release the power button. You are now in the Time setting.



STEP 3

Setting the Hour: The Hour will be flashing. Use the up or down button to adjust the hour. Once the desired hour has been selected, quickly press and release the power button together to confirm your entry and advance to the Minutes setting.
When setting the hour, be sure to properly select a.m. or p.m.



STEP 4

Setting the Minutes: The Minutes will be flashing. Use the up or down button to adjust the minutes. Once the desired minutes has been selected, quickly press and release the power button to confirm your entry and advance to the Time Format setting.



STEP 5

The Gmate® Origin System allows you to choose your time format setting to either the 12 hour (i.e. 9:00pm) or 24 hour(i.e. 21:00) format.
Setting the Time Format: The "12h" or "24h" will be flashing. Use the up or down button to adjust the time format to your preferred setting. Once the desired time format has been selected, quickly press and release the power button to confirm your entry and exit the Time setting.

Setting the Beep

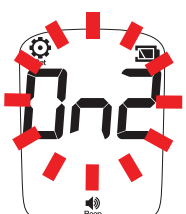


STEP 1

The meter is in the Set mode and the "Set" symbol appears at the top of the screen with the different setting appearing below.

STEP 2

Use either the up or down button to scroll through settings. Once you see that the Beep setting is blinking, quickly press and release the power button. You are now in the Beep setting.



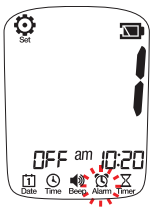
STEP 3

The "OFF", "On1" or "On2" will be flashing. Use the up or down button to adjust the beep sound that you prefer. Once the desired beep sound has been selected, quickly press and release the power button to confirm your entry and exit the Beep setting.

- OFF: Beep function is off.
- On1: The meter makes a few kinds of beeps.
- On2: The meter makes a variety of beeps.

Setting the Alarm

The Alarm will only ring when the meter is turned off.



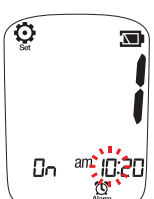
STEP 1

The meter is in the Set mode and the "Set"symbol appears at the top of the screen with the different setting appearing below.



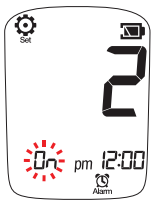
STEP 2

Use either the up or down button to scroll through settings. Once you see that the Alarm setting is blinking, quickly press and release the power button. You may now set your alarm. You may have up to 4 alarms.



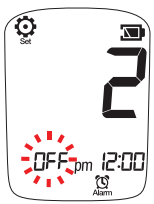
STEP 3

To turn the alarm "On" or "Off", use the up or down button to make your selection then quickly press and release the power button. If "On" is selected, to set your 1st alarm, select the hour and minutes (be sure to properly select a.m. or p.m.) by using the up or down buttons.



STEP 4

Once you have selected the desired hour and minutes quickly press and release the power button and you can proceed to scheduled the 2nd alarm time. By following the same process, you may enter up to 4 alarm times.



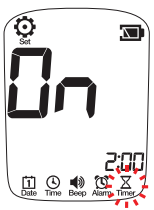
STEP 5

If "Off" is selected, you can quickly press and release both the left and right buttons together to advance to the next alarm and so forth (up to 4 alarm times). To quickly exit Alarm setting, press both the left and right buttons together for 2 seconds.

Setting the Timer

Important:

- Setting the Timer on the meter will set an alarm reminder for you to test. For example, if you would like the Timer to remind you to test 2 hours after meal, set the Timer to 2:00.
- The Timer has to be pre-set before you test your glucose level.
- The Timer will only ring when the meter is turned off.

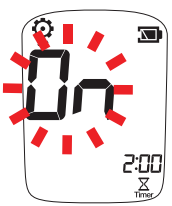


STEP 1

The meter is in the Set mode and the "Set" symbol appears at the top of the screen with the different setting appearing below.

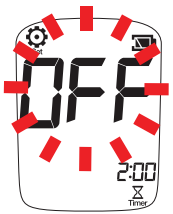
STEP 2

Use either the up or down button to scroll through settings. Once you see that the Timer setting is blinking, quickly press and release the power button. You are now in the Timer setting.



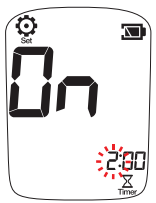
STEP 3

To turn the timer "On" or "Off", use the left or right button to make your selection then quickly press and release both up and down buttons together.



STEP 4

If "Off" is selected, you can quickly press and release the power button to exit the Timer setting.



STEP 5

If "On" is selected, to set your timer, use the up or down button to adjust the hour.
The up button will increase the number and the down button will decrease the number. Once the desired hour has been selected, quickly press and release the power button to confirm your entry and advance to the minutes setting.



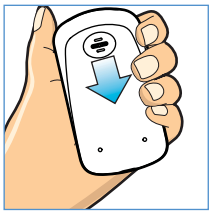
STEP 6

The minutes will be flashing. Use the up or down button to adjust the minutes. Once the desired minutes are selected, quickly press and release the power button to confirm your entry.

STEP 7

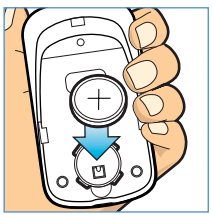
To exit the timer setting, press and release the power button.

How to replace the battery



STEP 1

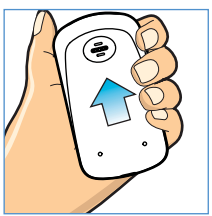
Your Gmate® Origin meter requires one 3volt Lithium battery(CR2032). To remove the battery cover, slide in the direction of the arrow.



STEP 2

Remove the used battery and insert the new one into the tray with the "+" side facing up.

Caution: Dispose of battery according to your local environmental regulations.

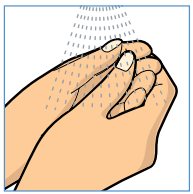


STEP 3

Slide the battery cover back into place and close firmly until it clicks.

Important:

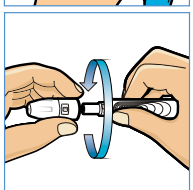
Replacing the battery may require you to reset the date and time. It will NOT affect the meter's memory or the other settings.



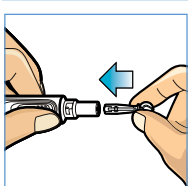
Wash your hands thoroughly with soap and water. Use warm water to increase blood circulation into the fingers.



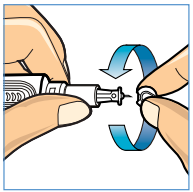
Then dry your hands completely including your puncture site.



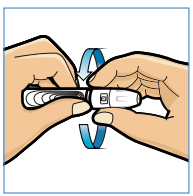
Unscrew the adjustable cap.



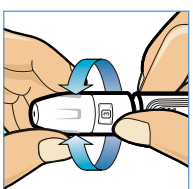
Insert a new sterile lancet into the lancet holder and fix it in firmly.



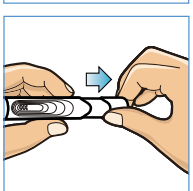
Hold the lancet and the lancing device together in one hand and twist off the protective cap with the other hand.



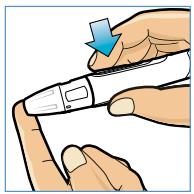
Place the adjustable cap back on the lancing device.



Set your desired depth level by twisting the adjustable cap. The smaller numbers are for shallower puncture that is more suitable for softer skin and bigger numbers are for deeper puncture that is more suitable for thicker or calloused skin.



Draw the sliding barrel to cock the lancing device.

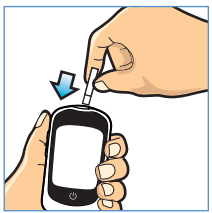


Hold the lancing device against the finger you have chosen to lance. Then press the release button to puncture the spot and collect a blood sample.

After the blood glucose measurement is complete, open the lid of the lid and remove the ladder. The lancet must be discarded in an appropriate container. It is also a good idea to put the lancet on the lancet lid.

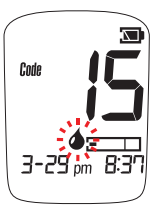
Caution : To reduce the chance of infection:

- Make sure to wash the puncture site with soap and water before sampling.
- Do NOT share lancets and lancing device.
- Do NOT reuse lancets. Lancets are for single use only.
- Keep your meter and lancing device clean.



STEP 1

Insert the Gmate® Test Strip with the electrode end facing up into the test strip port of the Gmate® Origin meter. Make sure that the test strip is inserted all the way. The meter will automatically power on and you will hear a beep.



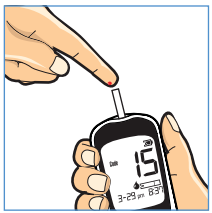
STEP 2

The screen will display the code, date and time. A test strip symbol with a blood drop will appear and flash. The meter and test strip are now ready to test your blood sample.



STEP 3

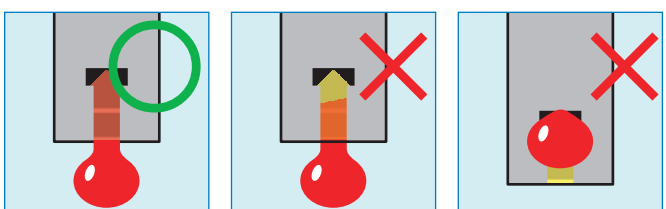
Before you begin, make sure the code number displayed on the screen is the same as the code number printed on the test strip vial. If the code number is different, insert a new test strip. If the code number still does not match, contact your local distributor.



STEP 4

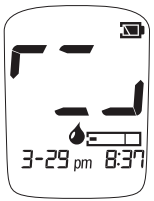
Using the lancing device to obtain the blood drop, place the blood from your finger to the tip of the Gmate® Test Strip. Do NOT press your finger against the test strip. The test strip will automatically draw the blood. Continue to keep your finger on the test strip until the meter chimes indicating that thee volume of blood is sufficient and the meter will begin calculating your blood glucose level.

Important: The volume of blood sample must be at least 0.5 microliter.



Caution:

Please make sure that the blood sample completely fills the designated area of the Gmate® Test Strip.



STEP 5

The meter will now show counting progress during 5 seconds.



STEP 6

When the test is complete, your blood glucose test result will be displayed on the LCD screen.





Caution:

- If your test result is above 600 mg/dL (33.3 mmol/L), "HI" will appear on the display screen.
- If your test result is below 20 mg/dL (1.1 mmol/L), "Lo" will appear on the display screen.



STEP 7

If you want to mark the test as pre-meal or post-meal, press and release up button or down button once. The pre-meal or postmeal symbol will be displayed.

Important:

 Pre-meal  Post-meal

STEP 8

Discard the used test strip. The test result will automatically be stored in memory.

- The meter automatically turns off when not in use for 1 minute. Even in this case, the test results are saved in the meter.
- If your blood glucose test results are below 50mg/dL, above 250mg/dL, or if "Lo" or "HI" displayed on the screen, contact your healthcare professional immediately.
- If your second blood test result is also unusual, perform a control solution test to ensure that your system is working properly (see Control Solution Testing in this user's guide on page 37). Retest your blood.
- If you continue to get unexpected results, immediately contact your physician or healthcare professional.



Caution:

Used test strips and lancets may be considered a biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

Range of expected results

Blood glucose levels may vary depending on food intake, medication, health condition, stress, or physical activity. The following ranges are general reference values only. This system is intended to help users monitor blood glucose levels and blood glucose fluctuations, and is not intended to diagnose diabetes.

Fasting:

* Fasting means not having anything (except water) for at least 8 hours before the test.

Normal	less than 100 mg/dL (5.55 mmol/L)
Prediabetes	100 mg/dL (5.55 mmol/L) to 125 mg/dL (6.94 mmol/L)
Diabetes	126 mg/dL (7.00 mmol/L) or higher

2 hours after a meal:

Normal	less than 140 mg/dL (7.77 mmol/L)
Prediabetes	140 mg/dL (7.77 mmol/L) to 199 mg/dL 11.05 mmol/L)
Diabetes	200 mg/dL or higher (11.11 mmol/L)

* References: http://www.diabetes.org/diabetes-basics/diagnosis

Interpreting Results and Recommended Actions

- Use your test result to help monitor your blood glucose level and blood glucose fluctuations.
- Consider your test result together with your symptoms and the conditions that may affect blood glucose, such as fasting, meals, medication, stress, or physical activity.
- If your test result is unexpectedly high or low, or does not match your symptoms, repeat the test with a new test strip. If repeated results remain unexpected or symptoms persist, seek medical advice.
- Do not change your medication, diet, exercise, or diabetes management plan based only on the test result.
- Test results may be inaccurate due to improper storage of test strips, incorrect testing procedures, or interfering substances. For more information, refer to the section “Interfering Substances (Interference).”



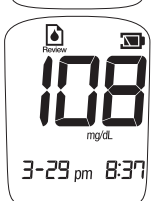
STEP 1

If the meter is off, press and release power button to power the meter on. The screen will display the date, time, and the test strip symbol will begin to blink.



STEP 2(To enter review mode)

When a strip shape is blinking, press and hold the up button. The number of last glucose result will be displayed. Release the up button. The last glucose result will be displayed.



Important:

- If there is no results stored in memory, the meter will display "- - -".

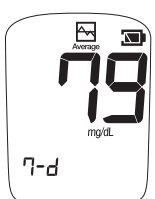


STEP 3

Press and hold the up button. The number of next glucose result will be displayed.
Release the up button. The next glucose result will be displayed. The higher number of the stored result shows you the older result.
Press and release the up button to see the old test results and press and release the down button to see the recent test result.
To exit Review mode, press and release the power button.



STEP 4(To enter the average mode)



To view your glucose test result averages, press and release the power button when a strip symbol is blinking.
Your 7 day average will display. Press and release either the up or down button to view your 7-day, 14-day and 30-day averages.

Important:

The average function will only display the average test result stored in memory within the recent 7-day, 14-day and 30-day.



STEP 5

To switch between Average mode and Standby mode, press and release the power button. To exit the Review mode or Average mode, press and release the power button.



Tip:

- To scroll quickly, press and hold either the up or down button.
- To delete a test result, press and hold both the up and down buttons together. "dEL" will be displayed on the screen and you can select "yes" or "no" by pressing and releasing the up or down button and confirm "yes" or "no" by pressing and releasing the power button.

Power and Stand-by Mode Operation

- Stand-by Mode: The meter automatically enters stand-by mode if there is no operation for approximately 30 seconds. Press the power button to reactivate the meter.
- Power Off: The meter automatically turns off when the test strip is removed or if there is no activity for 2 minutes. You can also manually turn off the meter by pressing and holding the power button for 3 seconds.
- When Not in Use: If the meter will not be used temporarily, remove the batteries to prevent leakage. Store the meter in a dry location at 10 °C ~ 40 °C.

Gmate® Control Solution contains a defined concentration of glucose. It is formulated with buffers, stabilizers, and preservatives. Gmate® Control Solution is used with the Gmate® Blood Glucose Monitoring System to check that the meter and Gmate® Blood Glucose Test Strips are working properly. When the control solution is applied to the Gmate® Blood Glucose Test Strip, glucose in the control solution reacts with the glucose oxidase (GOD) enzyme reagent on the test strip. This reaction generates an electrical current proportional to the glucose concentration. The meter detects this current and displays a glucose result. The result should fall within the control solution range printed on the test strip vial.

- to practice the test process instead of using blood,
- whenever you open a new vial of test strips,
- if you suspect the meter or the test strips are not working properly,
- if you have had repeated unexpected blood glucose results, or
- if your meter is damaged.

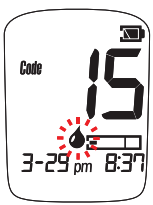
For inquiries regarding the purchase of control solutions, please contact your local GenBody customer service or visit 'www.genbody.com / support / contact'.

Control Solution Infomation
REF No.: PC002-N (Normal Range)
REF No.: PC003-H (High Range)



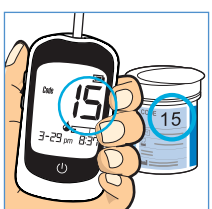
STEP 1

Insert the Gmate® Test Strip with the electrode end facing up into the test strip port of the Gmate® Origin meter. Make sure that the test strip is inserted all the way. The meter will automatically power on and you will hear a beep.



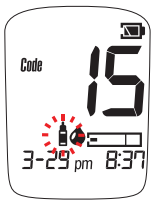
STEP 2

The screen will display the code, date and time. A test strip symbol with a blood drop will appear and flash. The meter and test strip are now ready to test with the control solution.



STEP 3

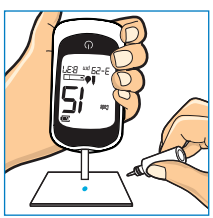
Before you begin, make sure the code number displayed on the screen is the same as the code number printed on the test strip vial. If the code number is different, insert a new test strip. If the code number still does not match, contact your local distributor.



STEP 4

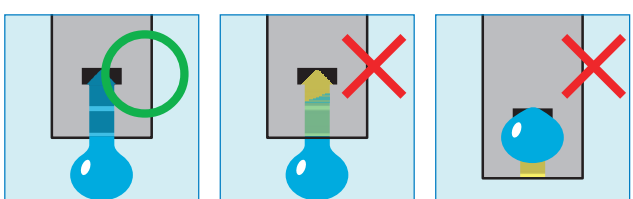
Make sure to mark the test as a control solution test. Press and release either the up or down button once. The control solution symbol will be displayed.

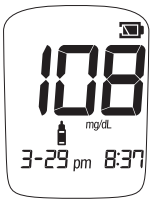
Important: If you mark the Control Solution tests with the control solution symbol, the results will NOT be included in your average results.



STEP 5

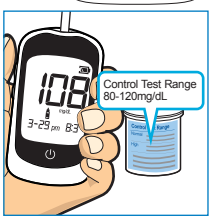
Shake the control solution vial and remove the cap. Gently squeeze a drop of the control solution onto a clean, flat, hard surface. Place the tip of the test strip to the control solution until the meter chimes. The meter will start calculating the result.





STEP 6

When the test is complete, your control solution test result will be displayed on the screen.



STEP 7

Compare the control solution test result displayed on the meter to the control solution range printed on the test strip vial. If the result is not within the indicated range on the test strip vial, the meter and test strips may not be working properly.

Out of range results may be caused by:

- not following the instructions on this USER'S GUIDE,
- expired, contaminated or watered-down control solution,
- expired or damaged test strip,
- control solution test done outside 20°C to 25°C(68°F to 77°F), or a problem with the meter.

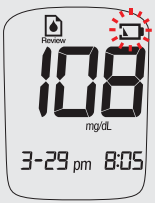
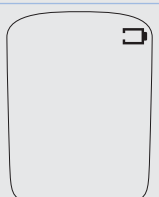
If you continue to get control solution results that fall outside the range printed on the test strip vial, do not use the meter, the test strips, or the control solution. Contact your local distributor.

STEP 8

Discard the used test strip.

Message	*Probable cause*	*What to do*
	Used test strip has been inserted.	The test strip is disposable. This message is displayed on the screen when the used test strip has been inserted in the meter. Please use a new test strip.
	There is a problem in recognizing the test strip.	There is a problem recognizing the test strip. Remove the test strip completely and try again. If the same error appears again, even if you put it in several times, please use a new test strip.
	A meter error has occurred.	This is an error message when there is a problem with the meter. Please read the User's manual carefully and Start again from the beginning.

Message	Probable cause	What to do
	The ambient temperature or the temperature of the meter is too low or too high for a test.	This message is displayed on the screen when the ambient temperature is outside the range of temperatures the meter can use. The operating temperature of the meter is 10-32 °C (50-89.6 °F). If this message is displayed on the screen, please put the meter and the test strip at room temperature for 20 minutes, and then start again from the beginning.
	Error message that may appear during the test.	Error message that may appear during your blood glucose testing. Please check "Performing the Test" page in the User's Guide and repeat the test with a new strip.

Message	Probable cause	What to do
	Battery is running low.	This message is displayed on the screen when the batteries are low. The Meter can measure several tens of times, but it is recommended to replace with a new battery as soon as possible.
	Battery is running way too low.	Battery is too low to perform a test. Replace the battery immediately.
The test strip is inserted in the meter, but the meter is not started.	Battery is running low.	Please replace the battery.
	The batteries are not installed, or the batteries are installed incorrectly.	Check if the batteries are installed correctly. (refer to p.23)
	The test strip is not inserted properly.	Re-insert the test strip making sure it is placed all the way in the meter slot.

Message	Probable cause	What to do
	The meter or test strip is defective	Repeat the test with a new test strip. If the error message appears again, please contact your local distributor.
	Blood or foreign matters have entered the test strip port.	Please contact your local distributor.
The blood samples are applied, but the meter is not start	Applied blood volume is too low.	After inserting a new test strip, test with enough blood volume.
	The meter or test strip is defective	Repeat the test with a new test strip. If the error message appears again, please contact your local distributor.

How to store after use

- Do not store the Blood Glucose Monitoring System near water.
- Store the Blood Glucose Monitoring System in a place where temperature, humidity, etc. are not adversely affected.
- Do not expose the Blood Glucose Monitoring System to direct sunlight for a long time.
- Be careful not to let any foreign materials such as dirt and blood and water on the test strip port.
- Do not store the Blood Glucose Monitoring System in the chemical storage area or gas generating place.

How to store (Gmate® Origin)

- Store the meter in a cool and dry place at room temperature.
- Storage condition: Temperature -20 to 50°C, Relative Humidity 90% or less.
- Operating condition: Temperature 10 to 32°C, Relative Humidity 90% or less.
- Store the meter in a well-ventilated place.

How to store (Gmate® Test Strip)

- Storage condition: Temperature 2 to 32 °C, Relative Humidity 90% or less.
- Operating condition: Temperature 10 to 32 °C, Relative Humidity 90% or less.
- Please be sure to close the vial after use.

Expiration dates (Gmate® Test Strip)

- Unopened: 24 months from date of manufacture.
- Opening: 3 months from the date of first opening.

Be sure to check the expiration dates of the test strip and the control solution.

- Test strips and control solution have expiration dates printed on their vials. When you first open the test strip or control solution vial, please record the open date in the space provided on the label. All test strips and control solutions are valid for no more than three (3) months after the first opening.
- Do not use the test strip and the control solution that passed the expiration date or 3 months after the first opening. The test result may be inaccurate.
- Do not use the test strip with damaged packaging or the lid opened that have been stored for a long time. If the test strip is used, an error message may be displayed on the screen or incorrect test results may be obtained.

Cleaning the meter

- Cleaning frequency: Clean the glucose meter after use or if the device surface becomes contaminated (daily or as needed).
- Cleaning method: Gently wipe the outside of the meter with a soft cloth. This meter is not waterproof, so do not use alcohol or other strong solvents or immerse it in water. Make sure no liquid, dirt, or foreign material enters the test strip port.
- Test strip insertion area: If the strip insertion area becomes contaminated, gently wipe the area with a lint-free cotton swab and allow to dry completely before use.
- Storage: When not using the meter, store it in a dry, clean place at a temperature of 10 to 40 °C.

Cleaning the lancing device

- Wipe the exterior of the lancing device using a soft cloth dampened with water and mild soap.
- Wash the adjustable cap with water and mild soap.
- Do not immerse the lancing device in liquid.

Accuracy

(Gmate® Blood Glucose Test Strips (PS-004))

Accuracy results obtained with Gmate® Origin Blood Glucose Monitoring System have been compared with glucose results obtained through laboratory testing. The evaluation was conducted with 100 different subjects, providing 600 measured values.

System accuracy result for glucose concentrations < 100 mg/dL(5.55 mmol/L)

within ±5 mg/dL (0.27 mmol/L)	within ±10 mg/dL (0.55 mmol/L)	within ±15 mg/dL (0.83 mmol/L)
157 / 180 (87.2%)	180 / 180 (100%)	180 / 180 (100%)

System accuracy result for glucose concentrations ≥ 100 mg/dL(5.55 mmol/L)

within ±5 %	within ±10 %	within ±15 %
346 / 420 (82.3%)	406 / 420 (96.6%)	420 / 420 (100%)

System accuracy results for glucose concentrations between 34.1 mg/dL (1.9 mmol/L) and 475 mg/dL (26.4 mmol/L)

Within ± 15 mg/dL or Within ± 15%
600 / 600 (100%)

Measurement range

Measurement range of Gmate® Origin Blood Glucose Monitoring System is 20 to 600 mg/dL.

Measurement precision

Measurement repeatability

Results for venous blood samples

Mean glucose	Standard deviation	Coefficient of variation(%)
48 mg/dL (2.67 mmol/L)	2.0 mg/dL (0.11 mmol/L)	4.2
99 mg/dL (5.50 mmol/L)	3.3 mg/dL (0.18 mmol/L)	3.3
130 mg/dL (7.22 mmol/L)	5.7mg/dL (0.32 mmol/L)	4.4
230 mg/dL (12.78 mmol/L)	6.1 mg/dL (0.34 mmol/L)	2.6
360 mg/dL (20.00 mmol/L)	6.2 mg/dL (0.34 mmol/L)	1.7

Intermediate measurement precision

Results for control solution

Mean glucose	Standard deviation	Coefficient of variation(%)
48 mg/dL (2.67 mmol/L)	2.0 mg/dL (0.11 mmol/L)	4.2
105 mg/dL (5.83 mmol/L)	2.8 mg/dL (0.16 mmol/L)	2.7
330 mg/dL (18.33 mmol/L)	5.9 mg/dL (0.33 mmol/L)	1.8

User performance evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 laypersons showed the following results:

100 % within ±0,83 mmol/l (±15 mg/dL) of the medical laboratory values at glucose concentrations below 5,55 mmol/l (100 mg/dL), and 100 % within ±15 % of the medical laboratory values at glucose concentrations at or above 5,55 mmol/l (100 mg/dL).

Interference

The effect of various interfering substances was evaluated in whole blood samples on glucose measurements.

Interfering Substance	Therapeutic Concentration	Allowable Concentration
Acetaminophen	2 mg/dL	< 20 mg/dL
Ascorbic acid	0.8 mg/dL	< 3 mg/dL
Bilirubin	1 mg/dL	< 40 mg/dL
Cholesterol	154 mg/dL	< 500 mg/dL
Creatinine	1 mg/dL	< 30 md/dL
Dopamine	0.000002 mg/dL	< 13 mg/dL
EDTA	10 mg/dL	< 200 mg/dL
Galactose	0.1 mg/dL	< 1000 mg/dL
Gentisic acid	10 mg/dL	< 50 mg/dL
Glutathione	-	< 12.3 mg/dL
Hemoglobin	10 g/dL	< 20000 mg/dL

Heparin	0.278 mg/dL (50 IU/dL)	< 2.14 mg/dL (300 IU/dL)
Ibuprofen	1 mg/dL	< 40 mg/dL
Icodextrin	-	< 500 mg/dL
L-DOPA	0.2 mg/dL	< 4 mg/dL
Maltose	100 mg/dL	< 200 mg/dL
Methyl-DOPA	1 mg/dL	< 2.5 mg/dL
Pralidoxime Iodide (PAM)	-	< 20 mg/dL
Salicylate	0.1 mg/dL	< 50 mg/dL
Tolbutamide	1 mg/dL	< 100 mg/dL
Tolazamide	4 mg/dL	< 200 mg/dL
Triglycerides	100 mg/dL	< 3000 mg/dL
Uric acid	5 mg/dL	< 20 mg/dL
Xylose	20 mg/dL	< 60 mg/dL

- Interference that is not listed in this table may affect the results.
- Patients who are undergoing pharmacotherapy may yield false results. Please contact your doctor before use.
- Glucose concentration interval : 100, 300 mg/dL
- The 'allowable concentration' shown in this table is the concentration of interference checked by the test

Product Name	Gmate® Origin
Item	Blood Glucose Monitoring System
Model	PG-310
Certification No.	CE 0197
Test Method	Electrochemical sensor
Sample	Capillary whole blood
Sample Size	0.5㎕
Test Time	5 seconds
Memory	500 Blood glucose tests
Result Range	20-600 mg/dL (1.1 ~ 33.3 mmol/L)
Hematocrit Level	20-60%
Operating Temperature	10-32℃ (50-89.6℉)
Operating Relative Humidity	Less than 90%
Altitude	Up to 3,048 meters (10,000 feets)
Rated Voltage	DC 3Vd.c, lithium battery (CR2032) 1ea,10mW
Size	50.0 mm x 91.5mm x 19.0 mm (1.97" x 3.60" x 0.75")
Weight	57g (2.01oz)

Lancing Device and Lancet Manufacturers

	Lancing Device	***Lancet***
Brand	-	-
Product Name	Lancing Device	Sterile single-use lancet for blood collection
Model	HH Device 1	28G
Item Authorization Number	-	CE0197
Packing Unit	1ea	1 PACK (10 ea)
Intended Use	A device used to collect small quantity of blood sample from the body. Excluding lancet.	A disposable auto-device used for collecting blood sample
Manufacture	Tianjin Huahong Technology Co., Ltd. A01, Plant B, No. 278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin 300308, China	Tianjin Huahong Technology Co., Ltd. A01, Plant B, No. 278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin 300308, China
EU Representative	GMMC S.L. Carrer de Garbí, 15, 46240 Carlet (Valencia), Spain	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Note	-	Disposable medical device Do not re-use

Product Safety Information

Strong electromagnetic fields can interfere with the operation of the meter. However, to ensure reliable operation, the meter should not be used near strong electromagnetic sources (e.g., mobile phones, microwave ovens, or radio transmitters). To avoid electrostatic discharge, do not use the device in very dry environments, especially those with synthetic materials.
The Gmate® Origin meter meets IEC 61010-1, IEC 61010-2-101 safety standards.

Electromagnetic Compatibility (EMC)

The Gmate® Origin meter meets electromagnetic emission standards according to IEC 61326-1, IEC 61326-2-6.

Handling after Transportation and Unpacking

This device has been validated to withstand standard transportation conditions. However, after transportation, allow the product to reach room temperature before use. Avoid excessive shock, impact, or vibration when unpacking.
If the packaging is damaged or the contents appear to have been exposed to moisture, do not use the product and contact the manufacturer.

Reporting of Incidents

In the event of a serious incident related to the use of this product, the user or healthcare professional should report the incident immediately to the manufacturer (GenBody Co., Ltd.) or to the competent authority of the Member State where the user or patient is located.

For any adverse event, safety-related information, or incident report concerning this product, please contact:

GenBody Co., Ltd.
E-mail: help@genbody.co.kr

Tel: +82-63-453-1421
Fax: +82-63-453-1423

SSP is available in EUDAMED

SSP: Summary of safety and performance
The SSP of Gmate® Origin is located at the following URL.
https://ec.europa.eu/tools/eudamed/#/screen/search-device

GenBody warrants that the Gmate® Origin Meter alone should be free of defects in materials and workmanship under regular use without damage for a period of five years since the date of purchase. This warranty pertains only to the original purchaser.

Web site: https://www.genbody.co.kr

Gmate® is created and supported by GenBody Corporation. If you have any questions or concerns, please contact your local GenBody customer service or ‘www.genbody.co.kr/support/contact’.