REF PG300-INT

IVD

User's Guide

Gmate® WHEEL



CE
0197

GenBody

GenBody Inc.
4F, 1-dong, 15, Jayumuyeok 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

PM300-CE0-2101(HH) Rev. Date 2026-10 Printed in Korea

Thank you for purchasing the Gmate® WHeeL 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.

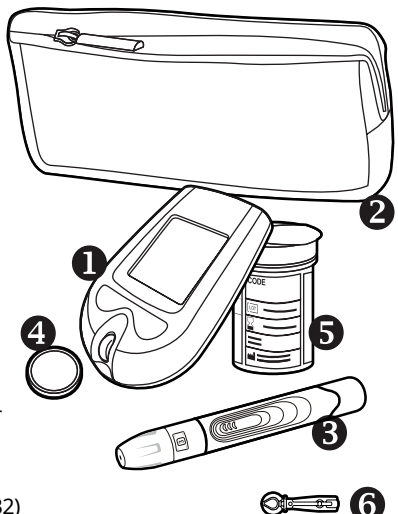
If you are using this product for the first time, it is very helpful to practice with a control solution that can replace your blood. For more information, please refer to the user's manual of the test solution (see page 34).

Contents

Package Contents	4
Before use	5
Identifying Parts and Functions	7
General warnings and Precautions	11
Setting the meter	15
Collecting a blood	20
Alternative Site Testing	23
Performing the Test	26
Check the result	31
Control Solution Testing	34
Error Messages and Troubleshooting	37
Caring for System	41
Performance Characteristics	44
System Specifications	52
Warranty	54

Package Contents

Contained in your package



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

Note

- Please call your local distributor if any items are missing.
- Gmate® Control Solutions are an available separately.
- Documents include this User's Guide, Quick Guide, Log Book and Strip Insert.

Before Use

Symbols

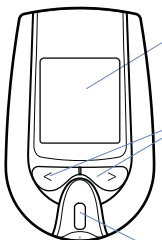
	Caution, see instructions for use
	Single use only
	Expiration date
SN	Serial number
LOT	Lot number
UDI	Unique Device Identifier
IVD	In Vitro Diagnostic medical device
	Manufacturer
EU REP	Authorised representative
	Symbol for temperature limitation
	Consult instructions for use
	Biological risks
	Contains sufficient for <n> tests
	Direct current
	Separate disposal from other household waste
REF	Reference number
CE 0197	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.

Intended Use

- Self-testing, in-vitro blood glucose monitoring system : The Blood Glucose Monitoring System is intended for self-testing in diabetes management. It is used outside the body (in vitro diagnostic use) by layperson with diabetes at home and by healthcare professionals in clinical setting as an aid to monitor the effectiveness of diabetes control.
  This meter can test the glucose levels of blood from your fingertip, Upper arm, Forearm, Hand, Thigh or Calf. However, test results from sites other than the fingertip may differ from fingertip measurements. Consult your doctor or healthcare professional before testing blood from the Upper arm, Forearm, Hand, Thigh or Calf.
- 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 glucose test strip is coated with a reagent between two electrodes. When the reagent reacts with glucose in the blood, current is generated. This product measures the current using whole blood and displays the concentration of glucose in the blood.



Front View

Display Screen

Display test result and other information.

Buttons

Review stored results and adjust parameters in setup mode. You can turn the meter off by pressing '<' button and '>' button at same time.

Eject Wheel

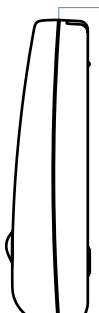
Remove the tested strips by rolling.

Test Strip Port

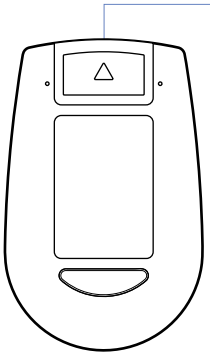
Insert the Gmate® Test Strip. The meter will turn on automatically when inserting the test strip.

Data Port

Transfer test results to computer (Cable is optional.)



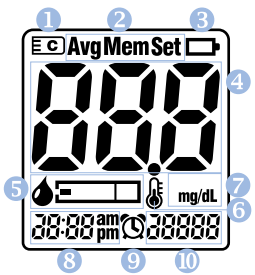
Side View



Battery Cover

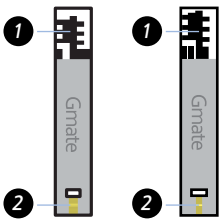
Slide cover off for replacing battery.

Rear View



Display

1. Indicates strip code number.
2. Displays current mode.
3. Warning when the battery is low or need to be replaced.
4. Display test results and messages.
5. Indicate ready to test.
6. Indicates abnormal temperature warning.
7. Display measuring unit.
8. Display current time.
9. Indicates alarm.
10. Display date and year.



Gmate® Blood Glucose Test Strips (PS-004)

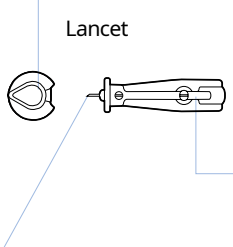
Gmate® Plus Blood Glucose Test Strips (PS-003)

1. Electrodes

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

2. Sample Tip

Apply your blood sample on the edge of this window. Hold the test strip with your fingers here.



Lancet Cap

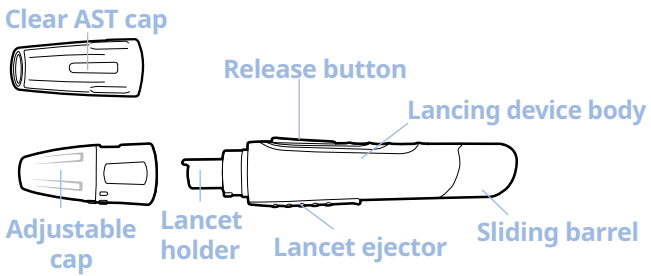
It protects the needle part of the lancet, prevents contact with foreign matter and unintentional puncture. After placing the lancet to the lancing device, remove the cap by twisting it.

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 comes 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.

Clear AST cap

It's a transparent AST cap that is used when blood sampling is done in other area than the fingertips.

* Clear AST cap is an optional accesory. Please contact your local distributor for availability. Lancing device may vary and is subjected to change without notice.

Precautions while using blood glucose Monitoring system

- Since this product is for self-diagnosis or self-monitoring, it is not used for diagnosis of diabetes without the help of a doctor.
- This product is for in vitro diagnostic use only.
- Blood glucose test strips used for testing newborn and pregnant women blood specimens are not validated.
- Be aware of sudden temperature changes. If there is a sudden change in temperature, wait at room temperature for 30 minutes before measuring.
- Do not drop the meter or apply strong impacts.
- Do not disassemble, repair, or modify.
- If any abnormality is found, stop the operation of the device immediately, and request for an inspection from the manufacturer.
- This product should be used with the test strip and control solution manufactured by GenBody.
- Before using this product, please read this manual carefully to ensure safe and accurate measurements.
- In case of using the product with children under 15 years old, It should be get trained about using product and is available under guardian.
- This product contains small measuring instruments which can 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 ℃.
- 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 can result in inaccurate measurement results due to the blood does not enter the test strip in a 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 test strip 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.
- Patients with renal dialysis may be affected by blood glucose measurement. Please use the product after consultation with your doctor.
- Patients with immunoglobulin treatment may be affected by blood glucose measurement. Please use the product after consultation with your doctor.

Precautions when 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.
- The blood glucose test using this system cannot replace medical care at the medical institution. It is just trying to help diagnosis and treatment when consulting a doctor by providing blood glucose information.
- Be careful of sudden temperature changes. If there is a sudden change in temperature, wait at room temperature for 30 minutes before measuring.
- Blood glucose test strips used for testing newborn and pregnant women blood specimens are not validated.
- If the blood sample exceeds 20 ~ 60% of the hematocrit range, the measurement value is not correct. Please contact your doctor or specialist.
- The test strip should be used within 3 months after opening the container lid.
- Conditions of use: Temperature 10 ~ 32 ℃, Relative Humidity 90% or less, Altitude 3,048m.
- The test strip is disposable. Do not re-use.

Precautions when using the lancet

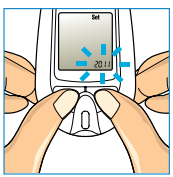
- For the safety of the user, when attaching the lancet to the Lancet holder, connect it without removing the protective lid of the lancet. And then remove the lid before attaching the Adjustable cap.
- Do not use products that have damaged or no protective cap.
- The lancet is a disposable, sterilized 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.

Gmate® WHeeL comes with a preset time, date and year. Before initial use, or when you change battery, you should check the setting of time and date for your local time zone.

You will hear beep sound for 3 times when inserting a test strip if you haven't set your meter at first or you have replaced battery.



STEP 1

Press both '<' and '>' buttons together for 3 seconds. "Set" is displayed on screen while the year is blinking.

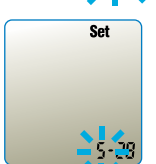
Important :

- Click the '<' button or '>' button to adjust the parameter.
- Press the '<' and '>' buttons together simultaneously to move to the next setting.
- Press the '<' and '>' buttons together for 3 seconds to exit the setting.



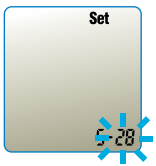
STEP 2

Press and release the button until the correct year appears. Decreasing by '<' button, and increasing by '>' button. Press and release '<' and '>' buttons together to move to "month" setting.



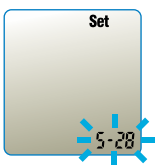
STEP 3

During the month is flashing, press and release the button until the correct month appears. Decreasing by '<' button, and increasing by '>' button. Press and release '<' and '>' buttons together to move to "day" setting.



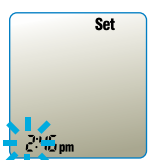
STEP 4

During the day is flashing, press and release the button until the correct day appears. Decreasing by '<' button, and increasing by '>' button.Press and release '<' and '>' buttons together to move to the "date format" setting.



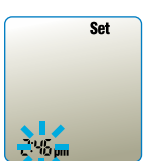
STEP 5

During the date is flashing, click the '<' and '>' button to select "month-day" or "day month" format. Press and release '<' and '>' buttons together to move to "hour" setting.



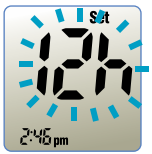
STEP 6

During the hour is flashing, press and release the button until the correct "hour" appears. Decreasing by '<' button, and increasing by '>' button. Press and release '<' and '>' buttons together to move to "minute" setting.



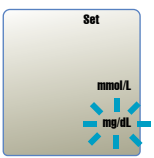
STEP 7

During the minute is flashing, press and release the button until the correct minute appears. Decreasing by '<' button, and increasing by '>' button. Press and release '<' and '>' buttons together to move to the "time format" setting.



STEP 8

During "12h" or "24h" is flashing, press and release the '<' or '>' button to select 12-hour or 24-hour format. Press and release '<' and '>' buttons together to move to "beeper" setting.



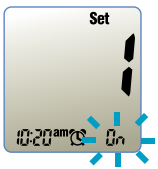
STEP 9

During mg/dL or mmol/L is flashing, press and release the '< ' or '>' button to select mg/dL or mmol/L glucose unit. Press both buttons simultaneously to exit the Set mode.



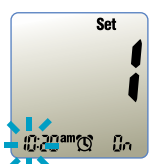
STEP 10

During "On" or "Off" is flashing, press and release the button to select beeper-on or beeper-off. Press and release '<' and '>' buttons together to move to the "alarm" setting.



STEP 11

During "On" or "Off" is flashing, press and release the button to select the first alarm on or off. Press and release '<' and '>' buttons together to move to the second alarm setting when the first alarm is off. Press and release '<' and '>' buttons together to set the time of first alarm when the first alarm is on.



STEP 12

Press and release '<' or '>' button to set the first alarm time when the first alarm is on by the same way of previous the hour and minute settings.

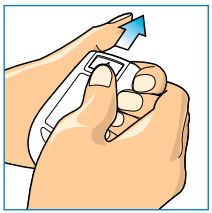
STEP 13

After totally settings of four alarms are completed, press and release '<' and '>' buttons together to finish setup and turn off the Gmate® WHeeL.

Important :

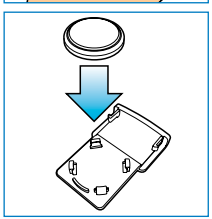
- If you cannot change the Unit of Measurement (UoM) in your device, it means that the local distributor has fixed it as default unit. Please contact the local distributor, if you have any inquiries regarding UoM.

How to replace the battery



STEP 1

Prepare the 3V Lithium Button Cell (CR2032) for replacement. Slide the battery cover off to arrow direction.

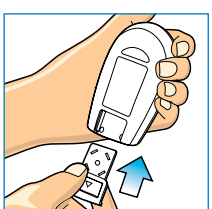


STEP 2

Remove the old battery and place the new one in the tray while the "+" side facing down.

Caution :

Dispose of battery according to your local environmental regulations.

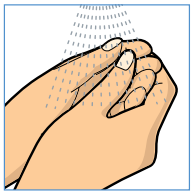


STEP 3

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

Important :

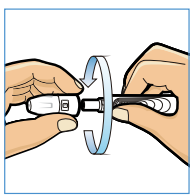
If you do not replace the new battery within one minute after taking the old one out, you must setup again the date and time. Replace the battery do not affect to the meter's memory or user settings.



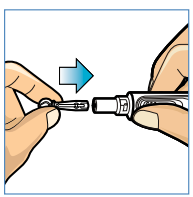
Wash your hands thoroughly with soap and water. Use warm water to increase blood circulation into the fingers.



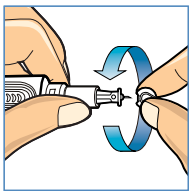
Then dry your hands completely including your puncture site.



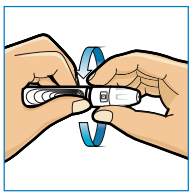
Unscrew the adjustable cap.



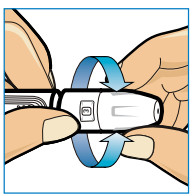
Insert a new sterile lancet into the lancet holder and fix it in firmly.



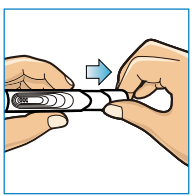
Hold the lancet and the lancing device together in one hand and twist off the protective cap with the other hand.



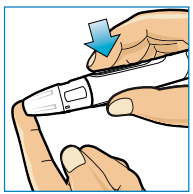
Place the adjustable cap back on the lancing device.



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.

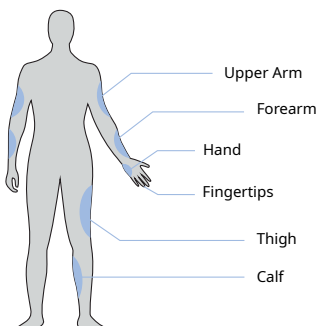
After the blood glucose measurement is complete, open the lid of the lid and remove the lancet. The lancet must be discarded in an appropriate container. It is also a good idea to put the lancet on the lancet lid.

To reduce the risk of infection, follow these steps:

- 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.

Alternative Site Testing

This meter can test the glucose levels of blood from your fingertip, Upper arm, Forearm, Hand, Thigh or Calf. However, test results from sites other than the fingertip may differ from fingertip measurements. Consult your doctor or healthcare professional before testing blood from the Upper arm, Forearm, Hand, Thigh or Calf.

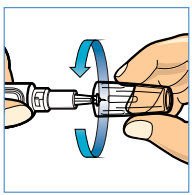


Use blood from	If you are going to test
Fingertip, Upper arm, Forearm, Hand, Thigh, Calf	* Before meals * Two hours or more after meals * Two hours or more after exercise
Fingertip	* When there is the possibility of your blood glucose levels changing rapidly. (e.g. after meals or exercise) * When experiencing symptoms of hypoglycemia such as perspiration, cold sweats, a floating sensation or trembling. * When immediate testing is needed for suspected hypoglycemia * When in poor physical condition, such as with a head cold, etc.

Caution :

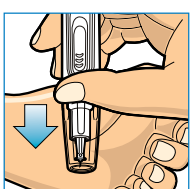
- Please consult with your healthcare professional before taking alternative site measurements.
- Avoid moles, veins, bones, and tendons.
- Do not take alternate site testing if you think your blood glucose level will change drastically within two hours of exercise, within two hours of insulin administration, or within two hours of a meal.
- Do not take alternate site testing if hypoglycemia is suspected or hypoglycemia is not noticeable.
- Do not use an alternative site testing to calibrate a continuous glucose monitoring system.
- Do not use an alternative site testing to calculate insulin doses.
- Finger blood sampling can detect hypoglycemia more quickly than alternative site testing.

Alternative site blood sampling is different from finger blood sampling.



Step 1

After inserting a new sterile lancet firmly into the lancet carrier, place the clear AST cap on top.

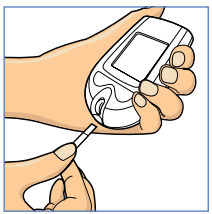


Step 2

Hold the lancing device against the site you have chosen to lance. Avoid moles, veins, bones, and tendons. Press and hold the lancing device on the spot for a few seconds. Then press the release button to collect a blood sample. Observe through the clear cap to see if sufficient amount of blood sample is visible. If the blood volume is insufficient, massage the area gently.

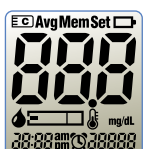
Preparation before Test

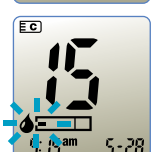
- Stabilize the user's condition before test and ensure that easurements are made in the correct state.
- Make sure that the batteries are connected properly with the meter.
- Make sure that the temperature of environment is 10 ~ 32°C.
- Make sure that the blood glucose test strip has not expired.
- Wash your hands thoroughly with soap and warm water and dry them well.



STEP 1

Insert the test strip while electrode end facing up into the test strip port until stop. The meter turns on automatically.





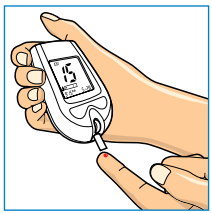
STEP 2

After time and date is displayed for a while. The code number and strip symbol are displayed. A strip symbol with filling blood tells you Gmate® WHeeL is ready to test.



STEP 3

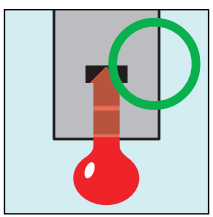
Compare and ensure the displayed code number is same as printed code on test strip container. If displayed code number is different, please use another new strip.

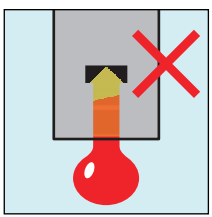


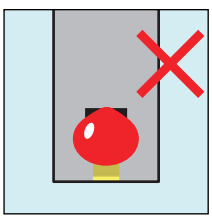
STEP 4

Touch the drop to test strip tip, and hold until the Gmate® WHeeL beeps. Blood sample is drawn into test strip.

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









STEP 5

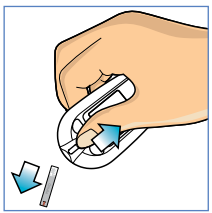
The screen shows counting progress during 5 seconds.





STEP 6

When the measuring complete, there is beep sound. The blood glucose test result display on screen.



STEP 7

Roll the eject wheel to discard the used strip. Test result will be stored in memory automatically.

Important :

The meter turns off automatically after one minute unused. But the test result still remains in memory.

- Repeat the test if your test result is displayed as one of the following:
  - Below 50 mg/dL (2.8 mmol/L)
  - Above 250 mg/dL (13.9 mmol/L)
- If your blood glucose test results display "Lo" or "HI" on the screen, contact your healthcare professional immediately.
- "HIGH": Your test result is above 600 mg/dL (33.3 mmol/L)
- "LOW": Your test result is below 20 mg/dL (1.1 mmol/L)

If you continue to get unexpected results, check your system with control solution. See Control Solution Testing(page 34).

Caution :

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

Range of expected results

Blood glucose levels will vary depending on food intake, medication dosage, health, level of stress, or exercise. Consult your healthcare professional for the target range that is appropriate for you.

Following is the expected blood glucose level.

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:

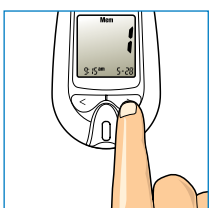
Normal	less than 140 mg/dL (7.77 mmol/L)
Prediabetes	140 mg/dL (7.77 mmol/L) to 199 mg/dL 11.05 mmol/L)
Diabetes	200 mg/dL or higher (11.11 mmol/L)

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



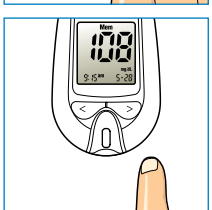
STEP 1

The present time and date will be displayed by clicking any button when the meter is off. After then, a strip symbol is blinking.



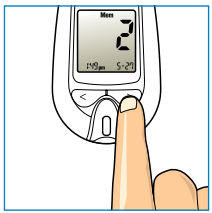
STEP 2 (To enter review mode)

When a strip symbol is blinking, press the '>' button. The last test sequence number (=1) is displayed. Release the '>' button, the last test result is displayed.



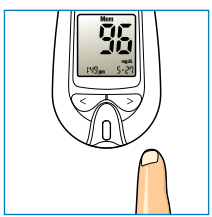
Important :

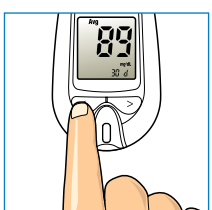
- If there is no result, "- - -" is displayed.



STEP 3

Press the '>' button, the previous test number (=2) is displayed. When release the '>' button, the appropriate glucose result is displayed. Press and release the '>' button, you can review the older test results and the '<' button is for the later results one by one.



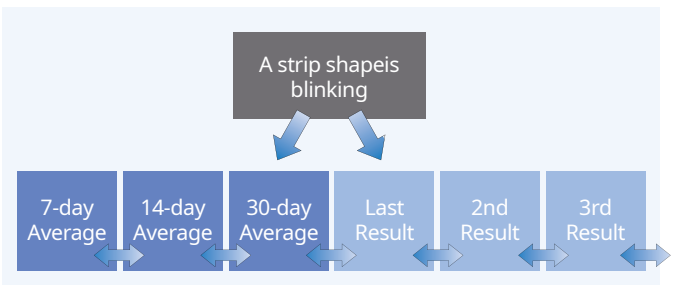


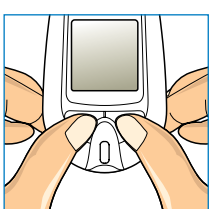
STEP 4 (To review average)

To review your 30-day result average, press and release '<' button while a strip symbol is blinking.
Pressing and releasing the '<' button allow you to scroll forward to 14-day and 7-day averages.

STEP 5

Press and release the '<' button at the last test result, you can see the 30-day average. Press and release the '>' button at the 30-day average, you can see the last test result.





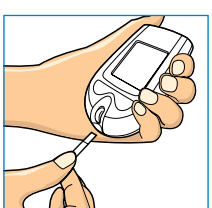
STEP 6

Press both '<' and '>' buttons together to turn the Gmate® WHeeL off.

Control Solution Testing

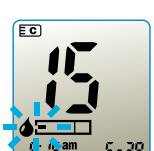
The Gmate® control solution contains an amount of glucose, it is used to ensure your meter and test strips are working properly. Control Solutions are available to purchase separately. Perform a control test in the following instances.

- You want to practice the test process without sampling blood.
- You open a new vial of test strips.
- You suspect the meter or test strips are not working properly.
- You get repeatedly unexpected blood glucose results.
- You have dropped or damaged the meter.



STEP 1

Insert the test strip while the electrode end facing up into the test strip port until it stops. The Gmate® WHeeL will turn on automatically.



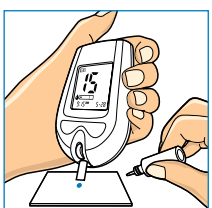
STEP 2

After time and date being shortly displayed, the code number and strip symbol will be displayed. A strip symbol with filling blood indicates the Gmate® WHeeL is ready to test.



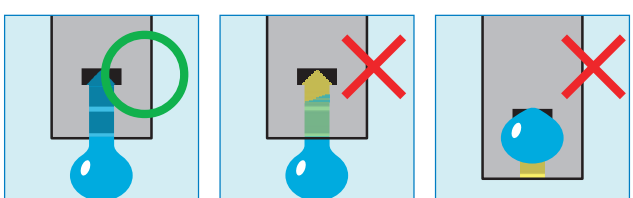
STEP 3

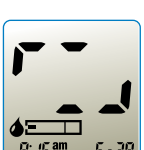
Make sure the displayed code number is the same as printed code of the test strip container. If the displayed code number is different, please use another new strip.



STEP 4

Shake the control solution vial and open the cap. Gently touch test strip tip to control solution drop and stay until it beeps.





STEP 5

The Gmate® WHeeL shows counting progress during 5 seconds.





STEP 6

After the test is finished you will hear the beep sound. The test result of control solution is displayed on screen.



STEP 7

Compare the test result with control solution range which is printed on test strip container. If the test result is not within the range, the Gmate® WHeeL and strip may worked improperly. Repeat the control solution test.

Out-of-range results may occur due to following reasons.

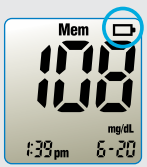
- Error in following the test steps.
- Use expired or contaminated control solution.
- Use expired or damaged test strip.
- Control Solution test done outside 20°C to 25°C(68°F to 77°F), or a problem with the meter.

If your control solution test results are out of the range continuously, do not use the Gmate® WHeeL, the test strips and/or the control solution. Please contact the local distributor.

STEP 8

Roll the eject wheel to discard the used strip. Test result is stored in memory automatically.

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.
	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.

Error Messages and Troubleshooting

Message	Probable cause	What to do
	Battery is running way too low.	Battery is too low to perform a test. Replace the battery immediately.
There is no response after you insert the test strip into the meter.	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.19)
	The test strip is not inserted properly.	Re-insert the test strip making sure it is placed all the way in the meter slot.
	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.

Message	*Probable cause*	*What to do*
	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® WHeeL)

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

How to store (Gmate® Test Strip)

- Storage condition: Temperature 2 to 32 ℃, RH 90% or less.
- Operating condition: Temperature 10 to 32 ℃, RH 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

With a soft cloth dampened with water and mild detergent, gently wipe the exterior of your meter. Do not use alcohol or other solvents to clean. Do not get any liquids, dirt, or other foreign objects through the test strip port.

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 and clear AST cap with water and mild soap. Do not immerse the lancing device in liquid.

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

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)
170 / 180 (94.4%)	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 %
305 / 420 (73%)	395 / 420 (94%)	420 / 420 (100%)

Measurement precision

Measurement repeatability

Mean glucose	Standard deviation	Coefficient of variation(%)
48 mg/dL (2.66 mmol/L)	2.3 mg/dL (0.12 mmol/L)	4.8
100 mg/dL (5.55 mmol/L)	3.1 mg/dL (0.17 mmol/L)	3.1
137 mg/dL (7.61 mmol/L)	4.7 mg/dL (0.26 mmol/L)	3.4
232 mg/dL (12.88 mmol/L)	7.5 mg/dL (0.41 mmol/L)	3.2
365 mg/dL (20.27 mmol/L)	8.3 mg/dL (0.46 mmol/L)	2.3

Intermediate measurement precision

Mean glucose	Standard deviation	Coefficient of variation(%)
48 mg/dL (2.66 mmol/L)	2.0 mg/dL (0.11 mmol/L)	4.2
107 mg/dL (5.94 mmol/L)	3.8 mg/dL (0.21 mmol/L)	3.6
338 mg/dL (18.77 mmol/L)	7.4 mg/dL (0.41 mmol/L)	2.2

User performance evaluation

The blood glucose values of finger capillary blood samples measured by 100 laypersons are shown below.

	Glucose concentration <100 mg/dL (5.55 mmol/L)	Glucose concentration ≥100 mg/dL (5.55 mmol/L)
Within ±15 mg/dL (0.83 mmol/L)	600 / 600 (100%)	
Within ±15%		600 / 600 (100%)

Interference

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

Interference	lower limit (mg/dL)	Upper limit (mg/dL)
Acetaminophen	5	20
Bilirubin	10	40
Ascorbate	0.75	3
Uric acid	5	20
Maltose	50	200
Galactose	250	1000
Urea	125	500
L-DOPA	1	4
Methyl-DOPA	0.625	2.5

Dopamine	3.25	13
Ibuprofen	10	40
Salicylic acid	12.5	50
Tolbutamide	25	100
EDTA	50	200
Pralidoxime Iodide(PAM)	5	20
Cholesterol	125	500
Caffeine	12.5	50
Fructose	12.5	50
Lactose	12.5	50
Lipoic acid	12.5	50
Sucrose	12.5	50
Hemoglobin	5	20
Triglyceride	750	3000
Creatinine	7.5	30
Gentisic acid	12.5	50
Tolazamide	50	200
Glutathione	3.07	12.3
Sodium	787.5	3150
Heparin	0.53	2.14
Icodextrin	125	500
Xylose	15	60

- Glucose concentration interval : 50, 100, 250, 300 mg/dL
- The 'upper limit' shown in this table is the concentration of interference checked by the test.
- 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.

System Accuracy
(Gmate® Plus Blood Glucose Test Strips (PS-003))

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)
109 / 180 (61%)	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 %
214 / 420 (51%)	420 / 420 (100%)	420 / 420 (100%)

Measurement precision

Measurement repeatability

Mean glucose	Standard deviation	Coefficient of variation(%)
45 mg/dL (2.50 mmol/L)	2.8 mg/dL (0.16 mmol/L)	6.3
104 mg/dL (5.78 mmol/L)	3.2 mg/dL (0.18 mmol/L)	3.1
129 mg/dL (7.17 mmol/L)	3.9 mg/dL (0.22 mmol/L)	3.0
212 mg/dL (11.78 mmol/L)	6.3 mg/dL (0.35 mmol/L)	3.0
326 mg/dL (18.11 mmol/L)	10.2 mg/dL (0.57 mmol/L)	3.1

Intermediate measurement precision

Mean glucose	Standard deviation	Coefficient of variation(%)
47 mg/dL (2.59 mmol/L)	2.9 mg/dL (0.16 mmol/L)	6.3
121 mg/dL (6.70 mmol/L)	4.1 mg/dL (0.23 mmol/L)	3.4
314 mg/dL (17.47 mmol/L)	9.7 mg/dL (0.54 mmol/L)	3.1

User performance evaluation

The blood glucose values of finger capillary whole blood samples measured by 100 laypersons are shown below.

	Glucose concentration <100 mg/dL (5.55 mmol/L)	Glucose concentration ≥100 mg/dL (5.55 mmol/L)
Within ±15 mg/dL (0.83 mmol/L)	600 / 600 (100%)	
Within ±15%		600 / 600 (100%)

Interference

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

Interference	**lower limit (mg/dL)**	**Upper limit (mg/dL)**
Acetaminophen	5	20
Acscorbric acid	0.75	3
Bilirubin	5	40
Cholesterol	62.5	500
Creatinine	0.5	10
Dopamine	2.5	20
EDTA	25	200
Galactose	1.56	15
Gentisic acid	125	1000

Glutathione	12	92
Hemoglobin	7	20
Heparin	62.5	500
Ibuprofen	6.25	50
Icodextrin	136.8	1094.4
L-DOPA	0.0625	0.5
Maltose	1250	10000
Methyl-DOPA	125	1000
Pralidoxime Iodide (PAM)	2.5	20
Salicylate	7.5	60
Tolbutamide	12.5	100
Tolazamide	5	40
Triglycerides	187.5	1500
Uric acid	3	24
Xylose	25	200

- Glucose concentration interval : 50, 100, 250, 300 mg/dL
- The 'upper limit' shown in this table is the concentration of interference checked by the test.
- 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.

System Specifications

Product Name	Gmate® WHeeL
Item	Blood Glucose Monitoring System
Model	PG-300
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,15mW
Size	56.0 mm x 88.0 mm x 23.6 mm (2.20" x 3.46" x 0.93')
Weight	46.5g (1.64oz)

Lancing Device and Lancet Manufacturers

	Lancing Device	Lancet
Brand Name	-	-
Item	Lancing Device	Sterile single-use lancet for blood collection
Model	HH Device 1	28G
Certification No.	-	CE0197
Packing Unit	1ea	1PACK (10ea)
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 (Airport Industrial Park), Tianjin 300308, China	Tianjin Huahong Technology Co., Ltd. A01, Plant B, No.278, Hangkong Road, Tianjin Pilot Free Trade Zone (Airport Industrial Park), Tianjin 300308, China
EU Representative		Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Remarks	-	Disposable medical device Do not reuse

Warranty

Warranty

GenBody warrants that the Gmate® WHeeL 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.