REF PG301-INT

IVD

User's Guide

Gmate® VOICE



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 S.A
Boulevard Général
Wahis, 53 1030
Brussels, Belgium

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

PM301-CE0-2101(HH) Rev. Date 2026-10

Printed in Korea

Thank you for purchasing the Gmate® VOICE Blood Glucose Monitoring System.
Please read this User Guide thoroughly before operating the system as it provides important information for proper use.
It is recommended that you this User Guide in a safe place for your future reference.

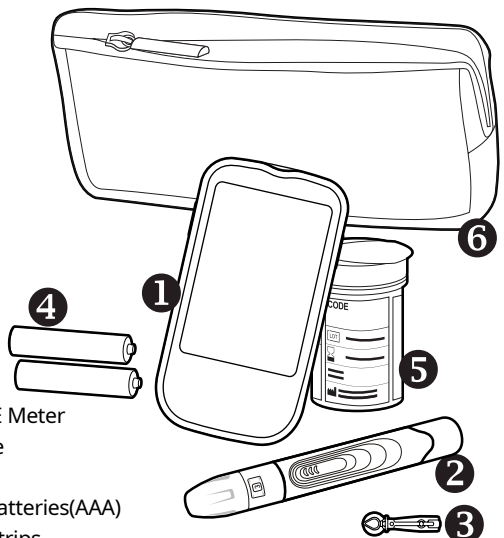
If you are using this product for the first time, it is very helpful to practice with a control solution that can replace your blood.
For more information, please refer to the user's manual of the test solution (see page 41).

contents

Package Contents	4
Before use	5
Identifying Parts and Functions	7
General Warnings and Precautions	11
Setting the meter	15
Collecting a blood	25
Alternative Site Testing	30
Performing the Test	33
Reviewing Results	38
Control Solution Testing	41
Error Messages and Troubleshooting	46
Caring for System	50
Performance Characteristics	53
System Specifications	61
Warranty	63

Package Contents

Contained in your package



1. Gmate® VOICE Meter
2. Lancing Device
3. Lancets
4. Two alkaline batteries(AAA)
5. Gmate® Test Strips
6. Carrying Case

Note

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

Before Use

Symbol

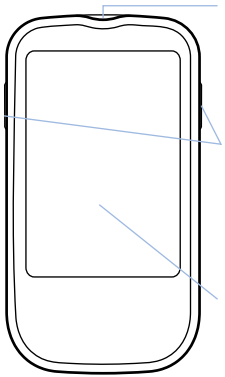
⚠	Caution, see instructions for use
	Single use only
	Expiration date
SN	Serial number
LOT	Lot number
IVD	In Vitro Diagnostic medical device
	Manufacturer
EU REP	Authorised representative
	Symbol for temperature limitation
	Consult instructions for use
	Biological risks
Σ	Contains sufficient for <n> tests
⎓	Direct current
	Separate disposal from other household waste
REF	Reference number
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

Test Strip Port

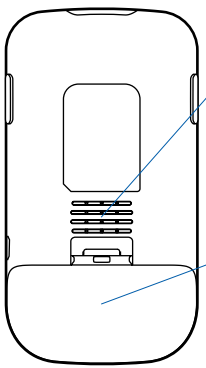
Insert the end of the Gmate® Test Strip here.

Side Buttons

Use the two side buttons to turn the meter on or off, recall stored test results, enter set mode, or adjust settings within set mode. See page 15 for instructions on setting the meter.

Display Screen

Measurement result, operation description with notification, saved result are displayed.



Back View

Speaker

The audible directions and test result readings will be provided through this speaker.

Battery Cover

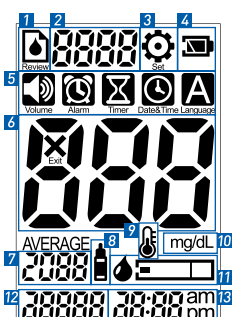
Open this cover to replace the batteries.



Side View

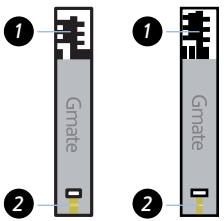
Data Port

Transfer your test results to your PC by connecting the cable here. (Software and cable are available separately.)



Display

1. Review mode
2. Number of saved test results
3. Set mode
4. Battery power level
5. Set mode features: Volume, Alarm, Timer, Date & Time, Language
6. Test results, average, and error messages
7. Year
8. Control solution test
9. Abnormal temperature warning
10. Unit of measure
11. Test strip and blood drop icon
12. Date
13. Time



Gmate® Blood Glucose Test Strips (PS-004)

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

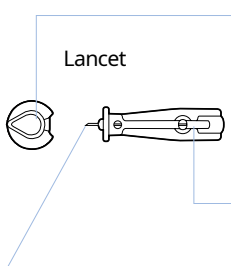
Electrodes

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.

Hold the test strip with your fingers here.



Lancet Cap

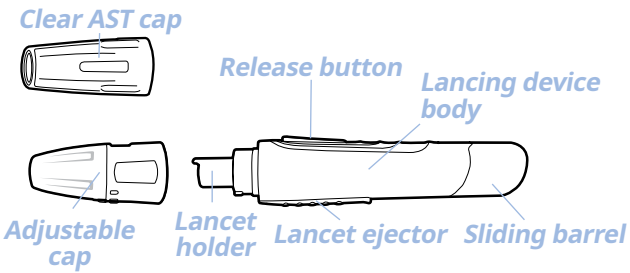
It protects the needle part of the lancet, prevents contact with foreign matter and unintentional puncture. After placing the lancet to the lancing device, remove the cap by twisting it.

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 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.

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 accessory. 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 should not be 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 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 the measurement immediately, and contact your nearest seller immediately.
- 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.
- 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 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.
- 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.

General Warnings and Precautions

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.
- The blood glucose test, using this system, should not be considered as replacement of medical care provided at medical institutions. It is just a method to monitor your sugar level and receive treatment while consulting a doctor and share the test results.
- 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.
- 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 while using the lancet

- For user's safety, while attaching a lancet into the lancing device, connect the lancet without removing the lancet's protective cover (lancet cap). Immediately before installing the lancing device's lid, remove the lancet 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 while 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 the seller as solution and follow up measures will be provided.

Navigating within Set Mode

The sound volume of Gmate® VOICE Meter is preset to level 4.



Step 1

Press either side button to move through each setting option. Shift to the right by pressing the right button, and left by pressing the left button.



Step 2

Press both side buttons simultaneously to enter your selected setting option.

Step 3

Within each setting option, the right button will increase the number and the left button will decrease the number.



Step 4

After the changes are made, press both side buttons simultaneously to confirm your entry.

Step 5

Press both side buttons simultaneously for two seconds to exit from set mode.

- Depending on the amount of batteries remaining, the sound may be limited in size.

Alarm setting

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



Step 1

When the meter is off, press any button to turn the meter on. The date and time are displayed, and the icon of the test strip blinks.

Step 2

Press both buttons at the same time to change to setting mode.

Step 3

Press the left or right button until the alarm icon flashes. Pressing both buttons simultaneously changes the alarm setting.



Step 4

The alarm number is displayed on the right side of the screen and whether or not the alarm is on is displayed at the lower right of the screen. "On" or "OFF" flashes. You can turn the alarm on or off by pressing the Left or Right button. If you turn off the alarm and press both buttons at the same time, you will proceed to the next alarm setting. If you turn on the alarm and press both buttons at the same time, you will advance to the alarm time setting.

Step 5

If the alarm is set to on, the corresponding of 'hour' to alarm flashes. Press the LEFT or RIGHT button until the desired ‘hour’ is displayed. When the adjustment is completed, press both buttons simultaneously to advance to ‘minute’ setting. When the minutes flash, press the left or right button to adjust until the desired ‘minute’ is displayed. When the adjustment is complete, press both buttons simultaneously to advance to the next alarm setting.



Step 6

Repeat steps 4 and 5 to set all four alarms. Press both buttons at the same time to return to setting mode.

Setting the Timer

If the timer is on, it will tell you when to take the next measurement after measuring your glucose in blood. For example, if the timer is set to 2 hours, it tells you to measure your blood glucose before meals and then measure again after 2 hours. However, the alarm and timer functions only when the instrument screen is off.



Step 1

When the meter is off, press any button to turn the meter on. The date and time are displayed, and the icon of the test strip blinks.

Step 2

Press both buttons at the same time to change to setting mode.

Step 3

Press the left or right button until the timer icon blinks. Press both buttons simultaneously to change the timer setting.



Step 4

"On" or "OFF" flashes in the center of the screen, and the timer time is displayed at the bottom of the screen. You can turn the timer on or off by pressing the left button or right button. If you turn off the timer and adjust both buttons at the same time, the timer setting is completed and you are returned to the setting mode again.
If you turn on the timer and press both buttons at the same time, you will advance to the time setting for that timer.



Step 5

If the alarm is set to on, the corresponding of 'hour' to timer flashes. Press the LEFT or RIGHT button until the desired ‘hour’ is displayed. When the adjustment is completed, press both buttons simultaneously to advance to ‘minute’ setting. When the ‘minutes’ flash, press the left or right button to adjust until the desired ‘minute’ is displayed.

Step 6

hen timer setting is completed, press both buttons to return to setting mode.

Setting the Date and Time



Step 1

When the meter is off, press any button to turn the meter on. The date and time are displayed, and the icon of the test strip blinks.

Step 2

Press both buttons at the same time to change to setting mode.

Step 3

Press the Left or Right button until the date and time icon flashes. Pressing both buttons simultaneously changes the date and time setting.



Step 4

If the ‘year’ is blinking, adjust it with the left or right button until the desired ‘year’ appears. Press both buttons at the same time to advance to ‘month’ setting.



Step 5

If the ‘month’ is blinking, adjust it with the left or right button until the desired ‘month’ appears. Press both buttons at the same time to advance to the ‘day’ setting.



Step 6

If the ‘day’ is blinking, adjust it with the Left or Right button until the day appears. Press both buttons at the same time to advance to the ‘hour’ setting.



Step 7

If the ‘hour’ is blinking, adjust it with the left or right button until the desired ‘hour’ appears. Press both buttons at the same time to advance to the ‘minute’ setting.



Step 8

If the ‘minutes’ blink, adjust with the left or right button until the desired ‘minute’ appears. Press both buttons at the same time to advance to the time display setting.



Step 9

If the ‘time’ is blinking, select either 12-hour or 24-hour clock with the left or right button. When the date and time setting is completed, press both buttons at the same time to return to the setting mode.

Setting the Language

The language(s) displayed and spoken by Gmate® VOICE Meter vary by geographic market.
English(En) language option shown in the display images below are for illustrational purpose only, and does not represent the language option of all Gmate® VOICE Meters.



Step 1

When the meter is off, press any button to turn the meter on. The date and time are displayed, and the icon of the test strip blinks.

Step 2

Press both buttons at the same time to change to setting mode.

Step 3

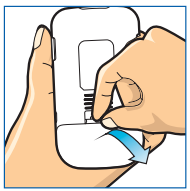
Press the left or right button until the ‘voice guidance’ icon blinks. Press both buttons at the same time to change the ‘voice guidance’ setting.



Step 4

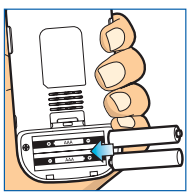
Whether or not voice guidance is on is displayed in the lower left corner of the screen. "On" or "OFF" flashes. You can turn on or turn off voice guidance by pressing the left or right button. When the ‘voice guidance’ setting is completed, press both buttons simultaneously to return to setting mode.

How to replace the battery



Step 1

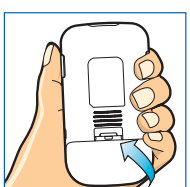
Prepare two new alkaline batteries (AAA, LR03). With the meter turned off, you can open the battery cover by pulling it in the direction of the arrow.



Step 2

Remove the old battery and insert the new one in the correct direction.

- Separate used batteries.



Step 3

Insert the two protruding parts of the bottom of the battery cover first, then push and slide it until it 'Clicks'.

- If you remove the old battery, the date and time will be reset after a while. However, removing the batteries has no effect on the measurement results or other settings.

Be sure to have these items ready before you test :

- Gmate® VOICE Meter
- Gmate® Test Strips
- Lancing Device
- Sterile Lancets

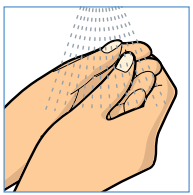
Important

- Gmate® VOICE Meter works only with Gmate® Test Strips.
- Make sure the meter and test strips are about the same temperature before you test. Room temperature is recommended.
- Store unused test strips in their original vial only.
- Do not open the test strip vial until you are ready to perform a test.
- Write the date you first opened the vial on the label. The test strips are only valid for three months from then.
- Close the test strip vial immediately after use to avoid damage from humid environments.
- Do not re-use or share a test strip that has blood or control solution applied. Test strips are for single use only.

Warning

To reduce the risk of infection, follow these steps:

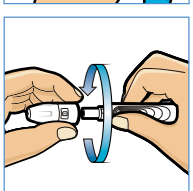
- Wash the blood collection area thoroughly before collection.
- Do not use the lancet and the lancet with others.
- The lancet is disposable. Always use a new lancet.
- Keep the meter and the lancet clean.



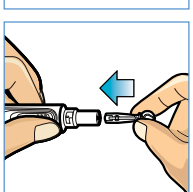
Wash your hands thoroughly with soap and water. Use warm water to increase blood circulation into the fingers.



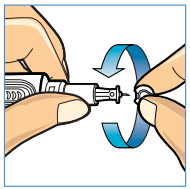
Then dry your hands completely including your puncture site.



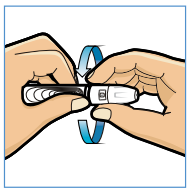
Unscrew the adjustable cap.



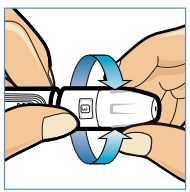
Insert a new sterile lancet into the lancet holder and fix it in firmly.



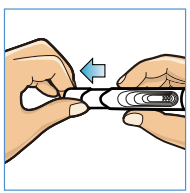
Hold the lancet and the lancing device together in one hand and twist off the protective cap with the other hand.



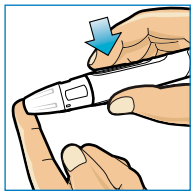
Place the adjustable cap back on the lancing device.



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.

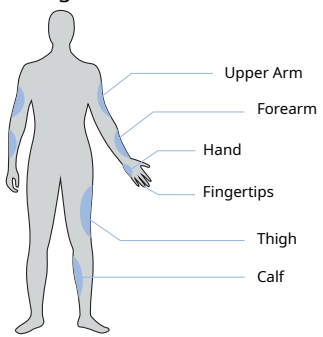


Hold the lancing device against the finger you have chosen to lance. Then press the release button to puncture the spot and collect a blood sample.

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.

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.

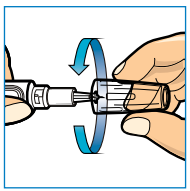


Use blood from	If you are going to test
Fingertip, Upper arm, Forearm, Hand, Thigh, Calf	* Before meals * Two hours or more after meals * Two hours or more after exercise
Fingertip	* When there is the possibility of your blood glucose levels changing rapidly (e.g. after meals or exercise) * When experiencing symptoms of hypoglycemia such as perspiration, cold seats, 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 :

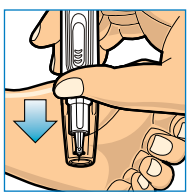
- Please consult with a specialist before taking alternative site measurements.
- Avoid moles, veins, bones, and tendons.
- Do not take alternate site testing if you think your blood glucose level will change drastically within two hours of exercise, within two hours of insulin administration, or within 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.

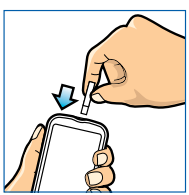


Step 2

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 measurements 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 Gmate® Test Strip into the test strip port of the meter.
Make sure the electrodes of the test strip are facing up, and test strip is inserted all the way in. The meter will automatically turn on and you will hear a sound “Please apply blood,” spoken in your selected language option.



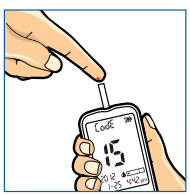
Step 2

Make sure the code number displayed on the meter matches the code number printed on the test strip vial. If the two codes are different, insert a new test strip.



Step 3

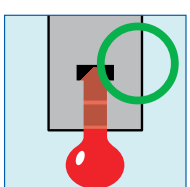
The screen will display the code, date and time. A test strip icon will flash. After a while, blood drop icon flashes, indicating that the meter is ready for the test.

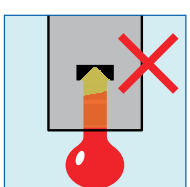


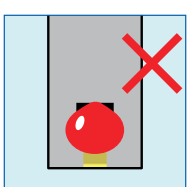
Step 4

Collect a blood sample using the lancing device and then bring the blood sample to the Yellow Filling Window until the meter gives a recognition sound. The yellow window will automatically draw your blood.

- The blood sample volume must be at least 0.5 $\mu\ell$.
- The meter may not start the test if there is not enough blood or drops blood on the test strip.









Step 5

Along with the sound notification, the meter will show the activity indicator for five seconds.

Step 6

The meter will display your blood glucose result on the screen.

- 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)
- "Lo": Your test result is below 20 mg/dL (1.1 mmol/L)
- "HI": Your test result is above 600 mg/dL (33.3 mmol/L)

Step 7

Remove the test strip from the meter. Test results are automatically saved in the meter.

- The meter automatically turns off when not in use for 1 minute. Even in this case, the test results are saved in the meter.
- Used test strips and lancets may be considered a biohazardous waste in your area. Be sure to conform to your local regulations for proper disposal.
- If your blood glucose test results are below 50 mg/dL, above 250 mg/dL, or if "Lo" or "HI" displayed on the screen, contact your healthcare professional immediately.

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 after not having anything to eat or drink (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



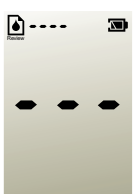
Step 1

When the meter is off, press any button to turn the meter on. The date and time are displayed on the screen, and the test strip icon is blinking on the screen.



STEP 2 Entering results mode

When the test strip icon is blinking, press either side button once. Your most recent test result with date and time will be displayed on the screen.



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



STEP 3 Checking Past results

Press the right button again to see the previous result. Repeat as necessary to view older results. The test number is shown beside the Review icon on the upper left corner. The higher the test number the older the test result. Reversely, press the left button to see more recent results.



STEP 4 Scrolling through Past results

To scroll through the results, press and hold a side button. Then release the button to see one of the displayed results. To skip through 50 results at a time, press one button for a very short time, then quickly press the same button again and hold. Exit review mode by pressing both side buttons and holding for two seconds.



STEP 5 Entering average mode

Press both side buttons while in review mode. Your 7-day average will be displayed. Press and release either side button to view 14-day, and 30-day averages. To scroll through the results, press and hold a side button.



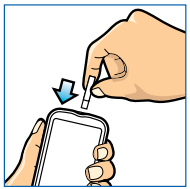
STEP 6 Switching modes

To switch between review mode and average mode, press both side buttons simultaneously. To exit from review mode or average mode, press and hold both buttons together and hold for two seconds.

- Press and hold the button in the result mode to quickly find the result.
- In the result mode, you can find the result more quickly by pressing the button twice shortly and then releasing it continuously. However, this function is available only when more than 100 test results are available.

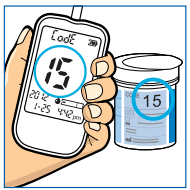
The Gmate® control solution contains an amount of glucose, it is used to ensure your meter and test strips are working properly. Control Solutions are available to purchase separately. Perform a control test in the following instances.

- 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 Gmate® Test Strip into the test strip port of the meter.
Make sure the electrodes of the test strip are facing up, and test strip is inserted all the way in. The meter will automatically turn on and you will hear a sound "Please apply blood," spoken in your selected language option.



Step 2

Make sure the code number displayed on the meter matches the code number printed on the test strip vial. If the two codes are different, insert a new test strip

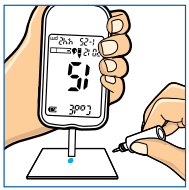


The screen will display the code, date and time. A test strip icon will flash. After a while, blood drop icon flashes, indicating that the meter is ready for the test.



Step 3

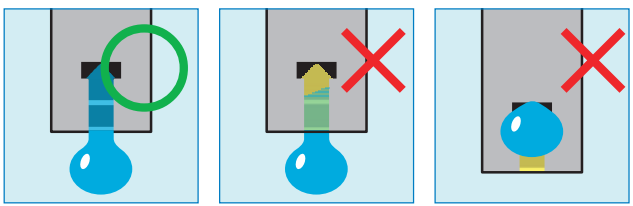
Press either side button to mark the test as control solution test. The control solution icon will be displayed beside the blood drop icon.



Step 4

Shake the control solution vial and remove the cap. Gently squeeze a sample of control solution onto a clean, flat, and hard surface. Place the tip of the yellow filling window of the test strip to the control solution until the meter gives a notification sound. The yellow window will automatically draw the control solution.

- The meter may not start the test if there is not enough blood or drops blood on the test strip.





Step 5

Along with the sound notification, the meter will show the activity indicator for five seconds.

Step 6

The control solution result with the date and time 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 control solution range printed on the vial, the meter or test strip may not be working properly. 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.
- The control solution test is not performed within temperature range of 20 to 25°C (68 to 77°F).
- The meter has some defect.

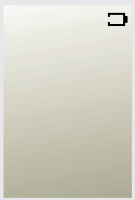
Step 7

Remove the test strip from the meter. Test results are automatically saved in the meter.

- If you mark the control solution tests with the control solution icon, those results will NOT be included in your average results.

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.

Message	*Probable cause*	*What to do*
	Battery is running way too low.	The battery is too low to be performed. Please replace the battery.
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.24)
	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 sample is applied, but the meter is not start.	Applied blood volume is too low. The meter or test strip is defective.	After inserting a new test strip, test with enough blood volume. 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® VOICE)

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

How to store (Gmate® Test Strip)

- Storage condition: Temperature 2 to 32 °C, RH 90% or less.
- Operating condition: Temperature 10 to 32 °C, 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)
163 / 180 (90.5%)	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 %
313 / 420 (74.5%)	415 / 420 (98.8%)	420 / 420 (100%)

Measurement precision

Measurement repeatability

Mean glucose	Standard deviation	Coefficient of variation(%)
48 mg/dL (2.66 mmol/L)	1.9 mg/dL (0.10 mmol/L)	4.0
103 mg/dL (5.72 mmol/L)	4.3 mg/dL (0.23 mmol/L)	4.2
131 mg/dL (7.27 mmol/L)	5.6 mg/dL (0.31 mmol/L)	4.3
231 mg/dL (12.83 mmol/L)	6.4 mg/dL (0.35 mmol/L)	2.8
360 mg/dL (20.00 mmol/L)	6.1 mg/dL (0.33 mmol/L)	1.7

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
106 mg/dL (5.88 mmol/L)	2.8 mg/dL (0.15 mmol/L)	2.7
331 mg/dL (18.38 mmol/L)	6.1 mg/dL (0.33 mmol/L)	1.8

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)	100%	
Within ±15%		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)
131 / 144 (89.6%)	142 / 144 (98.6%)	144 / 144 (100%)

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

within ±5 %	within ±10 %	within ±15 %
429 / 456 (94.1%)	450 / 456 (98.7%)	456 / 456 (100%)

Measurement precision

Measurement repeatability

Mean glucose	Standard deviation	Coefficient of variation(%)
42 mg/dL (2.33 mmol/L)	3.2 mg/dL (0.18 mmol/L)	7.5
91 mg/dL (5.06 mmol/L)	3.2 mg/dL (0.18 mmol/L)	3.5
125 mg/dL (6.94 mmol/L)	3.7 mg/dL (0.21 mmol/L)	3.0
198 mg/dL (11.00 mmol/L)	5.4 mg/dL (0.30 mmol/L)	2.7
372 mg/dL (20.67 mmol/L)	10.6 mg/dL (0.59 mmol/L)	2.9

Intermediate measurement precision

Mean glucose	Standard deviation	Coefficient of variation(%)
45 mg/dL (2.50 mmol/L)	3.3 mg/dL (0.18 mmol/L)	7.3
113 mg/dL (6.28 mmol/L)	3.2 mg/dL (0.18 mmol/L)	2.8
309 mg/dL (17.17 mmol/L)	8.8 mg/dL (0.49 mmol/L)	2.9

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)	100%	
Within ±15%		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.

Product Name	Gmate® VOICE
Item	Blood Glucose Monitoring System
Model	PG-301
Certification No.	CE 0197
Test Method	Electrochemical sensor
Sample	Capillary whole blood
Sample Size	0.5㎕
Test Time	5 seconds
Memory	5000 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, Alkaline batteies (AAA) 2ea,1.5W
Size	62.0 mm x 114.6 mm x 13.0 mm (2.44" x 4.52'' x 0.51')
Weight	80g (2.82oz)

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

GenBody warrants that the Gmate® VOICE 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.