$C \epsilon$
0197

ıl̇ philosys

▲▲

PHILOSYS Co., Ltd.
28-5, Gwangwol-gil, Okgu-eup, Gunsan-si,
Jeollabuk-do, 54172, Republic of Korea

Tel +82-63-453-1421
Fax +82-63-453-1423
Email help@philosys.com

| EC | 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

PM310-CE0-210H   Rev. Date 2021-01   Printed in Korea

User's Guide

Gmate® *Origin*

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

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

Contents

Package Contents

Contained in your package

1. Gmate® Origin 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 Guide and Quick Start Guide.

Symbols

⚠ Caution, see instructions for use

Single use only

Expiration date

SN Serial number

LOT Lot number

IVD In Vitro Diagnostic medical device

Manufacturer

EC 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 dis- posable 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.
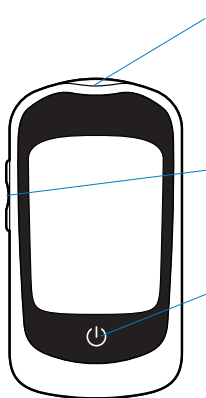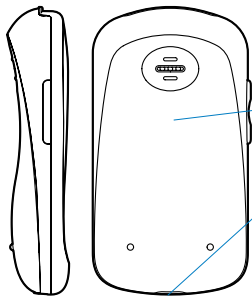
Test Strip Port

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

Side Buttons(Up/Down Button)

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

Power Button

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

Front View

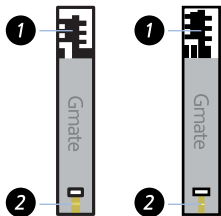### Battery Cover

Open this cover to replace battery.

Data Port

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

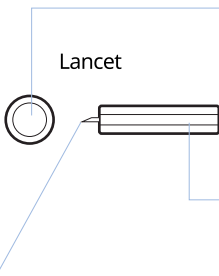Side View   Back View

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.

Lancet

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.
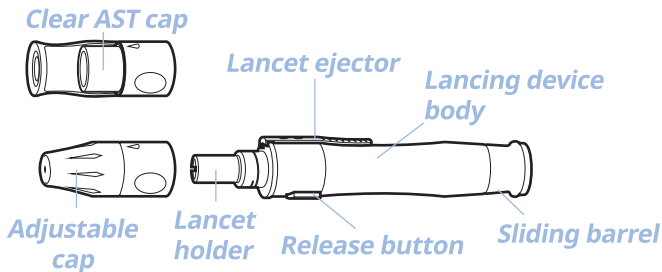
Lancet Body Holder

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 accesory. Please contact your local distributor for availability.
Lancing device may vary and is subjected to change without notice.
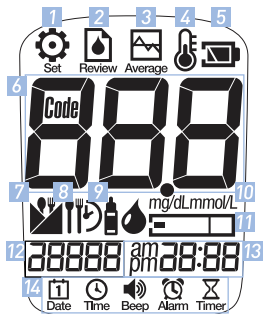
Display

1. Set mode

2. Review mode

3. Average mode

4. Indicates abnormal temperature warning

5. Warning that the battery is low or needs to be replaced

6. Displays test results, average, and error messages

7. Indicates Pre-meal

8. Indicates Post-meal

9. Indicates control solution test

10. Measuring Unit

11. Test strip and blood drop

12. Date

13. Time

14. Features within the Set Mode: Date, Time, Beep, Alarm, Timer

Precautions when using blood glucose monitoring system

- ◼ 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 Philosys.
- ◼ Before using this product, please read this manual carefully to ensure safe and accurate measurements.
- ◼ 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.

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.

The Gmate® Origin Blood Glucose Monitoring System has five user settings: Date, Time, Beep, Alarm, and Timer.
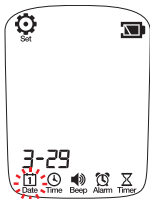
To enter the Set mode, press and hold the power button for 2 seconds when the meter is off. The Date, Time, Beep, Alarm, and Timer settings will appear on the bottom of the screen.

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

Important :

■ Press and release up or down button to make your setting selection.

■ Press and release power button to confirm your setting selection.

■ Press and release power button for 2 seconds to exit the Set mode.

Tip :

■ By pressing on either the up or down buttons, it will allow you to scroll through the different features within each setting.

■ By pressing the power button, this will confirm your entry or desired feature.

■ Within each feature, the up button will scroll the numbers up.

■ Within each feature, the down button will scroll the numbers down.

Setting the Date

STEP 1

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

STEP 2

Use either the up or down button to scroll through settings. Once you see that the Date setting is blinking, quickly press and release the power button. You are now in the Date setting.
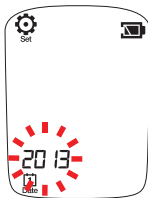
STEP 3

Setting the Year: The Year will be flashing. Use the up or down button to adjust the year. The up button will increase the number and the down button will decrease the number. Once the desired year has been selected, quickly press and release the power button to confirm your entry and advance to the Month setting.
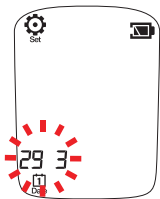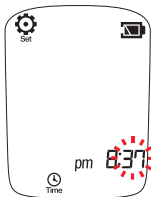
STEP 4

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

STEP 5

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

17

STEP 6

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

Setting the Time

STEP 1

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

STEP 2

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

STEP 3

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

When setting the hour, be sure to properly select a.m. or p.m.

STEP 4

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

STEP 5

The Gmate® Origin System allows you to choose your time format setting to either the 12 hour(i.e. 9:00pm) or 24 hour(i.e. 21:00) format. Setting the Time Format: The "12h" or "24h" will be flashing. Use the up or down button to adjust the time format to your preferred setting. Once the desired time format has been selected, quickly press and release the power button to confirm your entry and exit the Time setting.
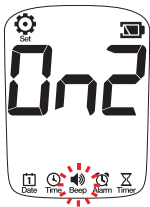
19

Setting the Beep

STEP 1

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

STEP 2

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

STEP 3

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

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

Setting the Alarm

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

STEP 1

The meter is in the Set mode and the "Set"symbol appears at the top of the screen with the different setting appearing below.
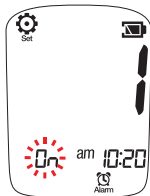
STEP 2

Use either the up or down button to scroll through settings. Once you see that the Alarm setting is blinking, quickly press and release the power button. You may now set your alarm. You may have up to 4 alarms.
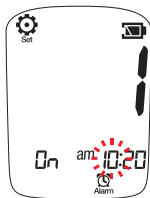
STEP 3

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

21

Setting the meter
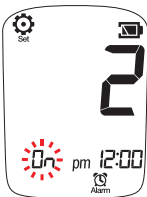
STEP 4

Once you have selected the desired hour and minutes quickly press and release the power button and you can proceed to scheduled the 2nd alarm time. By following the same process, you may enter up to 4 alarm times.
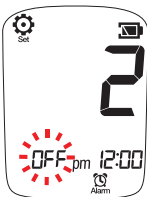
STEP 5

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

Setting the Timer

Important :

■ Setting the Timer on the meter will set an alarm reminder for you to test. For example, if you would like the Timer to remind you to test 2 hours after meal, set the Timer to 2:00.

■ The Timer has to be pre-set before you test your glucose level.

■ The Timer will only ring when the meter is turned off.

STEP 1

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

STEP 2

Use either the up or down button to scroll through settings. Once you see that the Timer setting is blinking, quickly press and release the power button. You are now in the Timer setting.
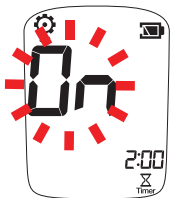
STEP 3

To turn the timer "On" or "Off", use the left or right button to make your selection then quickly press and release both up and down buttons together.
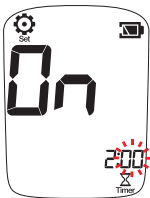
STEP 4

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

STEP 5

If "On" is selected, to set your timer, use the up or down button to adjust the hour.
The up button will increase the number and the down button will decrease the number. Once the desired hour has been selected, quickly press and release the power button to confirm your entry and advance to the minutes setting.
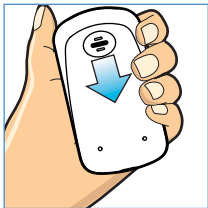
STEP 6

The minutes will be flashing. Use the up or down button to adjust the minutes. Once the desired minutes are selected, quickly press and release the power button to confirm your entry.
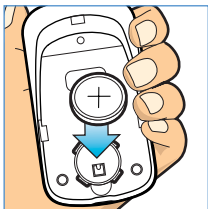
STEP 7

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

How to replace the battery

STEP 1

Your Gmate® Origin meter requires one 3volt Lithium battery(CR2032). To remove the battery cover, slide in the direction of the arrow.
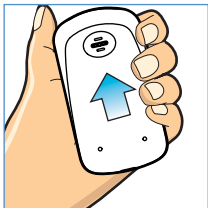
STEP 2

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

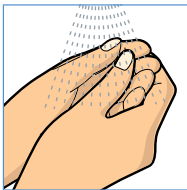*Caution :* Dispose of battery according to your local environmental regulations.

STEP 3

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

Important :

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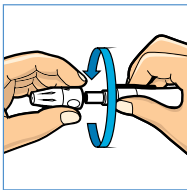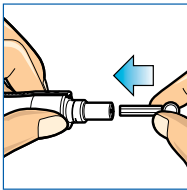
Collecting a blood

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

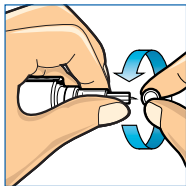Then dry your hands completely including your puncture site.
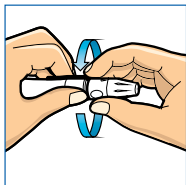
Unscrew the adjustable cap.

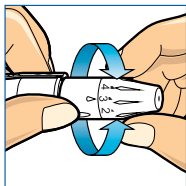Insert a new sterile lancet into the lancet holder and fix it in firmly.

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

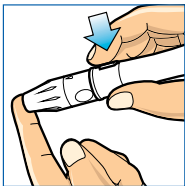Place the adjustable cap back on the lancing device.

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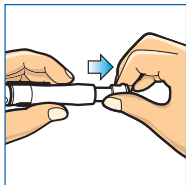
Draw the sliding barrel to cock the lancing device.

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

After the blood glucose measurement is complete, open the lid of the lid and remove the ladder. The lancet must be discarded in an appropriate container. It is also a good idea to put the lancet on the lancet lid.
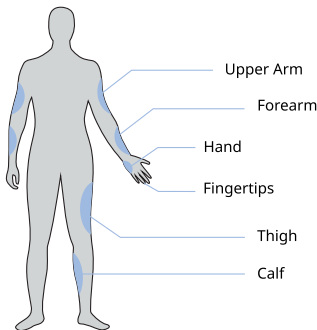
Caution : To reduce the chance of infection :
■ Make sure to wash the puncture site with soap and water before sampling.
■ Do NOT share lancets and lancing device.
■ Do NOT reuse lancets. Lancets are for single use only.
■ Keep your meter and lancing device clean.

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.

Upper Arm
Forearm
Hand
Fingertips
Thigh
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.

Precaution

■ 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.
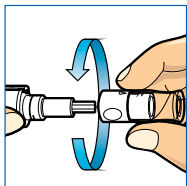
Step 1

After inserting a new sterile lancet firmly into the lancet carrier, place the clear AST cap on top.
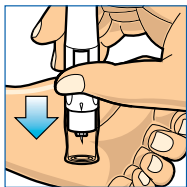
Step 2

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.

Alternative Site Testing

## *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℃.

■ 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 with the electrode end facing up into the test strip port of the Gmate® Origin meter. Make sure that the test strip is inserted all the way. The meter will automatically power on and you will hear a beep.
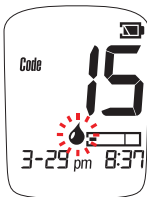
STEP 2

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

STEP 3

Before you begin, make sure the code number displayed on the screen is the same as the code number printed on the test strip vial. If the code number is different, insert a new test strip. If the code number still does not match, contact your local distributor.
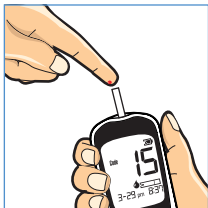
STEP 4

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

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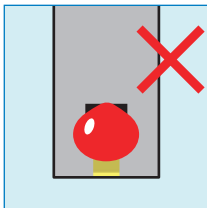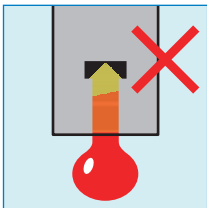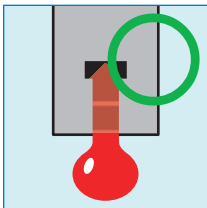
Caution :

Please make sure that the blood sample completely fills the designated area of the Gmate® Test Strip.
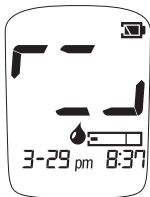
STEP 5

The meter will now show counting progress during 5 seconds.
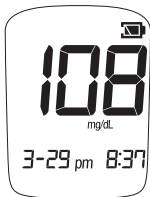
STEP 6

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

Caution :

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

STEP 7

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

Important :

Pre-meal   Post-meal

STEP 8

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

- The meter automatically turns off when not in use for 1 minute. Even in this case, the test results are saved in the meter.
- If your blood glucose test results are below 50mg/dL, above 250mg/dL, or if "Lo" or "HI" displayed on the screen, contact your healthcare professional immediately.
- If your second blood test result is also unusual, perform a control solution test to ensure that your system is working properly (see Control Solution Testing in this user's guide on page 25). Retest your blood.
- If you continue to get unexpected results, immediately contact your physician or healthcare professional.

Caution :

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

Range of expected results

Blood glucose levels 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

Check the result

STEP 1

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

STEP 2(To enter review mode)

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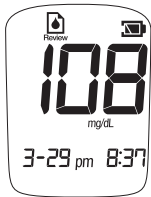
Important :

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

STEP 3

Press and hold the up button. The number of next glucose result will be displayed.
Release the up button. The next glucose result will be displayed. The higher number of the stored result shows you the older result.
Press and release the up button to see the old test results and press and release the down button to see the recent test result.
To exit Review mode, press and release the power button.
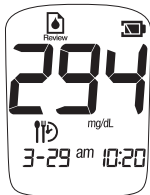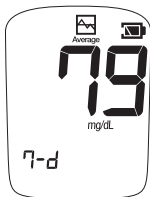
STEP 4(To enter the average mode)

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

Important :

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

39

STEP 5

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

Tip :

■ To scroll quickly, press and hold either the up or down button.

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

Gmate® Control Solution contains a known amount of glucose and is used to verify that the meter and the test strips are working properly. Control solutions are available separately.
Do a control solution test:

■ to practice the test process instead of using blood,

■ whenever you open a new vial of test strips,

■ if you suspect the meter or the test strips are not working properly,

■ if you have had repeated unexpected blood glucose results, or

■ if your meter is damaged.
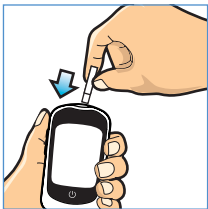
STEP 1

Insert the Gmate® Test Strip with the electrode end facing up into the test strip port of the Gmate® Origin meter. Make sure that the test strip is inserted all the way. The meter will automatically power on and you will hear a beep.
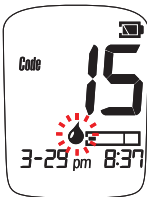
STEP 2

The screen will display the code, date and time. A test strip symbol with a blood drop will appear and flash. The meter and test strip are now ready to test with the control solution.
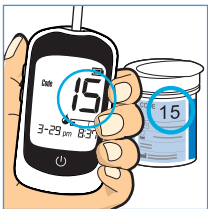
STEP 3

Before you begin, make sure the code number displayed on the screen is the same as the code number printed on the test strip vial. If the code number is different, insert a new test strip. If the code number still does not match, contact your local distributor.
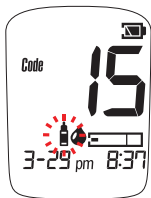
STEP 4

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

Important : If you mark the Control Solution tests with the control solution symbol, the results will NOT be included in your average results.
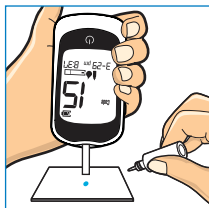
STEP 5

Shake the control solution vial and remove the cap. Gently squeeze a drop of the control solution onto a clean, flat, hard surface. Place the tip of the test strip to the control solution until the meter chimes. The meter will start calculating the result.
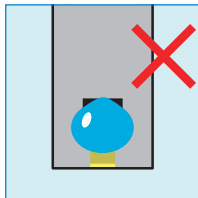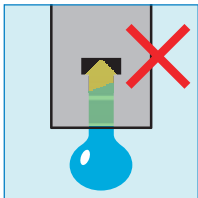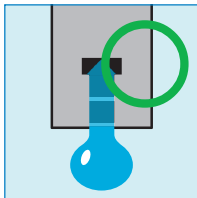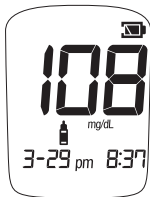
STEP 6

When the test is complete, your control solution test result will be displayed on the screen.
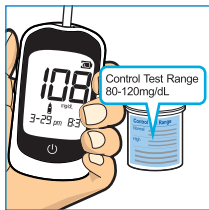
STEP 7

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

Out of range results may be caused by:

■ not following the instructions on this USER'S GUIDE,

■ expired, contaminated or watered-down control solution,

■ expired or damaged test strip,

■ control solution test done outside 20°C to 25°C(68°F to 77°F), or a problem with the meter.

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

STEP 8

Discard the used test strip.
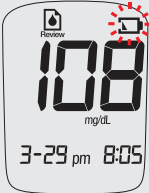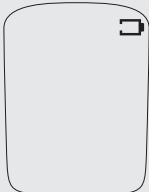
Massage	Probable cause	What to do
E01	Used test strip has been inserted.	The test strip is disposable. This message is displayed on the screen when the used test strip has been inserted in the meter. Please use a new test strip.
E02	There is a problem in recognizing the test strip.	There is a problem 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.
E03	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.

Massage	Probable cause	What to do
E04	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.
E05	Error message that may appear during the test.	Error message that may appear during your blood glucose testing. Please check "Performing the Test" page in the User's Guide and repeat the test with a new strip.

Massage	Probable cause	What to do
	Battery is running low.	This message is displayed on the screen when the batteries are low. The Meter can measure several tens of times, but it is recommended to replace with a new battery as soon as possible.
	Battery is running way too low.	Battery is too low to perform a test. Replace the battery immediately.
The test strip is inserted in the meter, but the meter is not started.	Battery is running low.	Please replace the battery.
	The batteries are not installed, or the batteries are installed incorrectly.	Check if the batteries are installed correctly. (refer to p.25)
	The test strip is not inserted properly.	Re-insert the test strip making sure it is placed all the way in the meter slot.

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

How to store after use

◼ Do not store the Blood Glucose Monitoring System near water.

◼ Store the Blood Glucose Monitoring System in a place where temperature, humidity, etc. are not adversely affected.

◼ Do not expose the Blood Glucose Monitoring System to direct sunlight for a long time.

◼ Be careful not to let any foreign materials such as dirt and blood and water on the test strip port.

◼ Do not store the Blood Glucose Monitoring System in the chemical storage area or gas generating place.

How to store (Gmate® Origin)

◼ Store the meter in a cool and dry place at room temperature.

◼ Storage condition: Temperature -20 to 50℃, 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.

Clinical 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)
157 / 180(87.2%)	180 / 180 (100%)	180 / 180 (100%)

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

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

Measurement precision

Measurement repeatability

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

Intermediate measurement precision

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

User performance evaluation

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

	Glucose concentration <100mg/dL (5.55 mmol/L)	Glucose concentration ≥100mg/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.

Clinical 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)
101 / 120 (84%)	120 / 120 (100%)	120 / 120 (100%)

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

within ±5 %	within ±10 %	within ±15 %
442 / 480 (92%)	466 / 480 (97%)	480 / 480 (100%)

Measurement precision

Measurement repeatability

Mean glucose	Standard deviation	Coefficient of variation(%)
47 mg/dL (2.61 mmol/L)	1.9 mg/dL (0.10 mmol/L)	4.0
102 mg/dL (5.67 mmol/L)	2.9 mg/dL (0.16 mmol/L)	2.9
135 mg/dL (7.50 mmol/L)	3.4 mg/dL (0.19 mmol/L)	2.6
187 mg/dL (10.39 mmol/L)	5.6 mg/dL (0.31 mmol/L)	3.0
302 mg/dL (16.78 mmol/L)	8.7 mg/dL (0.48 mmol/L)	2.9

Intermediate measurement precision

Mean glucose	Standard deviation	Coefficient of variation(%)
42 mg/dL (2.35 mmol/L)	3.1 mg/dL (0.17 mmol/L)	7.3
118 mg/dL (6.57 mmol/L)	3.6 mg/dL (0.20 mmol/L)	3.0
299 mg/dL (16.61 mmol/L)	9.0 mg/dL (0.50 mmol/L)	3.0

User performance evaluation

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

	Glucose concentration <100mg/dL (5.55 mmol/L)	Glucose concentration ≥100mg/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
Haemoglobin	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® Origin
Item	Blood Glucose Monitoring System
Model	PG-310
Certification No.	CE 0197
Test Method	Electrochemical sensor
Sample	Capillary whole blood
Sample Size	0.5$\mu\ell$
Test Time	5 seconds
Memory	500 Blood glucose tests
Result Range	20-600mg/dL (1.1 ~ 33.3 mmol/L)
Hematocrit Level	20-60%
Operating Temperature	10-32℃ (50-89.6℉)
Operating Relative Humidity	Less than 90%
Altitude	Up to 3,048 meters (10,000 feets)
Rated Voltage	DC 3Vd.c, lithium battery (CR2032) 1ea,10mW
Size	50.0 mm x 91.5mm x 19.0 mm (1.97" x 3.60" x 0.75")
Weight	57g (2.01oz)

Lancing Device and Lancet Manufacturers

	Lancing Device	Lancet
Brand	LANZO	NANOLET TM
Product Name	Lancing Device	Sterile single-use lancet for blood collection
Model	Lanzo 1.5 Lancing Device	DB905B
Item Authorization Number	-	CE1639
Packing Unit	1ea	1 PACK (10 ea)
Intended Use	A device used to collect small quantity of blood sample from the body. Excluding lancet.	A disposable auto-device used for collecting blood sample
Manufacture	GMMC Bongseonglo 82-16 (506-6, Dangjeongdong), Gunpo-si, Gyeonggi-do, Republic of Korea	Dong Bang medical co., Ltd. 40&30 Saneopdanji-gil, Ungcheon-eup,Boryeong-si, Chungcheongnam-do, Korea
EU Representative	GMMC S.L. Carrer de Garbí, 15, 46240 Carlet (Valencia), Spain	Meridius Medical Europe Ltd. Unit 3D, North PointHouse, North Point Business Park, New Mallow Road, Cork, T23 AT2P, Ireland
Note	-	Disposable medical device Do not reuse

Warranty

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