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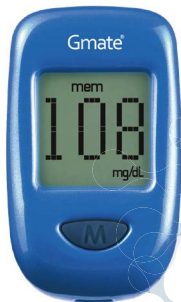
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User's Guide

Gmate[®]STEP



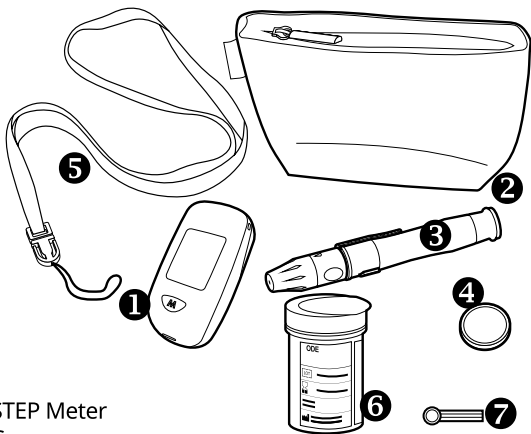
Thank you for purchasing the Gmate® STEP Blood Glucose Monitoring System.

Please read this User Guide thoroughly before operating the system as it provides important information for proper use. It is recommended that you keep 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 for Control Solution Testing (see page 33).

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Package Contents



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

Note

- Please call your local distributor if any items are missing.
- Gmate® Control Solutions are available separately.
- Documents include this User Guide and Quick Start Guide.

Symbols



Caution, see instructions for use



Single use only



Expiration date



Serial number



Lot number



In Vitro Diagnostic medical device



Manufacturer



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



Reference number



This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.

Before Use

Intended Use

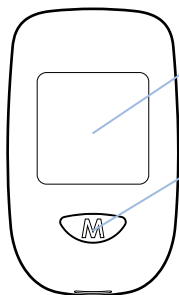
- Self-testing, in-vitro blood glucose monitoring system : The Blood Glucose Monitoring System is intended for self-testing in diabetes management. It is used outside the body (in vitro diagnostic use) by layperson with diabetes at home and by healthcare professionals in clinical setting as an aid to 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.

Identifying Parts and Functions

Gmate® STEP Meter



Front View

Display Screen

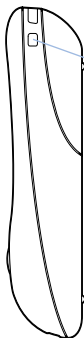
Read your test results, steps and other information.

M-button

Press this button to recall the stored results and adjust the parameters in set-up mode. You can turn the meter off by pressing and holding the 'M' button for 2 seconds.

Test Strip Port

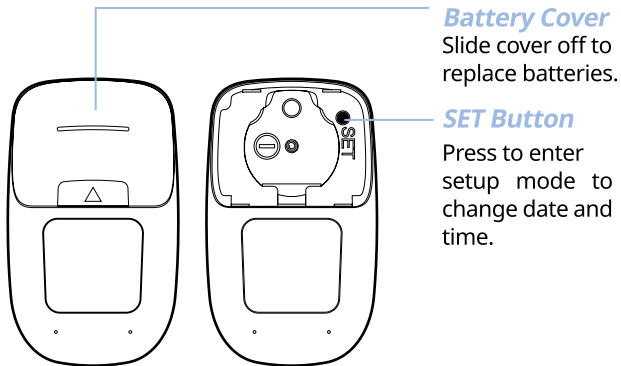
Insert the end of a Gmate® test strip here. The meter will turn on when you insert the test strip.



Side View

Insert hand strap or neck strap.

Identifying Parts and Functions



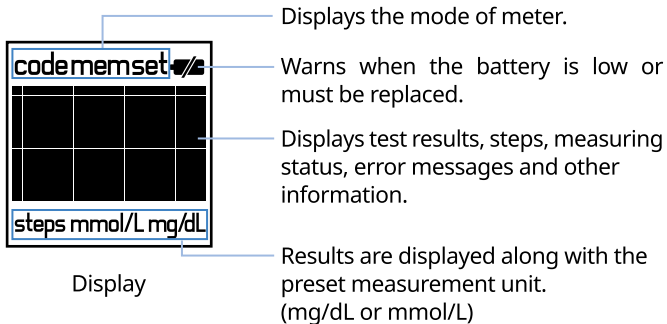
Battery Cover

Slide cover off to replace batteries.

SET Button

Press to enter setup mode to change date and time.

Back View



Displays the mode of meter.

Warns when the battery is low or must be replaced.

Displays test results, steps, measuring status, error messages and other information.

Results are displayed along with the preset measurement unit. (mg/dL or mmol/L)

Display

Identifying Parts and Functions



Gmate® Blood
Glucose Test
Strips
(PS-004)



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

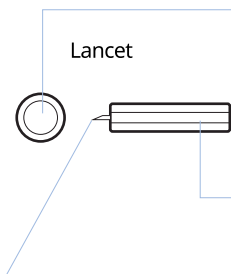
Electrodes

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.

Identifying Parts and Functions



Lancet

Lancet Cap

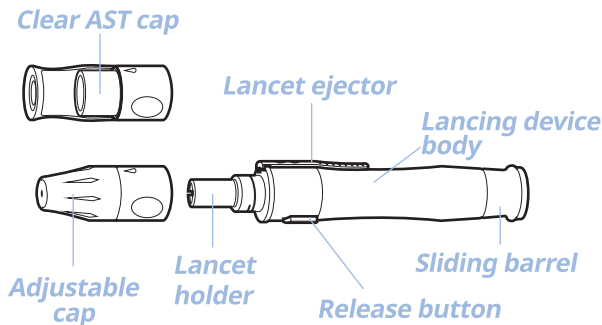
It protects the needle part of the lancet, prevents contact with foreign matter and unintentional puncture. After placing the lancet to the lancing device, remove the cap by twisting it.

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.



Clear AST cap

Lancet ejector

Lancing device body

Adjustable cap

Lancet holder

Release button

Sliding barrel

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.

General Warnings and Precautions

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 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 °C.

General Warnings and Precautions

- 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 Caution

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 °C, 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.

About the Pedometer

Gmate® STEP System is your walking partner, along with built-in pedometer and can help you control your diabetes by counting your steps and testing your blood glucose level.

We recommend that you place the meter in an upper front pocket of your jacket, in a bag tightly held, or worn around your neck with its neck strap.

Place the meter in your pocket

Do not place the meter in the back pocket of your pants.
Place the meter in a tight pocket.

Place the meter in your bag

Place the meter in your pocket or the partition of your bag.

Wear the meter with neck strap around your neck

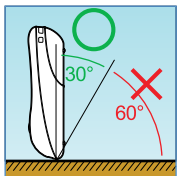
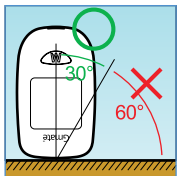
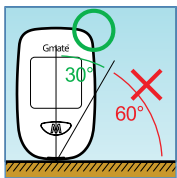
Use the supplied neck strap and place the meter near your chest.

Important :

The meter can count steps only in the following cases :

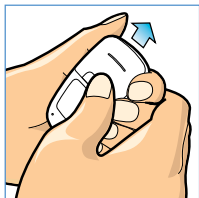
- When the meter is turned off with battery installed.
- 'M' button is pressed and released when the meter is off.

The meter may not be able to count the steps correctly in the following cases:



- When the meter is in review mode, the blood glucose is being tested or the meter is being set.
- When the front of the meter is placed in the angle of less than 60° or horizontal to the ground.
- When the meter is placed in the bag that moves irregularly because it hits your foot, your belt or pants.
- When the unit hangs from your belt, your pants or bag.
- When you walk at an inconsistent pace.
- When you use the meter in a place where lots of up-down movements or vibrations take place.
- When you walk extremely slowly or fast.

Setting the Meter



STEP 1

When the meter is turned off, remove battery cover.



STEP 2

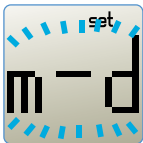
Then press the 'SET' button located in the battery compartment. The meter is now in the setting mode. You may start setting the meter.





STEP 3

The year will flash. Press the 'M' button until the correct year appears. Press the 'SET' button to move to date format setting.



STEP 4

While "m-d" or "d.m" flashes, press the 'M' button to select "month-day" or "day.month" format. Press the 'SET' button to move to month setting.



STEP 5

While the month flashes, press the 'M' button until the correct month appears. Press the 'SET' button to move to day setting.



STEP 6

While the day flashes, press the 'M' button until the correct day appears. Press the 'SET' button to move to hour setting.

Setting the Meter



STEP 7

While the hour flashes, press the 'M' button until the correct hour appears. The meter displays only the 24-hour time format. Press the 'SET' button to move to minute setting.



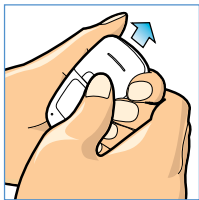
STEP 8

While the minute flashes, press the 'M' button until the correct minute appears.

STEP 9

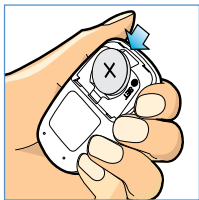
Press the 'SET' button to complete meter set-up and turn off the meter.

Replacing the Battery



STEP 1

Prepare the 3v lithium battery(CR2032) for replacement. Press firmly on the battery cover and slide in the direction of the arrow.

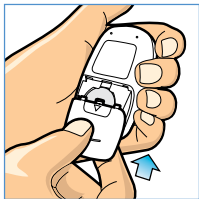


STEP 2

Remove the old battery and place the new one in the tray with the "+" side facing up.



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



STEP 3

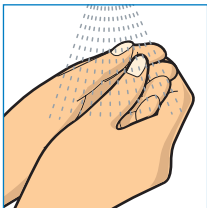
Slide the battery cover back into place and close firmly.

Important :

If you do not replace the new battery within one minute of taking the old one out, you have to reset the date and time. Removing the battery does not affect the meter's memory or user settings.

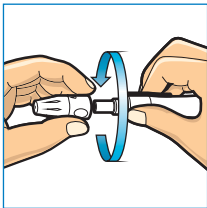
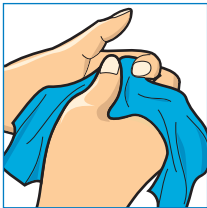
Collecting a blood

Blood Sampling



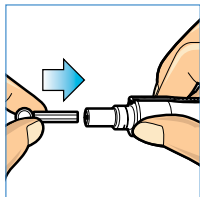
STEP 1

Wash your hands with warm water to increase blood circulation into the fingers. Then dry your hands completely.



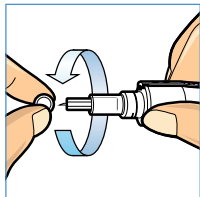
STEP 2

Unscrew the adjustable cap.



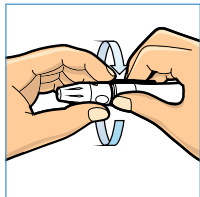
STEP 3

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



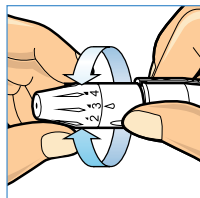
STEP 4

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



STEP 5

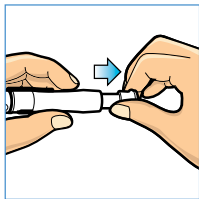
Place the adjustable cap back on the lancing device.



STEP 6

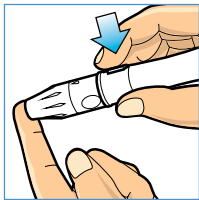
Set your desired depth level by twisting the adjustable cap. The smaller numbers are for shallower puncture that is more suitable for softer skin while bigger numbers are for deeper puncture that is more suitable for thicker or calloused skin.

Collecting a blood



STEP 7

Draw the sliding barrel to cock the lancing device.



STEP 8

Hold the lancing device against the desired finger area. Then press the release button to collect a blood sample.

STEP 9

After the blood glucose measurement is completed, open the cap of the lancing device and remove the used lancet. The lancet must be discarded in an appropriated container according to your local regulations. It's also recommended to put the lancet protective cap back on the used lancet before disposal.

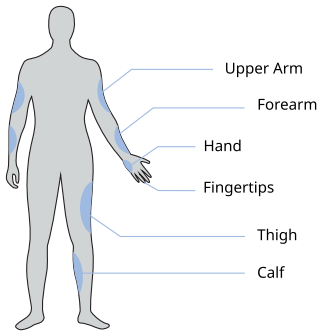
To reduce the risk of infection, follow these steps:

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

Alternative Site Testing

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.



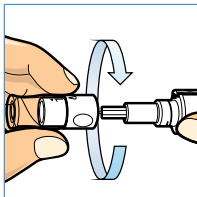
Use blood from	If you are going to test
Fingertip, Upper arm, Forearm, Hand, Thigh, Calf	<ul style="list-style-type: none">* Before meals* Two hours or more after meals* Two hours or more after exercise
Fingertip	<ul style="list-style-type: none">* When there is the possibility of your blood glucose 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.

Alternative Site Testing

Caution :

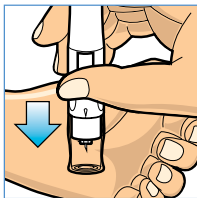
- Please consult with a specialist before taking alternative site measurements.
- Avoid moles, veins, bones, and tendons.
- Do not take alternate site testing if you think your blood glucose level will change drastically within two hours of exercise, within two hours of insulin administration, or within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

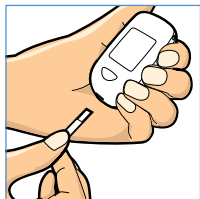
After inserting a new sterile lancet firmly into the lancet carrier, place the clear AST cap on top.



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.

Performing the Test



STEP 1

Hold the test strip with the electrode end facing up. Insert the electrode end into the test strip port on the meter. Insert a new test strip all the way in the test strip port of the meter. The meter will turn on.



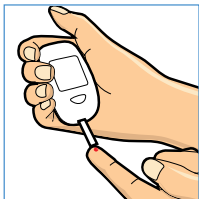
STEP 2

Time will be displayed for a moment. Then the code number and strip symbol will be displayed. An icon of the strip with blood-filled window will appear letting you know the meter is ready to test.



STEP 3

Make sure the code number displayed on the screen is identical to the code number printed on the test strip vial. If the code number does not match, insert new strip.

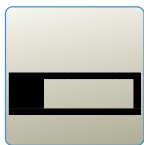
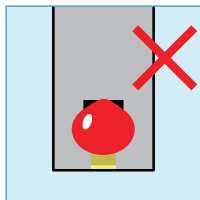
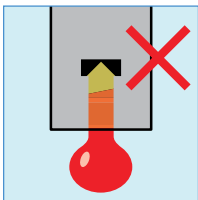
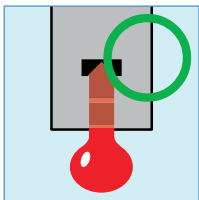


STEP 4

Bring tip of the test strip to touch the drop of blood gently and hold until the meter beeps. Blood is automatically pulled into the test strip.

Important :

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



STEP 5

The meter will now show counting progress for 5 seconds.



STEP 6

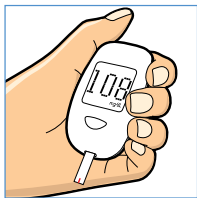
The test result is complete when you hear beeps. Your blood glucose test result is shown on the display screen.

Performing the Test



Caution :

- If your test result is above 600 mg/dL (33.3 mmol/L), "HIGH" will appear on the display screen.
- If your test result is lower than 20mg/dL (1.1 mmol/L), "LOW" will appear on the display screen.



STEP 7

To turn your meter off, simply remove the used test strip. It will turn off automatically. Your test result will automatically be stored in memory with your steps from last blood glucose test.

Important :

- The meter turns off automatically after one minute of nonuse. Test results are still saved in memory nevertheless.

Caution :



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

Unexpected results

If your test result is below 50mg/dL(2.8mmol/L), above 250mg/dL(13.9mmol/L), or you see “LOW” or “HIGH” on the meter display, call your physician or healthcare professional immediately.

If you continue to get unexpected results, check your system with control solution. See Control Solution Testing(page 33).

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.

The expected blood glucose level is as per mentioned below.

■ Fasting:

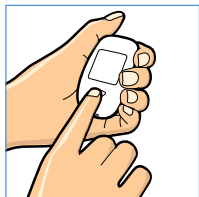
* Fasting means not having anything (except water) for at least 8 hours before the test.

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)

Reviewing Results



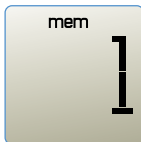
STEP 1 (To enter pedometer mode)

When the meter is turned off, press and release the 'M' button on the meter. Your step count will be displayed. If you carry the meter properly, the built-in pedometer will count your steps.



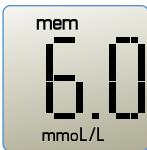
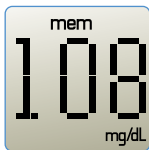
Important :

- Your step count will not increase on the display until after you have walked more than 5 steps.
- Your step count is reset to zero every midnight or when pressing 'SET' button for 2 seconds in pedometer mode.



STEP 2 (To enter review mode)

In the pedometer mode, Press and hold the 'M' button. The number of last glucose result will be displayed. Release the 'M' button to see the first result.



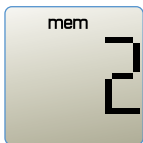
Important :

- If there is no result, the meter will display "- - -".
- The meter will display time, date and the result alternatively the 'M' button is not pressed for 3 seconds.



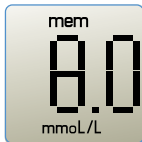
STEP 3

Press and release the 'M' button. Your step count between previous and next glucose results will be displayed.



STEP 4

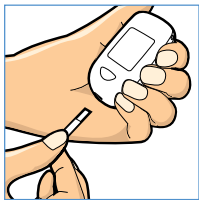
Press and hold the 'M' button. The number of next glucose result will be displayed. Release the 'M' button to see the next glucose result. Each time you press and release the 'M' button, the meter will display the next result up to the last 500 test results.



Control Solution Testing

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

- You want to practice the test process with- out 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

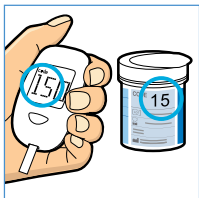
Hold the test strip with the electrode end facing up. Insert the electrode end into the test strip port of the meter. Insert a new test strip into the meter until it stops. The meter will turn on.



STEP 2

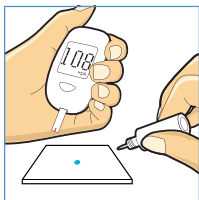
Time will be displayed for a moment. Then the code number and strip symbol will be displayed. An icon of the strip with blood-filled window will appear letting you know the meter is ready to test.

Control Solution Testing



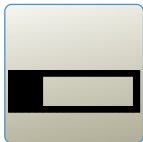
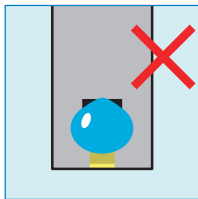
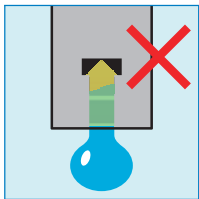
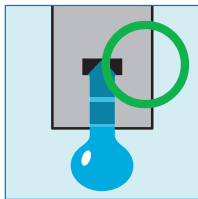
STEP 3

Make sure the code number displayed on the screen is identical to the code number printed on the test strip vial. If the code number does not match, insert new strip.



STEP 4

Shake the control solution vial and remove the cap. Gently touch a drop of control solution to the tip of the test strip. Hold until the meter beeps.



STEP 5

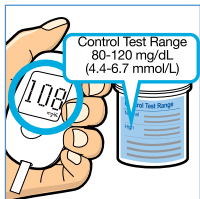
The meter will now show counting progress for 5 seconds.

Control Solution Testing



STEP 6

The test result is complete when you hear beeps. Your control solution test result is shown on the display screen.



STEP 7

Compare the result displayed on the meter to the control solution range printed on the test strip vial. If the results you get are not within this range, the meter and strips may not be working properly. Repeat the control solution test.

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




- not following the instructions on this USER'S GUIDE.
- use of expired, contaminated or watered-down control solution.
- use of expired or damaged test strip.
- malfunctioning 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 and contact the local distributor.

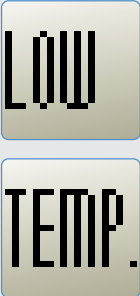
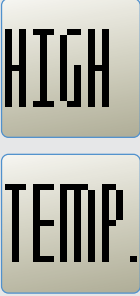
STEP 8

To turn your meter off, remove the used test strip.




Error Messages and Troubleshooting

<i>Message</i>	<i>Probable cause</i>	<i>What to do</i>
	Used test strip has been inserted.	Re-test with a new test strip.
	This error message indicates the test strip may be inserted incorrectly or it is defective.	Repeat to remove and re-insert the test strip or repeat the test with a new test strip.
	This error message indicates a possible meter malfunction.	Review the instructions and retest with a new test strip. If this message reappears, contact the local distributor.

Error Messages and Troubleshooting

<i>Message</i>	<i>Probable cause</i>	<i>What to do</i>
 The error message consists of two stacked rectangular boxes. The top box contains the word "LOW" in a large, black, digital-style font. The bottom box contains the word "TEMP." in the same font style.	Out of operating temperature range.	Appears when environmental temperature is BELOW system operation range, 10~40°C (50~104°F). Repeat the test after the meter and test strip have reached this temperature range.
 The error message consists of two stacked rectangular boxes. The top box contains the word "HIGH" in a large, black, digital-style font. The bottom box contains the word "TEMP." in the same font style.	Out of operating temperature range.	Appears when environmental temperature is ABOVE system operation range, 10~40°C (50~104°F). Repeat the test after the meter and test strip have reached this temperature range.

Error Messages and Troubleshooting

<i>Message</i>	<i>Probable cause</i>	<i>What to do</i>
 The icon shows a battery level indicator with a small black icon of a battery with a slash through it. Below the battery icon, the number '897' is displayed in a large, stylized font. At the bottom left of the icon, the word 'steps' is written in a smaller font.	Battery is low.	Battery is low but you can still perform a few tests. Replace the battery as soon as possible.
  The top icon shows the word 'LOW' in a large, stylized font. The bottom icon shows the word 'BATT.' in a large, stylized font. Both icons include a small black battery icon with a slash through it in the top right corner.	Battery is too low.	Battery is too low to perform a test. Replace the battery immediately.

Error Messages and Troubleshooting

<i>Message</i>	<i>Probable cause</i>	<i>What to do</i>
Meter does not enter the test mode after inserting a test strip.	Battery is running low.	Replace the battery.
	The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive(+) sign facing upward. Insert the test strip with the printed side.
	Test strip is not inserted properly or incompletely inserted into the meter.	Insert the test strip with the printed side up and the electrode end of the strip into the test strip port on the meter.
	Defective meter or test strips.	Contact your local distributor.
	Blood or foreign objects put into the test strip port.	Contact your local distributor.

Error Messages and Troubleshooting

<i>Message</i>	<i>Probable cause</i>	<i>What to do</i>
Test does not start after applying the blood sample.	Blood sample is too small.	Repeat the test with a new test strip and a larger blood sample.
	Defective meter or test strips.	Repeat the test with a new test strip. If same problem occurs, contact your local distributor.
	Sample applied after meter is automatically turned off. (The meter will turn off when left idle for one minute.)	Repeat the test using a new test strip.

Caring for System

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 to 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® STEP)

- 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 opened lid 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.

Caring for System

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.

Performance Characteristics

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)
130/186 (69.8%)	183/186 (98.3%)	186/186 (100%)

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

within ± 5 %	within ± 10 %	within ± 15 %
276/414 (66.6%)	380/414 (91.7%)	414/414 (100%)

Performance Characteristics

Measurement precision

Measurement repeatability

Mean glucose	Standard deviation	Coefficient of variation(%)
48 mg/dL (2.66 mmol/L)	2.0 mg/dL (0.11 mmol/L)	4.2
94 mg/dL (5.22 mmol/L)	3.2 mg/dL (0.17 mmol/L)	3.4
142 mg/dL (7.88 mmol/L)	4.8 mg/dL (0.26 mmol/L)	3.4
241 mg/dL (13.38 mmol/L)	5.8 mg/dL (0.32 mmol/L)	2.4
380 mg/dL (21.11 mmol/L)	5.8 mg/dL (0.32 mmol/L)	1.5

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
110 mg/dL (6.11 mmol/L)	3.2 mg/dL (0.17 mmol/L)	2.9
360 mg/dL (20.00 mmol/L)	6.1 mg/dL (0.33 mmol/L)	1.7

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%)

Performance Characteristics

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.

Performance Characteristics

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)
95 / 198 (48%)	157 / 198 (79%)	198 / 198 (100%)

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

within ± 5 %	within ± 10 %	within ± 15 %
266 / 402 (66%)	398 / 402 (99%)	402 / 402 (100%)

*Measurement precision***Measurement repeatability**

Mean glucose	Standard deviation	Coefficient of variation(%)
40 mg/dL (2.22 mmol/L)	3.8 mg/dL (0.21 mmol/L)	9.4
85 mg/dL (4.72 mmol/L)	3.7 mg/dL (0.20 mmol/L)	4.3
135 mg/dL (7.50 mmol/L)	5.1 mg/dL (0.28 mmol/L)	3.8
202 mg/dL (11.22 mmol/L)	7.3 mg/dL (0.40 mmol/L)	3.6
365 mg/dL (20.28 mmol/L)	11.8 mg/dL (0.65 mmol/L)	3.2

Performance Characteristics

Intermediate measurement precision

Mean glucose	Standard deviation	Coefficient of variation(%)
45 mg/dL (2.50 mmol/L)	3.8 mg/dL (0.21 mmol/L)	8.4
115 mg/dL (6.39 mmol/L)	3.8 mg/dL (0.21 mmol/L)	3.3
377 mg/dL (20.94 mmol/L)	13.0 mg/dL (0.72 mmol/L)	3.5

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	92
Ibuprofen	10	20
Salicylic acid	12.5	500
Tolbutamide	25	50
EDTA	50	1094.4
Pralidoxime Iodide(PAM)	5	0.5
Cholesterol	125	10000
Caffeine	12.5	1000
Fructose	12.5	20
Lactose	12.5	60

Performance Characteristics

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 Specifications

Product Name	Gmate® STEP
Item	Blood Glucose Monitoring System
Model	PG-201
Certification No.	CE 0197
Test Method	Electrochemical sensor
Sample	Capillary whole blood
Sample Size	0.5 μl
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°C (50-89.6°F)
Operating Relative Humidity	Less than 90%
Altitude	Up to 3,048 meters (10,000 feet)
Rated Voltage	DC 3V, lithium battery (CR2032) 1ea,10mW
Size	36.7mm x 61.7 mm x 15.8 mm (1.44" x 2.43" x 0.62")
Weight	30g (1.06oz)

System Specifications

	Lancing Device	Lancet
Brand Name	Lanzo	NANOLET TM
Item	Lancing Device	Sterile single-use lancet for blood collection
Model	Lanzo 1.5 Lancing Device	DB905B
Certification No.	-	CE1639
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	GMMC Bongseonglo 82-16 (506-6, Dangjeong-dong), 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 Point House, North Point Business Park, New Mal-low Road, Cork, T23 AT2P, Ireland
Remarks	-	Disposable medical device Do not reuse

Philosys warrants that the Gmate® STEP 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.