

Gmate™ **STEP**

User's Guide

Thank you for purchasing the Gmate™ System.

Please read this User's Guide carefully before using to ensure correct use.

Please keep this User's Guide for your future reference.

Gmate™ System is very easy to carry around and able to be used for measuring the glucose level in whole blood and steps anytime. It is also very simple, easy and foolproof. You don't have to worry about coding your meter because the Gmate™ meter does it automatically. The system should be used only for testing glucose and only with fresh capillary whole blood samples. The system is intended for self-testing by persons with use at home and in clinical settings. It should not be used for the diagnosis of diabetes without the guidance of a healthcare professional or for the testing of newborn.

Features

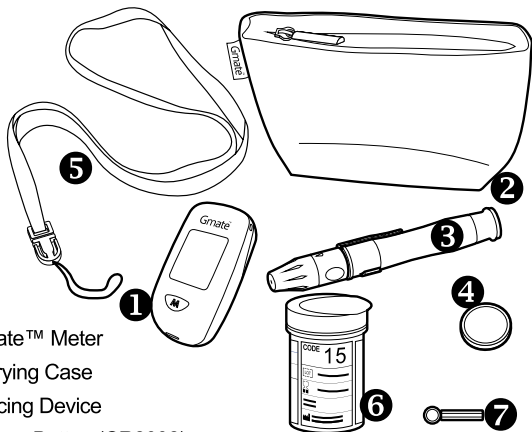
- 1** Gmate™ meter has only one button to navigate all functions easily with simple operation.
- 2** It is small size, stylish design, and ease of use allows you to take it everywhere.
- 3** It can show all information variously.
- 4** It requires very small volume(0.5uL) and display the result in 5 seconds.
- 5** It can measure glucose in whole blood at AST(Alternate site testing).
- 6** It can measure glucose concentration when the test strip inserted without changing the code number or using the code chip.

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About Gmate™ System

Gmate™ System includes:



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

Documents in your system include this USER'S GUIDE, QUICK GUIDE and LOGBOOK.

If any items are missing, call your local distributor.

Before Starting

Symbols



Caution, see instructions for use



Single use only



Expiration date

SN

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

Intended Use

Gmate™ system is intended for self-testing to monitor glucose concentrations in fresh whole blood. Gmate™ system is for use outside body(in vitro diagnostic use) in fingertips, forearm, upper arm, hand, thigh and calf testing.

Test principle

The Gmate™ system is based on measurement of a small electrical current produced by the reaction of glucose in the blood sample with the reagents on the strip. This current is changes to the amount of glucose in the blood sample. The glucose concentration in the sample is calculated based on the electrical current and displayed on the meter.

Setting the time and date

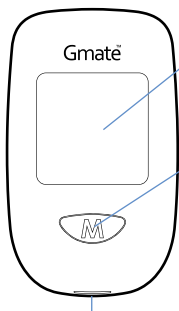
Your Gmate™ meter comes with the time, date and year pre-set. Before using your meter for the first time or if you change the meter battery, you should check and set the time and date. If you does not set your meter for the first time or after changing the battery, you can hear beep 3 times when inserting a test strip.

See the 30 page(Setting the Meter) to ensure your desired settings are saved.

There are two types of glucose units: mg/dL and mmol/L.

Your Gmate™ meter does not allow you to change the glucose unit yourself in order to prevent misinterpretation of the test results. The glucose unit has been preset before leaving our factory. If you have received a Gmate™ meter with the glucose unit different from the method you use to measure your glucose levels, do not perform any tests, and contact your local Philosys distributor for assistance .

Names and Functions of the Parts



Front View

Display Screen

This is where you read your test results, steps and other informations.

M-button

The 'M' button is used 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.



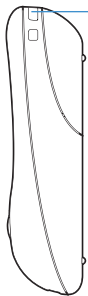
Gmate™ Test Strip

Electrodes

The end of the test strip is inserted into the test strip port of the meter with the end facing up.

Sample Tip

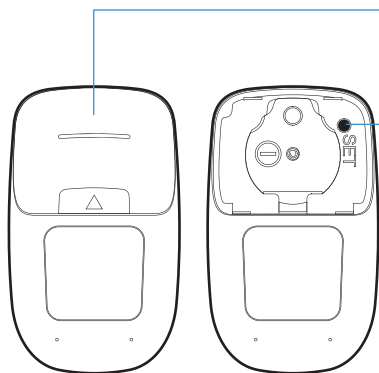
The end of the test strip where the blood sample is drawn into.



Strap Hole

It is for hand-strap or neck-strap.

Side View



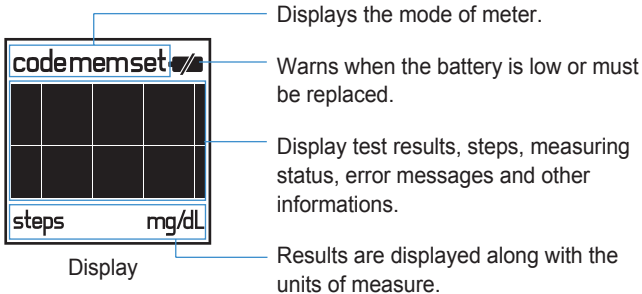
Battery Cover

Slide cover off to replace batteries.

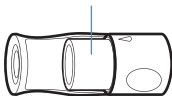
SET Button

Used to enter the set-up mode for changing the date and time.

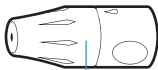
Back View



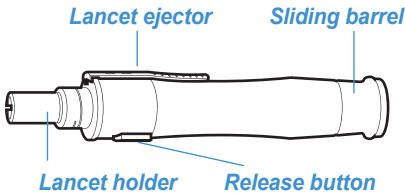
Clear AST cap



Adjustable cap



*Clear AST cap is an optional accessory.
Please contact your local distributor.



Lancing Device

Cautions

Cautions for System

- The Gmate™ System is intended for use outside the body (in vitro diagnostic use) only.
- The Gmate™ System is used only for measuring fresh capillary whole blood.
- The Gmate™ meter should only be used with Gmate™ Test Strip and Gmate™ Control Solution.
- Do not use the Gmate™ System for diagnosis of diabetes without the guidance of healthcare professional, for testing on newborns and with arterial blood.
- The Gmate™ System contains small parts that may be dangerous if swallowed.
- Check the package before starting the measurement.
- Be sure to read user's guide and the test strip insert found in the test strip box carefully before testing.
- Do not make any decision of medical relevance without first consulting your physician and/or having received appropriate training.

Cautions for Meter

- Keep the meter out of reach of young children. If a young child swallows battery, battery cover, immediately consult with a doctor.
- Do not swing the meter by holding the neckstrap. You may injure yourself or other people.
- Do not throw the battery into fire.
- Do not disassemble or modify the meter.
- Do not subject the meter to severe shock, drop or step on meter.
- The meter is not waterproof. Do not wash it or touch it with wet hands.
- Do not wipe the meter with thinner, or abrasive cleaners.
- Avoid the meter being exposed to high temperature, high humidity, rain and/or dust when using or storing the meter.
- Do not test glucose instantly when the meter move to a place where it is a sudden change in temperature. Wait 20 minutes and start testing.

Cautions for Test Strip

- Store the test strip in a cool, dry place between 2° and 32°C(36° and 90°F).
- Keep away from direct sunlight and heat.
- After removing test strip from the vial, immediately close the vial cap tightly.
- You may get the inaccurate result if vial cap opened long period of time.
- Don't drop the blood on the surface of test strip directly.
- Do not press the test strip against your finger. This may affect inaccurate aspiration of blood.
- Do not use a test strip that appears damaged or has been used. Test strips are for single use only.
- Store test strips in their original vial.
- After you take a test strip out of the vial, be sure to use it within three minutes.
- Always use test strips within 3 months(90days) after first opening.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.
- Do not bend, cut, or alter test strips.

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 the upper front pocket of your jacket, in a bag you hold tightly, or wear the meter with neck strap around your neck.

Place the meter in your pocket

Do not place the meter in the back pocket of your pants.
Place the meter in the pocket you hold tightly.

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

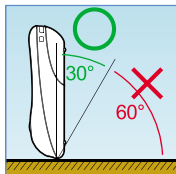
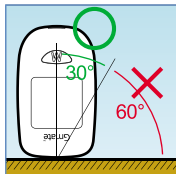
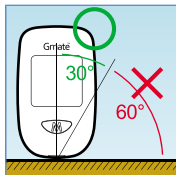
Use the supplied neck strap and place the meter near your chest.

Important :

The meter can count steps only in the following cases:

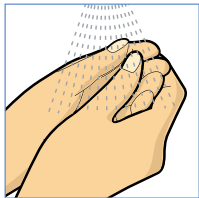
- When the meter is off with battery installed.
- 'M' button is pressed and released when the meter is off.

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



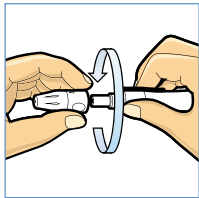
- When the memory is being displayed, the blood glucose is being tested or the meter is being set.
- When the front of the meter is placed in the angle of less than 60° or horizontal to the ground.
- When the meter is placed in the bag that moves irregularly because it hits your foot, your belt or the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

Obtaining Blood Drop



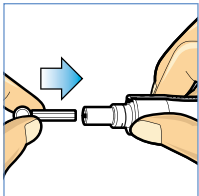
STEP 1

Wash your hands carefully with warm water to increase the circulation of the blood into the fingers. Dry hands thoroughly until the finger to be pricked is completely dry.



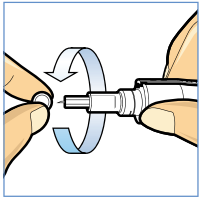
STEP 2

Unscrew the cap of the lancing device by turning it counter-clockwise while holding the base firmly.



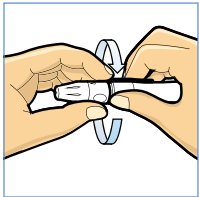
STEP 3

While holding the lancet carrier, insert a new sterile lancet into the bottom of lancet carrier.



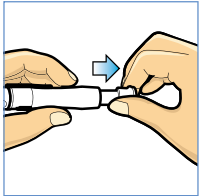
STEP 4

Twist the cap of the lancet off.



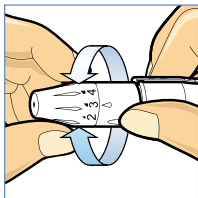
STEP 5

Put the cap of the lancing device back on and turn it clockwise.

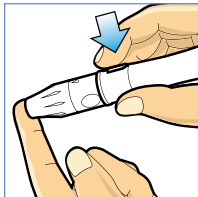


STEP 6

Hold the tip firmly in one hand then pull out the sliding barrel with the other hand. This will cock the lancing device.

**STEP 7**

Set the proper depth of penetration by rotating the cap of lancing device. 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin.

**STEP 8**

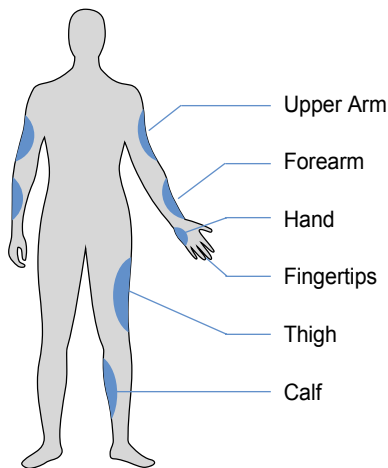
Place the lancing device in place. Hold the lancing device firmly against the side of the finger, with the cap resting on the finger. (The harder it is pressed the deeper the puncture). Press the release button to take a sample.

Caution : To reduce the chance of infection :

- Make sure to wash the puncture site with soap and water before sampling.
- Do not share a lancet or a lancing device with anyone.
- Always use a new lancet - lancets are for single use only.
- Keep your meter and lancing device clean.

About Alternate Site Testing

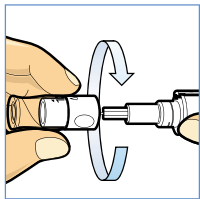
The Gmate™ Meter lets you obtain a blood sample from your Upper arm, Forearm, Hand, Thigh or Calf. Obtaining a drop of blood from these “alternate site testing” may be less painful than a fingertip sample. Following figure shows the areas where you can test with the Gmate™ System. Avoid moles, veins, bones and tendons. Consult to your healthcare professional before using alternate site testing.



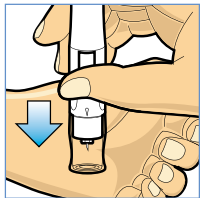
Caution : Do not test on alternate sites :

- when you think your blood glucose level is changing rapidly, such as within two hours of exercise, a rapid-acting insulin injection or insulin pump bolus or within two hours after a meal.
- if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Obtaining a blood sample from alternate sites is different than getting a sample from fingertips.

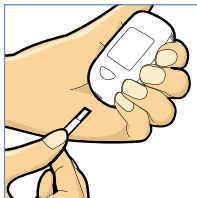


After inserting a new sterile lancet into the bottom of lancet carrier, put the clear AST cap to the lancing device.



Place the lancing device on the skin in the chosen site, press and hold the lancing device continuously for a few seconds, then push the release button to take a sample. watch through the clear cap until a sufficient blood sample is taken. If there is not enough blood, gently massage the area until a sufficient sample has been collected.

Testing Your Blood Glucose



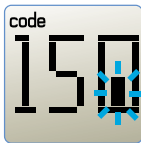
STEP 1

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 into the meter until it stops. The meter will turn on.



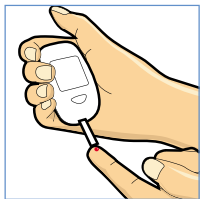
STEP 2

Time will be displayed for a moment. Then Code number and strip symbol will be displayed. A strip symbol with filling blood will appear letting you know the meter is ready to test.



STEP 3

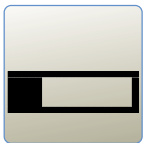
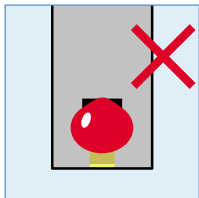
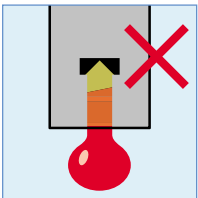
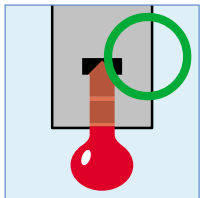
Make sure the code number showed on the screen is same as the code number printed in the test strip vial. If the code number on the screen is different from the code number printed in the strip vial, try to insert new strip.



STEP 4

Bring tip of the test strip to lightly touch the drop of blood. 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(real size" .").



STEP 5

The Meter will now show counting progress during 5 seconds.



STEP 6

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



Caution :

- If your test is above 600 mg/dL (33.3 mmol/L), "HIGH" will appear on the display screen.
- If your test result is lower than 10 mg/dL (0.6 mmol/L), "LOW" will appear on the display screen.



STEP 7

To turn your Meter off, simply remove the used test strip. The Meter turns 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. When this happens, test results are still saved in memory.



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 24).

Range of expected results

Blood glucose levels will vary depending on food intake, medication dosages, health, stress or exercise. Consult your healthcare professional for the target value that is appropriate for you. Expected blood glucose levels for non-pregnant people without diabetes:

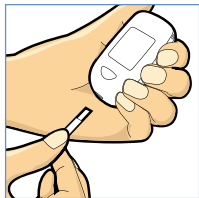
- Fasting : Less than 100 mg/dL(5.6 mmol/L)
- 2 hours after meals : Less than 140 mg/dL(7.8 mmol/L)

Control Solution Testing

Gmate™ control solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly. Control solution is 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

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 into the meter until it stops. The meter will turn on.

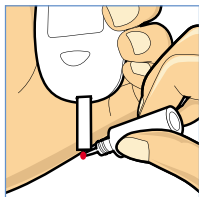


STEP 2

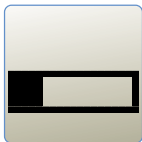
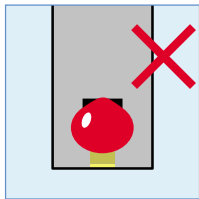
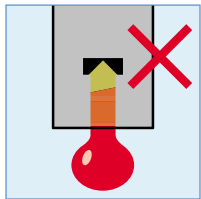
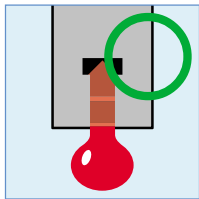
Time will be displayed for a moment. Then Code number and strip symbol will be displayed. A strip symbol with filling blood will appear letting you know the meter is ready to test.

**STEP 3**

Make sure the code number showed on the screen is same as the code number printed in the test strip vial. If the code number on the screen is different from the code number printed in the strip vial, try to 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 during 5 seconds.

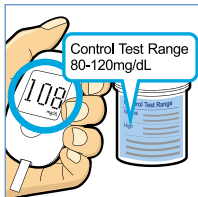


STEP 6

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 be caused by:

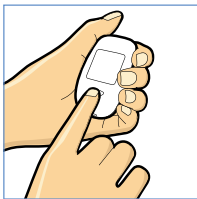
- not following the instructions on this USER'S GUIDE,
- expired, contaminated or watered-down control solution,
- expired or damaged test strip,
- control solution test done outside 20°C to 25°C (68°F to 77°F),
- or a problem with the meter.

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. Call the local distributor.

STEP 8

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

Reviewing Results



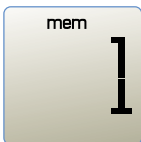
STEP 1 (To enter pedometer mode)

With the meter off, press and release the 'M' button on the meter. The number of your steps will be displayed. If you attach the meter properly, the meter will start to count the number of your step.



Important :

- The meter's display will not change or display steps until after you have walked more than 5 steps.
- The number of your step is reset to zero at 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. The last glucose result will be displayed.



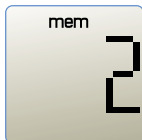
Important :

- If there is no result, the meter will display "- - -".
- The meter will display time, date and the result alternatively after no pressing 'M' button for 3 seconds.



STEP 3

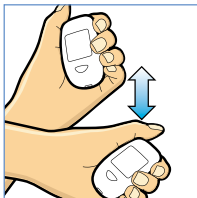
Press and release the 'M' button. The counts of step between previous and next glucose results will be displayed.



STEP 4

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



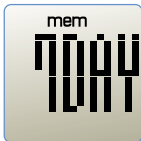


STEP 5 (To review average)

To review your 7-day average, shake the meter slowly in the review mode. The meter will display 7-day average and "7DAY" alternatively.

Shaking the meter again allows you to scroll forward to 14- and 30-day averages with beep.

Continue to press the 'M' button to view stored test results.



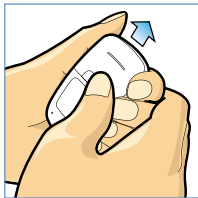
Important :

Your average result does not contain control test result.

STEP 6

The Meter is off if you press and hold 'M' button for 2 seconds.

Setting the Meter



STEP 1

When the meter is off, remove battery cover.



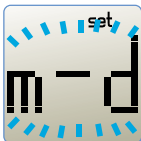
STEP 2

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



STEP 3

The year will appear first, with the year flashing. Press the 'M' button until the correct year appears. Press the 'SET' button to move to the date format setting.



STEP 4

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

**STEP 5**

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

**STEP 6**

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

**STEP 7**

With the hour flashing, 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 the minute setting.

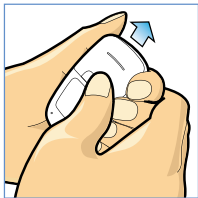
**STEP 8**

With the minute flashing, press the 'M' button until the correct minute appears.

STEP 9

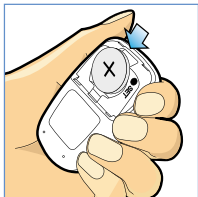
Press the 'SET' button to complete meter set-up and turn off the meter.

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.

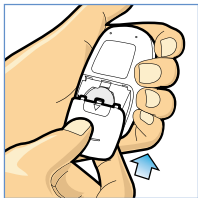


STEP 2

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

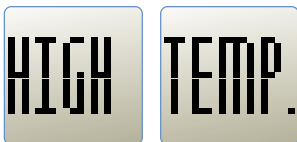
Slide the battery cover back into place and close firmly.

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.

Error Messages



Appears when environmental temperature is BELOW system operation range. System operation range is 10~40°C (50~104°F). Repeat the test after the meter and test strip have reached the above temperature range.



Appears when environmental temperature is ABOVE system operation range. System operation range is 10~40°C (50~104°F). Repeat the test after the meter and test strip have reached the above temperature range.



Appear when inserting a used test strip. Re-test with a new test strip.



This error message indicates the test strip may be inserted incorrectly or have a problem. Repeat to remove and re-insert the test strip or repeat the test with a new test strip.



This error message indicates the meter has problem. Review the instructions and re-test with a new test strip. If this messages appears again, contact the local dealer.



Battery is low but you can still perform a few tests. Replace the battery as soon as possible.



Battery is too low to perform a test. Replace the battery immediately.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.

Probable cause	What to do
The battery is dead.	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.
Test strip inserted upside down, wrong end in, 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.

Test does not start after applying the blood sample.

Probable cause	What to do
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 happens, contact your local distributor.
Sample applied after meter times out(one minutes) and turns off.	Repeat the test using a new test strip.

Performance Characteristics

Clinical accuracy

The Gmate™ System is calibrated to yield results equivalent to plasma glucose concentrations and is traceable to a NIST standard. The accuracy of the Gmate™ mini System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI 2300 Glucose Analyzer.

System accuracy result for glucose concentrations < 75 mg/dL(4.2 mmol/L)

within ± 5 mg/dL(0.28 mmol/L)	87%(26/30)
within ± 10 mg/dL(0.56 mmol/L)	100%(30/30)
within ± 15 mg/dL(0.83 mmol/L)	100%(30/30)

System accuracy result for glucose concentrations ≥ 75 mg/dL(4.2 mmol/L)

within ± 5%	63%(107/170)
within ± 10%	95%(162/170)
within ± 15%	99%(169/170)
within ± 20%	100%(170/170)

Regression statistics

Slope	0.9955
Intercept	-1.9843 mg/dL
R ²	0.9954
No. of samples	100
Range tested	31.4~430 mg/dL(1.7~23.9 mmol/L)

Within run precision(100 venous blood tests per glucose level)

Mean glucose	Gmate™ STEP System	
	Standard deviation	Coefficient of variation(%)
41 mg/dL(2.3 mmol/L)	1.2mg/dL(0.07mmol/L)	3.0
102 mg/dL(5.7 mmol/L)	2.8mg/dL(0.16mmol/L)	2.7
147 mg/dL(8.2 mmol/L)	2.9mg/dL(0.16mmol/L)	2.0
237 mg/dL(13.2 mmol/L)	4.3mg/dL(0.24mmol/L)	1.8
394 mg/dL(21.9 mmol/L)	9.9mg/dL(0.55mmol/L)	2.5

Total precision(100 control solution tests per glucose level)

Mean glucose	Gmate™ STEP System	
	Standard deviation	Coefficient of variation(%)
40 mg/dL(2.2 mmol/L)	0.8mg/dL(0.04mmol/L)	2.1
106 mg/dL(5.9 mmol/L)	2.5mg/dL(0.14mmol/L)	2.4
322 mg/dL(17.9 mmol/L)	7.8mg/dL(0.43mmol/L)	2.4

Caring for System

Your Gmate™ System does not need any special maintenance.

Storing your system

Store your meter, strips and control solution in your carrying case after each use. Store each item in a cool, dry place below 32°C(90°F), but do not refrigerate. Keep all items away from direct sunlight and heat.

Tightly close the cap on the test strip vial and/or control solution vial immediately after use to avoid contamination or damage. Store test strips only in their original vial.

Checking for expiration to strips and control solution

Test strips and control solution have expiration dates printed on their vials. When you first open a test strip or control solution vial, you must record the opening date in the space provided on the label. Use all test strips within 3 months after the first opening.

Caution :

- Do not use the strips or control solution after the expiration date printed on the vial or the discard date(date first opened plus 3 months), whichever comes first, or your results may be inaccurate.
- Do not use test strips if the vial is damaged or left open to air. This could lead to error messages or tests that read higher than the actual result.

Cleaning your meter

To clean your meter, wipe the outside with a soft cloth dampened with water and mild detergent. Do not use alcohol or another solvent to clean your meter.

Do not get any liquids, dirt, dust, blood, or control solution inside the meter through the test port.

Cleaning your lancing device and clear AST cap

Clean and wipe the outside of the lancing device with a soft cloth, dampened with mild soap and water. Wash the adjustable cap and clear AST cap with mild soap. Do not immerse the lancing device in any liquid.

Specifications

Model	PG-201 (Gmate™ STEP Blood Glucose Monitoring System)
Test Method	Electrochemical sensor
Calibration Method	Plasma-equivalent
Sample	Whole blood, capillary
Sample Size	0.5 µL
Test Time	5 seconds
Memory	500 Blood glucose tests and steps
Result Range	10 ~ 600 mg/dL(0.6~33.3 mmol/L)
Maximum Step	99,999 steps
Hematocrit	20 - 60%
Operating Temperature	10~40°C(50~104°F)
Operating Relative Humidity	10 - 90%
Altitude	Up to 3,048 meters(10,000 feet)
Power Source	One CR2032, 3 volt, lithium battery, replaceable
Size	36.7mm x 61.7mm x 15.8mm (1.44" x 2.43" x 0.62")
Weight	30g(1.06oz)

Electrical and safety standards

The meter has been tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. The meter has been tested for immunity to radio frequency interference at the frequency range and test levels specified in IEC 61000-4-3. The meter has been tested for electromagnetic emissions specified in IEC 61326.

Warranty

Philosys warrants that your Gmate™ meter will be free of defects in materials and workmanship for 5 years, valid from the date of purchase. The warranty extends only to the original purchaser and is not transferable.



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