

Gmate™ WHeeL User's Guide

Thank you for purchasing the
Gmate™ WHeeL System.

Please read this User's Guide
thoroughly before using, and
ensuring correct operation.

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



Table of Contents

Gmate™WHeeL is very easy to carry around and used for measuring the glucose level by whole blood whenever you need. It is also very simple, easy to use and smart. You don't worry about coding your meter, the Gmate™WHeeL does it automatically. Gmate™WHeeL is only used for testing glucose level and using only fresh capillary whole blood samples. Gmate™WHeeL is intended for use outside the body (*in vitro* diagnostic use) by people diabetes at home and by healthcare professionals in clinical setting. Gmate™WHeeL should not be used for the diagnosis of diabetes without the guidance of a healthcare professional or for the testing of newborn.

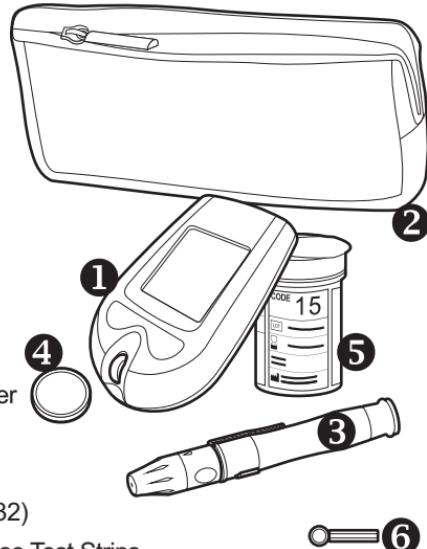
Features

- 1 Gmate™WHeeL meter has wheel button to eject the used strip easily and simply.
- 2 The small size with stylish design and ease operation, allows you can bring everywhere.
- 3 Shows much useful information.
- 4 Requires very small volume(0.5 μ L) and display the result within 5 seconds.
- 5 Measures glucose level of whole blood by AST(Alternate site testing).
- 6 No need to change Code number or to use Code chip when test strip inserting.

About Gmate™WHeeL	4
Before Starting	5
Name and Function	7
Cautions	10
Obtaining Blood Drop	13
About Alternate Site Testing	16
Testing Your Blood Glucose	18
Control Solution Testing	22
Reviewing Results	25
Setting the Meter	28
Replacing the Battery	32
Error Messages	33
Troubleshooting	35
Performance Characteristics	36
Caring for System	38
Specifications	40

About Gmate™WHeeL

Gmate™WHeeL includes:



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

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

If any items are missing, please contact to local distributor.

Before Starting

Symbols

	Caution, see instructions for use
	Single use only
	Expiration date
SN	Serial number
LOT	Lot number
IVD	<i>In Vitro Diagnostic medical device</i>
	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
	Catalogue number

Intended Use

Gmate™WHeeL is intended to be for personal self-testing to monitoring glucose concentration in fresh whole blood. Gmate™ WHeeL can apply for outside body (*in vitro* diagnostic use) on fingertips, forearm, upper arm, hand, thigh and calf.

Test principle

The Gmate™WHeeL is designed for detecting a small electrical current variation, which produced by the reaction of glucose in the blood sample with the reagents on the strip. This current is varied by the amount of glucose in the blood sample. The current variation is calculated to glucose concentration of sample.

Setting the time and date

Your Gmate™WHeeL comes with a preset time, date and year. Before your first using the meter, or when you change battery, you should check the setting of time and date for your local time zone. In case of you don't set your meter at first time or after changing battery, you can hear beep 3 times when inserting a test strip. See the 28 page(Setting the Meter).

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



Front View

Display Screen

Display test result and other information.

Buttons

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

Eject Wheel

Remove the tested strips by rolling.



Gmate™ Test Strip

Test Strip Port

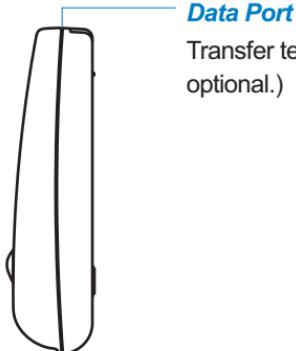
Insert the Gmate™ Test Strip. The meter will turn on automatically when inserting the test strip.

Electrodes

Insert into test strip slot while facing up.

Sample Tip

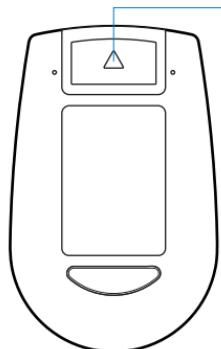
The fresh blood sample is drawn into.



Side View

Data Port

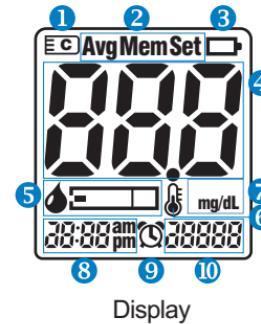
Transfer test results to computer(Cable is optional.)



Rear View

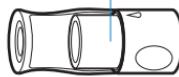
Battery Cover

Slide cover off for replacing battery.

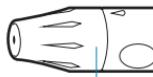
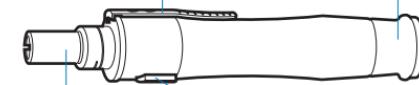


Display

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

Clear AST cap

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

Lancet ejector**Adjustable cap****Sliding barrel****Lancet holder****Release button**

Lancing Device

Cautions

Cautions for System

- The Gmate™WHeeL is intended for use outside the body (*in vitro* diagnostic use) only.
- The Gmate™WHeeL uses only the fresh capillary whole blood for measuring.
- The Gmate™WHeeL must use with Gmate™ Test Strip and Gmate™ Control Solution.
- Do not use the Gmate™WHeeL for diagnosis of diabetes without the guidance of healthcare professional, for testing on newborns and with arterial blood.
- The Gmate™WHeeL contains small parts that may be dangerous if swallowed.
- Check the packages when purchasing and before using the Gmate™WHeeL.
- Before operating, be sure to read User's Guide and Insert found in test strip container carefully.
- Do not make any of medical relevance decision without consulting your physician and/or having received appropriate training.

Cautions for Meter

- Keep the Gmate™WHeeL out of children's reach. When a children swallowed battery or battery cover accidentally, consult with a doctor immediately.
- Do not dispose the battery into fire.
- Do not disassemble or modify the meter.
- Do not attempt to severe shock, drop or step on meter.
- The Gmate™WHeeL is not waterproof. Do not wash by water or touch it with wet hands.
- Do not wipe the meter with chemical solvent or abrasive cleaners.
- Avoid the Gmate™WHeeL being exposed to high temperature, high humidity, rain and/or dust when using or storing.
- Do not test instantly when the Gmate™WHeeL moves to where sudden temperature changes. Please wait 20 minutes and start testing.

**Cautions
for Test Strip**

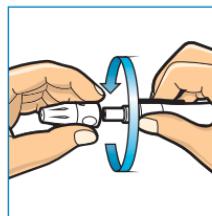
- Store Gmate™ Test Strip in a cool, dry place between 2°C and 32°C(36°F and 90°F).
- Keep away from direct sunlight and heat.
- After taking a test strip out of the container, close cap tight immediately.
- You may get inaccurate result if container cap remains opened long time.
- Don't drop the blood sample on the surface of strip directly.
- Do not press test strip against your finger. It may affect bad aspiration of blood sample aspiration.
- Do not use a test strip that looks damaged and/or used. Test strips are for single use only.
- Store the test strips in their original container.
- After you take a strip out of the container, be sure to use it within three minutes.
- Use test strips within 3 months(90days) after opening the container.
- By clean and dried hands, you may touch when taking out test strip and/or insert to port.
- Do not bend, cut, or modify test strips.

Obtaining Blood Drop

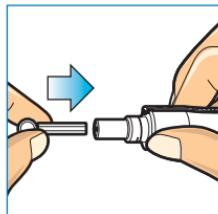
**STEP 1**

Wash and cleaning your hands carefully with soap and warm water for increasing the blood circulation in finger vein.

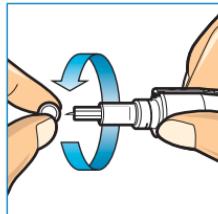
Dry hands thoroughly until pricked skin is dried off.

**STEP 2**

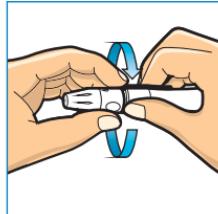
Unscrew the lancing device cap by turning counter-clockwise while holding firmly.

**STEP 3**

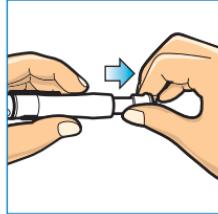
Insert a new sterile lancet into the lancet holder.

**STEP 4**

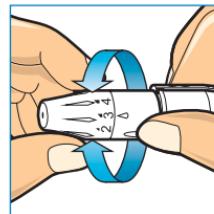
Twist the lancet cap off.

**STEP 5**

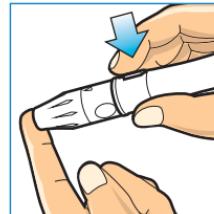
Put the lancing device cap on and close by turning clockwise.

**STEP 6**

Hold the lance holder firmly, and pull back and release the sliding barrel. Now the lancing device is cocked.

**STEP 7**

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

**STEP 8**

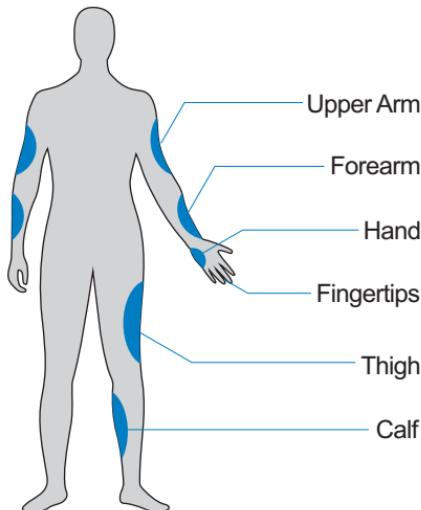
Place the lancing device on finger tip.
While lancing device rest on the finger.
(The harder it is pressed, the deeper the lance), press the release button to lance.

Caution : To avoid the infection possibility:

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

About Alternate Site Testing

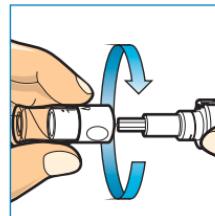
The Gmate™WHeeL can measure a blood sample from your Upper arm, Forearm, Hand, Thigh or Calf alternatively. Obtaining a blood drop from these “alternate site” may be less pain than a fingertip. Following figure shows where you can test with the Gmate™WHeeL. Do not apply to moles, veins, bones and tendons. Consult to your healthcare specialist before doing alternate site test.



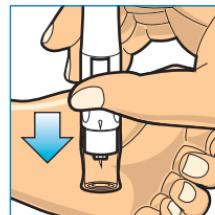
Caution : Do not test on alternate sites :

- 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.
- When 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 a fingertips sample collecting.



After inserting a new sterile lancet, put on the clear AST cap to the lancing device.



Place the lancing device on selected position, pressing the lancing device for a few seconds. After 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

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



STEP 2

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

STEP 3

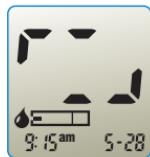
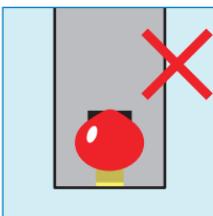
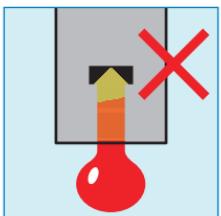
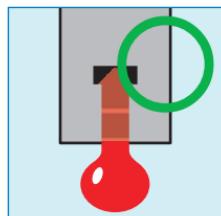
Compare and ensure the displayed code number is same as printed code on test strip container. If displayed code number is different, please use another new strip.



STEP 4

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

Important : The volume of blood sample must be over 0.5 microliter(real size ".") at least.



STEP 5

The screen shows counting progress during 5 seconds.

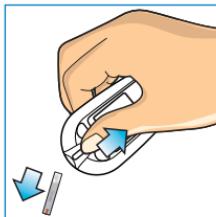


STEP 6

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

**Caution :**

- When the test result is above 600 mg/dL(33.3 mmol/L), "HI" is displayed.
- When the test result is lower than 10 mg/dL(0.5 mmol/L), "Lo" is displayed.

**STEP 7**

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

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

**Caution :**

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

Unexpected results

When the test result is lower than 50mg/dL(2.7mmol/L) and over than 250mg/dL(13.8mmol/L), or displays "Lo" or "HI", contact your physician or healthcare professional immediately.

If unexpected results are continued, check Gmate™WHeeL by control solution. See Control Solution Testing(page 22).

Range of expected results

Blood glucose levels will vary depending on food intake, medication dosages, health condition, stress or exercise status. Consult your healthcare professional for the target value that is appropriate for you.

Expected blood glucose levels for non-pregnant person without Diabetes:

- Fasting : Less than 110 mg/dL (6.0 mmol/L)
- 2 hours after meals : Less than 140 mg/dL (7.8 mmol/L)

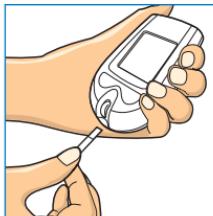
Reference: International Diabetes Federation 2009. Self-Monitoring of Blood Glucose in Noninsulin Treated Type 2 Diabetes.

Control Solution Testing

Gmate™ Control Solution contains a known index of glucose and is used for checking that the Gmate™WHeeL and test strips are working properly or not. Control solution is optional.

Do a control solution test:

- when doing practice the test process instead of using blood sample,
- when you open a new test strips container,
- when you suspect the Gmate™WHeeL or the test strips are not working properly,
- when you have unexpected blood glucose results repeatedly,
- when the Gmate™WHeeL is damaged.



STEP 1

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



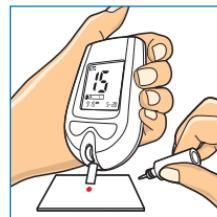
STEP 2

After time and date will be displayed for a while, code number and strip symbol are displayed. A strip symbol with filling blood tells you the Gmate™WHeeL is ready to test.



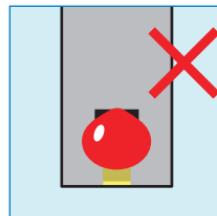
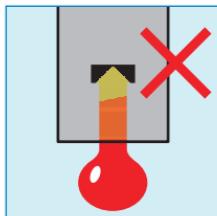
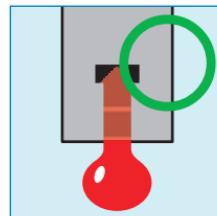
STEP 3

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



STEP 4

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



STEP 5

The Gmate™WHeeL shows counting progress during 5 seconds.

**STEP 6**

Beeps when test is finished. The test result of control solution is displayed on screen.

**STEP 7**

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

Out of range results may be caused by:

- when you are not comply the instructions on this USER'S GUIDE,
- expired, contaminated or watered-down control solution,
- expired or damaged test strip,
- control solution test is done out of temperature range 20°C to 25°C,
- or a problem on the Gmate™ WHeeL.

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

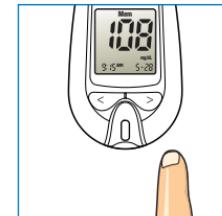
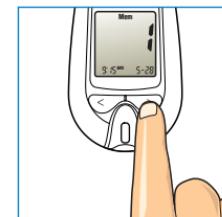
STEP 8

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

Reviewing Results

**STEP 1**

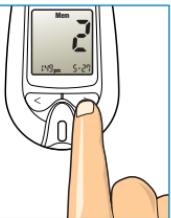
During the meter is off, when click any button, the present time and date are displayed. After then, a strip symbol is blinking.

**STEP 2(To enter review mode)**

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

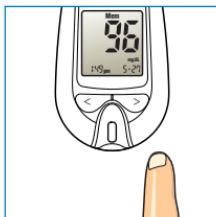
Important :

- If there is no result, “---” is displayed.

**STEP 3**

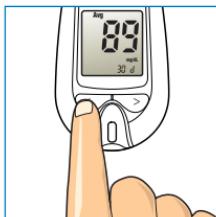
Press the '>' button, the previous test number (=2) is displayed. When release the '>' button, the appropriate glucose result is displayed.

Press and release the '>' button, you can review the older test results and the '<' button is for the later results one by one.

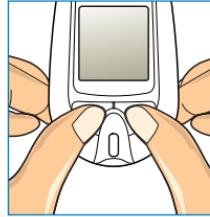
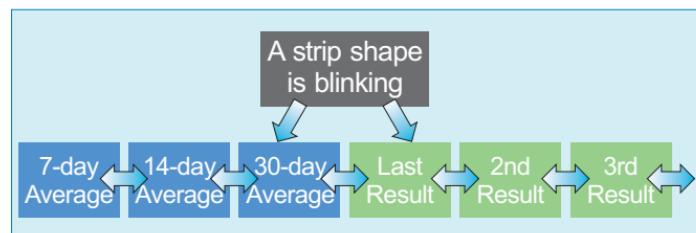
**STEP 4(To review average)**

To review your 30-day result average, press and release '<' button while a strip symbol is blinking.

Pressing and releasing the '<' button allow you to scroll forward to 14-day and 7-day averages.

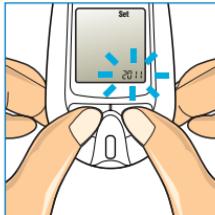
**STEP 5**

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

**STEP 6**

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

Setting the Meter



STEP 1

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

Important :

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



STEP 2

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



STEP 3

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



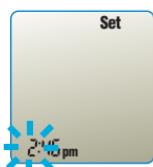
STEP 4

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



STEP 5

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



STEP 6

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



STEP 7

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

**STEP 8**

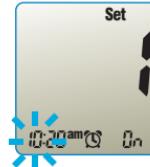
During "12h" or "24h" is flashing, press and release the '<' or '>' button to select 12-hour or 24-hour format. Press and release '<' and '>' buttons together to move to "beeper" setting.

**STEP 9**

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

**STEP 10**

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

**STEP 11**

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

STEP 12

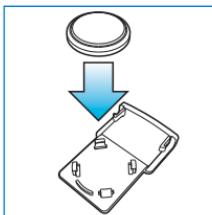
After totally settings of four alarms are completed, press and release '<' and '>' buttons together to finish setup and turn off the Gmate™WHeeL.

Replacing the Battery



STEP 1

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



STEP 2

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



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



STEP 3

Slide the battery cover back into place and close firmly.

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

Error Messages



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 Gmate™ WHeeL has problem. Review the instructions and re-test with a new test strip. When this messages appears again, contact the local distributor.



Appears when working temperature is BELOW or ABOVE system operation range. The system operation range is 10°C~40°C(50°F~104°F). Re-test after the working temperature reach to the above range.



Battery is low, still but you can do 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 out.	Replace the battery.
The battery is installed wrong or there is no battery.	Check that the battery is installed correctly. See 32 page.
Test strip inserted upside down, wrong end in, or incompletely.	Insert the test strip with the printed side up and the electrode end into the test strip port.
Defective meter or test strips.	Contact your local distributor.
Blood or foreign objects put into test strip slot.	Contact your local distributor.

Test does not start after applying the blood sample.

Probable cause	What to do
Blood sample is too small.	Re-test with a new test strip and a larger blood sample.
Defective meter or test strips.	Re-test with a new test strip. If same problem happens, contact your local distributor.
Sample applied when turn off due to time out(3 minutes after ready to test).	Re-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™ WHeeL 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)	27% (8/30)
within ± 10 mg/dL(0.56 mmol/L)	93% (28/30)
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 $\pm 5\%$	58% (99/170)
within $\pm 10\%$	95% (162/170)
within $\pm 15\%$	99% (169/170)
within $\pm 20\%$	100% (170/170)

Regression statistics

Slope	1.0004
Intercept	-2.1214 mg/dL
R ²	0.9903
No. of samples	100
Range tested	32.7~442 mg/dL(1.8~24.5 mmol/L)

Performance Characteristics

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

Mean glucose	Standard deviation	Coefficient of variation(%)
43 mg/dL(2.3 mmol/L)	1.3 mg/dL(0.07 mmol/L)	3.1
101 mg/dL(5.6 mmol/L)	2.6 mg/dL(0.14 mmol/L)	2.5
133 mg/dL(7.3 mmol/L)	2.6 mg/dL(0.14 mmol/L)	2.0
232 mg/dL(12.8 mmol/L)	3.6 mg/dL(0.20 mmol/L)	1.6
373 mg/dL(20.7 mmol/L)	8.8 mg/dL(0.49 mmol/L)	2.4

Total precision(100 control solution tests per glucose level)

Mean glucose	Standard deviation	Coefficient of variation(%)
41 mg/dL(2.2 mmol/L)	0.8 mg/dL(0.04 mmol/L)	2.0
103 mg/dL(5.7 mmol/L)	2.5 mg/dL(0.14 mmol/L)	2.4
295 mg/dL(16.3 mmol/L)	8.5 mg/dL(0.47 mmol/L)	2.9

Caring for System

Your Gmate™WHeeL is maintenance-free.

Storing your system

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

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

Checking for expiration to strips and control solution

Test strips and control solution have expiration date, which is printed on their containers. When open a test strip or control solution vial first time, you must write down the opening date on provided label. Use all test strips within 3 months after opening.

Caution :

- Do not use the strips or control solution after the expiration date printed on the container or the discard date(date first opened plus 3 months), or your results may be inaccurate.
- Do not use test strips if the container is damaged, broken or left open to air. It cause to error, or is higher than the actual result.

Caring for System

Cleaning your meter

To clean up your meter, wipe the outside with a soft cloth, dampened with water and mild detergent. Do not use alcohol or any chemical solvent. Do not remain any liquids, dirt, dust, blood or control solution inside of the test slot.

Cleaning your lancing device and clear AST cap

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

Specifications

Model	PG-300 (Gmate™ WHeeL 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 with time and date
Result Range	10 ~ 600 mg/dL (0.6 ~ 33.3 mmol/L)
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	56.0mm x 88.0mm x 23.6mm (2.20" x 3.46" x 0.93")
Weight	46.5g(1.64oz)

Specifications

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™WHeeL 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.



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



philosys Co., Ltd.
827-3, Sangpyeong-ro,
Okgu-eup, Gunsan-si,
Jeollabuk-do, Korea

Tel +82-63-453-1421
Fax +82-63-453-1423
Email help@gmate.biz



0120

 philosys

REF 0602R8

Rev. Date 2014-12

Printed in Korea