

Gmate™ On User Guide



Contents

Introduction	4
Precautionary Information	8
What's Inside	10
Identifying Parts and Functions	12
Running the App	16
Performing the Test	17
Alternate Site Testing	26
Control Solution Testing	29
Reviewing Past Results	34
Troubleshooting	36
Care and Maintenance	38
System Specifications	40
Meaning of Symbols	43

Welcome to Gmate™ On Blood Glucose Monitoring System

Thank you for purchasing the Gmate™ On Blood Glucose Monitoring System. Please read this User Guide thoroughly before operating the system as it provides important information on the proper use of the system. It is recommended you keep this User Guide in a safe place for your future reference. The Gmate™ On Blood Glucose Monitoring System combined with your Android device is used to measuring your blood glucose level anytime, anywhere in a convenient manner. Compatible with your Android mobile device, Gmate™ On Blood Glucose Monitoring System is very easy and simple to use. The automatic coding of Gmate™ On Blood Glucose Monitoring System returns accurate test results. The Gmate™ On Blood Glucose Monitoring System should not be used for diagnosis of diabetes.

Features of Gmate™ On Blood Glucose Monitoring System

- 1** Small, cutting-edge design with a convenient hand grip
- 2** Transportable anywhere with your mobile device
- 3** The meter does not require batteries nor prior settings
- 4** The app is easy and intuitive use
- 5** Sound support provides clear instructions and readings
- 6** All test results automatically saved into your mobile device
- 7** Only requires a small volume(0.5µL) of your blood
- 8** Displays your results in just five seconds
- 9** Approved for alternate site testing(AST)

Intended Use

The Gmate™ On Blood Glucose Monitoring System is intended for the following uses:

- Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearms, upperarms, hands, thighs, and calves as an aid in monitoring the effectiveness of diabetes management at home by patients with diabetes.
- A single patient only, and should not be shared with any other persons.
- Self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitoring for effective diabetes control.
- Alternative site testing should be done only during a steady state when glucose levels are not changing rapidly.

The Gmate™ On Blood Glucose Monitoring System is compatible with the following Android mobile devices: Samsung Galaxy S2, Galaxy S3, Galaxy S4, Galaxy S5, Galaxy Note, Galaxy Note 2, and Galaxy Note 3. The Gmate™ On Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes.

The Gmate™ On Blood Glucose Monitoring System should not be used for neonates.

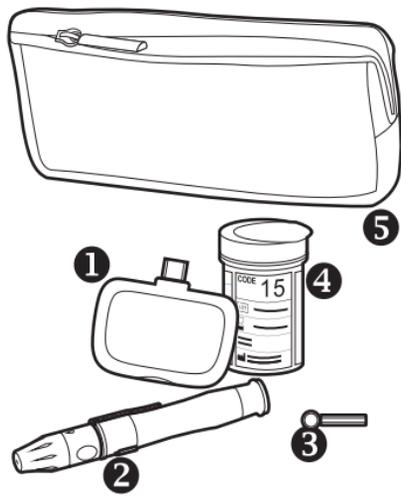
The Gmate™ Blood Glucose Test Strips are intended for use with Gmate™ On Blood Glucose Monitoring System only for the purpose of quantitative measurement of blood glucose in fresh capillary whole blood samples.

The Gmate™ Blood Glucose Control Solutions are intended for use with Gmate™ On Blood Glucose Monitoring System to check that the meter and the test strips are working properly. Gmate™ Blood Glucose Control Solutions are available to purchase separately.

For safety reasons, please read the following instructions prior to using Gmate™On Blood Glucose Monitoring System.

- Do not use the Gmate™On Blood Glucose Monitoring System for any purposes other than testing your blood glucose level with fresh capillary whole blood.
- Before using the Gmate™On Blood Glucose Monitoring System, read all instructions in this User Guide and the test strip insert found in the test strip box carefully, and then practice the procedure for safe and accurate testing.
- Keep the Gmate™On Blood Glucose Monitoring System out of reach from children as it contains parts that may be dangerous if swallowed.
- Do not make any decisions for medical treatment based on the test results and having received appropriate training.
- Do not touch the Gmate™On Blood Glucose Monitoring System with wet hands, or place it in or near liquids.
- All parts of the blood glucose monitoring system may be considered a biohazard and is capable of transmitting infectious diseases even after the cleansing procedures. Please follow all regulations concerning proper disposal of system components, including lancets and test strips.

There are two types of glucose units: mg/dL and mmol/L. Your Gmate™ On 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.



Contained in your package:

1. Gmate™ On Meter
2. Gmate™ Lancing Device
3. Gmate™ Lancets
4. Gmate™ Blood Glucose Test Strips
5. Carrying Case

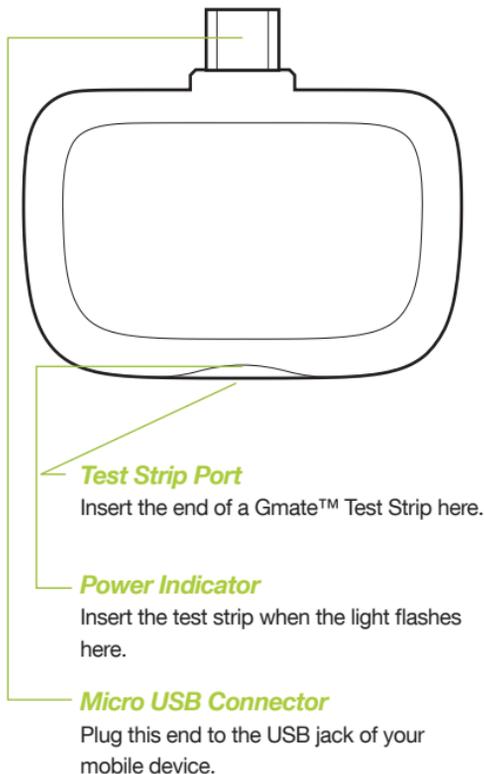
Documents in your package include this User Guide.

Note:

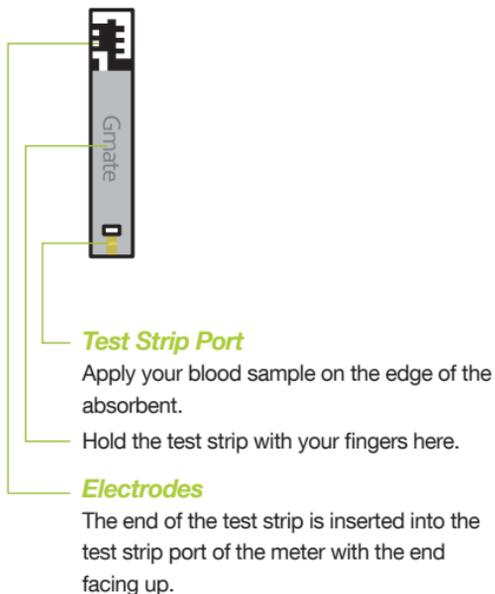
- Please call your local distributor if any items are missing.
- Gmate™ On Control Solutions are available separately.
- Mobile devices are not included.
- Gmate™ On Meter is compatible with Android 4.0 or higher version platform based mobile devices: Samsung Galaxy S2, Galaxy S3, Galaxy S4, Galaxy S5, Galaxy Note, Galaxy Note 2, and Galaxy Note 3.

*Galaxy is a trademark of Samsung Electronics Co., Ltd. and Android is a trademark of Google Inc.

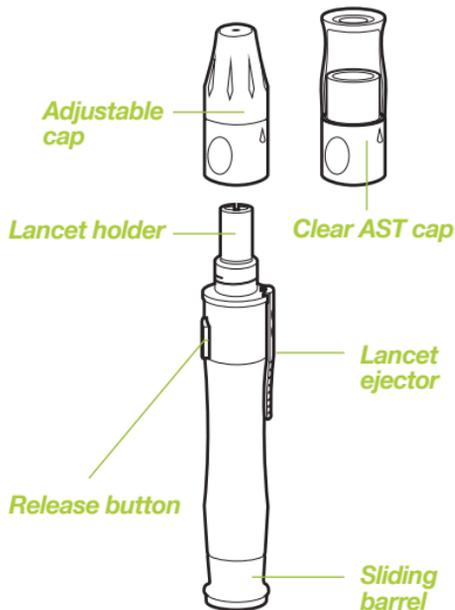
Gmate™ On meter



Gmate™ Test Strip

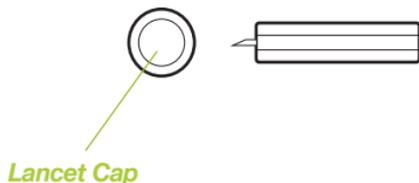


Lancing Device



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

Lancet



Twist off here when placed in the lancet holder.

* Lancet and Lancing Device are subject to change without notice.

Test Principle

Performing a test using Gmate™ On Blood Glucose Monitoring System involves the measurement of electrical currents caused by the reaction of glucose with the reagent of the test strip. This current is converted to the amount of glucose in the blood sample which is then displayed as a result on your mobile device.

Step 1 - Downloading the app

From your Android mobile device, enter Play store by tapping Play Store icon. Type in “gmate on” in the search bar, locate the app, then download it.



Step 2 - Installing the app

Follow the instructions through the installation process. After the installation is complete, run the app by either tapping “Open” option at the end, or tapping the newly downloaded Gmate™ On app.

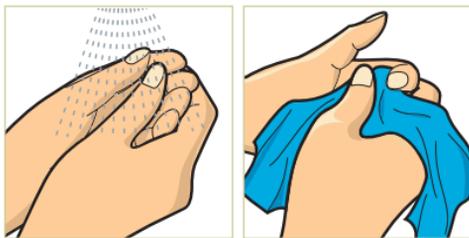
Step 3 - Starting up the app

Tap “Start” button then proceed to the main start-up screen. Plug your Gmate™ On Meter to the USB jack. If your device recognizes the meter, the power indicator will flash and then you will be instructed to insert a test strip.



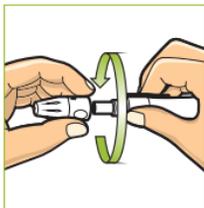
Step 1 - Preparing the app and the meter

Start the app and plug your meter to the USB jack of your mobile device. When the meter's power indicator is on, insert the test strip into the test strip port of the meter. Make sure the Gmate logo of the test strip is facing up.

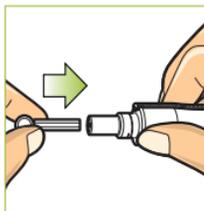


Step 2 - Preparing the lancing device

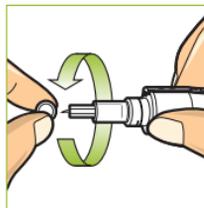
Wash your hands thoroughly with warm water to increase blood circulation into the fingers. Then dry your hands completely including your puncture site.



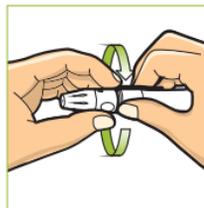
Unscrew the lancing device cap.



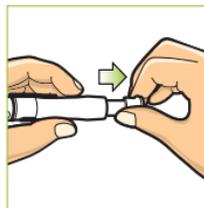
Insert a new sterile lancet into the lancet holder and fix it in firmly.



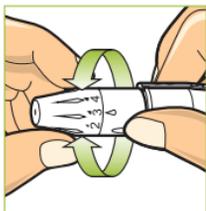
Hold the lancet in one hand and twist off the protective cap with the other hand.



Place the cap back on the lancing device.

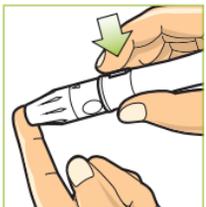


Cock the lancing device by drawing the sliding barrel.



Set your desired depth level by twisting the adjustable cap. The puncture will be deeper as the number increases. The smaller numbers are for shallower puncture that is more suitable for softer skin and deeper puncture is more suitable for thicker or calloused skin.

Step 3 - Obtaining a blood sample



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

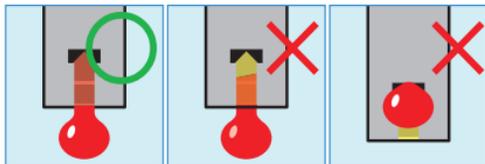


Step 4 - Applying blood to the test strip

Touch the end of the yellow absorbent gently to the edge of your blood drop. The yellow absorbent will automatically draw your blood.

IMPORTANT

The blood sample volume must be at least 0.5 microliter. (actual size: “. ”)



Step 5 - Reading the test result

Along with the recognition sound, the display of your mobile device will show the progress bar for five seconds. Then your blood glucose result will be announced as it appears on the screen along with the date and time. All your test results will be automatically saved in your mobile device.

CAUTION

The screen will display “HIGH” if your test result is above 600 mg/dL (33.3mmol/L), and “LOW” if below 10mg/dL (0.6 mmol/L).

Step 6 - Saving the test result

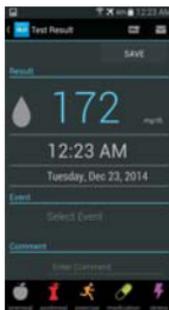
You can customize your results by selecting a relevant icon (Premeal, Postmeal, Exercise, Medication, and Stress) from the icon bar at the bottom.



You may also type in additional comments.

Comment

Enter Comment



Tap “SAVE” button on the top right corner to save your customized test result.

Step 7 - Removing and discarding used test strip and lancet

Remove the test strip from the meter, and the lancet from the lancing device. Dispose of them in accordance with your local regulations.

CAUTION

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

IMPORTANT

Repeat the test if your test result is displayed as one of the following:

- Below 50mg/dL(2.8mmol/L)
- Above 250mg/dL(13.9mmol/L)
- “LOW”
- “HIGH”

If you continue to get unusual test results, call your healthcare professional. Check your system with control solution if you have purchased it with the system. See Control Solution Testing for details. (page 29) Call your healthcare professional without delay if your control solution result is within range printed on the test strip vial.

Range of expected test results

Blood glucose levels will vary depending on food intake, medication dosage, health, level of stress, or exercise. Consult your healthcare professional for the target range that is appropriate for you.

Following is the expected blood glucose level for a non-pregnant patient with diabetes:

- After fasting: Less than 110mg/dL (6.0mmol/L)
- Two hours after a meal: Less than 140mg/dL (7.8mmol/L)¹

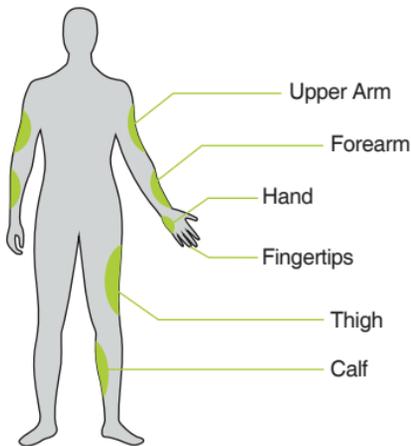
¹Fasting means not having anything to eat or drink (except water) for at least eight hours.²

References: [1] “Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes.” (2009). International Diabetes Federation.

[Online]. Available: https://www.idf.org/webdata/docs/SMBG_EN2.pdf

[2]“Diabetes Basics, Diagnosis.” (1995-2014). American Diabetes Association. [Online]. Available: <http://www.diabetes.org>

The Gmate™ On allows blood glucose testing using other regions of your body besides your fingertips. These parts are your hand, forearm, upper arm, thigh and calf. The purpose of this alternate site testing is to use your fingertips less to avoid calluses and pain from repeated lancing in the same spot. Sampling from alternate sites may also cause less pain. The following are the body parts you can choose to perform as alternate site testing. Be sure to consult your healthcare professional before you perform an AST.



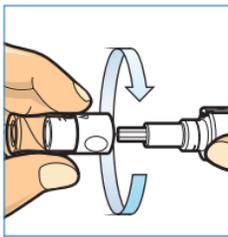
Perform an AST in the following circumstances:

- two or more hours after meals
- physical exercises, or any other activities that may affect blood glucose levels
- two hours after a rapid-acting insulin injection or insulin pump bolus

Avoid an AST under following situations:

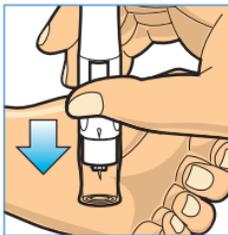
- during or within two hours after a meal, physical exercises or other activities that may affect blood glucose levels
- when intending to calibrate continuous blood glucose results
- when making insulin dosing calculations
- when testing for hypoglycemia or for those with a history of recurrent hypoglycemia

Sampling Blood from Alternate Sites



Unlike with fingertips, the method for sampling blood from alternate sites is different.

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



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 taken. If there is not enough blood, massage the area gently.

The control solution is used to ensure your meter and test strips are working properly. It contains a known amount of glucose, and in this test, the control solution will replace the role of your blood sample. Control solutions are available to purchase separately.

Perform a control test in the following instances:

- to check the test process without sampling blood
- every time you open a new vial of test strips
- you get repeated unexpected blood glucose results
- you suspect the meter or test strips are not working properly
- you have dropped or damaged the meter
- your test strips were stored in extreme temperatures or humid settings

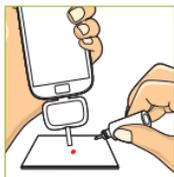
Performing the Control Solution Test

Step 1 - Preparing the app and the meter

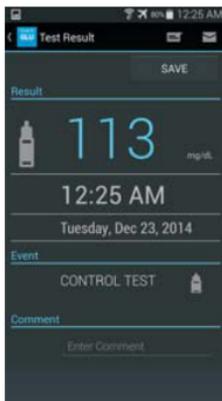


Tap the Gmate™ On app to enter. (If not installed, please see page 16.) Plug your meter to the USB jack of your mobile device. When the meter's power indicator is on, insert the test strip into the test strip port of the meter. Make sure the Gmate logo of the test strip is facing up.

Step 2 - Applying control solution



The app will instruct you to apply blood. Slide over to Control Solution display to the right. The animation of applying control solution will be displayed. Shake the control solution vial, remove the cap, then squeeze to release a drop of control solution. Then touch the edge of the yellow absorbent gently to the drop of control solution.



Step 3 - Reading control solution test result

Along with the recognition sound, the display of your mobile device will show the progress bar for about five seconds. Then the control solution result will be announced as it appears on the screen along with the date and time.



Step 4 - Verifying the result

Compare the result with the control solution range printed on the test strip vial. If the result is within range, your meter and test strips are proven to work properly. If not within range, repeat the control solution test. If out-of-range result occurs again, contact your local distributor.

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

- error in following the test steps
- not used the control solution level you intended
- expired or contaminated control solution
- expired or damaged test strip
- defective meter
- the test not performed within temperature range of 20°C to 25°C (68°F to 77°F)

If you continue to get control solution results that do not fall within the range printed on the test strip vial, withdraw use and call your local distributor.

All test results are automatically saved in your mobile device along with the date and time. You can check your results from the app without connecting the meter to your mobile device.

The test results are displayed as a list with the most recent result displayed on the top. Tap on each result to view details. You can transfer the test results by SMS and e-mail by using the Message icon  and Mail icon  respectively.

IMPORTANT

For security reasons, use of cellular data networks instead of Wi-Fi is recommended.



Above you can see how your test results will be listed, and what will show when you tap on one of the results.

There is no response after you connect the meter to your mobile device.

Probable cause	To do
The meter is not properly connected to the mobile device.	Connect the meter again properly. Contact your local distributor if recognition fails again.
The meter will not connect to the mobile device with certain phone cases.	Remove the phone case and try connecting again.
The meter is defective.	Contact your local distributor.

There is no response after you insert the test strip into the meter.

Probable cause	To do
The test strip is not inserted properly.	Insert the electrode of the test strip completely into the test strip port of the meter.
Foreign objects have entered the test strip port.	Remove visible foreign objects on the surface gently with a dry cloth. Contact your local distributor if it still does not work.

There is no response after the blood sample is applied to the test strip.

Probable cause	To do
The meter or test strips are defective.	Redo the test with a new test strip. Contact your local distributor if it still does not work.

Keeping Your System

- Keep your meter, test strips, and control solution in the carrying case after use.
- Store all parts of the system in a cool, dry place between 2 and 32°C(36 and 90°F).
- If your meter has been exposed to extreme temperatures, perform the test after you have kept it in room temperature for at least 20 minutes.
- Do not subject the meter to severe shock.
- Do not leave the vial cap open for a long time as it may cause inaccurate test results. Leave the vial cap closed immediately after each use.
- Use all test strips and control solution within three months after first exposed in air.

Cleaning Your System

Keeping your meter and lancing device clean is essential for avoiding malfunction (such as foreign objects contaminating the meter causing it to fail) and spreading of infection.

Use soft cloth dampened with mild soap and water to wipe the exterior of your meter, lancing device and clear AST cap. Do not use alcohol or other solvents to clean. Do not immerse your meter and lancing device in liquid.

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™ On 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 < 100 mg/dL(5.5 mmol/L)

within ±5 mg/dL(0.28 mmol/L)	87.3% (165/189)
within ±10 mg/dL(0.56 mmol/L)	100% (189/189)
within ±15 mg/dL(0.83 mmol/L)	100% (189/189)

System accuracy result for glucose concentrations ≥ 100 mg/dL(5.5 mmol/L)

within ±5 %	90.9% (374/411)
within ±10 %	100% (411/411)
within ±15 %	100% (411/411)

Regression statistics

Slope	0.9857
Intercept	2.9141 mg/dL
R ²	0.9976
No. of samples	600
Range tested	34.2-447 mg/dL (1.9 - 24.8 mmol/L)

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

<i>Mean glucose</i>	<i>Standard deviation</i>	<i>Coefficient of variation (%)</i>
48 mg/dL (2.7 mmol/L)	2.0 mg/dL (0.1 mmol/L)	4.1
93 mg/dL (5.2 mmol/L)	3.4 mg/dL (0.2 mmol/L)	3.6
137 mg/dL (7.6 mmol/L)	4.4 mg/dL (0.2 mmol/L)	3.2
240 mg/dL (13.3 mmol/L)	6.4 mg/dL (0.4 mmol/L)	2.7
371 mg/dL (20.6 mmol/L)	6.1 mg/dL (0.3 mmol/L)	1.6

Total precision(100 control solution tests per glucose level)

<i>Mean glucose</i>	<i>Standard deviation</i>	<i>Coefficient of variation (%)</i>
48 mg/dL (2.7 mmol/L)	2.0 mg/dL (0.1 mmol/L)	4.1
108 mg/dL (6.0 mmol/L)	4.2 mg/dL (0.2 mmol/L)	3.9
355mg/dL (19.7 mmol/L)	9.3 mg/dL (0.5 mmol/L)	2.6

Specifications

Model	PG-110 (Gmate™ On 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	No limit
Result Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Hematocrit Level	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	From the smart phone
Size	41.5mm x 33.6mm x 9.0mm (1.63" x 1.32" x 0.35")
Weight	5.9g (0.21 oz)

Meaning of Symbols

-  Caution, see instructions for use
-  Single use only
-  Expiration date
-  Serial number
-  Lot number
-  *In Vitro* Diagnostic medical device
-  Manufacturer
-  Authorised representative of European Community
-  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

Electrical and Other Safety Standards

The meter has been tested for protection from electric shock and mechanical hazards specified as requirements in IEC 61010-1. Additionally, it meets the requirements of electromagnetic compatibility (EMC) as specified in IEC 61326-1 and IEC 61326-2-6.

Warranty

Philosys warrants that the Gmate™ On 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.



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