



Owner's Manual

Small, Fast, Diabetes Monitoring System for your Smart Phone.

Thank you for choosing the Gmate® SMART Blood Glucose Monitoring System. Gmate® SMART is the smallest meter in the world. Please read the Owner's Manual carefully before use.

For use with the Gmate™ SMART App on your iPhone®, iPad® and iPod touch®. iOS 5.0 or higher is required.

Please keep this Owner's Manual in a safe place for reference.

GMATE® SMART BLOOD GLUCOSE MONITORING SYSTEM

Customer Service Toll-Free: 1-855-GO-GMATE (1-855-464-6283). Available 24 hours a day, 7 days a week.

In case of an emergency, contact your doctor or dial 911 for the emergency service in your area.

By using the Gmate® SMART Blood Glucose Monitoring System (Meter) with the Gmate™ SMART App, you agree that the use of this Gmate™ SMART App together with the iPhone, iPad or iPod touch shall only be used for personal organization or as a supplemental data display tool and NOT as a source of medical advice. You agree that the Gmate™ SMART App will never be used to replace the advice of your doctor, or your common sense, and that you will not at any time rely on any information presented on your iPhone, iPad or iPod touch as the basis for health care, medical or other decisions that may result in injury or other ill effects.

You agree to take sole responsibility for your health care decisions, including contacting your doctor or healthcare provider regarding all medical conditions, tests, diagnoses, and treatment options, and agree that Apple shall have no liability for any action taken by you or anyone using the Gmate™ SMART App, regardless of the information received, displayed, calculated or transmitted by your iPhone, iPad or iPod touch.

Apple assumes no risk for your use of the Gmate™ SMART App and makes no warranties whatsoever, expressed or implied, regarding the accuracy, completeness or usefulness of any information presented on your iPhone, iPad or iPod touch as a result of using the Gmate™ SMART App.

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INTENDED USE

- The Gmate® SMART Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf. The Gmate® SMART Blood Glucose Monitoring System is intended to be used by a single person and should not be shared with any other person.
- The Gmate® SMART Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use only) by people with diabetes at home to monitor the effectiveness of diabetes control. The Gmate® SMART should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly).

INTENDED USE

- The Gmate® Blood Glucose Test Strips are for use with the GMATE® SMART Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf.
- The Gmate™ SMART App is a component of the Gmate® SMART Blood Glucose Monitoring System and is intended to be used by people with diabetes at home as an aid to monitor and track the effectiveness of their diabetes management. The Gmate™ SMART App allows the user to view their glucose test results and stores a lifetime of results. The user may e-mail their glucose test results to their healthcare provider to help them review, analyze, and evaluate their glucose test results to support an effective diabetes management program. The user can also graph and trend their glucose test results to provide an outlook of their diabetes management.

CORE FEATURES OF THE GMATE® SMART:

The Gmate™ SMART App is designed solely for the use of the Gmate® SMART Blood Glucose Monitoring System.

- The Gmate® SMART is easy to use.
- Its small size, simple portability and sleek design allow you to take it everywhere and anywhere.
- No coding required. Insert a Gmate® Test Strip and you are ready to test.
- No batteries required.
- No settings required.
- Stores a lifetime of test results. It also displays information in various useful formats. You do not need to carry a log book.
- It requires a very small blood sample (0.5µL). Displays the result in 5 seconds.

CORE FEATURES OF THE GMATE® SMART:

- The Gmate® SMART is intended for alternate site testing (AST), providing less painful testing options.
- The Gmate® SMART Meter uses the smartphone technology, currently Apple's iOS (with use of the Apple iPhone 3GS, iPhone 4, iPhone 4S, iPhone 5, iPod touch 4th generation, iPad and iPad 2), to view glucose test results, store a lifetime of test results, manage your diabetes information, graph and review trends and share your diabetes management with your healthcare provider. The Gmate™ SMART App can be downloaded from the App StoreSM.

The Gmate™ SMART App has been specifically designed to work with your iPhone, iPad, iPod touch and has been certified by the developer to meet Apple's performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that when the Gmate™ SMART App is in use, it may affect the device's wireless performance.

IMPORTANT SAFETY INSTRUCTIONS

- The Gmate® SMART Blood Glucose Monitoring System is for use outside the body (in vitro diagnostic use only).
- Use the Gmate® SMART Blood Glucose Monitoring System to test your blood glucose level with fresh capillary whole blood. Do NOT use the Gmate® SMART for any other purpose.
- Read all the instructions in this Manual before using the Gmate® SMART System.
- The meter and lancing device are for single patient use. Do not share them with anyone, including family members! Do not use on multiple patients!
- Check with your doctor or healthcare provider for correct use of this meter.
- Only use the Gmate® SMART Meter with the Gmate® Test Strips and Gmate® Control Solution.
- Keep the Gmate® SMART Meter away from and out of reach from children. Do NOT swallow. If any parts are swallowed, contact your healthcare provider immediately or dial 911 for emergency help.

IMPORTANT SAFETY INSTRUCTIONS

- Practice good hygiene before and after using the Gmate® SMART Blood Glucose Monitoring System.
- Properly dispose of system components, including lancets and test strips. If you are a caregiver or helper to the owner of this blood glucose monitoring system, please refer to page 81 for a special message to avoid the transmission of diseases.
- Keep your Gmate® SMART Meter and iPhone, iPad or iPod touch clean. Clean and disinfect your Gmate® SMART Meter and iPhone, iPad or iPod touch at least once per week by following the instructions on page 73 of this manual. Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- It is important to clean and disinfect your Gmate® SMART Meter and iPhone, iPad or iPod touch. Cleaning and disinfecting your Gmate® SMART and iPhone, iPad or iPod touch should be completed in two steps:
Step 1 – Clean the surfaces of the Gmate® SMART Meter, lancing device, and iPhone, iPad or iPod touch with CaviWipes™ towelettes if there is any blood, dirt or residue.

Step 2 – Disinfect the surfaces of the Gmate® SMART Meter, lancing device, and iPhone, iPad or iPod touch to kill bloodborne pathogens such as hepatitis B, hepatitis C, or HIV.

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

If you are interested in additional information on the importance of disinfection, please use the following references:

1. "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

2. "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk or Transmitting Bloodborne Pathogens" (2010)

<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

Caution

- Do NOT use the Gmate® SMART Blood Glucose Monitoring System on patients who are critically ill, in shock, dehydrated or hyperosmolar.
- Severe dehydration may cause inaccurate test results. Check with your doctor or healthcare provider if you think you may be severely dehydrated.
- Repeat the test if your test results are below 50 mg/dL or greater than 250 mg/dL. If you continue to have the same test results, follow the treatment advice of your healthcare provider.
- Check with your doctor if you experience symptoms inconsistent with your test results.
- Do NOT disassemble or change the Gmate® SMART Meter.
- Do NOT drop, step on, or subject the Gmate® SMART Meter to severe shock.

Caution

- The Gmate® SMART Meter is NOT waterproof. Do NOT wash or touch with wet hands.
- Do NOT wipe the Gmate® SMART Meter with paint thinner or abrasive cleaners.
- Do NOT expose the Gmate® SMART Meter to rain, or high temperatures over 90°F (32°C), or under direct sunlight.
- Do NOT directly store the Gmate® SMART Meter in the refrigerator. Do NOT freeze.
- Keep the Gmate® SMART Meter at room temperature for best use.

ABOUT THE GMATE® SMART

Before you begin

Carefully read this manual and the inserts that come with the Gmate® Test Strips and the Gmate® Control Solution before using the Gmate® SMART Blood Glucose Monitoring System. Take note of the "Important" and "Caution" areas throughout the Owner's Manual.

Note: It may be helpful to practice the test with the control solution before testing with blood for the first time. See Control Solution Testing and the Control Solution Insert.

Test Principle

The Gmate® SMART Blood Glucose Monitoring System uses small electric currents to measure the reaction of glucose (sugar) in the blood with the reagents in the strip. The electric current changes with the amount of glucose in the blood sample. The Gmate® SMART Meter measures the current and calculates your blood glucose level. Combined with the Gmate™ SMART App, it displays the test results and stores them on your iPhone, iPad or iPod touch.

Gmate® SMART System Contents:

1. Gmate® SMART Meter
2. Gmate® Blood Glucose Test Strips
3. Gmate® Control Solution
4. Lancets
5. Lancing Device
6. Carrying Case

The Owner's Manual is also included with your Gmate® SMART Meter. If any items are missing, please contact Gmate® Customer Service at 1-855-GO-GMATE (1-855-464-6283).

iPhone, iPad or iPod touch is not included and must be purchased separately.

The Gmate® SMART Meter supports iPhone 5, iPhone 4S, iPhone 4, iPhone 3GS, iPad, iPad 2 and iPod touch 4th generation (iOS 5.0 or higher required).

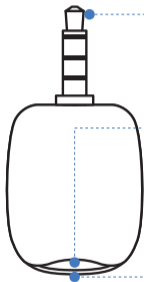
System Requirements

To use the Gmate® SMART Meter with your iPhone, iPad or iPod touch, you will need:

- Minimum of 30MB of available space
- iOS 5.0 or higher installed
- The Gmate™ SMART App

The Gmate™ SMART App is not included with the Gmate® SMART Meter. It can be downloaded from the App Store. To install the app, follow the simple instructions on page 19, Installing the Gmate™ SMART App.

SYSTEM FUNCTIONS



Gmate® SMART Meter

Phone Plug

Insert into headphone jack of iPhone, iPad or iPod touch.

Power Indicator

When this lights up, the meter is powered on and ready to test.

Test Strip Port

Insert the end of a Gmate® Test Strip into the test strip port to begin a blood glucose test.



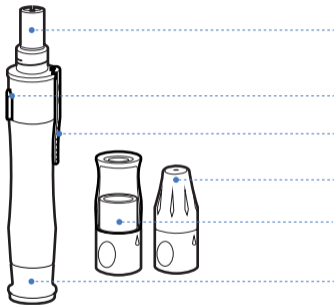
Sample Tip

Apply blood sample here.

Electrodes

Insert this end of the test strip into the test strip port of the meter with the electrodes facing up.

Gmate® Test Strip



Lancing Device

Lancing Device

Lancing Holder

Lancing Ejector

Adjustable Cap

Clear AST Cap*

Sliding Barrel

*Clear AST cap is an optional accessory. Please contact Gmate® Customer Service at 1-855-GO-GMATE (1-855-464-6283).

INSTALLING THE GMATE™ SMART APP

The Gmate® SMART may only be used with the Gmate™ SMART App.

The Gmate™ SMART App is a free download from the App Store. The App Store can be accessed through iTunes or by tapping the App Store icon on your iPhone, iPad or iPod touch. You must have internet access to download the App.

To begin the download to your iPhone, iPad or iPod touch:

Tap on the App Store.



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Select the Search Tab and type "Gmate Smart".

Select the Gmate™ SMART App and Install.

Once the App is installed, fill out the fields in the User Information section.

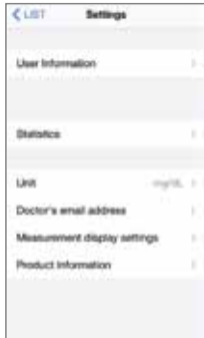


Tap the information icon to edit and view your User Information, Statistics, Unit of Measure, Doctor's email address, Measurement display settings and Product Information.

The screenshot shows the 'User Information' settings page. At the top, there is a back arrow and the title 'User Information'. Below the title is a profile picture placeholder and two text input fields for 'First name' and 'Last name'. Underneath these is a 'Birthday' section with a date picker set to '2013/05/29'. Below the birthday are three rows of settings: 'Sex' with 'Male' and 'Female' buttons; 'Height' with '175 Cm' and 'Feet' buttons; and 'Weight' with '132 lb' and 'Kg' buttons. At the bottom of the form is a button labeled 'Enter your information'.

User Information - Update this section with your personal information.

- Touch the uppermost button and type in your first name. When complete, touch Done.
- Touch the button below and type in your last name. When complete, touch Done.
- Touch the Birthday button and update with correct Month, Day and Year of birth. When complete, touch Done.
- Touch the next button down and select Male or Female.
- Touch the Height button and select your height. You may choose to display your height in centimeters (Cm) or Feet. When complete, touch Done.
- Touch the Weight button and select your weight. You may choose to display your weight in kilograms (Kg) or pounds (lb). When complete, touch Done.



Select the Settings button to go back to the Settings mode. Select LIST to exit Settings Mode.

Statistics - Details a list with the following Statistics:



- **Total measure count** – total number of times you have tested
- **Blood** – number of times you have tested with blood
- **Control Solution** – number of times you have tested with control solution
- **Average** – Lists the last 7 days, 14 days, 30 days, 60 days and Last Year Averages

You can reset this screen by selecting the **Reset** button. **This will delete all saved test results.**



Unit

Touch the Unit button to turn Auto Set on or off. When Auto Set is on, the measuring unit will be set automatically according to the user's current region.



Doctor's Email Address

Touch the Doctor's email address button and type your doctor's email address.



Measurement Display Settings

Touch the Measurement Display Settings button to adjust the color your test results will be displayed in. Touch and slide the two circles to adjust the desired range. Test results below the selected range will appear in yellow. Results within range will appear in black. Results above range will appear in red.

Product Information – View Product Information.

Note: Accessing the App Store requires internet connection. For assistance with this, visit: <http://www.apple.com/support>.

Warning:

The Gmate™ SMART App and the Gmate® SMART Meter should only be used as a reference tool. Do NOT make treatment decisions based on the information provided by the Gmate™ SMART App.

Consult your doctor or healthcare provider for all health-related concerns.

For instructions on how to use the Gmate™ SMART App, read the instructions built into the App.

Important:

The Gmate™ SMART App will store health-related information on your iPhone, iPad and iPod touch. We recommend that you keep your iPhone, iPad and iPod touch with the latest security software. For more information on keeping your information safe, visit: <http://www.apple.com/support/security/>.

TESTING YOUR BLOOD GLUCOSE

Preparing for a Test

Be sure to have these items ready when you test:

- Gmate® SMART Meter
- Gmate® Test Strips
- Lancing Device
- Sterile Lancets
- iPhone, iPad or iPod touch with the Gmate™ SMART App installed

Important:

Practice good hygiene before and after use. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

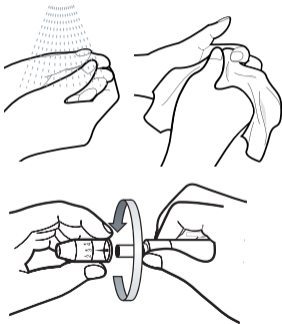
- Use only Gmate® Blood Glucose Test Strips.
- Wash the puncture site with soap and water before sampling.
- Make sure the Gmate® SMART Meter and test strips are about the same temperature before you test. Room temperature is best.
- Close the test strip vial after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- DO NOT open the test vial until you are ready to perform a test.
- DO NOT return the used test strip to the vial after performing a test.
- DO NOT reuse or share a test strip that had blood or control solution on it. Test strips are for single-use only.
- DO NOT share the lancing device. The lancing device is intended for a single user only.
- Write the discard date (3 months after first opening) on the test strip label.
- Keep your meter, lancing device, and iPhone, iPad or iPod touch clean. Follow the cleaning and disinfection procedures in this Owner's Manual (see page 73).

TESTING YOUR BLOOD GLUCOSE

Note: Your meter can show results either in "mg/dL" or "mmol/L" units. It is very important to use the correct unit of measurement to properly manage your diabetes. If you live in the USA, you should use mg/dL; your result will never have a decimal point. If you live in Canada and some European countries, you should use mmol/L; your result will always have a decimal point.

If the meter is not set to mg/dL when first purchased, do not use the meter. Contact Customer Service at 1-855-GO-GMATE (1-855-464-6283) for assistance.

Collecting a Blood Sample

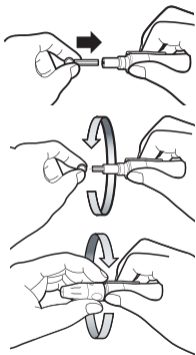


STEP 1

Wash your hands with soap and warm water. Dry your hands thoroughly. Make sure puncture site is completely dry.

STEP 2

Take your lancing device. Hold firmly and twist off the device cover by turning it counter-clockwise.



STEP 3

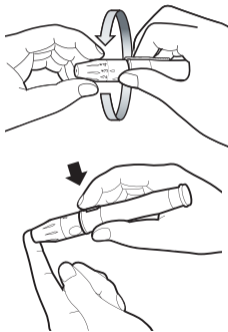
Insert a new sterile lancet into the bottom of the lancet carrier.

STEP 4

Twist off the protective cap from the lancet.

STEP 5

Replace the lancing device cover.



STEP 6

Select the desired puncture depth by turning the adjustable tip:

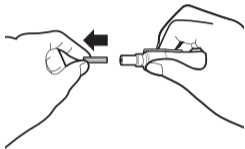
1-2 for delicate skin

3 for normal skin

4-5 for thick or calloused skin

STEP 7

Place the end of the lancing device against the puncture site. Press and release the top button. Remove the lancing device after the puncture is complete.



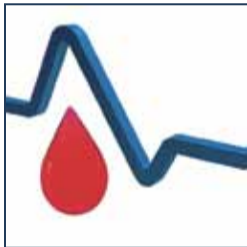
STEP 8

After you perform your blood glucose test, twist off the device cover and remove the lancet. Dispose of the lancet in an approved sharps container. Replace the lancing device cover.

Caution

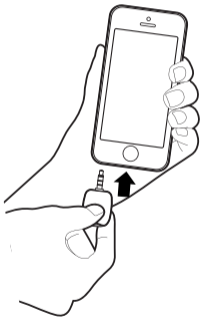
- Do NOT reuse lancets. Lancets are for single-use only.
- Do NOT share lancets and the lancing device.

Testing with a fingertip sample



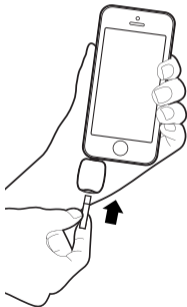
STEP 1

Tap the Gmate™ SMART icon to open the App. If the Gmate™ SMART App is not installed, install the App (See page 19 for instructions).



STEP 2

Insert the Gmate® SMART Meter into the headphone jack of your iPhone, iPad or iPod touch. You will see a volume control box appear on the screen. The Gmate® SMART requires maximum volume. Set the iPhone, iPad or iPod touch to maximum volume to make sure the Gmate® SMART Meter has enough power. The test strip port will light up. The meter is now powered on. "Insert Strip" will appear on the display.



STEP 3

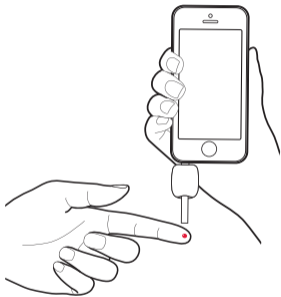
Insert the Gmate® Test Strip with the electrode end facing up into the test strip port of the Gmate® SMART Meter. Make sure the test strip is gently inserted all the way. Do not force the test strip into the meter.



STEP 4

"Apply Sample" will appear letting you know the meter is ready to test.

To mark the test result as a control solution test, slide the button at the bottom of the screen.



STEP 5

Use the lancing device to obtain a blood sample. Place the blood from your finger to the tip of the Gmate® Test Strip. **Do NOT press your finger against the test strip.** The test strip will automatically draw the blood. Keep your finger on the test strip while the meter is measuring the sample.

Important:

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



The volume of the blood sample must be at least 0.5 microliter (real size “•”). Please make sure that the blood sample completely fills the designated area of the Gmate® Test Strip.



STEP 6

Do not remove the test strip until this is complete. The reading will take 5 seconds.



STEP 7

Your test result will be displayed on the screen of the iPhone, iPad or iPod touch when the test is complete.



STEP 8

Add a note to your result by selecting the appropriate icon. Choose from pre meal, post meal, exercise, medication or stress. Make your selection and save. The note will be attached to that blood glucose reading. You may also type in a custom comment.

STEP 9

Remove and discard the used test strip. The test result will automatically be stored in memory.

Caution

Used test strips and lancets may be considered a biohazardous waste in your area. Follow your healthcare provider's recommendation for proper disposal.



Unexpected Results

If your test result is above 600 mg/dL, "HIGH" will appear on the display screen. If your test result is below 20 mg/dL, "LOW" will appear on the display screen. Immediately contact your doctor or healthcare provider if you receive a "HIGH" or "LOW" result.

Repeat the test:

- If your test result is below 50 mg/dL or above 250 mg/dL.
- If your second test result is also unusual, perform a control solution test. (see Control Solution testing in this Owner's Manual on page 60). Retest your blood.
- Contact your doctor or healthcare provider if you continue to get unexpected results.

Range of Unexpected Results

Blood glucose levels will change depending on many factors. Food intake, medication, health, stress or exercise can all affect your blood glucose. Consult your doctor or healthcare provider for the target that is right for you.

The American Diabetes Association suggests that the expected glucose values for persons without diabetes¹:

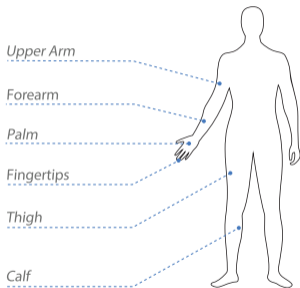
- Before eating < 100 mg/dL
- Two hours after meals < 140 mg/dL

Reference 1: American Diabetes Association (2013). Standards of Medical Care in Diabetes – 2013. Diabetes Care, 36 (Suppl 1): January 2013: S11-S66.

Caution for Gmate® Blood Glucose Test Strips

- Store the test strips in a cool, dry place between 36°F and 90°F (2°C and 32°C).
- Keep away from direct sunlight and heat.
- Do NOT leave the test strip vial open. This may damage the test strips, causing inaccurate test results.
- Do NOT use test strips that appear damaged.
- Do NOT press the test strip against your finger.
- Do NOT bend, cut or alter the test strips.
- Do NOT swallow.
- Keep away from children.

ALTERNATE SITE TESTING



The Gmate® SMART Blood Glucose Monitoring System allows you to test your blood from your Upper Arm, Forearm, Palm, Thigh or Calf.

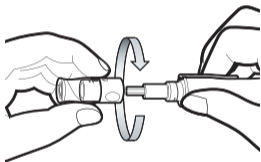
Getting a blood sample from these “alternate sites” may be considered less painful than your fingertip. The following figure shows the areas where you can test your blood with the Gmate® SMART.

Important Information About Using Alternate Site Blood Samples

- Check with your doctor or healthcare provider before using alternate sites for testing.
- Avoid moles, veins, bones and tendons.
- If you test during or after a meal, it can change your test results. Exercise can also affect your blood glucose results. It may differ from the alternate site and fingertip samples.
- Alternate site testing should only be used two or more hours after meals, exercise, or any other event that may affect blood glucose levels. (Testing within those two hours should be obtained through your fingertip).
- Alternate site testing should NOT be used to calibrate continuous blood glucose monitors.

- Alternate site testing should NOT be used to make insulin dosing calculations .
- Alternate site testing is NOT recommended for people with frequent hypoglycemia.
- **Alternate site testing may fail to detect hypoglycemia (insulin reactions). Use fingertip samples if you are hypoglycemic, especially when operating a vehicle. Use fingertip samples if you suffer from hypoglycemic unawareness (lack of symptoms to indicate an insulin reaction).**
- Testing with a fingertip sample may show low blood sugar sooner than a test from an alternate site.
- Routine testing before meals can be done at fingertips, forearm, upper arm, palm, thigh or calf.

Collecting a blood sample from alternate sites is different than fingertips.



Insert a sterile lancet into the lancing device. Place the lancing device against the designated puncture site and hold the lancing device continuously for a few seconds. Push the release button. If there is not enough blood, gently massage the area until enough of a sample has been collected.

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

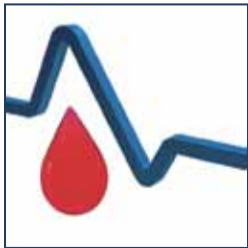


Please make sure that the blood sample completely fills the designated area of the Gmate® Test Strip.

Refer to page 27 for Collecting a Blood Sample and Testing your Blood Glucose.

REVIEWING RESULTS

The Gmate™ SMART App can store a lifetime of test results. The test results are stored in your iPhone, iPad or iPod touch. You can review your test results with or without the Gmate® SMART connected to your iPhone, iPad or iPod touch.



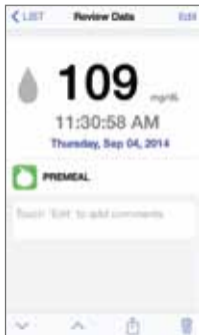
STEP 1

Tap the Gmate® SMART icon to open the App.



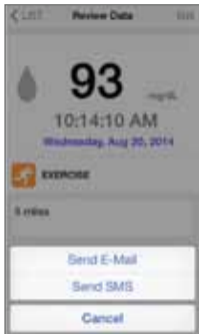
STEP 2

The Gmate™ SMART App displays your test results in a list format and in order by date and time stamp. Your most recent blood glucose result displays at the top of the list. Scroll down to view older test results.



STEP 3

Touch a blood glucose reading on the list to view a more detailed description of your test result.



Important:



If you would like to e-mail or SMS (text message) your test results, Touch the Forward button at the bottom of the screen and select the results on the list that you would like to send.

Touch the Forward button, select the test result, and Touch Send E-Mail to email the selected test result to your doctor or healthcare provider. Touch Send SMS to send a text message with the selected test result to your doctor or healthcare provider.



STEP 4

Rotate your iPhone, iPad or iPod touch to the landscape position. You will be able to view your average test results in graph format. The Gmate™ SMART App creates a graph view of your average blood glucose test results by selecting: Day, 7 Days, 14 Days, 30 Days, or 60 Days. In the graph view, it also allows you to see any trends in your blood glucose test results.



STEP 5

Select the period of time you would like to view your averages at the top of the screen.

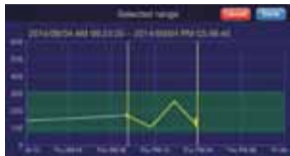


Note:

With the Gmate™ SMART App, you can send your test results by e-mail or SMS (text message).

Touch the Forward button to send your test results. Touch **Send all displayed range by email** to send all of the displayed test results to your doctor or healthcare provider.





Touch ***Send selected range by email*** to send a range of test results to your doctor or healthcare provider. Tap on the screen and slide your fingers to select the range. Once you've selected your desired range, touch Done to email the results to your doctor or healthcare provider.



The screenshot shows the Gmate SMART app interface. At the top, it says "Gmate SMART" and "Cancel". Below that, it lists test results for August 2014 and January 2014. Each entry includes a date and time, a score, and a status icon.

Date	Time	Score	Status
08/20	10:16 AM	90	Failed (Red circle with slash)
08/20	10:14 AM	93	Failed (Red circle with slash)
08/20	10:12 AM	87	Failed (Red circle with slash)
08/20	09:20 AM	79	Failed (Red circle with slash)
08/14	11:48 AM	99	Passed (Green circle with checkmark)
08/14	11:46 AM	107	Passed (Green circle with checkmark)
01/09	04:12 PM	79	Failed (Red circle with slash)

To send a group or full list of test results, touch the Forward button to send your test results. Select the test results you would like to send by tapping on the circle next to the test result. A check mark will mark the test result. You may select one result, multiple results or the full list of test results.

Important:

It is recommended to send your test results through your cellular provider (which is a secure network), instead of Wi-Fi. This is to ensure your privacy.



Once results are selected, touch the Send button. To send your test results in pdf file format, touch PDF FILE. To send your test results in csv file format, touch CSV FILE.

Note: A group or full list of test results can only be forwarded by e-mail in a pdf or csv file format.

CONTROL SOLUTION TESTING

The Gmate® Control Solution contains a known amount of glucose. It is used to verify that the meter and the test strips are working properly. (Level 2 Control Solution is included in the kit.)

The Gmate® Control Solution is available in three levels: Level 1, Level 2, Level 3. To receive the level of control solution you would like, please contact our Gmate® Customer Service at 1-855-GO-GMATE (1-855-464-6283).

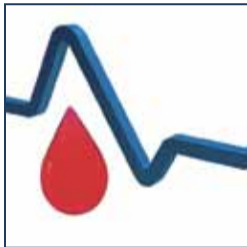
Important:

- Only use Gmate® Control Solution with your Gmate® SMART Meter.
- Control Solution test must be done at room temperature: 68°F-77°F (20°C-25°C).
- Make sure the meter, test strips and control solution are at room temperature before testing.
- Write the discard date (3 months after first opening) on the control solution label.

Do a control solution test:

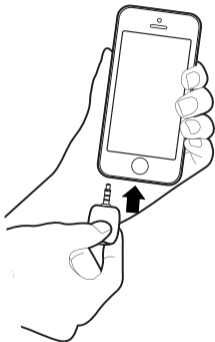
- To practice the test process instead of using blood.
- When you open a new vial of test strips.
- If you suspect the meter or the test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you think your meter may be damaged.

How to test with the Control Solution:



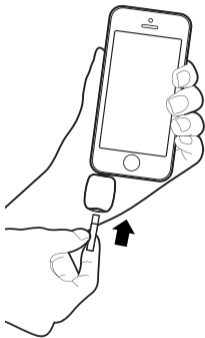
STEP 1

Tap the Gmate® SMART icon on your iPhone, iPad or iPod touch to open the App. If the Gmate™ SMART App is not installed, install the App (See page 19).



STEP 2

Insert the Gmate® SMART Meter into the headphone jack of your iPhone, iPad or iPod touch. You will see a volume control box appear on the screen. The Gmate® SMART requires maximum volume. Adjust to maximum volume to make sure the Gmate® SMART Meter has enough power. The test strip port will light up. The meter is now powered on. "Insert Strip" will appear on the display.



STEP 3

Insert the Gmate® Test Strip with the electrode end facing up into the test strip port of the Gmate® SMART Meter. Make sure the test strip is gently inserted all the way. Do not force the test strip into the meter.



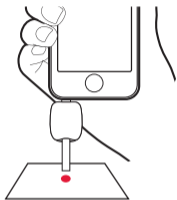
STEP 4

"Apply Sample" will appear letting you know the meter is ready to test. Slide the button at the bottom of the screen. This will mark the test result as a control solution test.



STEP 5

The picture of control solution test will be displayed on the screen.



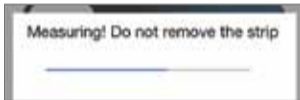
STEP 6

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



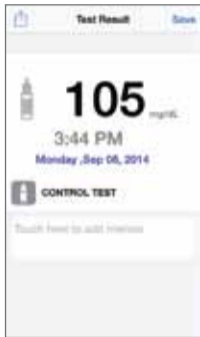
Please make sure that the control solution sample completely fills the designated area of the Gmate® Test Strip.

Note: If you mark the test as a Control Solution test, the results will NOT be included in your average results.



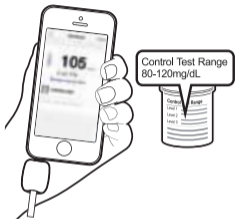
STEP 7

Do not remove the test strip until this is complete. The reading takes 5 seconds.



STEP 8

The control solution test result is displayed on the screen when the test is complete.



STEP 9

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

Results outside the expected range may indicate:

- Failure to follow the instructions for control solution testing in this manual.
- Control solution is contaminated, expired or past its discard date.
- Test strip is damaged, expired, or past its discard date.

- Control solution test was performed outside the correct temperature range between 68°F-77°F (20°C-25°C).
- Control solution is too cold or too warm.

If you continue to get results outside the range on the test strip vial, do NOT use the meter, test strips or control solution. Call Gmate® Customer Service Support toll-free, 24 hours a day, 7 days a week at 1-855-GO-GMATE (1-855-464-6283).

STEP 10

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

CARING FOR THE GMATE® SMART

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 at 36°F to 90°F (2°C to 32°C) and at relative humidity range between 0% and 90%.
- Keep all items away from direct sunlight and heat.
- Close cap tightly on the test strip and control solution vials immediately after use.

Checking the Expiration of Test Strips and Control Solution

The Gmate® Test Strips and Control Solution have expiration dates on the vials. When you first open the vials, record the discard date (3 months after first opening) on the vial labels. Use all test strips within 3 months after first opening.

Caution

- Do NOT use the test strips or control solution after the expiration or discard date.
- Do NOT use test strips if the vial is damaged or left open to air. This can lead to inaccurate test results and error messages.

Cleaning and Disinfection of the Gmate® SMART Meter, Lancing Device, and iPhone, iPad or iPod touch

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

The Gmate® SMART Meter should be properly maintained for safe and accurate use. The meter should be properly maintained to prevent the spread of infectious diseases. Your Gmate® SMART Meter should be cleaned and disinfected at least once a week, or when blood, dirt, or any visible residue is on the meter, lancing device or iPhone, iPad or iPod touch, for a total of two cleaning and disinfection cycles per week. Cleaning and disinfecting is a two-step process and should be done once a week.

Cleaning and disinfection are different. Cleaning removes dirt and blood, but does not kill germs. You should always clean your meter, lancing device, and iPhone, iPad or iPod touch before disinfecting, which does kill germs. Disinfection is the only way to reduce your exposure to disease. Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

1. First clean the meter, lancing device, and iPhone, iPad or iPod touch using CaviWipes™ towelettes to remove visible dirt, blood or other substances. The meter, lancing device, and iPhone, iPad or iPod touch should always be cleaned prior to the disinfecting step.
2. Then disinfect the meter, lancing device, and iPhone, iPad or iPod touch using a second CaviWipes™ towelette to kill the germs that may spread infection.

Caution

Be careful when disinfecting your meter and iPhone, iPad or iPod touch. Do not submerge in water or any other liquid. Do not get disinfectant inside the iPhone, iPad or iPod touch connector.

Cleaning:

Clean the meter, lancing device and iPhone, iPad or iPod touch by wiping it with CaviWipes™ towelettes. Insert the meter into the iPhone, iPad or iPod touch device. Wipe the outside of the meter, lancing device and iPhone, iPad or iPod touch. Before you begin, squeeze out any excess liquid from the towelette so that it is damp but not dripping wet. Take extreme care not to get liquid in the test strip port and connector. CaviWipes™ have been shown to be safe for use with the meter, lancing device and iPhone, iPad and iPod touch.

Disinfecting:

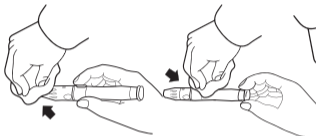
Insert the meter into the iPhone, iPad or iPod touch device. Wipe the meter, lancing device and iPhone, iPad or iPod touch with CaviWipes™ towelettes. It is very important to let it sit for two (2) minutes.

Wipe the outside of the meter, lancing device and iPhone, iPad or iPod touch with CaviWipes™ disinfecting towelettes. If the towelette is dripping wet, squeeze out excess liquid. Take extreme care to avoid getting liquid into the test strip port and connector.

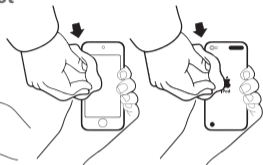
How to use the Caviwipes™ to Clean and Disinfect



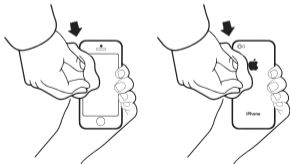
Gmate® SMART Meter



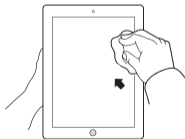
Lancing Device



iPod touch



iPhone



iPad



To achieve disinfection of all the stated efficacy claims, let the solution sit on the meter, lancing device and iPhone, iPad or iPod touch. Do this for at least 2 minutes. Allow the meter, lancing device and iPhone, iPad or iPod touch to dry completely before use. Do a control solution test after cleaning to make sure the meter was not damaged by the disinfection process.

Cleaning and disinfecting is important to prevent the spread of diseases. If you are interested in additional information of the importance of disinfection, please use the following references:

1. "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
2. "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk or Transmitting Bloodborne Pathogens" (2010)
<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

Your Gmate® SMART System has an expected life of five (5) years. It should withstand the cleaning and disinfecting recommended in this Owner's Manual.

"We cleaned and disinfected the Gmate® SMART Meter, lancing device, and iPhone, iPad, and iPod touch with CaviWipes™ disinfection towelettes. A total of 520 cleaning and disinfection cycles (these are two separate steps, please see page 73 for details) were performed. This testing simulates cleaning and disinfection once per week for five (5) years and whenever there is blood, dirt, or visible residue present (1 time per week minimum x 52 weeks x 5 years = 260 cycles, 1 time per week to remove blood, dirt, or visible residue x 52 weeks x 5 years = 260 cycles, total = 520. No change in performance, accuracy, or appearance was seen.

We recommend that you clean and disinfect the system at least once per week and whenever there is blood, dirt, or visible residue. The claimed use life of the system is five (5) years."

If you see changes in appearance (such as color fading, cracking, discoloration or display malfunctions) or you are obtaining results that are not accurate, stop using the meter or lancing device and call our Gmate® Customer Service Support for a replacement, 24 hours a day, 7 days a week at 1-855-GO-GMATE (1-855-464-6283).

The cleaning and disinfecting performance testing on the Gmate® SMART was done using CaviWipes™ with the EPA registration number of 46781-8. CaviWipes™ are manufactured by Metrex. CaviWipes™ are available through Metrex directly, Amazon.com, or Staples.com. If you see changes in appearance (such as color fading, cracking, discoloration or display malfunctions) or you are obtaining result that are not accurate stop using the meter or lancing device and call our Gmate® Customer Service Support for a replacement, 24 hours a day, 7 days a week at 1-855-GO-GMATE (1-855-464-6283).

Caution

- Place the Gmate® SMART Meter in the carrying case and store it in a cool and dry place.
- Keep out of reach of children.
- Do not store in the refrigerator. Do NOT freeze.
- Avoid exposure to the sun.
- Do NOT soak the meter and strips in water or liquid.
- Do NOT place the meter and strips in fire or microwave ovens.

Special Note to Caregivers

If you are a home health aide, family member or caregiver providing help to the owner of this Gmate® SMART Blood Glucose Monitoring System, it is important to prevent the spread of diseases. Always clean and disinfect the meter, lancing device, and iPhone, iPad or iPod touch following the steps on pages 73-81 before assisting the owner of this Gmate® SMART Blood Glucose Monitoring System.

Wash your hands thoroughly both before and after helping the patient. We also recommend you wear gloves while helping someone with their meter. After being exposed to blood, parts of the system are potential biohazards and can spread diseases such as HIV, hepatitis B and hepatitis C. For more information, please contact your local department of health or the toll-free help line at 1-855-GO-GMATE (1-855-464-6283).

ERROR MESSAGES

Unexpected results



If your test result is below 20 mg/dL, "LOW" will appear on the display screen. Repeat the test. If the result is still "LOW" and you are certain the meter is functioning correctly and no errors were made during the test procedure, the result may indicate severe hypoglycemia (low blood glucose). Contact your healthcare provider immediately.



If your test result is above 600 mg/dL, "HIGH" will appear on the display screen. Repeat the test. If the result is still "HIGH" and you are certain the meter is functioning correctly and no errors were made during the test procedure, the result may indicate severe hyperglycemia (high blood glucose). Contact your healthcare provider immediately.

Used strip error



The test strip has already been used. Repeat the test with a new test strip.

Temperature error



Indicates that the environmental temperature is ABOVE or BELOW the system operational range. System operational range is 50°F – 104°F (10°C – 40°C). Repeat the test after the meter and test strip have reached the correct temperature range.

TROUBLESHOOTING

Meter does not enter the test mode.

Probable Cause

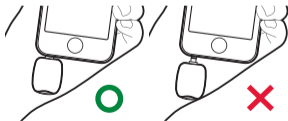


Volume on iPhone, iPad or iPod touch is not set to maximum.

What to do

Adjust to maximum volume.

Meter is not inserted right.



Insert the Gmate® SMART Meter again. Make sure that the meter is inserted all the way in. If the problem persists, contact Gmate® Customer Service Support toll-free at 1-855-GO-GMATE (1-855-464-6283).

Meter does not enter the test mode(continued).

Probable Cause

The meter is defective.
The meter does not light up.



What to do

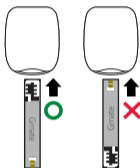
Disconnect the device and then reconnect.
If the same problem continues, contact Gmate®
Customer Service Support toll-free at 1-855-GO-GMATE
(1-855-464-6283).

Protective phone covers.

Remove the phone cover. Repeat the test.

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

Probable Cause



Test strip is inserted upside down, wrong end in, or not completely inserted into the meter.

What to do

Insert the test strip with the printed side up and the electrode end of the test strip into the test strip port of the meter.

The test strip is defective.

Repeat the test with a new test strip. If the same problem persists, contact Gmate® Customer Service Support toll-free at 1-855-GO-GMATE (1-855-464-6283).

Blood or foreign objects put into the test strip port.

Contact Gmate® Customer Service Support toll-free at 1-855-GO-GMATE (1-855-464-6283).

Test does not start after applying the blood sample.

Probable Cause

Blood sample is too small.

What to do

Repeat the test with a new test strip with a larger blood sample.



GMATE® SMART METER SPECIFICATIONS

Model	PG-101 (Gmate® SMART Blood Glucose Monitoring System)
Test Method	Electrochemical sensor
Calibration Method	Plasma
Sample	Whole blood, capillary
Sample Size	0.5 µL
Test Time	5 seconds
Memory	No limit (One test result is approximately 80 bytes stored in memory of your device)
Result Range	20-600 mg/dL (0.6~33.3 mmol/L)
Hematocrit	20-60%
Operating Temperature	50-104°F (10-40°C)
Operating Relative Humidity	10-90%
Altitude	Up to 10,000 feet (3,048 meters)
Power Source	From the smartphone
Size	21.0mm x 42.7mm x 8.8mm (0.83" x 1.68" x 0.35")
Weight	4.2g (0.15oz)

Electrical and Safety Standards

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

Warranty

Philosys warrants that your Gmate® SMART Meter will be free of defects in materials and workmanship for one (1) year, from the date of purchase. The warranty extends only to the original purchaser and is not transferable.

MEMO

Manufactured by philosys Co., Ltd.

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855-GO-GMATE (855-464-6283)

24 hours a day, 7 days a week

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