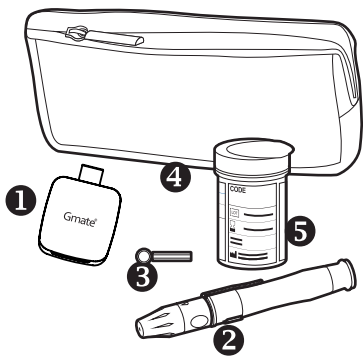# User's Guide

Gmate® SMART

with USB Type-C

Thank you for purchasing the Gmate® SMART Type-C Blood Glucose Monitoring System. Please read this User Guide thoroughly before operating the system as it provides important information for proper use. It is recommended that you keep this User Guide in a safe place for your future reference.

If you are using this product for the first time, it is very helpful to practice with a control solution that can replace your blood. For more information, please refer to the user's manual for Control Solution Testing (see page 53).

Contents

1. Gmate® SMART Type-C Meter
2. Lancing Device
3. Lancets
4. Carrying Case
5. Gmate® Test Strips

Note

■ Please call your local distributor if any items are missing.

■ Smartphone is not included.

■ Smartphone is required to use the Gmate® SMART Type-C Glucose Monitoring System.

■ Gmate® Control Solutions are an available separately.

Meaning of Symbols

⚠	Caution, see instructions for use
⊗	Single use only
⧖	Expiration date
SN	Serial number
LOT	Lot number
IVD	In Vitro Diagnostic medical device
🏭	Manufacturer
EC REP	Authorised representative
↟	Symbol for temperature limitation
🛈	Consult instructions for use
☣	Biological risks
Σ⧖	Contains sufficient for <n> tests
⎓	Direct current
🗑	Separate disposal from other household waste
REF	Reference number
CE 0197	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.

7

Intended Use

■ Self-testing, in-vitro blood glucose monitoring system : The Blood Glucose Monitoring System is intended for self-testing in diabetes management. It is used outside the body (in vitro diagnostic use) by layperson with diabetes at home and by healthcare professionals in clinical setting as an aid to monitor the effectiveness of diabetes control.This meter can test the glucose levels of blood from your fingertip, Upper arm, Forearm, Hand, Thigh or Calf. However, test results from sites other than the fingertip may differ from fingertip measurements. Consult your doctor or healthcare professional before testing blood from the Upper arm, Forearm, Hand, Thigh or Calf.

■ Disposable lancet : It is a single use disposable type instrument that is used for obtaining blood.

■ Lancing device : A device used to collect a small amount of blood from the body. The lancet is excluded.

Test Principle

The glucose test strip is coated with a reagent between two electrodes. When the reagent reacts with glucose in the blood, current is generated. This product measures the current using whole blood and displays the concentration of glucose in the blood.

Gmate® SMART Type-C Meter

Test Strip Port & Power Indicator

Insert the electrode part of a Gmate® Test Strip here when the light flashes.

Type-C USB Connector

Plug this end to the USB port of your Smartphone.
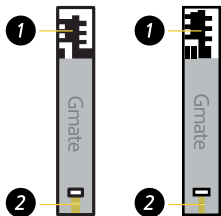
Gmate® Test Strip

Gmate® Blood
Glucose Test
Strips
(PS-004)

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

Electrodes

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

Yellow Filling Window

Apply your blood sample on the edge of this window.

10

Lancet

Lancet Body Holder

It fixes and secures the position of the lancet when placed in the lancing device.

Needle

The only part of the lancet that comes into contact with the human body while collecting blood sample. The Needle immediately come inside the lancing device after skin puncture.

Lancet Cap

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

Lancing device

Adjustable cap

Lancet holder

Clear AST cap

Lancet ejector

Release button

Lancing device body

Sliding barrel
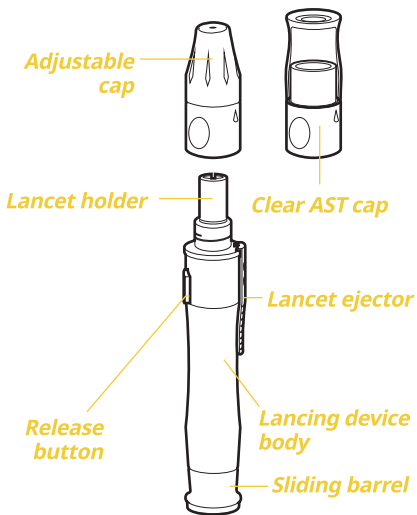
Adjustable cap

It adjusts the depth of puncture of the lancet.

Lancet holder

It's the part that being attached to the lancing device.

Release button

It's the button that release the lancet.

Lancet ejector

It's the part that eject the used lancet.

Sliding barrel

It's the part that need to be pulled out to prepare the lancing device to be ready for puncture.

Clear AST cap

It's a transparent AST cap that is used when blood sampling is done in other area than the fingertips.

Clear AST cap is an optional accesory. Please contact your local distributor for availability.
Lancing device may vary and is subjected to change without notice.
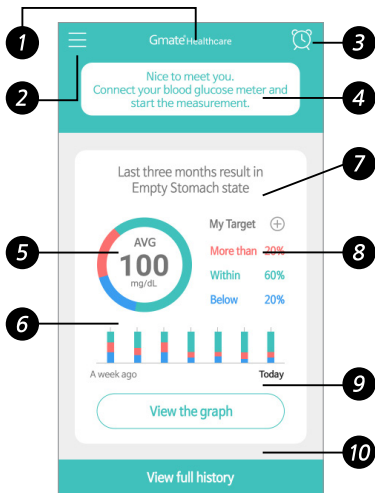
1. Title
Application logo image.

2. Menu
Go to the Settings menu.

3. Alarm
Go to Alarm Settings.

4. Guide area

- If there is no measured value, a measurement guide message is displayed.
- If a measured value is present, the latest measured value is displayed.
- If the number of test strips is less than 15, the number of remaining test strips and the shopping mall button will be displayed.

5. Pie graph

- The center shows the total average of last three months result in empty stomach state.
- Based on the recent three months result in empty stomach state, the percentage that goes above, within, or below the personal adjustment goal is displayed.

6. Bar graph

- Based on each day's measurements, the percentage corresponding to the personal control target range is displayed.
- The height of the bar graph shows the total average value of the measurements for that day.

7. Personal Adjustment Target

Go to the Personal Adjustment Target setting screen.

8. Target Value

The ratio is displayed above, within, and below, based on the last three months's measured values.

9. View the graph

Go to the graph view screen.

10. View full history

Go to the full history view screen.

Precautions while using blood glucose monitoring system

- ■ Since this product is for self-diagnosis or self-monitoring, it should not be used for diagnosis of diabetes without the help of a doctor.
- ■ This product is for in vitro diagnostic use only.
- ■ Blood glucose test strips used for testing newborn and pregnant women blood speci‑mens are not validated.
- ■ Be aware of sudden temperature changes. If there is a sudden change in temperature, wait for 30 minutes in a room temperature before measuring.
- ■ Do not drop the meter or apply strong impacts.
- ■ Do not drop the meter from high place or apply strong force on it.
- ■ If any abnormality is found, stop the measurement immediately, and contact your nearest seller immediately.
- ■ This product should be used with the Gmate® test strip and control solution, manufactured by Philosys.

- Before using this product, please read this manual carefully to ensure safe and accurate measurements.
- This product contains small measuring instruments which can be dangerous if swallowed.
- Keep the meter out of the reach of children. If a child swallows a battery or small part, seek immediate medical attention and consult a physician immediately.
- This product is not waterproof and should not be wiped with water or wet hands.
- Do not wipe this product with thinner or abrasive.
- The test strip should be stored in a cool, dry place at 2 ℃ ~ 32 ℃.
- The test strip should be stored away from direct sunlight or heat.

- After taking a test strip out from the storage container, close the storage container lid immediately.
- Do not drop the blood sample directly on the surface of the test strip.
- The blood is sucked in automatically when you put the collected blood at the end of the test strip.
- Do not press or bend the test strip with force. This may result in inaccurate measurement results due to blood not entering the test strip in suitable amount.
- Do not use damaged or re-use test strip. The test strip is disposable.
- Keep the test strip in its original container.
- Do not keep it mixed with other test strips in other containers.
- Do not cut or deform the test strips.

- Take the test strip out of the container and use it within 3 minutes. If the test strip is exposed to air for a long time, incorrect measurement results may occur.
- Use all the test strips within 3 months after opening the test strip container lid.
- Do not use a test strip that is expired. Incorrect measurement results may occur.
- Touch the test strip with clean and dry hands to perform the blood glucose measurement.
- Patients with renal dialysis may be affected by blood glucose measurement. Please use the product after consultation with your doctor.
- Patients with immunoglobulin treatment may be affected by blood glucose measurement. Please use the product after consultation with your doctor.

Precautions while using blood glucose test strip

- ■ This test strip should only be used for in vitro diagnostics.
- ■ This test strip should only be used with our approved Gmate® Blood Glucose Meter.
- ■ The blood glucose test, using this system, should not be considered as replacement of medical care provided at medical institutions. It is just a method to monitor your sugar level and receive treatment while consulting a doctor and share the test results.
- ■ Be careful of sudden temperature changes. If there is a sudden change in temperature, wait for 30 minutes in room temperature before measuring.

■ Blood glucose test strips used for testing newborn and pregnant women blood specimens are not validated.

■ If the blood sample exceeds 20 ~ 60% of the hematocrit range, the measurement value is not correct. Please contact your doctor or specialist.

■ The test strip should be used within 3 months after opening the container lid.

■ Conditions of use: Temperature 10 ~ 32 ℃, Relative Humidity 90% or less, Altitude 3,048m.

■ The test strip is disposable. Do not re-use.

Precautions while using the lancet

- ■ For user's safety, while attaching a lancet into the lancing device, connect the lancet without removing the lancet's protective cover (lancet cap). Immediately before installing the lancing device's lid, remove the lancet cap.
- ■ Do not use products that have damaged or no protective cap.
- ■ The lancet is a disposable, sterilized product, so reuse and re-sterilization are prohibited.
- ■ Do not apply excessive force to the product during use.
- ■ Be sure to only press the button on the lancing device to obtain blood sample. Be careful not to make any mistakes or other damage due to careless use of the button.

Precautions while using the lancing device

■ A non-standard lancet cannot be used with this lancing device, so be sure to use the appropriate lancet.

■ Use only for specified purpose, and do not use it for other purposes.

■ If there is any problem in storing and using, please inform the seller as solution and follow up measures will be provided.

The Gmate® SMART Type-C Blood Glucose Monitoring System should be used with the Gmate® Healthcare application.

The Gmate® Healthcare application is free and can be downloaded from the Google Play Store.

You can download the Gmate® Healthcare App by scanning the QR code.

For Android

To download the application to your smartphone, select the App Store or Play Store icon and enter "Gmate healthcare" in the search box on the screen.
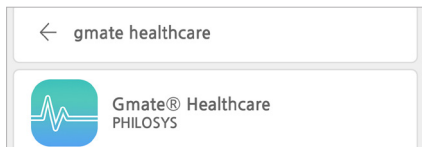
STEP 1

If you have downloaded the application, select "Register" after starting the app and proceed with the registration process.

*It is possible to measure blood without registration. However, user setting and data management facility will be unavailable.

STEP 2

After checking the terms and conditions, check the agreement. Then enter the email and password you will use to sign in.

STEP 3

Enter your name / birth year / height / weight (optional) to complete your membership.

Application settings

If you select the " " icon from the main screen, you can go to Screen setting. Personal settings, recording, sharing, and other settings are available.
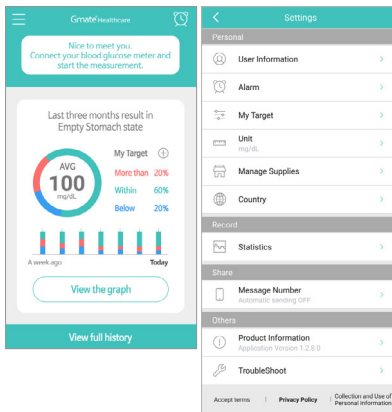
1. Personal settings

User Information: You can view and edit information entered by the user (name / age / height / weight). You can also change the password that you set when registering. If you forget the password you set, you can also use the registered e-mail to issue a temporary password. Logout and unsubscribe are also available on this page.

Measurement Time Setting Notification: You can set notifications for before breakfast / after breakfast / before lunch / after lunch / before dinner / after dinner / before bed / other. If you need to set time and use initialization, you can reset it by selecting "   " button.

Target Adjustment Setting: You can set and control the "Target Adjustment" for Empty Stomach/Before Meal/After Meal/Before bed/Others.

Unit Setting: You can set height / weight unit. If you cannot change the Unit of blood glucose Measurement (UoM) in your device, it means that the local distributor has fixed it as default unit. Please contact the local distributor, if you have any inquiries regarding UoM.

Consumables management: It is possible to manage the number of test strips and lancets. You can set it by scrolling the number to the left or right or by entering the number directly.

Country setting: You can set your country.

2. Recording

Statistics: You can see the total number of measurements and mean blood glucose values for your blood glucose data. You can view the latest holistic result of 7, 14, 30, 60, 90 days.

3. Sharing

Text message sending: If automatic transmission is set, the result is auto-matically sent to the desired mobile number after the measurement is completed.

*This feature is only applicable to Android devices.

4. Other settings

Product Information: You can check the application version and smartphone firmware version and model.

Troubleshoot: Gmate® SMART is a glucose meter which is being used by connecting to your smartphone, but may have problems depending on your smartphone settings. Please check if you have problems with blood glucose measurement. See page 59 for the list of problems and their solutions that are difficult to identify.

Blood Sampling
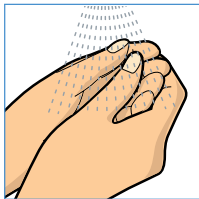
STEP 1

Wash your hands with warm water to increase blood circulation into the fingers. Then dry your hands completely.
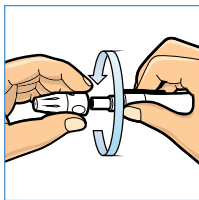
STEP 2

Unscrew the adjustable cap.
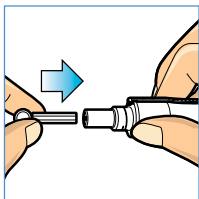
STEP 3

Insert a new sterile lancet into the lancet holder and fix it in firmly.
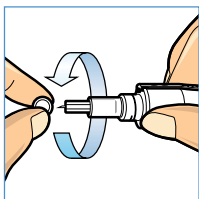
STEP 4

Hold the lancet and the lancing device together in one hand and twist off the protective cap with the other hand.
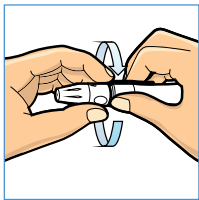
STEP 5

Place the adjustable cap back on the lancing device.
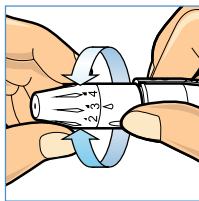
STEP 6

Set your desired depth level by twisting the adjustable cap. The smaller numbers are for shallower puncture that is more suitable for softer skin while bigger numbers are for deeper puncture that is more suitable for thicker or calloused skin.
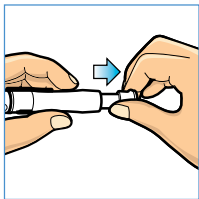
STEP 7

Draw the sliding barrel to cock the lancing device.
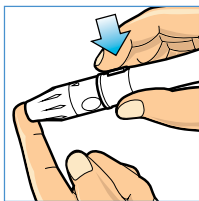
STEP 8

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

STEP 9

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

To reduce the risk of infection, follow these steps:

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

Alternative Site Testing

This meter can test the glucose levels of blood from your fingertip, Upper arm, Forearm, Hand, Thigh or Calf. However, test results from sites other than the fingertip may differ from fingertip measurements. Consult your doctor or health-care professional before testing blood from the Upper arm, Forearm, Hand, Thigh or Calf.

Upper Arm

Forearm

Hand

Fingertips

Thigh

Calf
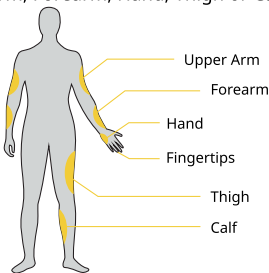
Use blood from	If you are going to test
Fingertip, Upper arm, Forearm, Hand, Thigh, Calf	* Before meals * Two hours or more after meals * Two hours or more after exercise
Fingertip	* When there is the possibility of your blood glucose levels changing rapidly (e.g. after meals or exercise) * When experiencing symptoms of hypoglycemia such as perspiration, cold seats, a floating sensation or trembling * When immediate testing is needed for suspected hypoglycemia * When in poor physical condition, such as with a head cold, etc.

37

Caution

- Please consult with a specialist before taking alternative site measurements.
- Avoid moles, veins, bones, and tendons.
- Do not take alternate site testing if you think your blood glucose level will change drastically within two hours of exercise, within two hours of insulin administration, or within two hours of a meal.
- Do not take alternate site testing if hypoglycemia is suspected or hypoglycemia is not noticeable.
- Do not use an alternative site testing to calibrate a continuous glucose monitoring system.
- Do not use an alternative site testing to calculate insulin doses.
- Finger blood sampling can detect hypoglycemia more quickly than alternative site testing.

Alternative site blood sampling is different from finger blood sampling.
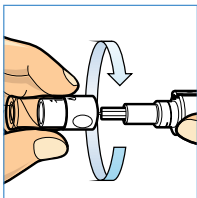
STEP 1

After inserting a new sterile lancet firmly into the lancet carrier, place the clear AST cap on top.
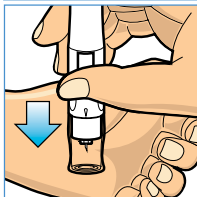
STEP 2

Hold the lancing device against the site you have chosen to lance. Avoid moles, veins, bones, and tendons. Press and hold the lancing device on the spot for a few seconds. Then press the release button to collect a blood sample. Observe through the clear cap to see if sufficient amount of blood sample is visible. If the blood volume is insufficient, massage the area gently.

Preparation before Test

- Stabilize the user's condition before measurement and make the measurement in the correct state.
- Make sure that the connection between the smartphone and the meter is good.
- Make sure that the temperature of the measurement environment is 10 ~ 32 ℃.
- Make sure that the blood glucose test strip has not expired.
- Wash your hands thoroughly with soap and warm water and dry them well.

Performing the Test

STEP 1

Touch the Gmate® Healthcare icon on your smartphone to launch the application. If you have not installed the Gmate® Healthcare application, please install the application first.
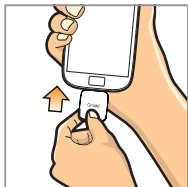
STEP 2

Insert the Gmate® SMART Type-C Blood Glucose Meter into the external connector connection jack on your smartphone. You will see a guiding window on the screen, which ensures that enough power is supplied to the Gmate® SMART Type-C Blood Glucose Meter. A white light blinking on the meter indicates that Gmate SMART Type-C is ready to use.

■ The location of the external connection jack may differ depending on the smartphone model. So please refer to the smartphone user manual.
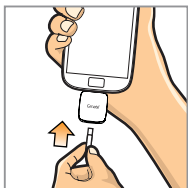
STEP 3

When the message "Insert the Electrode part of the strip in the glucometer" is displayed, hold the electrode of the test strip up and insert the electrode part into the test strip port of the meter. Slide the test strip until it is no longer inserted.

STEP 4

On the screen, you will see "Put the blood at the end side of the strip". This indicates that the meter is ready for measurement.
Check that the code number displayed on the meter matches the code number of the strip vial. If the two code numbers are different, remove the test strip and insert it again.
If the two code numbers are still different, insert a new test strip. If the code number differs even when a new test strip is inserted, please contact the customer service office.
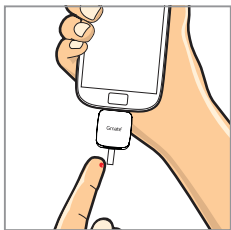
STEP 5

Collect a blood sample using the lancing device and then bring the blood sample to the Yellow Filling Window. The yellow window will automatically draw your blood.

- ■ The blood sample volume must be at least 0.5 microliter.
- ■ The meter may not start the test if there is not enough blood sample on the test strip.
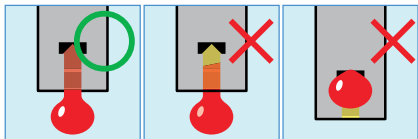
STEP 6

The test will take 5 seconds
to complete.
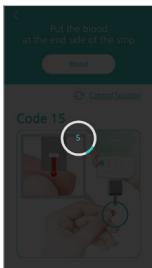
STEP 7

The meter will display
your blood glucose
result on the screen.
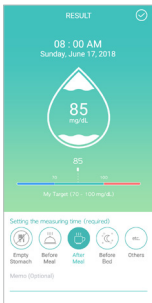
- Repeat the test if your test result is displayed as one of the following:
  - Below 50 mg/dL (2.8 mmol/L)
  - Above 250 mg/dL (13.9 mmol/L)
- "HIGH": Your test result is above 600 mg/dL(33.3 mmol/L)
- "LOW": Your test result is below 20 mg/dL(1.1 mmol/L)

STEP 8

You can customize your results by selecting a relevant icon (Empty Stomach, Before Meal, After Meal, Before bed, Others) You may also type in additional comments.

STEP 9

Remove the test strip from the meter.
The test results can be saved on the smart phone
by pressing the " " button.

- Used test strips and lancets may be considered biohazardous waste in your area.
- Be sure to confirm with your local regulation for proper disposal.
- If your blood glucose test results are below 50 mg/dL, above 250 mg/dL, or if "LOW" or "HIGH" is displayed on the screen, contact your healthcare professional immediately.

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

The expected blood glucose level is as per mentioned below.

▇ Fasting

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

Normal	less than 100 mg/dL (5.55 mmol/L)
Prediabetes	100 mg/dL (5.55 mmol/L) to 125 mg/dL (6.94 mmol/L)
Diabetes	126 mg/dL (7.00 mmol/L) or higher

▇ 2 hours after a meal:

Normal	less than 140 mg/dL (7.77 mmol/L)
Prediabetes	140 mg/dL (7.77 mmol/L) to 199 mg/dL 11.05 mmol/L)
Diabetes	200 mg/dL or higher (11.11 mmol/L)

References: http://www.diabetes.org/diabetes-basics/diagnosis

Performing the Test

The results of your measurements with the Gmate®SMART Type-C are stored on your smartphone. Even if you do not have a Gmate® SMART Type-C meter, you can check your test results anytime, anywhere.

You can check the test results on the PC through the link below.
http://gmate.philosys.com

STEP 1

Select and run the icon for the Gmate® healthcare application installed on your smartphone. If you select "Show all records" at the bottom of the main screen, the measurement results will be displayed as in the list.
The most recent measurement is displayed at the top of the screen.
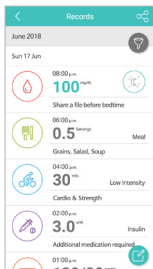
STEP 2

Select one of the measurement results in the list to display the corresponding details.

STEP 3

If you select "Graph view" on the main screen, it shows the average of the last week's measured values. You can also see the achievement rate and trend of personal adjustment goals.
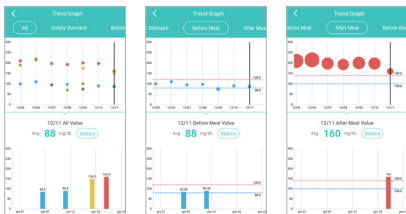
STEP 4

Pressing the graph view button shows the average of the whole day, Empty Stomach, Before Meal, After Meal, Before bed and Others. By scrolling left and right, you can observe the transition from past measurement to today's measurement. If you select the day in the top graph, you can also check detailed measurements for each time of the day.

51

Transfer test result

The results of the test using the Gmate® SMART Type-C meter can be transmitted through the shared application installed on the smartphone such as text message and e-mail using the wireless communication function of the smartphone.

STEP 1

Once you have selected the full history view, you can see the Share button . Press the Share button to send a single result or multiple measurement results.
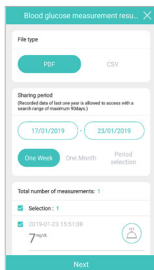
STEP 2

Shared file types can be selected as PDF / CSV, and the sharing period can be selected within 90 days from the record within 1 year. You can select or deselect data to share.

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

■ You want to practice the test process without sampling blood.
■ You open a new vial of test strips.
■ You suspect the meter or test strips are not working properly.
■ You get repeatedly unexpected blood glucose results.
■ You have dropped or damaged the meter.

STEP 1

Touch the Gmate® Healthcare icon on your smartphone to launch the application. If you have not installed the Gmate® Healthcare application, please install the application first.

STEP 2

Insert the Gmate® SMART Type-C B Blood Glucose Meter into the external connector connection jack on your smartphone. You will see a guiding window on the screen, which ensures that enough power is supplied to the Gmate® SMART Type-C Blood Glucose Meter. A white light is on the meter which indicates that the meter is on.

■ The location of the external connector connection jack may differ depending on the smartphone model. So please refer to the smartphone user manual.

STEP 3

When the message "Insert the Electrode part of the strip in the glucometer" is displayed, hold the electrode of the test strip up and insert the electrode part into the test strip port of the meter. Slide the test strip until it is no longer inserted.
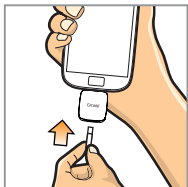
STEP 4

If you want to measure the control solution, please select " ↻Control Sloution " on the right screen.
The Control Solution screen is displayed.
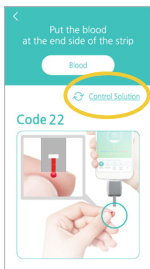
STEP 5

On the screen, you will see "Put the control solution at the end side of the strip". This indicates that you are ready to measure your glucose. Make sure that the code number displayed on the meter matches the code number of the strip vial. If the two code numbers are different, remove the test strip and insert it again. If the two code numbers are different, insert a new test strip. If the code number differs even when a new test strip is inserted, please contact the customer service office.
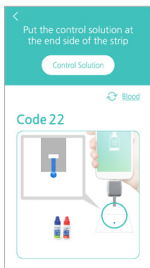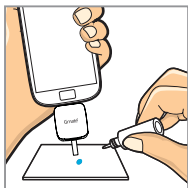
STEP 6

Shake the bottle of the control solution well and open the lid. Discard the first drop. Gently squeeze a sample of control solution onto a clean, flat, and hard surface and place it on the end of the test strip. Control solution will be automatically sucked into the test strip.
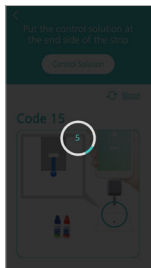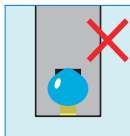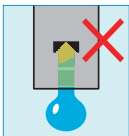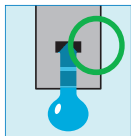
STEP 7

The measurement will take 5 seconds. A bar graph will indicate the duration.

STEP 8

The meter will display the control solution test result on the screen.
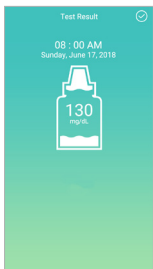
STEP 9

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.

Control Test Range
80-120mg/dL
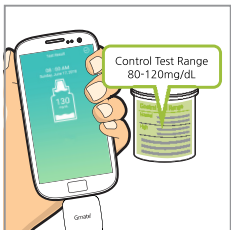
Out-of-range results may occur due to following reasons:

- ■ An error occurred while following the test steps.
- ■ Usage of expired test strip, mixed with water or contaminated control solution.
- ■ Usage of expired or damaged test strip.
- ■ The meter has some defect.

STEP 10

Remove the test strip from the meter.

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

Message	**Used Strip Error** Remove the used strip. Please insert a new strip.
Probable cause	Used test strip has been inserted.
To do	It's a disposable one time use test strip. This message is displayed on the screen when used test strip has been inserted in the meter. Please use a new test strip.
Message	**Recognizing Code Number** Code number can not be recognized. Please insert the strip again.
Probable cause	There is a problem in recognizing the test strip.
To do	There is a problem recognizing the test strip. Remove the test strip completely and try again. If the same error appears again, even if you put it in several times, please use a new test strip.

59

Message	**Error** Meter has problem.
Probable cause	A meter error has occurred.
To do	This is an error message when there is a problem with the meter. Try again to connect the meter, but if you still have the same error, please contact Customer Services Center.
Message	**Temperature error (high / low)** Ambient temperature out of range.
Probable cause	Out of operating temperature range.
To do	This message is displayed on the screen when the ambient temperature is outside the range of temperatures the meter can be used. The operating temperature of the meter is 10-32 ℃ (50-89.6 ℉). If this message is displayed on the screen, please put the meter and the test strip at room temperature for 20 minutes, and then start again from the beginning.

Message	There is no response after you connect the meter to your smartphone.
Probable cause	The meter is defective.
To do	Try to reconnect. If the error message appears again, please contact your local distributor.
Probable cause	Gmate® SMART Type-C meter is not properly connected to the smartphone.
To do	Insert the meter to the end of the USB jack on your smartphone.
Probable cause	The meter will not connect to the smartphone with certain phone cases.
To do	Remove the phone case and try connecting again.

Message	There is no response after you insert the test strip into the meter.
Probable cause	The test strip is not inserted properly.
To do	Re-insert the test strip and make sure it is placed all the way to the test strip port.
Probable cause	The meter or test strip is defective.
To do	Repeat the test with a new test strip. If the error message appears again, please contact your local distributor.
Probable cause	Foreign objects have entered the test strip port.
To do	Please contact your local distributor.
Message	There is no response after the blood sample is applied to the test strip.
Probable cause	Applied blood volume is too low.
To do	After inserting a new test strip, repeat the test with enough blood volume.
Probable cause	The meter or test strip is defective.
To do	Repeat the test with a new test strip. If the error message appears again, please contact your local distributor.

How to store after use

- Do not store the Blood Glucose Monitoring System near water.
- Store the Blood Glucose Monitoring System in a place where temperature, humidity, etc. are not adversely affected.
- Do not expose the Blood Glucose Monitoring System to direct sunlight for a long time.
- Be careful not to let any foreign materials such as dirt and blood and water to the test strip port.
- Do not store the Blood Glucose Monitoring System in the chemical storage area or gas generating place.

How to store (Gmate® SMART Type-C)

- Store the meter in a cool and dry place at room temperature.
- Storage condition: Temperature -20 to 50 ℃, RH 90% or less.
- Operating condition: Temperature 10 to 32 ℃, RH 90% or less.
- Store the meter in a well-ventilated place.

How to store (Gmate® Test Strip)

- Storage condition: Temperature 2 to 32 ℃, RH 90% or less.
- Operating condition: Temperature 10 to 32 ℃, RH 90% or less.
- Please be sure to close the vial after use.

Expiration date (Gmate® Test Strip)

- Unopened: 24 months from date of manufacture.
- Opened: 3 months from the date of first opening.

Be sure to check the expiration date of the test strip and the control solution.

- Test strips and control solution have expiration dates printed on their vials. When you first open the test strip or control solution vial, please record the open date in the space provided on the label. All test strips and control solutions are valid for no more than three (3) months after the first opening.

- Do not use the test strip and the control solution that passed the expiration date or 3 months after the first opening. The test result may be inaccurate.

- Do not use the test strip with damaged packaging or opened lid that have been stored for a long time. If the test strip is used, an error message may be displayed on the screen or incorrect test results may be obtained.

Cleaning the meter

■ With a soft cloth dampened with water and mild detergent, gently wipe the exterior of your meter. Do not use alcohol or other solvents to clean. Do not get any liquids, dirt, or other foreign objects through the test strip port.

Cleaning the lancing device

■ Wipe the exterior of the lancing device using a soft cloth dampened with water and mild soap. Wash the adjustable cap and clear AST cap with water and mild soap. Do not immerse the lancing device in liquid.

Performance Characteristics

Clinical accuracy
(Gmate® Blood Glucose Test Strips (PS-004))

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

within ±5 mg/dL (0.27 mmol/L)	within ±10 mg/dL (0.55 mmol/L)	within ±15 mg/dL (0.83 mmol/L)
92/144 (64%)	137/144 (95%)	144/144 (100%)

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

within ±5 %	within ±10 %	within ±15 %
239/456 (52.4%)	431/456 (94.5%)	456/456 (100%)

Measurement precision
Measurement repeatability

Mean glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation(%)
46.07 mg/dL (2.56 mmol/L)	2.6 mg/dL (0.14 mmol/L)	5.64
92.85 mg/dL (5.16 mmol/L)	3.15 mg/dL (0.18 mmol/L)	3.39
141.87 mg/dL (7.88 mmol/L)	2.94 mg/dL (0.16 mmol/L)	2.07
222.63 mg/dL (12.37 mmol/L)	6.41 mg/dL (0.36 mmol/L)	2.88
328.38 mg/dL (18.24 mmol/L)	9.47 mg/dL (0.53 mmol/L)	2.88

Intermediate measurement precision

Mean glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation(%)
35.09 mg/dL (1.95 mmol/L)	2.46 mg/dL (0.14 mmol/L)	7.02
128.84 mg/dL (7.16 mmol/L)	3.67 mg/dL (0.20 mmol/L)	2.85
344.2 mg/dL (19.12 mmol/L)	10.24 mg/dL (0.57 mmol/L)	2.97

User performance evaluation

The blood glucose values of finger capillary blood samples measured by 100 lay persons are shown below.

	Glucose concentration <100mg/dL (5.55 mmol/L)	Glucose concentration <100mg/dL (5.55 mmol/L)
Within ±15 mg/dL (0.83 mmol/L)	600 / 600 (100%)	
Within ±15%		600 / 600 (100%)

Interference

The effect of various interfering substances was evaluated in whole blood samples on glucose measurements.

Interference	lower limit (mg/dL)	Upper limit (mg/dL)
Acetaminophen	5	20
Acscorbric acid	0.75	3
Bilirubin	5	40
Cholesterol	62.5	500
Creatinine	0.5	10
Dopamine	2.5	20
EDTA	25	200
Galactose	1.56	15
Gentisic acid	125	1000
Glutathione	12	92
Haemoglobin	7	20
Heparin	62.5	500
Ibuprofen	6.25	50
Icodextrin	136.8	1094.4
L-DOPA	0.0625	0.5
Maltose	1250	10000
Methyl-DOPA	125	1000
Pralidoxime Iodide (PAM)	2.5	20
Salicylate	7.5	60

Tolbutamide	12.5	100
Tolazamide	5	40
Triglycerides	187.5	1500
Uric acid	3	24
Xylose	25	200

- Glucose concentration interval : 50, 100, 250, 300 mg/dL
- The 'upper limit' shown in this table is the concentration of interference checked by the test.
- Interference that is not listed in this table may affect the results.
- Patients who are undergoing pharmacotherapy may yield false results. Please contact your doctor before use.

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

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

within ±5 mg/dL (0.27 mmol/L)	within ±10 mg/dL (0.55 mmol/L)	within ±15 mg/dL (0.83 mmol/L)
77 / 156 (49%)	150 / 156 (96%)	156 / 156 (100%)

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

within ±5 %	within ±10 %	within ±15 %
202 / 444(45%)	428 / 444 (96%)	444 / 444 (100%)

Measurement precision
Measurement repeatability

Mean glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation(%)
46.07 mg/dL (2.56 mmol/L)	2.6 mg/dL (0.14 mmol/L)	5.64
92.85 mg/dL (5.16 mmol/L)	3.15 mg/dL (0.18 mmol/L)	3.39
141.87 mg/dL (7.88 mmol/L)	2.94 mg/dL (0.16 mmol/L)	2.07
222.63 mg/dL (12.37 mmol/L)	6.41 mg/dL (0.36 mmol/L)	2.88
328.38 mg/dL (18.24 mmol/L)	9.47 mg/dL (0.53 mmol/L)	2.88

Intermediate measurement precision

Mean glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation(%)
32.98 mg/dL (1.83 mmol/L)	3.22 mg/dL (0.18 mmol/L)	9.76
120.37 mg/dL (6.69 mmol/L)	4.36 mg/dL (0.24 mmol/L)	3.62
384.16 mg/dL (21.34 mmol/L)	10.24 mg/dL (0.57 mmol/L)	2.97

User performance evaluation

The blood glucose values of finger capillary blood samples measured by 100 lay persons are shown below.

	Glucose concentration <100mg/dL (5.55 mmol/L)	Glucose concentration <100mg/dL (5.55 mmol/L)
Within ±15 mg/dL (0.83 mmol/L)	600 / 600 (100%)	
Within ±15%		600 / 600 (100%)

Interference

The effect of various interfering substances was evaluated in whole blood samples on glucose measurements.

Interference	lower limit (mg/dL)	Upper limit (mg/dL)
Acetaminophen	5	20
Acscorbic acid	0.75	3
Bilirubin	5	40
Cholesterol	62.5	500
Creatinine	0.5	10
Dopamine	2.5	20
EDTA	25	200
Galactose	1.56	15
Gentisic acid	125	1000
Glutathione	12	92
Haemoglobin	7	20
Heparin	62.5	500
Ibuprofen	6.25	50
Icodextrin	136.8	1094.4
L-DOPA	0.0625	0.5
Maltose	1250	10000
Methyl-DOPA	125	1000
Pralidoxime Iodide (PAM)	2.5	20
Salicylate	7.5	60

Tolbutamide	12.5	100
Tolazamide	5	40
Triglycerides	187.5	1500
Uric acid	3	24
Xylose	25	200

- Glucose concentration interval : 50, 100, 250, 300 mg/dL
- The 'upper limit' shown in this table is the concentration of interference checked by the test.
- Interference that is not listed in this table may affect the results.
- Patients who are undergoing pharmacotherapy may yield false results. Please contact your doctor before use.

System Specifications

Product Name	Gmate® SMART Type-C
Item	Blood Glucose Monitoring System
Model	PG-115
Certification No.	CE0197
Test Method	Electrochemical sensor
Sample	Capillary, Venous, Arterial Blood
Sample Size	0.5$\mu\ell$
Test Time	5 seconds
Memory	No limit (depends on smartphone capacity)
Result range	20-600mg/dL(1.1-33.3mmol/L)
Hematocrit Level	20-60%
Operation Temperature	10-32℃ (50-89.6℉)
Operating Relative Humidity	Less than 90%
Altitude	Up to 3,048 meters (10,000 feets)
Rated Voltage	5V d.c., 11mA
Power Source	From the Smartphone
Size	28.0 mm x 39.9 mm x 8.5 mm (1.1023" x 1.5708" x 0.3346")
Weight	6.8 g (0.23 oz)

	Lancing Device	Lancet
Brand Name	Lanzo	NANOLET TM
Item	Lancing Device	Sterile single-use lancet for blood collection
Model	Lanzo 1.5 Lancing Device	DB905B
ItemAuthorization Number	-	CE1639
Packing Unit	1ea	1PACK (10ea)
Intended Use	A device used to collect small quantity of blood sample from the body. Excluding lancet.	A disposable auto-device used for collecting blood sample
Manufacture	GMMC Bongseonglo 82-16 (506-6, Dangjeong-dong), Gunpo-si, Gyeonggi-do, Republic of Korea	Dong Bang medical co., Ltd. 40&30 Saneopdanji-gil, Ungcheon-eup, Boryeong-si, Chungcheongnam-do, Korea
EU Represetative	GMMC S.L. Carrer de Garbí, 15, 46240 Carlet (Valencia), Spain	Meridius Medical Europe Ltd. Unit 3D, North Point House, North Point Business Park, New Mallow Road, Cork, T23 AT2P, Ireland
Remarks	-	Disposable medical device Do not reuse

Warranty

Philosys warrants that the Gmate® SMART Type-C 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.