

BIONIME

Blood Glucose Monitoring System Instructions for Use

Rightest™ GM100

Preface

Thank you for choosing the **Rightest™** GM100 Blood Glucose Monitoring System. Please read this manual thoroughly before testing. It provides all information you need to use the product. **Please only purchase test strips in your country. Use of test strips from different countries might get deviated test results under such circumstance.** We hereafter call **Rightest™** GM100 Blood Glucose Monitoring System as GM100 BGMS, **Rightest™** GM100 Blood Glucose Meter as GM100 meter, and **Rightest™** GS100 Blood Glucose Test Strip as GS100 test strip for short. It is recommended to monitor blood glucose regularly. To prevent derived complications effectively, it is recommended to monitor blood glucose regularly. GM100 BGMS accurate and easy-to-use, is your reliable assistant for diabetes management.

GM100 BGMS was manufactured and supported by Bionime Corporation and its authorized representative. If you have any question or concern, please contact your local Bionime Customer Service or email to rightest@bionime.com. We will provide best assistance and solutions for you.

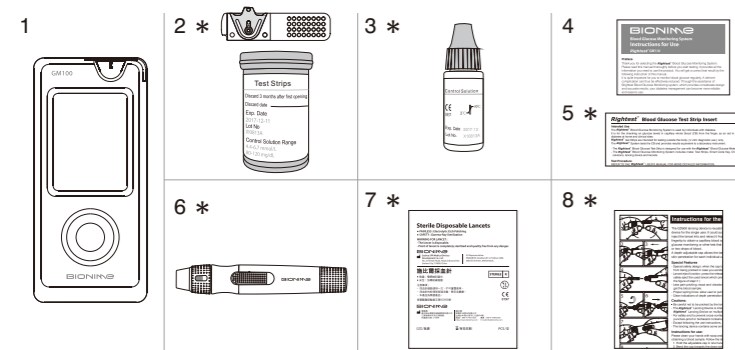
1. Intended Use

GM100 BGMS is intended for in vitro (outside the body) diagnostic use and self-testing only. **Coding is not required.** The testing result is calibrated to plasma equivalent with fresh capillary whole blood samples from the fingertip, palm or forearm. You may consult your healthcare professional for instructions how to use the system correctly. Our customer support staff is also available to assist you.

2. Package of Meter Kit

- | | |
|--|---|
| 1. GM100 Meter (with one CR2032 battery installed) | 6. GD500 Lancing Device * 7. Disposable Lancets (10pcs) * |
| 2. GS100 Test Strips (0/10/25 pcs) * | 8. Instructions for the lancing device * |
| 3. Control Solution * | 9. Log Book |
| 4. GM100 meter Instructions for Use | 10. Warranty Card + Emergency Card |
| 5. GS100 Test Strips Package Insert * | 11. Carrying Case * |

(Different packages have different bundled items. Some of packages might not include * items.)

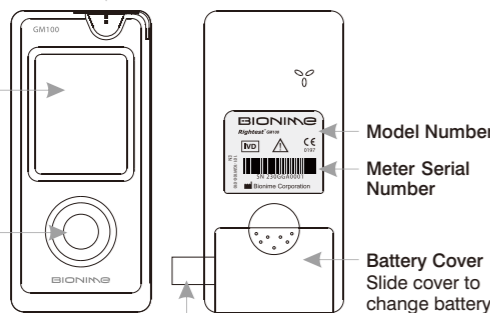


3. The Rightest™ Meter

Test Strip Port
Insert test strip here until you hear a click.

Display Window
Show your test result, messages and relative information.

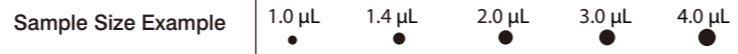
Main Button
For operating the meter, please check details in following sections.



Model Number
Meter Serial Number
Battery Cover
Slide cover to change battery.
Plastic Tape
Pull it off to activate meter.
(If time and date of your meter has been set in advance, the plastic tape will be removed. Hence, please discard this step)

4. Precautions

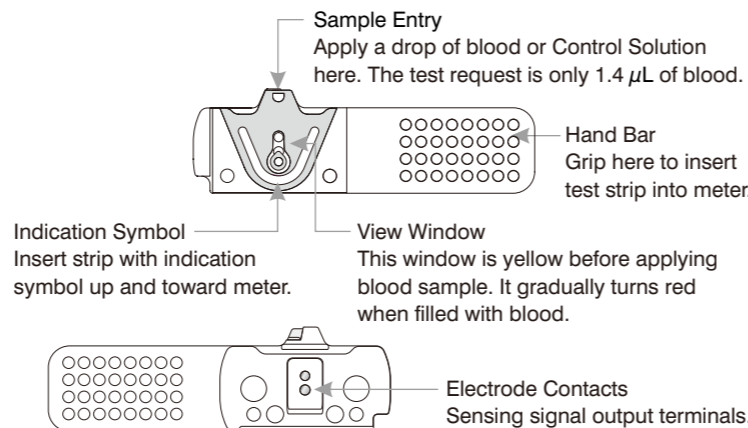
- Before using the GM100 BGMS to test your blood glucose, please read instructions and run the Quality Control Test.
- Please run the Quality Control Test regularly to make sure the entire system functions properly.
- The GM100 meter is only compatible with the GS100 test strip. Please do not use other test strips because they may cause inaccurate results.
- GM100 BGMS is intended for self-testing. It should not be used to diagnose diabetes mellitus.
- GM100 BGMS has not been validated for use on neonates. Therefore, it's not intended for use of neonates.
- GM100 BGMS is not intended for arterial blood testing .
- Do the test at least 30 minutes after moving into a different location with significant change in temperature.
- Dispose of used batteries properly.
- Please note the meter kit contains small parts like test strips which could result in a choking hazard for children.
- Prevent water from entering the meter. Never immerse the meter or hold it under running water.
- The minimum blood sample size for testing is 1.4 μL : (●)



We suggest you use a sample between 1.4~2.5 μL . A blood sample size above 4.0 μL is too large. A blood sample size below 1.4 μL may give an inaccurate test result. In this case, repeat the test with a new test strip.

5. GS100 Test Strips

GM100 meter is designed to use with GS100 test strip only. Please note that misuse of other test strips might cause unexpected damage or produce inaccurate test results.



PRECAUTION

- Re-cap the test strip vial immediately after removing a test strip.
- Do not reuse test strips.
- Do not use expired test strips.
- Record the date of opening a new test strip vial for the first time. Discard the vial of test strips after 3 months from opening.
- Store the test strips in a cool and dry location. Do not expose to direct sunlight or heat.
- For detailed information, please refer to the GS100 Test Strips Package Insert.

6. Battery Installation

Your meter comes with one CR2032, 3 volt, battery installed. One new battery will provide power to perform about 1,000 tests under normal use. Before using it, please pull off the plastic tape and press the main button to activate the meter (If time and date of your meter has been set in advance, the plastic tape will be removed. Hence, please discard this step).

1. Turn the meter over. Press and push battery cover to open.
2. Install the battery. Be sure to put battery in correct direction.
3. Slide the battery cover back until it snaps into place.
4. The meter performs a self-test and all symbols on the display will blink.
5. Press any button to exit the self-test and enter Setting Mode.

6. Set the time and date when the battery is replaced. See Setting the Date, Time and Unit section. Prior test results are still stored in the memory.

PRECAUTION

- Danger of explosion might happen if the battery is incorrectly replaced.
- Please follow the local regulation and discard a used battery properly .

7. Setting Up Your Meter-Setting the Date, Time, and Unit

You can enter Setting Mode by below two ways.

1. Reload battery
After removing the battery, please press the main button for several times until no signal on screen, then follow the battery installation steps to load battery. The meter will do self test. Press the main button to close the test and enter Setting Mode.
2. With Battery inserted
Press the main button first to turn on the meter. Then press and hold the main button for 5 seconds (the meter will be turned off during this period, please keep pressing) until you hear a beep, indicating you have successfully entered Setting Mode. The display screen will show setting data.

NOTE

- When you keep pressing the main button for 2 seconds, the display on screen will turn off. Please don't care it. Keep pressing the main button till entering setting data.
- Quick press the main button allows you to change setting while hold it for 2 seconds will confirm the setting. However, if you press and hold the main button over 5 seconds it will escape from setting mode and return to time screen.

1. Year setting
With the year format blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it. Meantime, it will shift to next digit for setting. Repeat the above action until the year setting is completed. Then it will move to month setting.
2. Month setting
With the month blinking, press the main button until the current month appears. Then hold the same button for 2 seconds to confirm it and move to day setting.
3. Day setting
With the day blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it. Meantime, it will shift to next digit for setting. Repeat the above action until the day setting is completed. Then it will move to time format setting.
4. Time format 12/24H selection
With the time format blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it and move to hours setting.
5. Hour setting
With the hour blinking, press the main button until the current hour appears. Then hold the same button for 2 seconds to confirm it and move to minute setting.
6. Minute setting
With the minute blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it. Meantime, it will shift to next digit for setting. Repeat the above action until the minute setting is completed. Then it will move to measurement of unit setting.
7. Setting the unit of measurement
With minimole per liter (mmol/L) blinking or milligrams per deciliter (mg/dL), press the main button to switch. Then hold the same button for 2 seconds to confirm it. (* This meter for some countries is fixed at mmol/L or mg/dL and is not able to be changed freely. In this case, please skip this step and go to next step directly.)
8. Ending setting
After confirming the measurement unit, you'll hear a sound of "beep". All the settings are saved and completed and will return to time screen.

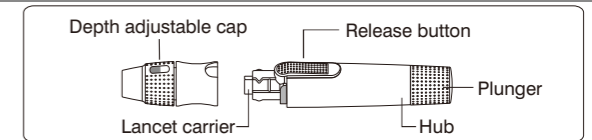
NOTE

- When you do not do any settings of meter for over 2 minutes, the meter will leave setting mode and power off automatically.
- Any time you would like to escape from the setting mode, please press and hold the main button for over 5 seconds. Meantime, all the current settings will be saved.

Turning on /off the Meter

1. How to turn on the Power
 - 1) Press the main button
 - 2) Insert one piece of test strip
2. Manual Power off
If you want to turn off the meter, please keep pressing the main button for 2 seconds.
3. Auto Power off
The meter will power off automatically if you don't operate it over 2 minutes.

8. Performing a Blood Test



1. Hold the adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side. When a gap appears between the cap and hub, pull them off in opposite directions.
2. Pull off the depth adjustable cap.
3. Insert a new disposable lancet firmly into lancet carrier.
4. Twist off and set aside the protective cover of the disposable lancet.
5. Replace the depth adjustable cap.
6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type: " " for soft or thin skin; " " for average skin; " " for thick or calloused skin.
7. Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, it will automatically move back to its original position near the hub.
8. Wash your hands with warm soapy water and dry thoroughly.
9. Take one strip from the vial. Re-cap the vial cap immediately.
10. Insert the strip into the strip port on meter with the indication symbol facing up.
11. While the blood drop symbol flashing, you are ready to apply the blood sample.
12. Place the lancing device against the pad of your fingertip and press the release button. The best puncture sites are on the middle or ring fingers. Press the release button.
13. Touch and hold the drop to the edge of sample entry until you hear a "beep" and the view window is totally filled with blood. If the view window is not totally filled with blood or the test does not start. Please discard the test strip and repeat the test with a new test strip.
14. You will see the countdown mode on the screen. After 8 seconds, the test result appears.
15. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.
16. Hold the release button in one hand and pull on the plunger in the other hand will safely eject the used disposable lancet.
17. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
18. Replace the depth adjustable cap after finishing the test.

PRECAUTION

- Do not touch your blood drop to the sample entry on the strip until you see the " " appear. The meter is performing an internal test and will display " " and "Error " if you apply blood too soon. Then you will waste a test strip.

