 **BIONIME CORPORATION**
No. 100, Sec. 2, Daqing St., South Dist.,
Taichung City 40242, Taiwan
Tel: +886 4 2369 2388
Fax: +886 4 2261 7586
Email: info@bionime.com
<http://www.bionime.com>
Made in Taiwan

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Email: EmergoVigilance@ul.com



0197

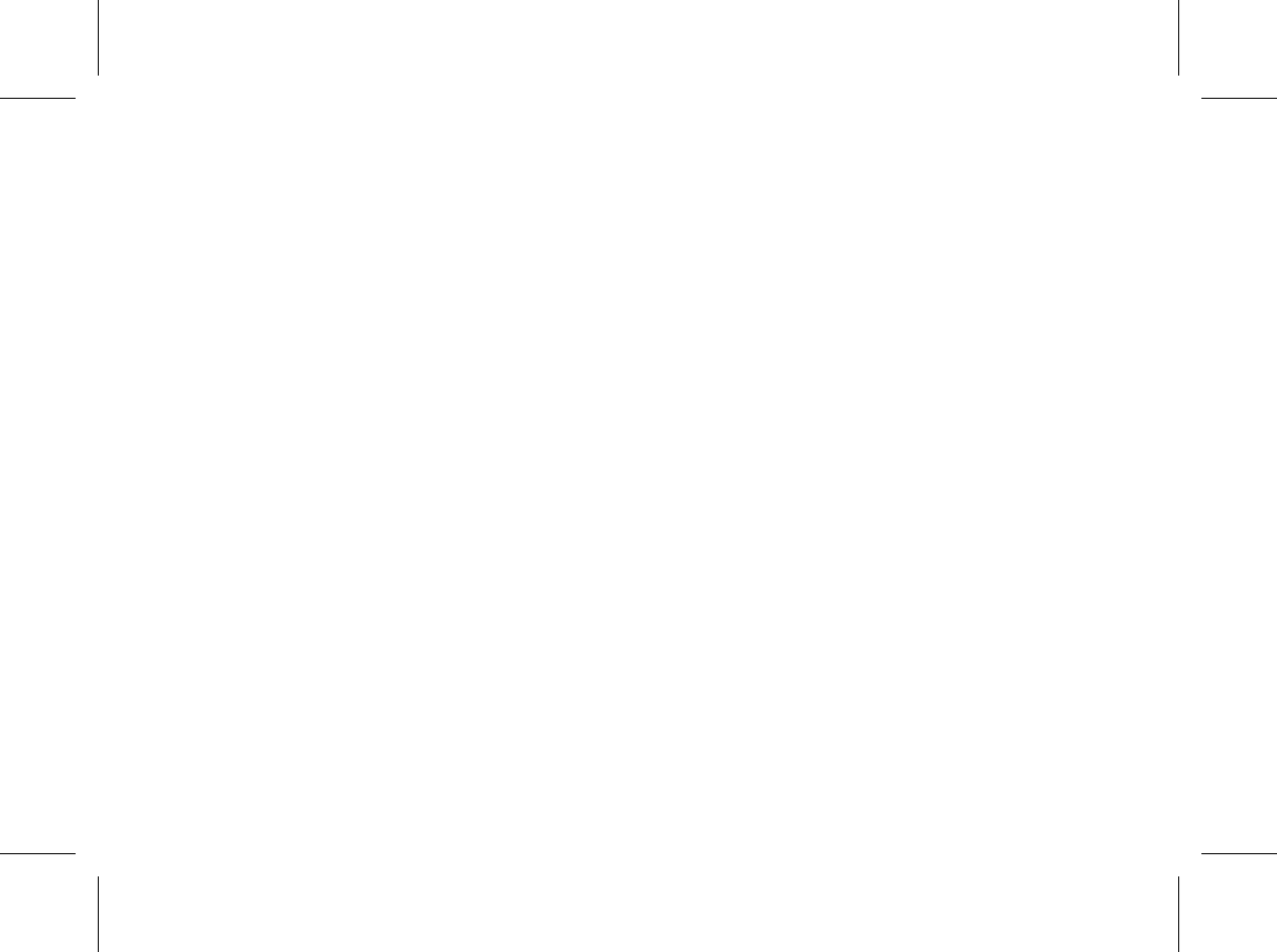
Rev. Date: 2022-07

101-3GM282-0A0
EN



RIGHTTEST™
Blood Glucose Monitoring System

GM280B
User's Manual



Intended Use

The RIGHTEST Blood Glucose Monitoring System GM280B is designed for *in vitro* diagnostic use (for self-testing outside the body) only, and can be used by home user and healthcare professional.

The system can test the glucose concentration in fresh capillary whole blood (drawn from fingertip, palm and forearm). The glucose result displayed is calibrated into the plasma glucose testing equivalent.

The system is not intended for the screening or diagnosis of diabetes mellitus.

The RIGHTEST GM280B is a Bluetooth Low Energy (BLE) device.

Preface

Thank you for choosing the RIGHTEST Blood Glucose Monitoring System GM280B. This manual contains all the information you need to use your product to start getting accurate blood glucose test results. Please read this entire manual before you get started with any testing.

It is important for people living with diabetes to regularly monitor their blood glucose levels to reduce complications. The easy-to-use RIGHTEST Blood Glucose Monitoring System GM280B provides accurate, reliable test results to help you manage your diabetes better.

You may wish to consult your healthcare professional for further advice on how to use this system. Our Customer Service information is on the cover and our staff are able to provide help.

Please contact a healthcare professional in an emergency or when our service is unavailable. Please forward your warranty card to customer support to activate your warranty coverage.

The RIGHTEST Blood Glucose Monitoring System GM280B is manufactured and supported by Bionime Corporation. If you have any questions or concerns, please contact your local Bionime Customer Service Representative or send an email to info@bionime.com for further assistance.

Caution

- Before using RIGHTEST Blood Glucose Monitoring System GM280B to test your blood glucose, please read all of this information and conduct all of the tests including the Quality Control Test (p39).
- We recommend you perform the Quality Control Test regularly to ensure test results are accurate.
- The RIGHTEST Blood Glucose Meter GM280B should only be used with RIGHTEST Blood Glucose Test Strip GS280. Test strips from other brands should not be used under any circumstances. The use of test strips from other brands may produce inaccurate results.
- If the RIGHTEST Meter and RIGHTEST Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature below 10°C (50°F) or above 50°C (104°F) - please wait at least 30 minutes before testing again.
- Follow all environmental protection regulations when disposing of batteries, strips and lancets.
- Avoid contact with spilled liquids.



Important Safety Notes

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the cleaning and disinfecting procedures. Please refer To the section "Maintaining the Products" on p45.
- Users should wash their hands with soap and water before and after handling the meter, lancing device, or test strips.

Caution

- The minimum blood sample size required for testing using the RIGHTEST Blood Glucose Monitoring System GM280B is 0.75 µL: (•)

Sample Size Example



Blood sample sizes greater than 3.0 µL may contaminate the test strip port and the meter. Samples smaller than 0.75 µL will result in an Er4 error message. If this occurs, repeat the test with a new test strip.

- The RIGHTEST System has not been validated for use on neonates. Do not use the RIGHTEST System to test neonates.
- The RIGHTEST System is not intended for arterial blood testing.
- Once a patient is suspected of having a rare disease (e.g. galactosemia), glucose results should be based on laboratory testing.

Limitations

- The RIGHTEST Blood Glucose Monitoring System GM280B is not intended for serum or plasma testing.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Patients going through oxygen therapy may yield falsely low results.
- The blood glucose test result may be affected by a high blood concentration of interference ingredients. If you need more detailed information about interference ingredients, please see the RIGHTEST Blood Glucose Test Strip GS280 Insert.
- Not for screening or diagnosis of diabetes mellitus.
- These test strips should not be used with meters to test critically ill patients or neonates.

Limitations

- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly). Please refer to the Alternative Site Testing (AST) chapter before you perform AST.
- DO NOT test on alternative sites (palm, forearm) if you are testing for insulin dose calculations, for Continuous Glucose Monitor (CGM) calibration or hypoglycemia (low blood glucose).
- To avoid potential electromagnetic interference, keep the meter away from electro magnetic radiation sources such as X-rays or MRI.

Table of Contents

About the RIGHTEST System GM280B	
RIGHTEST Blood Glucose Monitoring System GM280B	10
RIGHTEST Blood Glucose Meter GM280B	12
RIGHTEST Blood Glucose Test Strip GS280	16
Before Testing	
Meter Activation and Battery Change	18
Setting Up Your Meter- Setting the Date, Time, Volume and Test Unit	20
Turning On / Off the Meter	24
Testing Procedure	
Handling the RIGHTEST Blood Glucose Test Strip GS280	25
Performing a Blood Glucose Test	27
Setting Markers	32
Uploading Data	33
RIGHTEST CARE App	34
Alternative Site Testing (AST)	35
View Window Appearance	37

Table of Contents

Quality Control	
"Lo" and "Hi" Readings	38
About Quality Control Testing	39
Other Information	
Performing a Quality Control Test	42
Understanding Control Test Results	44
Maintaining the Products	45
Recalling Test Results	48
Recalling Average Test Results	50
Error Messages and Troubleshooting	52
Specification	56
Customer Service	58
Warranty	59
Expected Glucose Values	60

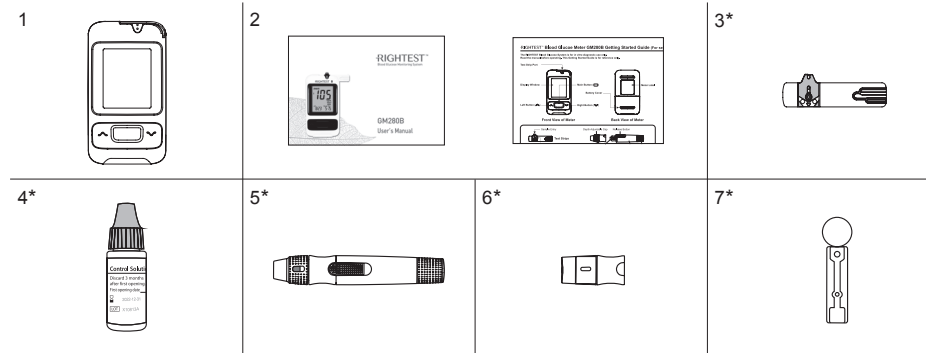
RIGHTEST Blood Glucose Monitoring System GM280B

Your RIGHTEST Blood Glucose Monitoring System GM280B consists of several items. Please identify each item and make sure you understand how to use them. The items in RIGHTEST Blood Glucose Monitoring System GM280B:

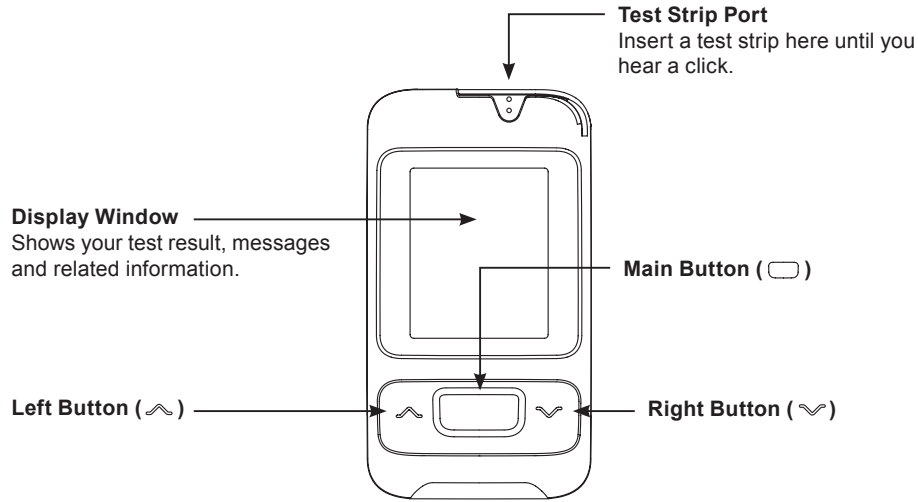
1. RIGHTEST Blood Glucose Meter GM280B (with 1 CR2032 battery installed)
2. Instruction documents (Getting Started and User's Manual (includes Log Book, Warranty Card, Emergency Card))
3. RIGHTEST Blood Glucose Test Strip GS280 (10/25 pcs)(with Insert) *
4. RIGHTEST Control Solution GC550 (with Insert) *
5. RIGHTEST Lancing Device (with Insert) *
6. Clear Cap *
7. Disposable Sterile Lancets (10 pcs) *
8. Carrying Case (not shown) *

* Different packages have different bundled items. If you want to purchase items not included in your kit, please contact your distributor.

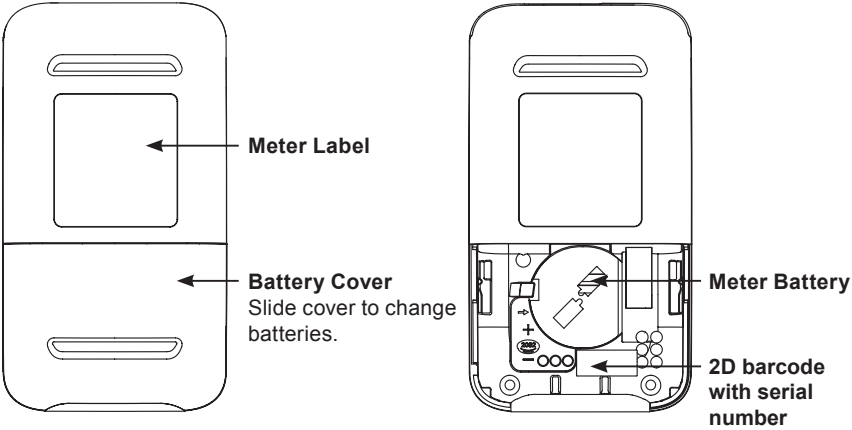
RIGHTEST Blood Glucose Monitoring System GM280B



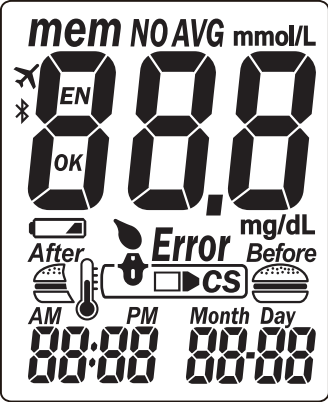
RIGHTEST Blood Glucose Meter GM280B



RIGHTEST Blood Glucose Meter GM280B



RIGHTEST Blood Glucose Meter GM280B



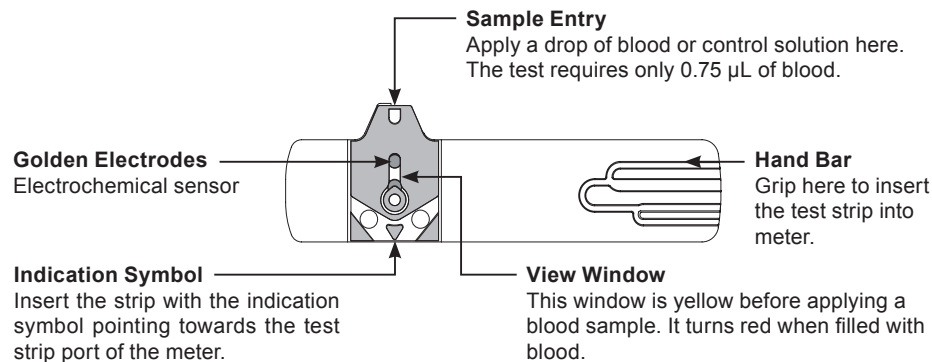
RIGHTEST Blood Glucose Meter GM280B

mem	Indicates a test result stored in memory		Indicates when to apply the blood sample
AVG	Indicates the average result		Appears after you insert test strip into meter
CS	Indicates a control solution test result	Error	Appears when an error occurs
mmol/L mg/dL	Unit of test result	Month Day 88-88	Current date under time mode or testing date under memory mode
888	Test result		Warns when the operational temperature limit is exceeded during testing
	Warns when the battery is low or must be replaced	AM PM	Indicates the time in 12H format
	indicates a meal marker with test result	88:88	Displays current time under time mode or testing time under memory mode
OK EN ✕ NO	Manufacturing use only		Transfer data via bluetooth(Bluetooth meter only)

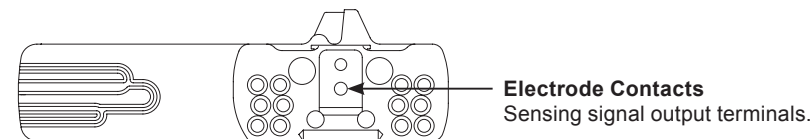
RIGHTEST Blood Glucose Test Strip GS280

The RIGHTEST Blood Glucose Meter GM280B must only be used with RIGHTEST Blood Glucose Test Strip GS280 and RIGHTEST Control Solution GC550.

The use of other test strips or control solutions may lead to incorrect results.



RIGHTEST Blood Glucose Test Strip GS280



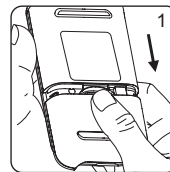
PRECAUTION

- Close the test strip vial immediately after taking out a test strip.
- Do not reuse RIGHTEST Test Strips.
- Do not use expired RIGHTEST Test Strips.
- Write the opening date on the label of each new vial of test strips you open. Use test strips within 3 months of opening or until the expiration date printed on the label, whichever comes first.
- Store RIGHTEST Test Strips at 4 - 30°C (39 - 86°F) and with 10 - 90% relative humidity. Do not expose to direct sunlight or heat.
- If the RIGHTEST Meter or RIGHTEST Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the operating range, please wait at least 30 minutes before testing again.
- For detailed strip information, please refer to RIGHTEST Blood Glucose Test Strip GS280 Insert.

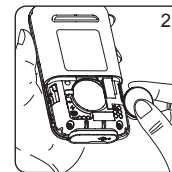
Meter Activation and Battery Change

Your meter comes with 1 CR2032 3V battery installed. 1 new battery provide sufficient power for approximately 1000 tests under normal usage. Press the main button or insert a strip to activate your meter.

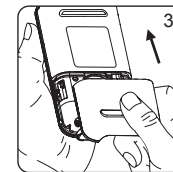
Meter Activation and Battery Change



1. Turn the meter over. Press and slide to open the cover.



2. Install the battery. Be sure to put the battery in the correct direction (+ symbol facing up).



3. Slide the battery cover back on until it snaps into place.

4. The meter will perform a self-test.
5. Press any button to exit the self-test and enter the Settings Mode.
6. You must set the time and date when replacing the battery. See "Setting Up Your Meter - Setting the Time, Date, Volume and Test Unit" on p20. Test results are still stored in the memory.



PRECAUTION

- Please follow local regulations to properly discard used battery.

Setting Up Your Meter- Setting the Date, Time, Volume and Test Unit

You can enter the Settings Mode in two ways:

1. Replace the Battery

After removing the battery, press the main button several times until there is no signal on screen. Then follow the battery installation steps to replace the battery. The RIGHTEST Meter will perform a self-test. Press the main button to exit the Self-Testing Mode and enter the Settings Mode.

2. With the Battery Inserted

Press the main button to turn on the meter. Hold down the main button for 7 seconds. During this time the screen will go blank until you hear a beep. After the beep, the meter will enter the Settings Mode.



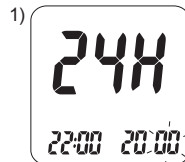
NOTE

- When you press and hold the main button the backlight will be active for 2 seconds. Continue pressing the main button until the display switches off.
- The display will switch off after 4 seconds. Continue pressing until the Settings Mode appears.
- Tap the main button to cycle through the settings.

Setting Up Your Meter- Setting the Date, Time, Volume and Test Unit

1. Year Setting

When the year blinks, press the Left or Right button to select the current year and press the main button to confirm.



2. Month Setting

When the month blinks, press the Left or Right button to select the current month and press the main button to confirm.



3. Day Setting

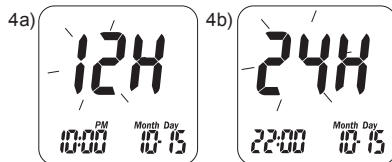
When the day blinks, press the Left or Right button to select the current date and press the main button to confirm.



Setting Up Your Meter- Setting the Date, Time, Volume and Test Unit

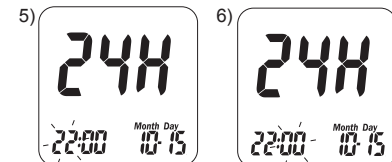
4. 12 or 24-hour Format Setting

When the time format blinks, press the Left or Right buttons to select the preferred time format and press the main button to confirm.



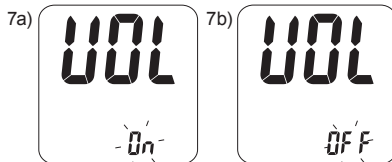
5. Hour Setting

When the hour blinks, press the Left or Right button to select the current hour and press the main button to confirm.



6. Minute Setting

When the minute blinks, press the Left or Right button to select the current minute and press the main button to confirm.



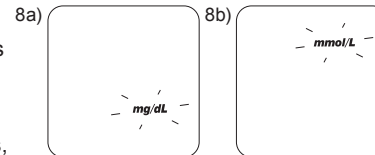
7. Volume Setting

When the "OFF" blinks, press the Left or Right button to turn the volume on or off and press the main button to confirm.

Setting Up Your Meter- Setting the Date, Time, Volume and Test Unit

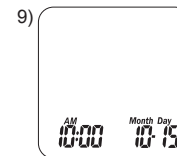
8. Test Unit Setting

When the milligrams per decilitre (mg/dL) or millimoles per litre (mmol/L) blinks, press the Left or Right button to select the preferred measurement unit and press the main button to confirm. (In some countries/regions, regulations stipulate the measurement be fixed. In this case, options to change units will not be displayed and you can skip this step.)



9. Ending Setting

After confirming the test unit setting, you will hear a beep (if volume is on). Your settings have been saved and the meter will return to the Time Screen.



NOTE

- When idle for more than 2 minutes, the RIGHTEST Meter will exit Settings Mode and power off automatically.

Turning On / Off the Meter

1. How to turn on the RIGHTEST Blood Glucose Meter GM280B

Press the main button or insert a test strip.

2. Manual Power Off


To power off the meter, press and hold the main button for 3 seconds.

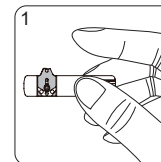
3. Auto Power Off

The meter will power off automatically after 2 minutes of inactivity.

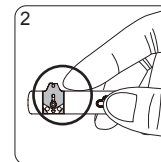
Handling the RIGHTEST Blood Glucose Test Strip GS280

Inserting the RIGHTEST Blood Glucose Test Strip GS280:

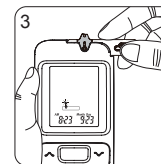
1. Hold the test strip between your thumb and middle finger with the View Window "  " facing up.



2. Put your forefinger on the side of the strip as shown.



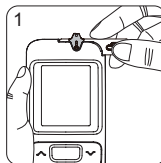
3. Insert the test strip into test strip port until it clicks in securely.



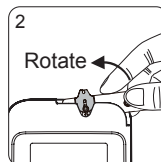
Handling the RIGHTEST Blood Glucose Test Strip GS280

Removing the RIGHTEST Blood Glucose Test Strip GS280:

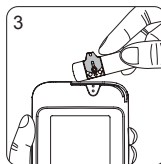
1. Hold the test strip as shown.



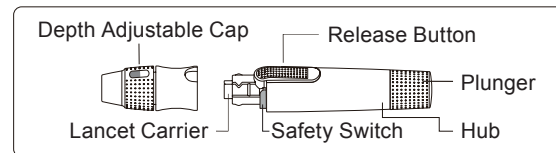
2. Rotate the test strip counterclockwise and pull up at the same time.



3. Take the test strip out of the test strip port. Please follow your local regulations to discard used strips properly.

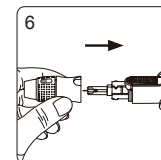
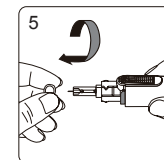
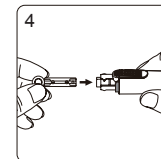
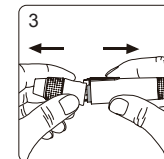
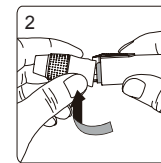
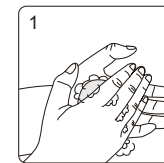


Performing a Blood Glucose Test



Prepare the Lancing Device:

1. Wash and dry your hands.
2. Hold the Depth Adjustable Cap in one hand and the hub in the other hand. Bend the cap downwards until a gap appears. The device will gently pop open.
3. Pull apart both ends to separate cap from the hub.
4. Insert a new disposable lancet firmly into the lancet carrier.
5. Twist off and set aside the protective cap of the lancet needle for later use.
6. Reconnect the Depth Adjustable Cap.



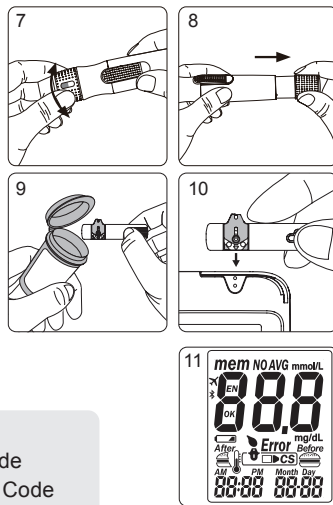
Performing a Blood Glucose Test

7. Rotate the clear top part of the cap to adjust the depth. Check the number of lines visible in the View Window. More lines correspond to a greater depth. Try: "▬▬▬" for soft or thin skin; "▬▬▬▬" for ordinary skin; "▬▬▬▬▬" for thick or calloused skin.
8. Pull back the plunger until you hear a click. The device is now primed. Let go of the plunger. It will return to its original position.
9. Take one test strip from the vial then immediately close the vial.
10. Insert the strip into the Test Strip Port of the meter with the View Window face up.
11. Once inserted, the screen will flash with all possible symbols and emit a beep (if volume is on).



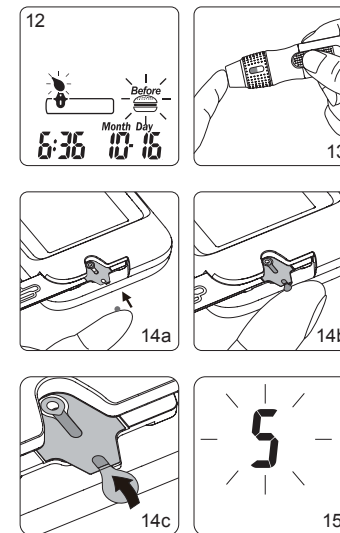
NOTE

- The RIGHTEST Meter will automatically detect the Code Number of the test strip. You do not need to check the Code Number on the meter display and strip vial.



Performing a Blood Glucose Test

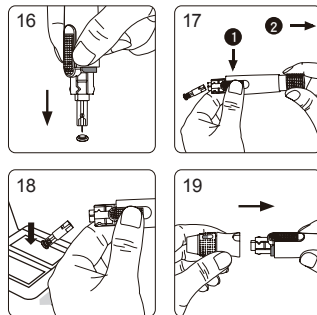
12. After inserting a test strip, the "▬▬▬" icon will flash on the screen. Pressing the Up or Down button to choose between the "Before" (before meal), "After" (after meal) and "Time", then apply a drop of blood. The meter will record the meal marker automatically.
13. Place the lancing device against your fingertip and press the release button.
14. Touch the blood drop to the edge of the sample port until the View Window is filled with blood. If the View Window is not filled, the test will not start. In this case, discard the test strip and repeat the test procedure with a new test strip.
15. The screen will display a countdown timer. Your test result will be displayed after 5 seconds.



Performing a Blood Glucose Test

Lancet and Test Strip Disposal:

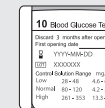
16. Separate the cap from the hub. Press the lancet needle into the side of its original protective cap.
17. Hold down the release button and pull back the plunger to eject the lancet.
18. Discard the lancet into a suitable biohazard container.
19. Replace the depth adjustable cap after finishing the test.



Performing a Blood Glucose Test

⚠ PRECAUTION




- Do not apply the blood sample to the strip's sample port until you see "▯" appear. If you apply blood too soon, the meter will perform an internal test and display "▯" and "Error". If this happens, please repeat the test with a new test strip.
- Write the opening date on the label of each new vial of test strips you Open. Use test strips within 3 months of opening or until the expiration date printed on the label, whichever comes first.
- Always keep the metal contacts of the test strip port clean. If there is any Dust or dirt, please clean it off with a small, soft brush.
- All parts of this kit are considered biohazards and can potentially transmit infectious diseases, even after you have performed the cleaning and disinfecting procedure.
- Users should wash their hands with soap and water after handling the meter, lancing device and test strips.
- Please refer to the section "Maintaining the Products" on p45 for surface cleaning.
- Do not reuse lancets. Discard used lancets properly.



Setting Markers

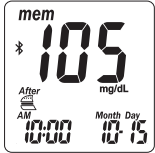
According to actual life status, you can set meal markers with test result.
You have to perform meal marker setting before testing.

1. Before test, press the Left or Right button to choose between the "Before" (before meal), "After" (after meal), " " (no marker). Then apply a drop of blood and the meter will record the marker automatically.

	Before meal: You test the blood glucose before meal.
	After meal: You test the blood glucose after meal.
	(Blank) no marker: regular test or definition by user.

Uploading Data


Bluetooth default is on and when mobile App turn on, it will automatically connect with your mobile device after you finished the pairing.
Once connected with the App, test results will start syncing with the connected mobile device.
When the sync is completed, the meter Bluetooth will disconnect automatically.



Bluetooth pairing.
The symbol of Bluetooth " " will show on the screen.



Data uploading.
The GM280B meter is now uploading test results to your mobile device.


CAUTION
 - No suggest to test blood sugar when the flight is strictly restrict the Bluetooth connection.
 Please turn off you meter to avoid the auto-on of Bluetooth.

RIGHTEST CARE App

"RIGHTEST CARE" App is designed for diabetes patients which assistants to provide digital and mobility system for your blood glucose analysis. Quick understanding and managed your blood glucose efficiently.

Search "RIGHTEST CARE" with iOS or Android system. You may start with the function from pairing the glucose meter to App. More instruction of App, please click "Learn and Assist" for "Operation Guide" on the App.

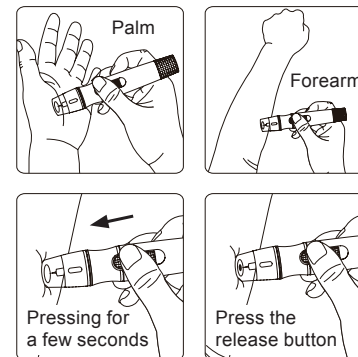
For more information, please visit the official website

<http://www.bionime.com>

Alternative Site Testing (AST)

Alternative site testing-palm or forearm blood sampling

- Before performing alternative site testing, please replace the depth adjustable cap of your Lancing Device with the clear cap. (For detailed information, refer to the instruction manual for the RIGHTEST Lancing Device.)
- To increase the blood flow, massage the intended puncture area of your palm or forearm for a few seconds.
- Immediately after massaging the area, press and hold the lancing device against palm or forearm.
- Press the release button.
- Continue pressing the lancing device against your palm or forearm and gradually increase the pressure for a few seconds until the blood sample is of sufficient size.



Alternative Site Testing (AST)

CAUTION

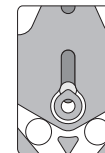
- Consult your healthcare professional before sampling from your palm or forearm.
- Alternate site testing should be done only during steady-state times (when glucose is not changing rapidly). Fingertip sampling can show rapid changes in glucose faster than palm or forearm samples
- Only the fingertip should be used when glucose levels are rapidly fluctuating: after drinking, after a meal, after insulin injection or exercise, during illness, during periods of stress, if you think your blood sugar is low, or if your results are inconsistent with how you feel.
- DO NOT test on the palm or forearm if you are testing for insulin dose calculations or hypoglycemia (low blood glucose).
- AST results should not be used to calibrate Continuous Glucose Monitors (CGM).
- Use the clear cap provided with the RIGHTEST Lancing Device when testing sites other than fingertips. The Depth adjustable cap may not produce a blood droplet of sufficient size when testing on the palm or forearm.

View Window Appearance

Make sure your blood sample covers the whole area of the View Window to get an accurate test result. An insufficient blood sample will result in an error message ("Er4"). If this occurs, repeat the test with a new test strip.



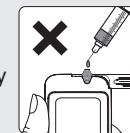
Insufficient blood sample



Enough blood sample

CAUTION

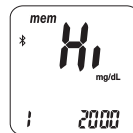
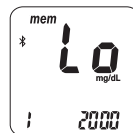
- Check the expiration date printed on the strip vial every time you use a test strip. Do not use expired test strips.
- Use each test strip rapidly after taking it out from the vial.
- Do not reuse test strips.
- If the RIGHTEST Meter or RIGHTEST Test Strips are exposed to extreme temperature changes, or environmental temperatures outside of the meter's operating range – below 10°C (50°F) or above 40°C (104°F)– please wait at least 30 minutes before testing again.
- Only apply the blood sample to the test strip's sample port.
- Please don't drip or inject the blood sample directly into the sample Entry of the test strip with a syringe. Doing so may contaminate the meter or cause damage.



"Lo" and "Hi" Readings

The meter displays results between 10 - 600 mg/dL (0.6 and 33.3 mmol/L). If your test result is below 10 mg/dL (0.6 mmol/L), "Lo" will appear on the screen. Please repeat your test with by a new test strip. If you still get a "Lo" result, contact your healthcare professional.

If your test result is above 600 mg/dL (33.3 mmol/L), "Hi" will appear on the screen. Please repeat your test with a new test strip. If you still get a "Hi" result, contact your healthcare professional.



NOTE

- If your blood glucose result is unusually high or low, or if you have any doubts about your test results, repeat the test with a new test strip. You can also run a Quality Control Test to check your meter and test strip. If the test result stays unexpectedly high or low, contact your healthcare professional immediately.
- If you experience symptoms that are inconsistent with your blood glucose test results and you have followed all the test instructions in this manual, contact your healthcare professional immediately.

About Quality Control Testing

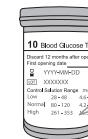
What is a Quality Control Test ?

We recommend users perform a quality control test on a regular basis to ensure that the blood glucose system is working properly.

Use a bottle of RIGHTEST Control Solution GC550 when testing your RIGHTEST Blood Glucose Monitoring System GM280B in the Control Solution Mode. If the test result falls within the Control Solution Range printed on the strip vial label, the RIGHTEST Blood Glucose Monitoring System has passed the Quality Control Test and is working properly.

Control Solution Range:

Example of Control Solution Range printed on your test strip vial label.



Control Solution Range:

28 - 48 mg/dL

1.6 - 2.7 mmol/L



NOTE

- RIGHTEST Control Solution GC550 is for the RIGHTEST Blood Glucose Monitoring System GM280B. If you want to purchase additional supplies please contact Bionime Customer Service.

About Quality Control Testing

When could a Quality Control Test Be Performed?

- To confirm that your RIGHTEST Meter and RIGHTEST Test Strip are working properly.
- To confirm that you are following the correct testing procedures.
- To prepare for your initial blood glucose test.
- To check RIGHTEST Test Strip when you open a new vial of strips.
- To check your RIGHTEST Meter after it has been dropped, damaged or exposed to liquids.
- If you suspect that your test results are inaccurate, or if your test results are not consistent with how you are feeling.
- To practice testing.

Required Items for Quality Control Tests

To perform a quality control test, prepare the following items:

- RIGHTEST Blood Glucose Meter GM280B
- RIGHTEST Blood Glucose Test Strip GS280
- RIGHTEST Control Solution GC550

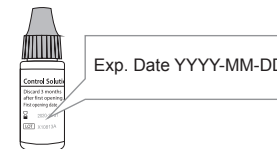
About Quality Control Testing



CAUTION

- Each time you open a new bottle of control solution, write the opening date on the label. RIGHTEST Control Solution GC550 should be used within 3 months of opening or until the expiration date printed on the label, whichever comes first.

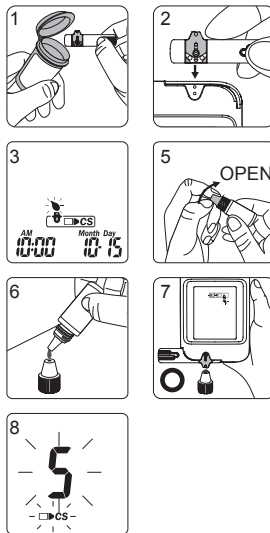
Example



- Wipe the bottle cap with a clean tissue before tightly closing the bottle of control solution.
- Close the bottle tightly immediately after use.
- Check the expiration date before use. Refer to RIGHTEST Control Solution GC550 Insert.
- Keep control solution bottles out of the reach of children.

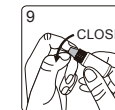
Performing a Quality Control Test

1. Take a test strip from the vial and close the cap immediately.
2. Insert the test strip into the test strip port with the View Window face up.
3. When the test strip icon flashes on the screen, press and hold the Main button for 3 seconds until "CS" appears.
4. "CS" and "CS" will flash on the screen. You are ready to apply Control Solution to the strip.
5. Gently swirl the bottle of RIGHTEST Control Solution GC550 to ensure it is evenly mixed before removing the cap.
6. Place the cap on a flat surface. Squeeze a drop of Control Solution onto the top of the cap.
7. Gently touch the sample port of the strip with the control solution from the top of the cap.
8. The screen will display a 5-second countdown timer. You will hear a beep if the volume is on.



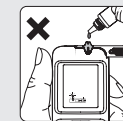
Performing a Quality Control Test

9. Replace the cap and ensure it is screwed on securely.
10. The Quality Control Test Result will appear on the screen. Compare the result with the Control Solution Range printed on the test strip vial label.



CAUTION

- Your Control Solution Test results will not be included in the average calculations but they can still be recalled and viewed. The Control Solution Test result will be displayed with the "CS" icon on the screen.
- The Control Solution Test should be performed at temperatures ranging from 15 to 40°C (59 to 104°F), with relative humidity ranging from 10 to 90%.
- Do not touch the control solution to the sample port on the strip before "CS" and "CS" appear. The meter is performing an internal check. Touching the control solution to the sample port before being prompted will result in an error message: "Error" and "CS" and be accompanied by beeps (if volume is turned on).
- Do not directly drip the control solution into the test strip's sample port. It is Possible that doing so will contaminate the meter or the control solution.
- Keep the test strip port clean and dry. Clean immediately if the test strip port is stained or is overly exposed to moisture.
- Do not touch the tip of the control solution bottle. If the tip is touched, clean with water.



Understanding Control Test Results

The control solution tests should fall within the control solution range printed on the Test Strip label, which means the RIGHTEST Blood Glucose Monitoring System is functioning properly.

If the control solution test results was out of range, following are possible reasons:

- Your RIGHTEST Control Solution GC550 is expired or was opened more than 3 months ago.
- Your RIGHTEST Test Strip was expired.
- You left the RIGHTEST Test Strip vial or the Control Solution opened for a long period after use.
- You did not perform the test procedure correctly.
- The RIGHTEST Meter or RIGHTEST Test Strip malfunctioned.

If RIGHTEST Control Solution GC550 results are out of range, your RIGHTEST Blood Glucose Monitoring System may be malfunctioning Repeat the Quality Control Test. If your control solution results are still out of range, do not use RIGHTEST Meter to test your blood glucose. Please contact Bionime customer service.

Maintaining the Products

Indirect transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) during the delivery of healthcare services has been increasingly reported. Persons using blood glucose monitoring systems have been identified as one risk group due to sharing of lancets, lancing devices, and blood glucose meters.

The cleaning procedure is to remove dust, blood and body fluid from the surface and should be performed whenever the meter or lancing device is visibly dirty. The disinfecting procedure is necessary to kill pathogens such as HIV, HBV and HCV on the device.

NOTE: The cleaning procedure can only remove visible contaminants from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

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 decontaminated prior to use by the second person.

The following disinfecting wipe has been tested and may be used to clean and disinfect the meter and lancing device.

CAVIWIPES DISINFECTING TOWELETTES, manufacturer: Metrex. It is with Isopropanol as the active ingredient, have been shown to be safe for use with the meter and lancing device.

Maintaining

Keep your meter and test strip free of dust, water or any other liquid. Store the meter in the carrying case when not in use. If your meter is dropped or damaged, perform a quality control test with the control solution before performing a blood glucose test.

Maintaining the Products

Cleaning and Disinfecting frequency: at least once a week.

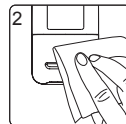
To clean the meter:

1. Wipe the whole surface of the meter using the disinfectant wipes listed above to remove any dirt, dust, blood, or other bodily fluids.



To disinfect the meter:

2. Take a new disinfecting wipe to wipe the meter thoroughly (Note: All blood and body fluids should be cleaned from surfaces before performing the disinfecting procedure).
3. Allow the surface to remain wet for 2 minutes.
4. Allow to air dry.



NOTE

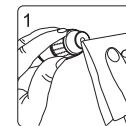
- Clean and disinfect the outside of the device only. Do not remove the battery cover when cleaning and disinfecting.

Maintaining the Products

Cleaning and Disinfecting frequency: at least once a week.

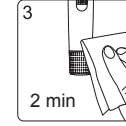
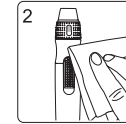
To clean the Lancing Device:

1. Wipe down the whole surface of the lancing device using the disinfecting wipes described above to remove any dirt, dust, blood, or other bodily fluids.



To disinfect the Lancing Device:

2. Take a new disinfecting wipe to wipe the lancing device thoroughly (Note: All blood and body fluids should be cleaned from surfaces before performing the disinfecting procedure).
3. Allow the surface to remain wet for 2 minutes.
4. Allow to air dry.



CAUTION

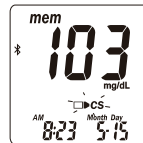
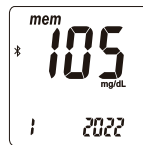
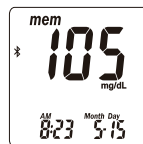
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- If you have any queries or issues, please contact Bionime Customer Service.

Recalling Test Results

The RIGHTEST Blood Glucose Meter GM280B can automatically store up to 500 test results along with the time and date. If your meter has 500 stored results, the most recent test result will take the place of the oldest.

To recall your test memory, start the meter without a test strip inserted.

1. Press the Main button to switch from the Time Mode to Memory Mode. You will see the "mem" icon in the upper left corner of the display. The latest test result will appear with the number " 1 ".
2. Use either the Left or Right button on the side to review all previous results with date and time. Results display from the most recent (Sequence no. " 1 ") to the oldest (Sequence no. " 500 ") in the lower right hand corner of the screen.
3. The Quality Control Test result can be recalled from the saved data. When "CS" appears next to the data, the test was performed using the RIGHTEST Control Solution GC550. The control solution test result will not be used when recalling test average results.



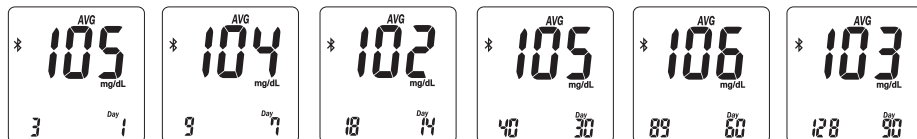
Recalling Test Results

4. Quick Searching:

To view test results in sequential order automatically, enter the Memory Mode. Press the Left or Right button for 2 seconds. (The Right button is for viewing from the most recent to the oldest test results. The Left button is for viewing from the oldest to the most recent test results). Release the button to stop at any particular test result.

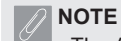
Recalling Average Test Results

The RIGHTEST Blood Glucose Meter GM280B provides several average test results. View the 1-day, 7-days, 14-days, 30-days, 60-days and 90-days average test results for better blood glucose monitoring.



1. Press the Main button to switch the screen to Average Mode.
2. On the average screen, use either the Up or Down button to view 1-day, 7-days, 14-days, 30-days, 60-days or 90-days averages.
3. The number shown in the lower left hand corner indicates how many test results have been calculated.

Recalling Average Test Results



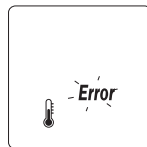
NOTE

- The Average function requires that the correct time and date be entered. Test results must be available during the specific time interval. For example: in order to calculate 14-days average on 1/30, you must have test results dated between 1/17 and 1/30. If no test results are available during that time period you will not be given an average.
- The CS test result is removed from the average calculation but it is still searchable in the Memory Mode. In Memory Mode, the CS test result will be displayed with a blinking "CS" icon.
- The "Lo", "Hi" results, as well as control solution test results and test results under abnormal temperature conditions of $< 10^{\circ}\text{C}$ (50°F), $> 40^{\circ}\text{C}$ (104°F) will be excluded from average calculations.

Error Messages and Troubleshooting

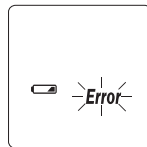
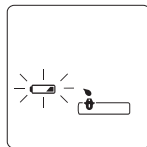
Temperature Error

1. Please test between 10°C (50°F) and 40°C (104°F) in order to obtain accurate test results.
2. The meter will not function if the temperature is below 10°C (50°F) or above 40°C (104°F), the "🌡️" will show and the "**Error**" symbol will blink.
3. If your RIGHTEST Meter or RIGHTEST Test Strips have been exposed to temperatures that below 10°C (50°F) or above 40°C (104°F), take the meter and strips back to an environment within the operating temperature of meter and wait at least 30 minutes before testing again.



Battery Error

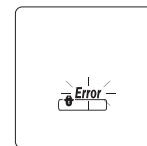
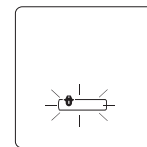
1. The "🔋" symbol is blinking when the battery power is low. Please replace the battery as soon as possible. While the battery low icon is blinking, you can still perform the test.
2. The "🔋" and "**Error**" symbols appear and the meter will not function when the battery is low. Change the batteries immediately.



Error Messages and Troubleshooting

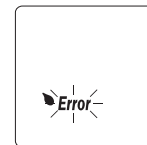
Strip Error

1. The meter will beep four times while the "📄" sign flashes if the test strip is put in incorrectly. Do not apply a sample on the test strip. Please re-insert the unused test strip correctly (refer to "Handling RIGHTEST Blood Glucose Test Strip GS280" on p25 for more information).
2. If the "📄" and flashing "**Error**" symbols appear on the screen after completing the proper steps, it signifies the RIGHTEST Test Strip has been inserted incorrectly more than twice. Please follow the steps in "Handling RIGHTEST Blood Glucose Test Strip GS280" on p25 to re-insert the unused test strip, or contact Customer Service for assistance. This error notice could mean that you used incorrect test strips. Make sure you are using RIGHTEST Blood Glucose Test Strip GS280 by checking the test strip vial.



Sampling Error

Please do not apply the blood to the sample port of the test strip until the meter displays "🩸". Discard the test strip if the meter shows "**Error**" and repeat the test with a new strip.



Error Messages and Troubleshooting

Er1 - The test strip was used or moist. Please try again with a new strip.

Er2 - The meter has malfunctioned. Reinstall the batteries, and perform a Quality Control Test to check whether the system is working properly.

If not, please contact customer service.

Er3 - The transmission of the signal has been disrupted. Repeat the test with a new test strip.

Er4 - The blood sample volume is insufficient. Repeat the test using a new test strip.

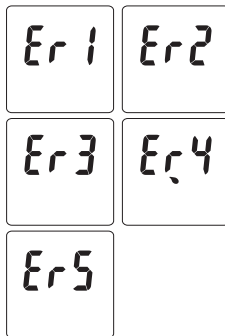
Er5 - An issue has occurred when calibrating the meter. Please follow the steps below:

(1) Remove the test strip from the meter.

(2) Press the Main button for 3 seconds to turn off the meter.

(3) Press the main button to turn the meter back on.

If after turning on the Meter, you do not see Er5, your meter is functioning properly and you are able to perform a test.



Error Messages and Troubleshooting

Meter Malfunction

If the meter will not start please follow the steps below:

1. Open the battery cover and remove the batteries.
2. Wait for 5 minutes and insert the batteries as described in "Meter Activation and Battery Change" on p18-19.

The RIGHTEST Meter should be working normally after finishing above steps. If not, please contact Bionime Customer Service.



A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and the " " symbol show.

If the symbol is NOT showing on the screen, do not apply a sample to the test strip.

Please re-insert the unused test strip correctly.

It takes about 3 seconds for the symbol to show after the test strip inserting correctly.

Please see p25 on the User's Manual and/or contact Customer Service for support on how to correctly insert a RIGHTEST Test Strip.

Specification

Measurement Technology	Oxidase Electrochemical Sensor
Measuring Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Test Time	5 seconds
Memory Capacity	500 blood glucose test results with date and time
Power Saving	Turn off automatically 2 minutes after last user action / Press the "□" button for 4 seconds.
Operating Temperature	10 - 40°C (50 - 104°F)
Operating Relative Humidity	10 - 90%
Power Supply	1 CR2032 battery
Meter Battery Life	About 1,000 tests
















Specification

Meter Dimension	82.0 mm x 45.0 mm x 15.5 mm
Meter Weight	43.0g ± 5g with batteries
Monitor	LCD
Display Area	34.0 mm x 27.5 mm
Meter Storage/ Transportation Conditions	-10 - 60°C (14 - 140°F)
Sample	
Minimum Sample Volume	Refer to RIGHTEST Blood Glucose Test Strip GS280 Insert.
Hematocrit	
Test Strip Storage / Transportation Conditions	

Customer Service

We aim to provide great service to our customers. Please review these instructions to make sure you know how to use your product correctly. If you have any questions or encounter any issues with your product, please contact Bionime Customer Service.

Description of used symbols

	For <i>in vitro</i> diagnostic use		Direct current		EU Representative
	Consult the instruction for use		Expiry date		Biological risks
	Temperature limitation		Manufacturer		For single use only
	CE-mark (with No. of notified body)		Importer		humidity limitation
	Caution (consult instructions for use and warnings)		Lot number		
	Method of sterilization using irradiation (only for lancet)				


Warranty

Bionime Corporation warrants that this product will be free from defects in materials and workmanship for five years from the date of purchase.

This warranty does not apply to the performance of a RIGHTEST Blood Glucose Meter GM280B that has been altered, misused, tampered with or abused in any way.
This warranty applies only to the original purchaser of RIGHTEST Blood Glucose Monitoring System GM280B.

Please complete and return the enclosed warranty card.

Different models have different specifications. This warranty applies only to the RIGHTEST Blood Glucose Monitoring System GM280B; other models are not covered with this warranty card.

 **NOTE**

- During blood glucose measurement, RIGHTEST Meter itself may come into contact with blood. All parts of RIGHTEST System are considered biohazardous and can potentially transmit infectious diseases. Please follow your local regulations to properly dispose of the used RIGHTEST Blood Glucose Monitoring System after removing the battery.

Expected Glucose Values

Expected glucose values without diabetes ⁽¹⁾

Fasting Blood Glucose	
GLUCOSE LEVEL	INDICATION
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
From 100 to 125 mg/dL (5.6 to 6.9 mmol/L)	Pre-diabetes (Impaired fasting glucose)
126 mg/dL (7.0 mmol/L) and above on more than one testing occasion	Diabetes

References

- 1) Diabetes Information - American Association for Clinical Chemistry (AACC)[Electronic Version] Retrieved Jan. 26, 2021 from www.labtestsonline.org/understanding/analytes/glucose/test.html