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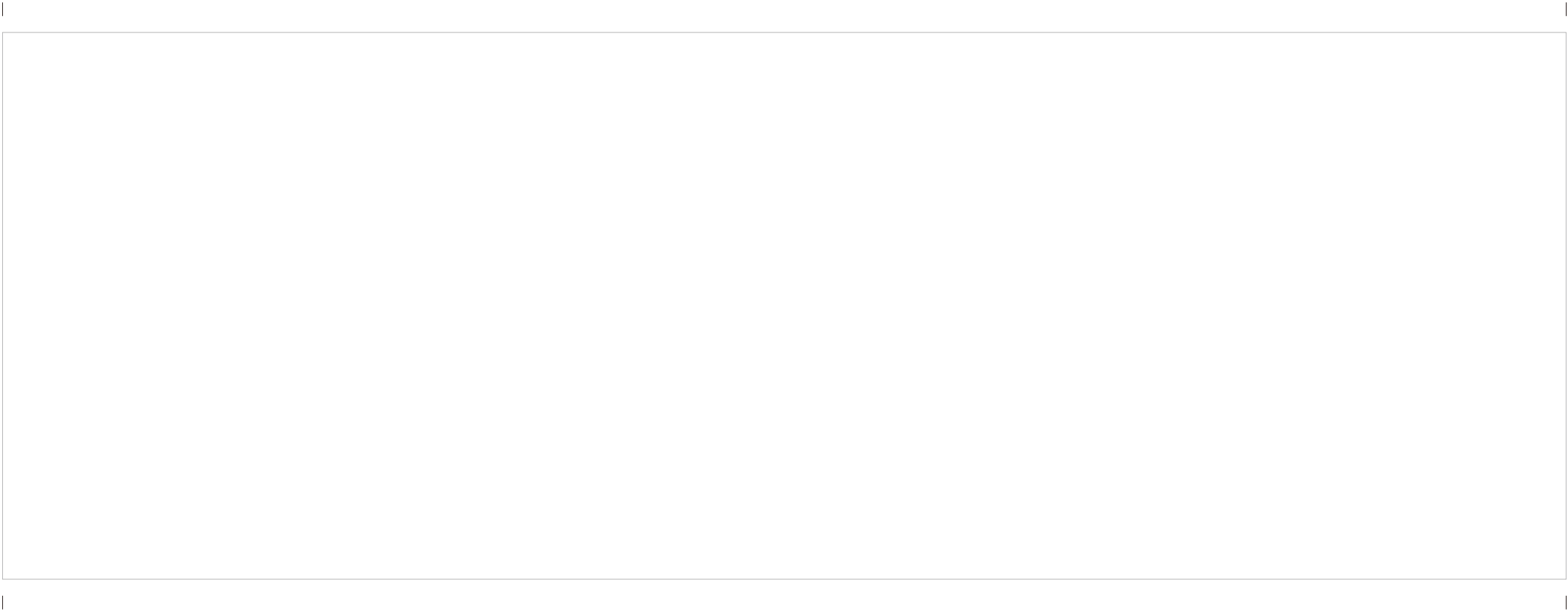
Rev. Date: 2019-04

101-3GM282-040
EN



RIGHTTEST™
Blood Glucose Monitoring System

GM280B
User's Manual



Indication for use

RIGHTEST Blood Glucose Monitoring System GM280B is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The testing result is calibrated to plasma equivalent with whole blood from capillary.

RIGHTEST Blood Glucose Monitoring System GM280B is intended for self- testing outside the body (*in vitro* diagnostic use), they can be used as an aid of diabetes control for home user or professional. RIGHTEST Blood Glucose Monitoring Systems GM280B should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

RIGHTEST Control Solutions GC550 is for use with RIGHTEST Blood Glucose Meter GM280B and RIGHTEST Blood Glucose Test Strip GS280 to check that the meter and test strips are working together properly and that the test is performing correctly.

Preface

Thank you for using our product, this manual provides all the information you need to operate this product for accurate test results. Please read this entire manual before you start any testing. For people living with diabetes, it is important to regularly monitor blood glucose level to effectively reduce complications from diabetes. The easy-use RIGHTEST Blood Glucose Monitoring System GM280B provides accurate, reliable test results to help you better manage your diabetes.

Our customer service information is on the cover, our staff is willing to assist you as well. Please contact healthcare professional if emergency or our service is not available. Please forward your warranty card to customer support to activate your warranty coverage. RIGHTEST Blood Glucose Monitoring System GM280B is made and supported by Bionime Corporation.

If you have any questions or concerns, please contact your local Bionime Customer Service or email to rightest@bionime.com

Caution

- Before using the RIGHTEST Blood Glucose Monitoring System GM280B to test your blood glucose, please read all of the instructions and conduct all of the tests including the quality control test.
- Please perform the quality control test regularly to make sure the test results are accurate.
- The RIGHTEST Blood Glucose Meter GM280B can only be used with RIGHTEST Blood Glucose Test Strips GS280 and RIGHTEST Control Solution GC550. The application of other Test Strips or control solutions can lead to incorrect results.
- RIGHTEST Blood Glucose Monitoring System GM280B is intended for self- testing outside the body (*in vitro* diagnostic use), it is not use for diagnosis of, or screening for diabetes.
- RIGHTEST Blood Glucose Monitoring System GM280B is NOT use for critically ill patients and neonate.
- If RIGHTEST Meter and Test Strips are exposed to temperature environments out of range for the meter – below 10 °C (50 °F) or above 40 °C (104 °F) – please wait 30 minutes before testing again.
- Follow all environmental protection regulations when disposing of batteries, strips and lancets.

Caution

- Avoid contact with dripping or splashing liquids.
- The minimum blood sample size to test using the RIGHTEST Blood Glucose Monitoring System GM280B is 0.75 µL: (•)

Sample Size Example



Blood sample size above 3.0 µL might contaminate the test strip port and the meter.
Blood sample size below 0.75 µL may cause an inaccurate result or may prevent a meter reading.
An Er4 reading will be displayed if the sample size is too small. In this case, repeat the test with a new test strip.



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.
- Users should wash their hands thoroughly with soap and water before and after handling the meter, lancing device, or test strips.

Limitations

- 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), it may cause inaccurate test results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Patients going through oxygen therapy may yield falsely low results
- For interfered substances (e.g. Hematocrit range, interference) please refer to strip insert.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use on critically ill patients (e.g. patients under dehydrated, hypo-osmolar or in shock).
- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly).

Limitations

- Please refer to the (Alternative site testing (AST)) chapter if you want to test on palm or forearm.
- DO NOT test on alternative site (palm, forearm) if you are testing for insulin dose calculations or for Continuous Glucose Monitoring (CGM) devices calibration, or hypoglycemia (Low blood glucose).
- To avoid potential electromagnetic or other interference, keep meter away from electromagnetic radiation sources such as X-ray or MRI.
- The Bluetooth is default on on your meter. 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.

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The RIGHTEST Blood Glucose Monitoring System GM280B

Contents

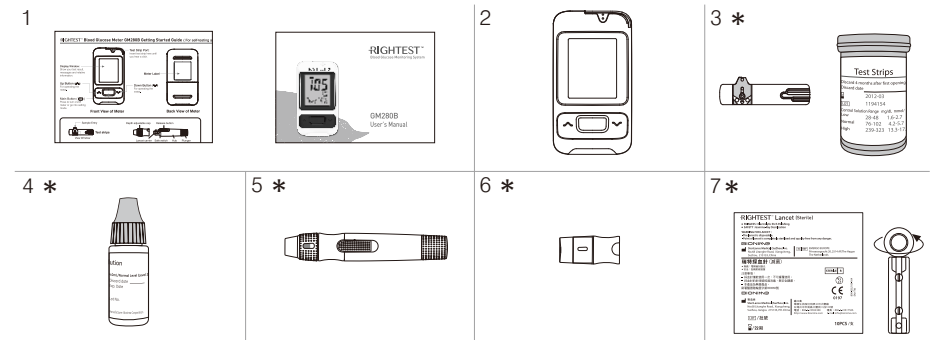
Your RIGHTEST Blood Glucose Monitoring System GM280B consists of several items. Please identify each item, learn its name and how it is used.

Below are the items included in your RIGHTEST Blood Glucose Monitoring System GM280B:

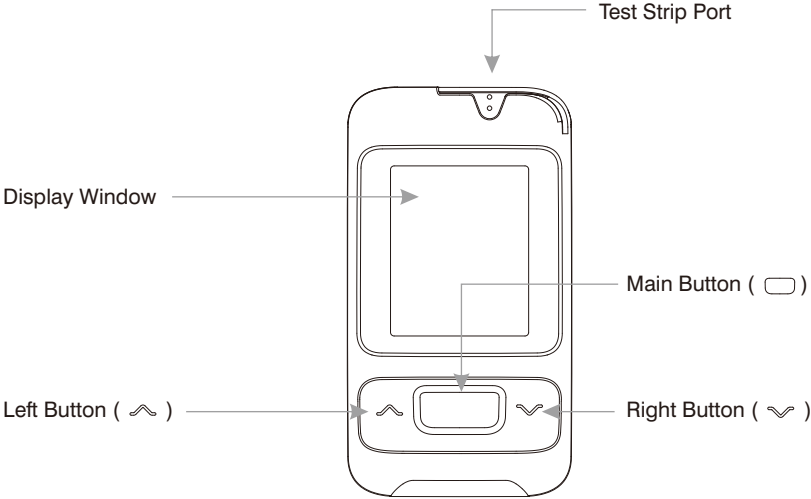
1. User Documents (Getting Started Guide, User's Manual, Log Book, Warranty Card, Emergency Card).
2. RIGHTEST Blood Glucose Meter GM280B (with 1 CR2032 battery installed)
3. RIGHTEST Blood Glucose Test strips GS280 10 or 25 pcs (with Package Insert) *
4. RIGHTEST Control Solution GC550 (with Package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

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

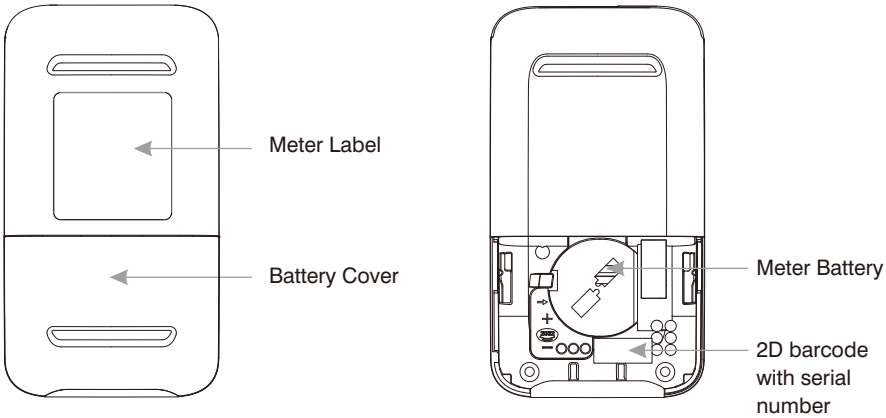
The RIGHTEST Blood Glucose Monitoring System GM280B



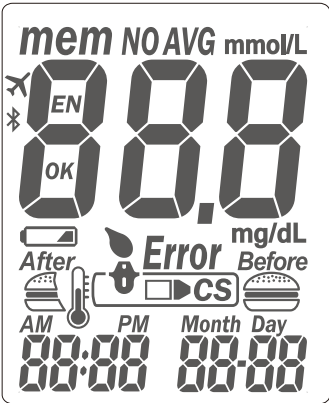
The RIGHTEST Blood Glucose Meter GM280B



The RIGHTEST Blood Glucose Meter GM280B



The RIGHTEST Blood Glucose Meter GM280B

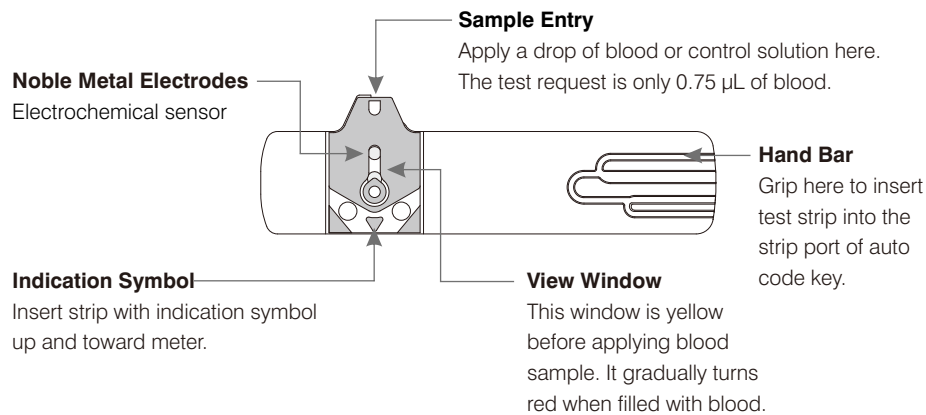


The RIGHTEST Blood Glucose Meter GM280B

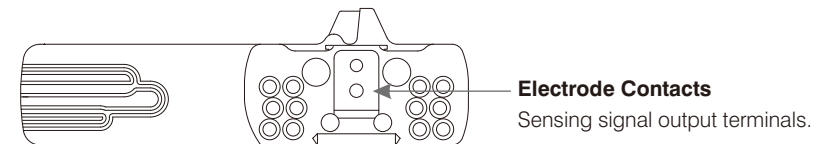
| | | | |
|-------------------------------|---|----------------------------------|---|
| mem | Indicates a test result stored in memory | | Indicates when to apply the blood sample |
| AVG | Indicates the average result | | Appears after you insert test strip into meter |
| CS | Indicates a control solution 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 |
| 88.8 | 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 |
| Before After | 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) |

The RIGHTEST Blood Glucose Test Strip GS280

The RIGHTEST Blood Glucose Meter GM280B can only be used with RIGHTEST Blood Glucose Test Strips GS280 and RIGHTEST Control Solution GC550. The use of other test strips or control solutions can lead to incorrect results.



The RIGHTEST Blood Glucose Test Strip GS280



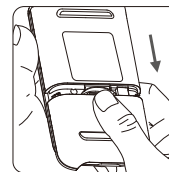
PRECAUTION

- Re-cap the test strip vial immediately after taking out a test strip.
- Do not reuse test strips. Test strip can be only used once.
- Do not use expired test strips.
- Record the date of opening a new test strip vial for the first time. Use test strips within 3 months after first opening or until the expiration date printed on the label (whichever comes first).
- Store the test strips in a cool (4 - 30°C or 39 - 86°F) and dry location (< 90 % relative humidity). Do not expose to direct sunlight or heat.
- For detailed information, please refer to the RIGHTEST Test Strip GS280 insert.
- If the RIGHTEST GM280B meters and strips are exposed to a high temperature difference, please wait 30 minutes before measurement.

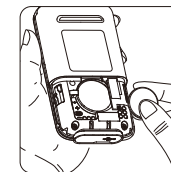
Meter Activation and Battery Change

Your RIGHTEST Blood Glucose Meter GM280B comes with one CR2032, 3 volt, battery installed. one new battery will provide power to perform approximately 1000 tests under normal use. Press the main button or insert a strip to activate your meter.

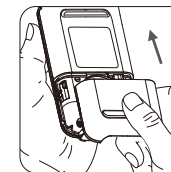
Meter Activation and Battery Change



1. Turn the meter over. Press and push battery cover to open.



2. Install the batteries. Be sure to put batteries in correct direction.



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

4. The RIGHTEST Blood Glucose Meter GM280B will enter Self-Testing Mode automatically when replacing the battery (all symbols will appear on the screen).
5. Press any button to exit the self-test and enter Setting Mode.
6. You must set the time and date when replacing the battery. See Chapter "Setting Up Your Meter - Setting the Date, Time, and Volume" on page 20. Test results are still stored in the memory.



CAUTION

- Please follow the local regulation to properly discard a used battery.

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

You can enter the Setting Mode 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 battery. The RIGHTEST Blood Glucose Meter GM280B will perform a self-test. Press the main button to exit the self-test and enter the Setting Mode.

2. With Battery Inserted

Press the main button to turn on the RIGHTEST Blood Glucose Meter GM280B. 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 turn on into the Setting Mode. The display screen will show setting data.

NOTE

- Use the Left and Right buttons to select your setting data and press the main button to confirm each selection. After confirming all of the settings, you will return to the Time Mode.

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

1. Year setting

With the year format blinking, press the Left or Right button until you see the current year. Press the Main button to confirm. Once the year is confirmed, the Month Setting will appear.



2. Month setting

With the month blinking, press the Left or Right button until you see the current month. Press the Main button to confirm. Once the month is confirmed, the Day Setting will appear.



3. Day setting

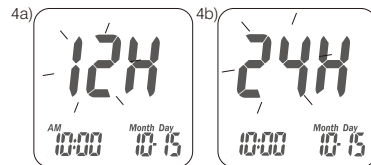
With the day blinking, press the Left or Right button until you see the current day. Press the Main button to confirm. Once the day is confirmed, the Time Setting will appear.



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

4. Time format 12/24H selection

With the time format blinking, press the Left or Right button to switch between 12H and 24H. Press the Main button to confirm. Once confirmed, the Hour Setting will appear.



5. Hour setting

With the hour blinking, press the Left or Right button until you see the current hour. Press the Main button to confirm. Once the hour is confirmed, the Minute Setting will appear.



6. Minute setting

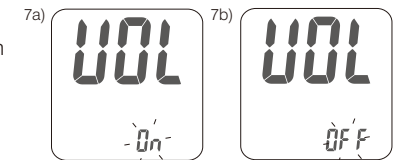
With the minutes blinking, press the Left or Right button until you see the current minute. Press the Main button to confirm. Once the minute is confirmed, the Volume Setting will appear.



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

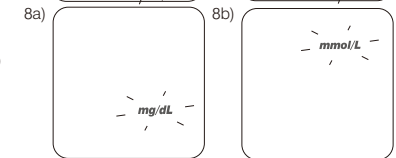
7. Volume Setting

With the volume blinking, press the Left or Right button to turn the volume on or off. Press the Main button to confirm and finish the settings.



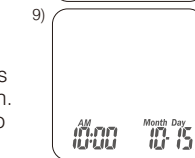
8. Setting the Unit of Measurement

With milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L) blinking, press the Left or Right button to switch. Then press the Main button to confirm it and finish the settings.



9. Ending setting

After measurement of unit setting, for confirmation you will hear a beep (if volume is turned on). All the settings are saved and completed and will return to time screen. (If Volume is turned off, the display will directly return to time screen without a sound of "beep".)



NOTE

- If you do no change any settings during Meter Set-up for over 2 minutes, the RIGHTTEST Blood Glucose Meter GM280B will leave setting 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 RIGHTEST Blood Glucose Meter GM280B, press and hold the Main button for 3 seconds.


3. Auto Power off

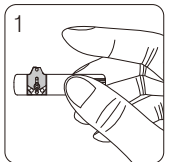
The RIGHTEST Blood Glucose Meter GM280B will power off automatically after 2 minutes if no buttons are pressed or no strip is inserted.

Handling the RIGHTEST Blood Glucose Test Strip GS280

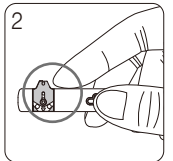
How to handle the RIGHTEST Blood Glucose Test Strip GS280.

Inserting the RIGHTEST Blood Glucose Test Strip GS280:

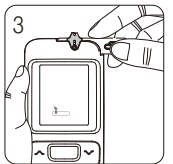
1. Hold the RIGHTEST Blood Glucose Test Strip GS280 between your thumb and middle finger with the view window "  " facing up.



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



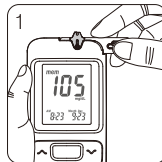
3. Insert the RIGHTEST Blood Glucose Test Strip GS280 into test strip port until it clicks and firmly stops.



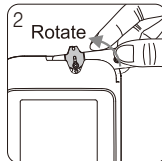
Handling the RIGHTEST Blood Glucose Test Strip GS280

Removing the RIGHTEST Blood Glucose Test Strip GS280:

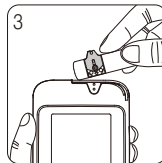
1. Hold the RIGHTEST Blood Glucose Test Strip GS280 as shown.



2. Rotate the RIGHTEST Blood Glucose Test Strip GS280 counterclockwise and pull up simultaneously.



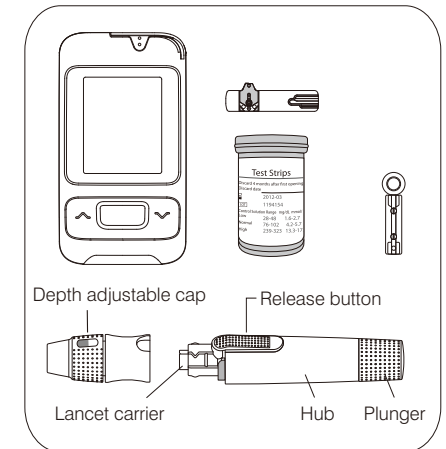
3. Take the RIGHTEST Blood Glucose Test Strip GS280 out of the test strip port.
Please follow your local regulations and discard used strips properly.






Getting Ready for Testing

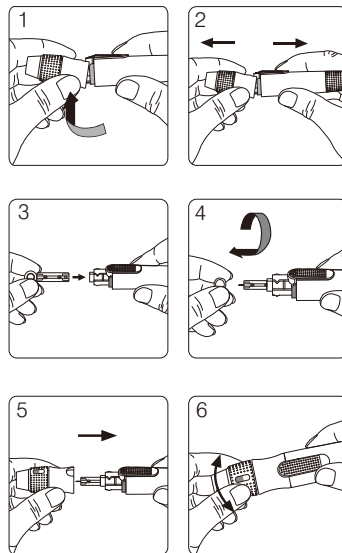
Before performing a blood glucose test, prepare the items below :

- RIGHTEST Blood Glucose Meter GM280B
- RIGHTEST Blood Glucose Test Strip GS280
(Please check the expiration date on the test strip vial. Do not use expired test strips)
- RIGHTEST Lancing device GD500
- Sterile lancet
- Alcohol swab (optional)



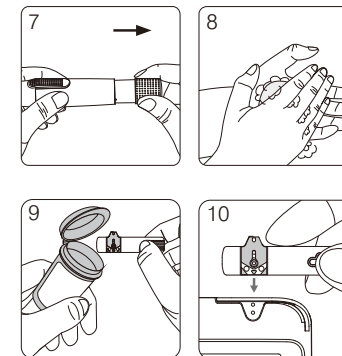
Performing a Blood Glucose Test

1. Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub.
2. Pull the cap and hub off in opposite directions, remove the 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 your desired setting is visible in the window. Settings are based on skin type
 "  " for soft or thin skin; "  " for average skin;
 "  " for thick or calloused skin.



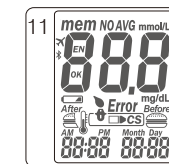
Performing a Blood Glucose Test

7. Hold the base in one hand and pull on the plunger with the other hand. The device will be cocked. Release the plunger and it will automatically move back to its original position near the base.
8. Wash your hands with warm soapy water and dry thoroughly.
9. Take one RIGHTEST Blood Glucose Test Strip GS280 from the vial. Close the vial cap immediately.
10. Insert the strip into the test strip port of the RIGHTEST Blood Glucose Meter GM280B with the view window facing up.
11. Once the strip is inserted, all symbols will appear on your meter display and will be accompanied by a beep (if volume is turned on).



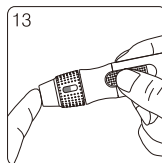
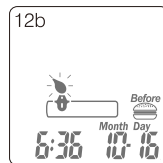
NOTE

- The meter will automatically detect Code number on strip. You don't have to check the Code number on the meter display and strip vial.

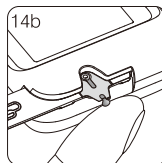
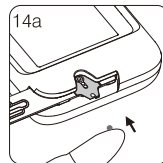


Performing a Blood Glucose Test

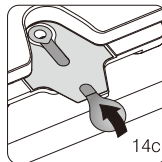
12. After inserting a test strip, the " " icon will flash on the screen. Pressing the Right or Left button to choose between the "Before" (before meal), "After" (after meal) and " ", then apply a drop of blood apply. The meter will record the meal marker automatically.



13. Place the lancing device against your fingertip and press the release button.

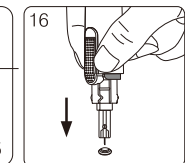
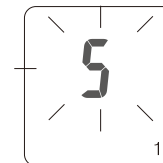


14. Touch and hold the blood drop to the edge of sample port until the view window is filled with blood. If the view window is not completely filled with blood the test will not start. If the blood sample was insufficient, discard the test strip and repeat with a new RIGHTEST Blood Glucose Test Strip GS280.



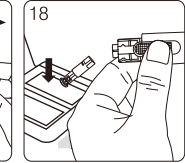
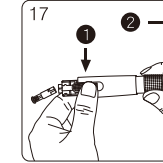
Performing a Blood Glucose Test

15. Countdown Mode will begin on the display window. After 5 seconds, your test result will appear.

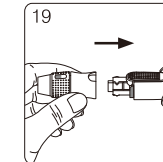


16. Pull off the depth adjustable cap. Without touching the used disposable lancet, insert the lancet tip into the protective lancet cover.

17. Hold the release button in one hand (see picture 17, step 1) and pull on the plunger with the other hand (see picture 17, step 2) to safely eject the used disposable lancet.






18. Discard the used disposable lancet and strip into an appropriate puncture-proof or biohazard container.



19. Replace the depth adjustable cap after finishing the test.

Performing a Blood Glucose Test

 CAUTION

- Do not apply your blood drop to the sample port on the strip until you see the "  " appear. The RIGHTEST Blood Glucose Meter GM280B is performing an internal test and will display "  " and " **Error** " if you apply blood too soon. If this occurs, please repeat the test with a new test strip.
- Record the 1st opening date of a new test strip vial. Discard the vial of test strips 3 months after 1st opening.
- Always keep the metal contacts of the test strip port clean. If any dust or impurities are present, please clean 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 clean the meter and wash hands thoroughly with soap and water after handling the meter, lancing device, and test strips.

Test Strips

Discard 4 months after first opening

Discard date

2012-03

1194154

Control Solution Range mg/dL mmol/L




Low 25-48 1.5-2.7




Normal 76-102 4.2-5.7

High 239-323 13.3-17.7

Setting Markers

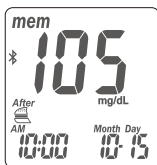
According to actual life status, you can set meal markers with test result. You have to perform meal marker setting before testing.


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

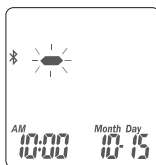
| | |
|---|--|
|  | Before meal: You test the blood glucose before meal. |
|  | After meal: You test the blood glucose after meal. |
|  | (Blank) no marker: regular test or definition by user. |

Uploading Data

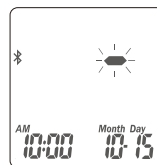
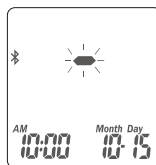
Bluetooth default is on and when mobile App turn on, it will automatically connect with your mobile device after you finished the pairing. Once connected with the App, test results will start syncing with the connected mobile device. When the sync is completed, the meter Bluetooth will disconnect automatically.



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.

RIGHTTEST CARE App

" RIGHTTEST 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.

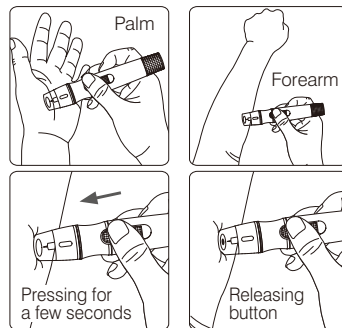
Search " RIGHTTEST CARE " with iOS or Android system. You may start with the function from pairing the glucose meter to App. More instruction of App, please click " Learn and Assist " for " Operation Guide " on the App.

For more information, please visit the official website
<http://www.bionime.com>

Alternative Site Testing

Alternative site testing: palm or forearm blood sampling

- To perform alternative site testing, install the clear cap for your RIGHTEST Lancing Device GD500. (For detailed information, refer to the instruction manual for the RIGHTEST Lancing Device GD500).
- To increase the blood flow, massage the intended puncture area of your palm or forearm for a few seconds.
- Immediately after massaging the intended puncture area, press and hold the lancing device with the clear cap against palm or forearm.
- Press the release button.
- Continue holding the lancing device against your palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient.



Alternative Site Testing



CAUTION

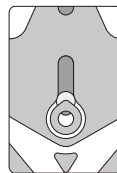
- Consult your healthcare professional before sampling from your palm or forearm.
- Alternate site testing should only be done during steady-state time (when glucose is not changing rapidly), fingertip can show the rapid change in glucose faster than palm or forearm samples.
- Only the fingertip should be used when glucose levels changing rapidly conditions are as following: after drinking, after a meal, after insulin injection or exercise, during illness, during times of stress, you think your blood sugar is low, or the results do not agree with the way you feel.
- DO NOT test on the palm or forearm if you are testing for insulin dose calculations or hypoglycemia (Low blood glucose).
- AST result should not be used to calibrate continuous glucose monitors (CGMs).
- Use the clear cap provided with RIGHTEST Lancing Device when testing sites other than fingertip. The normal lancing device cap for your palm or forearm, the blood sample may not be sufficient for meter operation.

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



Sufficient blood sample

CAUTION

- Check the expiration date printed on the strip vial every time you use a test strip. Do not use expired RIGHTEST Blood Glucose Test Strips GS280.
- Use each RIGHTEST Blood Glucose Test Strip GS280 immediately after removing it from the vial.
- Do not reuse RIGHTEST Blood Glucose Test Strip GS280.
- If the RIGHTEST GM280B meters and strips are exposed to temperature environments out of range for the meter – 10 °C (50 °F) or above 40 °C (104 °F) or a high temperature difference, please wait 30 minutes before measurement.
- Apply the blood sample only on the sample port of the test strip.
- Please don't drip or inject the blood sample directly by syringe to the sample entry of test strip. Doing this might contaminate the meter or cause damages and is not recommended.



Understanding Test Results and Messages

If your blood glucose result is unusually high or low, or if you question your test results, repeat the test with a new RIGHTEST Blood Glucose Test Strip GS280.

You can also run a Quality Control Test with the RIGHTEST Control Solutions GC550 to check your RIGHTEST Blood Glucose Meter GM280B and RIGHTEST Blood Glucose Test Strip GS280 (Refer to "Performing a Quality Control Test" on page 44) .

If the test result still remains unusually high or low, contact your healthcare professional immediately.

If you are experiencing symptoms that are not consistent with your blood glucose test results and you have made sure to follow all instructions in this manual, contact your healthcare professional immediately.

Follow local regulations or consult your health care provider for appropriate disposal of used test strips and lancets.

Understanding Test Results and Messages

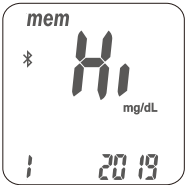
The RIGHTEST Blood Glucose Meter GM280B displays results between 10 and 600 mg/dL (0.6 and 33.3 mmol/L).

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

If you still get a " Hi " result, contact your healthcare professional.



About Quality Control Testing

What is a Quality Control Test ?
To ensure proper monitoring function, it is necessary to regularly perform a quality control test. Use one of the RIGHTEST Control Solutions GC550 when testing your RIGHTEST Blood Glucose Monitoring System GM280B in the Control Solution Mode. If the test result is within the Control Solution Range printed on the strip vial label, the passes 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 | mg/dL | mmol |
|------------------------|---------|-----------|
| Low: | 28-48 | 1.6-2.7 |
| Normal: | 107-145 | 5.9-8.1 |
| High: | 315-426 | 17.5-23.7 |

NOTE
- If you want purchase control solutions, please contact your authorized Bionime representative or Bionime customer service (printed on manual cover).

About Quality Control Testing

When should a Quality Control Test Be Performed ?

- To ensure that your RIGHTEST Blood Glucose Meter GM280B and RIGHTEST Blood Glucose Test Strip GS280 are working properly.
- To confirm that you are following the correct testing procedures.
- To prepare for your initial blood glucose test.
- To check the RIGHTEST Blood Glucose Test Strip GS280 when you open a new vial of strips.
- To check your RIGHTEST Blood Glucose Meter GM280B 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 the way you feel.
- To practice testing.

Required Items for Quality Control Tests

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

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

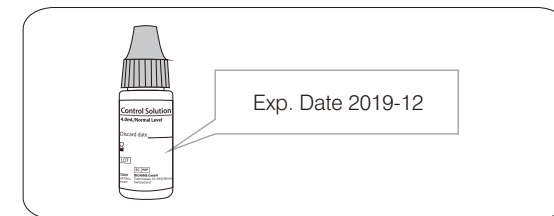
About Quality Control Testing



CAUTION




- Each time you open a new bottle of control solution, write the 1st opening date on the label. The RIGHTEST Control Solution GC550 is good for 3 months after you 1st opening the bottle, or until the expiration date printed on the label, whichever comes first.

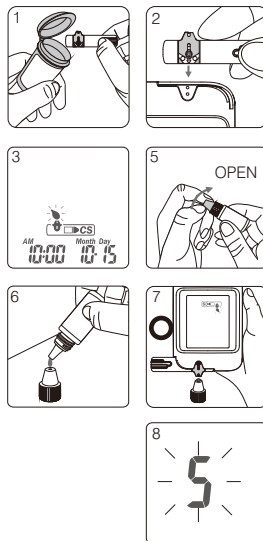
Example



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

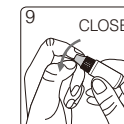
Performing a Quality Control Test

1. Take one RIGHTEST Blood Glucose Test Strip GS280 from the vial and close the vial cap immediately.
2. Insert the strip into the test strip port of the RIGHTEST Blood Glucose Meter GM280B with the view window facing up.
3. While the blood drop icon is flashing on the display window, press and hold the Main button for at least 3 seconds until the "  CS " symbol appears.
4. You will see the blinking "  " icon and "  CS " icon on the screen, prompting you to apply the corresponding level of RIGHTEST Control Solution GC550.
5. Shake the bottle of RIGHTEST Control Solution GC550 well before opening the cap. Place the cap on a flat surface.
6. Place 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 the count time starting from 5 (you will hear a beep if the volume is turned on).







Performing a Quality Control Test

9. Tightly replace the cap on the RIGHTEST Control Solution GC550 bottle.
10. The control solution result will appear. Compare your Quality Control Test result to the Control Solution Range printed on the RIGHTEST Blood Glucose Test Strip GS280 vial label.



CAUTION

- Your Control Solution Test results will not be included in the average calculations, however, they can still be recalled and viewed. The Control Solution Test result will be shown with the "  CS " icon on the screen.
- The Control Solution Test should be conducted between 15 - 40 °C (59 - 104 °F).
- Before "  " and "  CS " appear, do not touch the control solution to the sample port on the strip. The RIGHTEST Blood Glucose Meter GM280B is performing an internal check. Touching the control solution to the sample port before prompted will result in an error message: " **Error** " and "  " and be accompanied by beeps (if volume is turned on).
- Do not drip the control solution on to the sample port of the test strip directly. The reagent on the strip might leak into the bottle of control solution and may cause the degeneration of the control solution. This could contaminate the meter via the test strip port.
- 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

Your control solution test results should fall within the control solution range. If the results are within the range, the RIGHTEST Blood Glucose Monitoring System GM280B is working correctly.

Possible reasons your Control Solution results are out of the range :


- Your RIGHTEST Control solution GC550 is expired or was first opened more than 3 months ago.
- Your RIGHTEST Blood Glucose Test Strip GS280 has expired.
- You left the cap of the Blood Glucose Test Strip vial or the control solution off for a period of time.
- You did not perform the test procedure correctly.
- The RIGHTEST GM280B Blood Glucose Meter or RIGHTEST Blood Glucose Test Strip GS280 have malfunctioned.

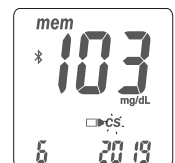
If RIGHTEST Control Solution GC550 results are out of range, your RIGHTEST Blood Glucose Monitoring System GM280B may not be working properly. Repeat the Quality Control Test. If your control solution results are still out of range, do not use RIGHTEST Blood Glucose Meter GM280B to test your blood glucose. Please contact customer service.

Recalling Test Results

The RIGHTEST Blood Glucose Meter GM280B is able to automatically store a maximum of 500 test results with time and date. If your meter has stored 500 results, the newest test result will replace the oldest one.

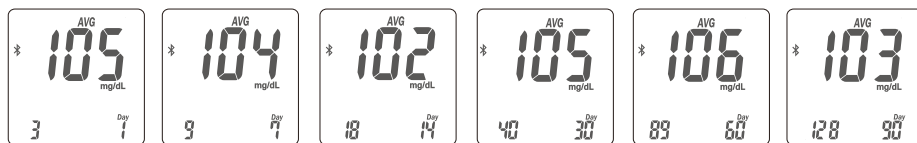
To recall your test memory, start the meter without a test strip inserted.

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 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 Left or Right button to view 1-day, 7-days, 14-days, 30-days, 60-days or 90-days averages.
3. The number shown in the lower right hand corner indicates how many test results have been calculated.

Recalling Average Test Results

5. Quick Searching:

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



NOTE

- The Average function requires that the correct time and date is set. Test results must exist during the desired time interval. For example: To get a 14-day average on 1/30, you must have test results dated between 1/17 and 1/30. If no test results exist during that time frame you will not receive an average.
- The "Lo", "Hi" results, control solution test results and test results under abnormal temperature < 50°F (10°C), > 104°F (40°C) will be excluded from average calculations.

Maintain the Products

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. Performing the cleaning procedure once per week is recommended. The disinfecting procedure is necessary to kill pathogens such as HIV, HBV and HCV on the device. This procedure should be performed regularly; once per week is recommended.

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

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

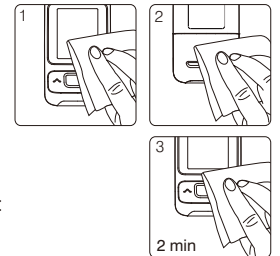
Keep your meter and test strip free of dust, water or any other liquid. Store the meter in the carrying case when not in use. If your meter is dropped or damaged, perform a quality control test with the control solution before performing a blood glucose test.

Maintain the Products

Cleaning and Disinfecting frequency: at least once a week.

To clean the meter:

1. Thoroughly wipe the entire surface of the meter with disinfecting wipes listed above to clean any possible dirt, dust, blood and other body fluids.



To disinfect the meter:

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



NOTE

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

Maintain the Products

CAUTION

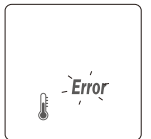
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.

If you have any questions or concerns, please contact your RIGHTEST Blood Glucose Monitoring System GM280B authorized distributor or contact your local Bionime customer service.

Error Messages and Troubleshooting



Temperature Error

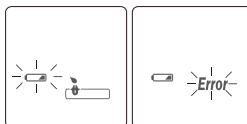
1. In order to get accurate testing results, please test between 10-40 °C (50-104 °F).
2. When the temperature is below 10 °C (50 °F) or over 40 °C (104 °F), the meter will not function and the "**Error**" symbol will blink.
3. If the RIGHTEST GM280B meters and strips are exposed to temperature environments out of range for the meter – 10 °C (50 °F) or above 40 °C (104 °F) or a high temperature difference, please wait 30 minutes before measurement.





Error Messages and Troubleshooting

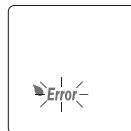
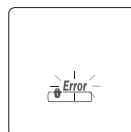
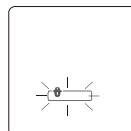
Battery Error

1. The "  " symbol blinks when the battery power is low. Please change the battery as soon as possible. You can still perform the test.
2. The "  " and " **Error** " symbols blink when the battery power is too low. Meter cannot test. Please change the battery immediately.




Strip Error

1. When the test strip is inserted incorrectly, the meter will beep 3 times while the "  " symbol flashes. Do not apply a sample on the test strip. Please re-insert the unused test strip correctly.
2. If, after performing the required steps, the "  " and flashing " **Error** " symbols appear on the screen, it means the RIGHTEST Blood Glucose Test Strip GS280 has been inserted incorrectly more than twice. Please, re-insert the unused test strip again or call Customer Service for support. This error message can also indicate that you may have used the wrong test strips. Please check the test strip vial to ensure you are using the RIGHTEST Blood Glucose Test Strip GS280.

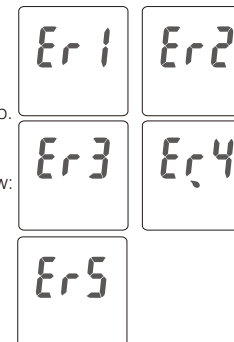


Sampling Error

Please do not apply the blood to the sample port of the test strip before the meter displays "  ". Discard the test strip If the meter shows " **Error** ".

Error Messages and Troubleshooting

- Er1** - The inserted test strip has been used or damaged. Please use a new test strip.
- Er2** - The meter has malfunctioned. Do a Quality Control Test or reinstall the battery to check if the meter works properly.
- Er3** - The signal transmission is disrupted. Repeat the test using a new test strip.
- Er4** - The blood sample volume is insufficient. Repeat the test using a new test strip.
- Er5** - An issue calibrating the Meter has occurred. Please follow the steps below:
- (1) Remove the test strip from the meter.
 - (2) Turn off the meter (press and hold the Main button for 3 seconds).
 - (3) Press the main button to turn ON the meter.
- If after turning on the Meter, you do not see Er5, your meter is functioning properly and able to perform a test.



If one of the above error messages still appears, please contact Bionime Customer Service.


Meter Malfunction

If the RIGHTEST Blood Glucose Meter GM280B will not turn on, please follow the steps below:

1. Open the battery cover and remove the battery.
2. Wait for 5 minutes and reinsert the battery as described.

The meter should work normally after finishing the above steps. If the meter still does not work, please contact your local Bionime customer service.

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 | Turns off automatically 2 minutes after last user action. To turn off manually, press the button "  " for 3 seconds. |
| Operating Temperature | 10 - 40 °C (50 - 104 °F) |
| Operating Relative Humidity | 10 - 90% |
| Power Supply | One CR2032 battery (3 Voltage) |
| Battery Life | Approximately 1000 standard tests |

Specification

| | |
|---|--------------------------------------|
| Meter Dimension | 82 mm x 45 mm x 15.5 mm |
| Meter Weight | 43 ± 5g with battery |
| Monitor | LCD |
| Display Area | 34 mm x 27.5 mm |
| Meter Storage/ Transportation Conditions | 10 - 40 °C (50 - 104°F) |
| Sample | Refer to RIGHTEST GS280 Strip insert |
| Minimum Sample Volume | |
| Hematocrit | |
| Test Strip Storage/ Transportation Conditions | |

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 the 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, the RIGHTEST Blood Glucose Meter GM280B itself may come into contact with blood. All parts of the RIGHTEST Blood Glucose Monitoring System GM280B 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 GM280B after removing the battery.

Customer Service

We sincerely like to provide complete, considerate services to our customers. Please review all the instructions to make sure you are performing the steps correctly. If you have any questions or in case of problems with the products, please contact your local Bionime customer service or email to rightest@bionime.com .

Description of used symbols

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

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 Mar. 02, 2018 from
www.labtestsonline.org/understanding/analytes/glucose/test.html

Component Manufacturer Information

Blood Glucose Meter, Test Strip, Control Solution

Manufacturer: Bionime Corporation
No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan
Product complies with *in vitro* Diagnostic Medical Device Directive 98/79/EC. (CE0197)
EC-Rep: Bionime GmbH, Tramstrasse 16, 9442 Berneck, Switzerland

Lancing Device

Manufacturer: Bionime Corporation
No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan
Product complies with Medical Device Directive 93/42/EEC
EC-Rep: Bionime GmbH, Tramstrasse 16, 9442 Berneck, Switzerland

Disposable Sterile Lancets

Manufacture information is as package printed.