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RIGHTTEST™
Blood Glucose Monitoring System

GT333
User's Manual

Preface

Thank you for selecting RIGHTEST GT333 Blood Glucose Monitoring System. 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 levels to effectively reduce complications from the disease. The easy-to-use RIGHTEST GT333 Blood Glucose Monitoring System provides accurate, reliable test results to help you better manage your diabetes.

RIGHTEST GT333 Blood Glucose Monitoring System is perfect for both self-testing and professional use. Designed for *in vitro* diagnostic use only, testing requires just a small amount of fresh capillary whole blood from either the fingertip, palm or forearm.

RIGHTEST GT333 Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. RIGHTEST GT333 Blood Glucose Monitoring System 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).

Preface

RIGHTEST GT333 Blood Glucose Monitoring System is manufactured and supported by Bionime Corporation. If you have any questions or concerns, please contact with your local distributor or visit our website at www.bionime.com. We will make every effort to assist you.

Please contact with your healthcare professionals while you feel seriously ill or customer service is not available.

Please forward your warranty card to RIGHTEST Diabetes Customer Support Center.

Caution

- Before using RIGHTEST Blood Glucose Monitoring System to test your blood glucose, please read all of the instructions.
- Please perform the quality control test regularly to make sure the test results are accurate.
- RIGHTEST GT333 Blood Glucose Meter can only be used with RIGHTEST GT333 Blood Glucose Test strip and RIGHTEST GC570 Control Solution. Other product should not be used under any circumstances. The use of other test strips may give inaccurate results.
- RIGHTEST Blood Glucose Monitoring System is intended for *in vitro* diagnostic use only. RIGHTEST Blood Glucose test results using fresh capillary whole blood samples from the fingertip, palm and forearm are calibrated to be the equivalent to that of plasma testing.
- RIGHTEST Blood Glucose Monitoring System is intended for self-testing. It should not be used to screen for or diagnose diabetes mellitus.
- If RIGHTEST Blood Glucose Meter and Test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.
- Follow all environmental protection regulations when disposing of batteries.
- RIGHTEST Blood Glucose Monitoring System is not for use on neonates and should not be used in the critically ill.
- A proven clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.

Caution

- Healthcare professionals should evaluate their technique and their patients' technique regarding the use of the RIGHTEST Blood Glucose Monitoring System regularly. To accomplish this, it is recommended that blood glucose monitoring results be compared with a concurrently obtained laboratory measurement on the same blood sample.
- The range of blood sample size please refer to strip insert.

Sample Size Example



Too much blood might contaminate the test strip port and the meter. Too little blood may cause an error or may prevent a meter reading.



Important Safety Notes:

- RIGHTEST Blood Glucose Meter and Lancing Device are for single patient use. Do not share them with anyone including other family members.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the Maintain the Products. Please refer to the section "Maintain the Products".
- Users should wash their hands thoroughly with soap and water before and after handling the meter, lancing device, or test strips.

Limitation

- Blood glucose meter readings may be significantly lower than "true glucose levels" in a hyperglycemic hyperosmolar state, with or without ketosis.
- Caution is advised when glucose values are below 50 mg/dL or above 250 mg/dL. Consult a Physician as soon as possible, if values in this range are obtained.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- Storage of strips near bleach as well as bleach containing products will affect the results of RIGHTEST Blood Glucose Test strip.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3,048 meters) above sea level.
- Do not perform the blood glucose test at temperatures below 10°C(50°F) or above 40°C(104°F), nor below 10% or above 90% relative humidity.
- To avoid potential electromagnetic or other interference, keep meter away from electromagnetic radiation sources such as X-ray or MRI.
- For interfered substances (e.g. Hematocrit range, interference) please refer to strip insert.
- Patients going through oxygen therapy may yield falsely low results.
- RIGHTEST Blood Glucose Test strip are designed for use with capillary whole blood samples. Do not use serum or plasma samples.

Limitation

- Not for screening or diagnosis of diabetes mellitus.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.
- Not for neonatal use.
- 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).
- Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).

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RIGHTEST Blood Glucose Monitoring System

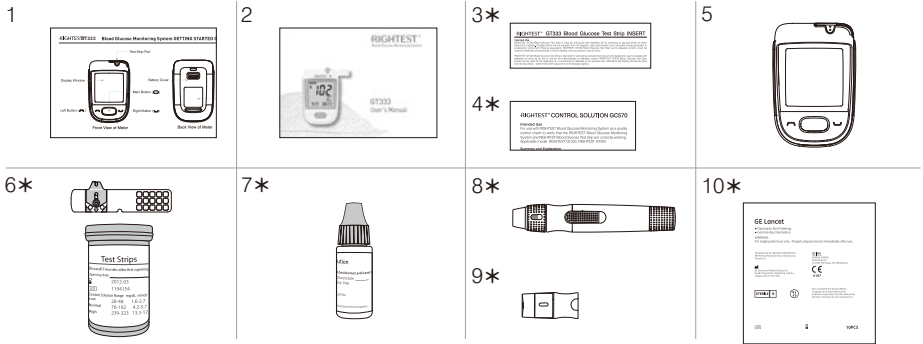
Contents

Your RIGHTEST GT333 Blood Glucose Monitoring System consists of several items. Please identify each item, learn its name and how it is used.

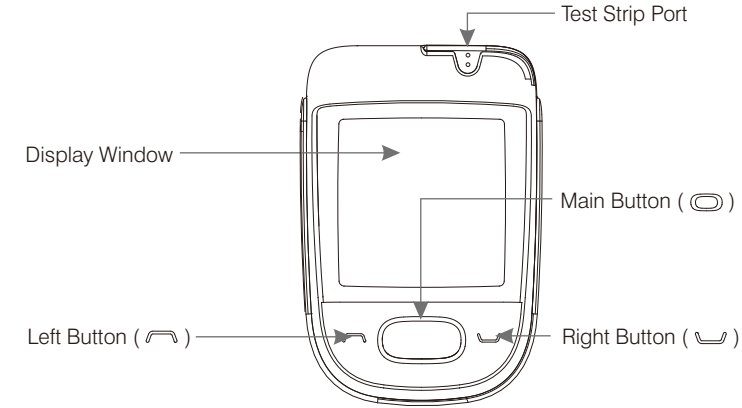
Below are the items included in your RIGHTEST Blood Glucose Monitoring System:

1. RIGHTEST GT333 Blood Glucose Monitoring System (with 2 AAA batteries installed)
 2. User's Manual (includes Log Book, Warranty Card, Emergency Card) *
 3. RIGHTEST GT333 Blood Glucose Test strip Package Insert *
 4. RIGHTEST Control Solution GC570 Package Insert *
 5. Getting Started Guide *
 6. RIGHTEST GT333 Blood Glucose Test strip (10/25 pcs) *
 7. RIGHTEST Control Solution GC570 *
 8. RIGHTEST Lancing Device *
 9. Clear Cap *
 10. Disposable Sterile Lancets (10 pcs) *
 11. Carrying Case (not shown) *
 12. Instruction for the lancing device (not shown) *
- (* Different packages have different bundled items. Some of packages might not include * items.)

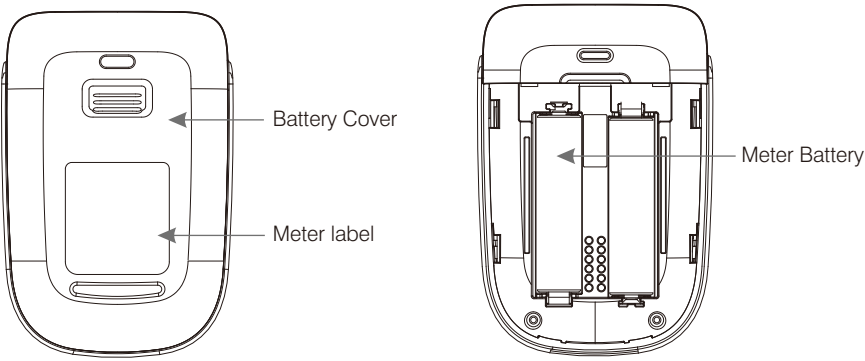
RIGHTEST Blood Glucose Monitoring System



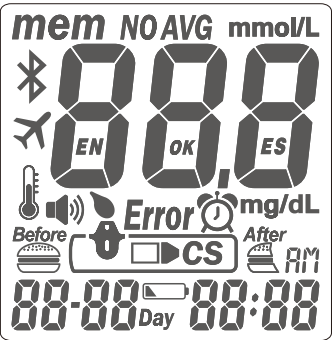
RIGHTTEST Blood Glucose Meter



RIGHTTEST Blood Glucose Meter



RIGHTTEST Blood Glucose Meter

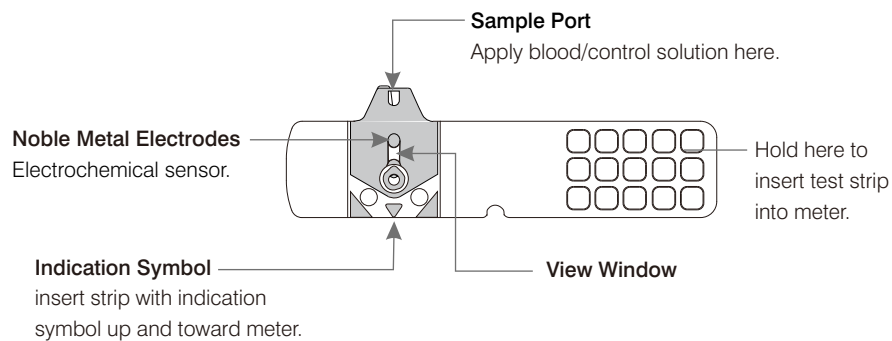


RIGHTTEST Blood Glucose Meter

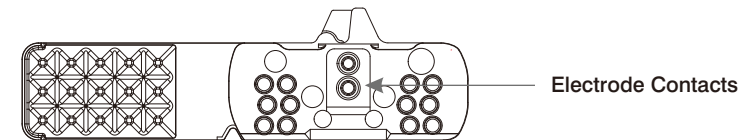
<i>mem</i>	Indicates a test result stored in memory		Indicates when to apply the blood sample
<i>AVG</i>	Indicates the average result		Appears after you insert test strip into meter
	Indicates a control solution test result	<i>Error</i>	Appears when an error occurs
<i>mmol/L</i> <i>mg/dL</i>	Unit of test result	<i>88:88</i>	Current date under time mode or testing date under memory mode
<i>888</i>	Test result		Warns when the operational temperature limit is exceeded during testing
	Warns when the batteries are low or must be replaced	<i>AM</i>	Indicates the time in 12H format
	Indicates a meal marker with test result	<i>88:88</i>	Displays current time under time mode or testing time under memory mode
	Indicates that the Bluetooth is turned on		
<i>EN OK ES Day</i>		Manufacturing use only	

RIGHTEST Blood Glucose Test strip

RIGHTEST GT333 Blood Glucose Meter can only be used with RIGHTEST GT333 Blood Glucose Test strip and RIGHTEST Control Solution GC570. The use of other test strips or control solutions can lead to incorrect results.



RIGHTEST Blood Glucose Test strip



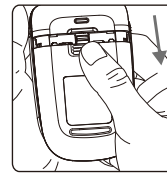
PRECAUTION

- Close RIGHTEST Blood Glucose Test strip vial immediately after removing a test strip.
- Do not reuse RIGHTEST Blood Glucose Test strip.
- Do not use expired RIGHTEST Blood Glucose Test strip.
- When you open a new vial of RIGHTEST Blood Glucose Test strip, record the date on the vial.
- Store RIGHTEST Blood Glucose Test strip between 4-30°C (or 39-86°F) and in a location with 10-90% relative humidity. Do not expose to direct sunlight or heat.
- If RIGHTEST Blood Glucose Meter and Test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.
- For detailed information, please refer to RIGHTEST GT333 Blood Glucose Test strip Package Insert.

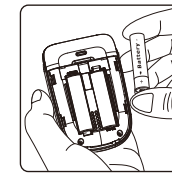
Meter Activation and Battery Change

Your RIGHTEST Blood Glucose Meter comes with 2 AAA batteries installed. New batteries will provide power to perform approximately 1000 tests under normal use with one data transfer. Press the main button or insert a strip to activate your meter.

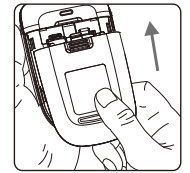
Meter Activation and Battery Change



1. Turn RIGHTEST Blood Glucose Meter over. Press and slide the battery cover to open.



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



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

4. RIGHTEST Blood Glucose Meter 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". Test results are still stored in the memory.



CAUTION

- Please follow the local regulation to properly discard a used battery.
- Risk of explosion if battery is replaced by an incorrect type.

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


You can enter the Setting Mode two ways.

1. Replace the Battery

Battery installation steps to replace battery. RIGHTEST Blood Glucose Meter 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 RIGHTEST Blood Glucose 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 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.

Set Up Your Meter - Set Up 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.



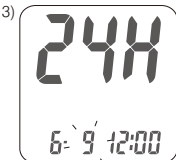
2. Month setting

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

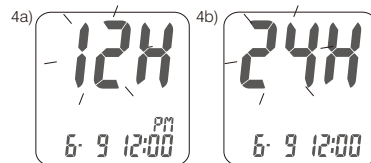
With the day blinking, press the Left or Right button until you see the current day. Press the Main button to confirm. Once the day is confirmed, the Time Setting will appear.



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

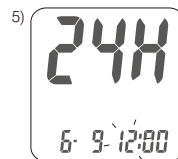
4. Time format 12/24H selection

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.



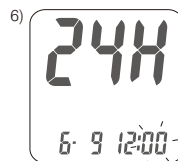
5. Hour setting

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

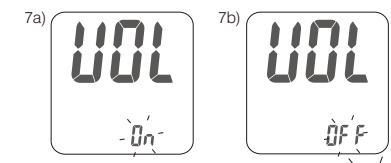
With the minutes blinking, press the Left or Right button until you see the current minute. Press the Main button to confirm. Once the minute is confirmed, the Volume Setting will appear.



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

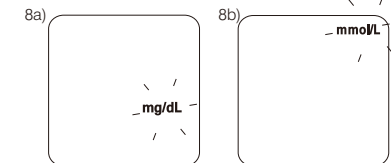
7. Volume Setting

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.



NOTE

- If you do not change any settings during Meter Set-up for over 2 minutes, RIGHTEST Blood Glucose Meter will leave setting mode and power off automatically.
- The meter default is set according to your local preference, if you have problem with it call customer service.

Turning On / Off the Meter

1. How to turn on RIGHTEST Blood Glucose Meter

Press the Main button or Insert a test strip.

2. Manual Power off

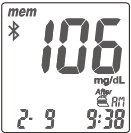
To power off RIGHTEST Blood Glucose Meter, press and hold the Main button for 3 seconds.

3. Auto Power off

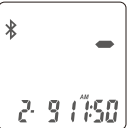
RIGHTEST Blood Glucose Meter will power off automatically after 2 minutes if no buttons are pressed or no strip is inserted.

Bluetooth function

Bluetooth default is with " ⌘ " symbol when mobile App turn on, it will automatically connect with your mobile device after user 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.

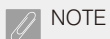


- 1) Bluetooth pairing.
The symbol of Bluetooth
" ⌘ " appears.



- 2) Data uploading.
The RIGHTEST Blood Glucose Meter is now
uploading test results to your mobile device.

Bluetooth function



NOTE

1. The meter will automatically turn off the Bluetooth after all the blood glucose readings have synced. In this case, the "⌘" icon will disappear on the screen.
2. Animated "—" symbol on the screen means the meter is transferring data.
3. 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.
4. When the meter and App cannot connect to each other successfully, please reboot the Bluetooth on both sides and try again.

If the issues still exist, please contact your local distributors for further assistance.



Auto Code / Detecting Limit

Auto Code

The RIGHTEST Blood Glucose Meter will automatically detect the Code number on the strip. You do not have to manually change the Code key or adjust the code number.



Detecting Limit

RIGHTEST Blood Glucose Meter displays results between 10 and 600 mg/dL.


If the test result is below 10 mg/dL, "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, "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.

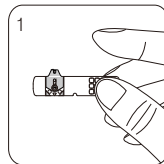


Handling RIGHTEST Blood Glucose Test strip

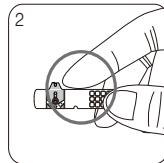
How to handle RIGHTEST Blood Glucose Test strip.

Inserting RIGHTEST Blood Glucose Test strip :

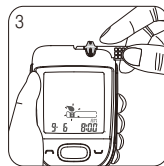
1. Hold RIGHTEST Blood Glucose Test strip between your thumb and middle finger with the view window "  " facing up.



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



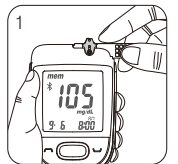
3. Insert RIGHTEST Blood Glucose Test strip into test strip port until it clicks and firmly stops.



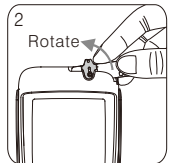
Handling RIGHTEST Blood Glucose Test strip

Removing RIGHTEST Blood Glucose Test strip:

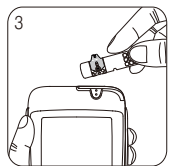
1. Hold RIGHTEST Blood Glucose Test strip as shown.



2. Rotate RIGHTEST Blood Glucose Test strip counterclockwise and pull up simultaneously.



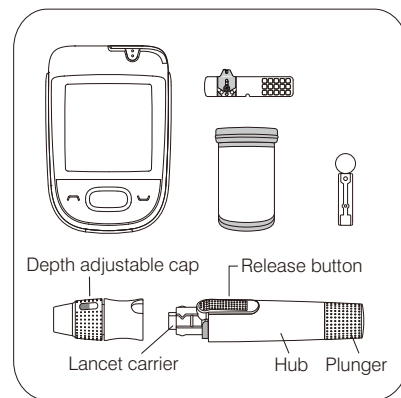
3. Take RIGHTEST Blood Glucose Test strip out of the test strip port. Please follow your healthcare professional's instructions and discard used strips properly.



Getting Ready for Testing

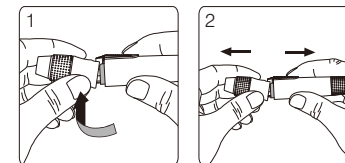
Before performing a blood glucose test, prepare the items below :

- RIGHTEST GT333 Blood Glucose Meter
- RIGHTEST GT333 Blood Glucose Test strip
(Please check the expiration date on the test strip vial. Do not use expired test strips)
- RIGHTEST Lancing device
- Sterile lancet
- Alcohol swab (optional)

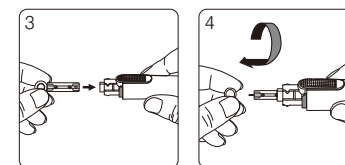


Performing a Blood Glucose Test

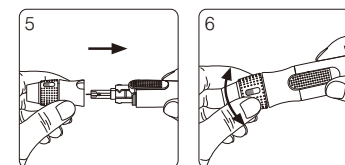
1. Hold the adjustable depth cap in one hand while holding the hub in the other hand. Lift the cap until a gap appears between the cap and hub.



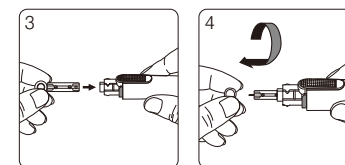
2. Pull the two parts in opposite directions to remove the adjustable depth cap.



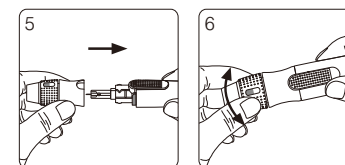
3. Insert a new disposable lancet firmly into lancet carrier.



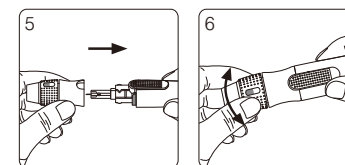
4. Twist off and set aside the protective cover of the disposable lancet.



5. Replace the depth adjustable cap.

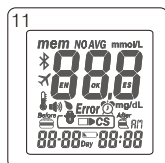
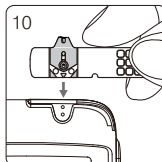
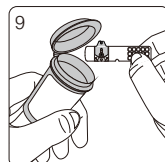
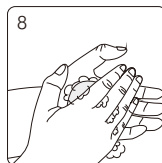
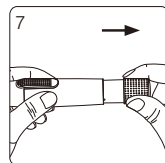


6. The adjustable cap with 7 depth levels allows you to select the depth of penetration by rotating the cap until the preferable depth display in the window. Settings are based on skin type " " for soft or thin skin; " " for average skin; " " for thick or calloused skin.



Performing a Blood Glucose Test

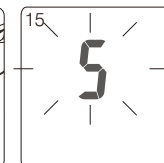
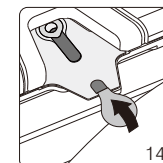
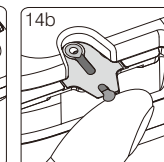
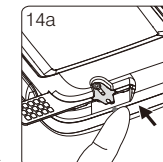
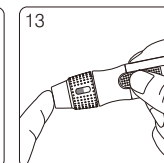
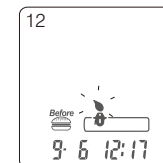
7. Hold the base in one hand and pull on the plunger with the other hand. The device will be cocked. Release the plunger and it will automatically move back to its original position near the base.
8. Wash your hands with warm soapy water and dry thoroughly.
9. Take one RIGHTEST Blood Glucose Test strip from the vial. Close the vial cap immediately.
10. Insert the strip into the test strip port of RIGHTEST Blood Glucose Meter 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
- RIGHTEST Blood Glucose Meter will automatically detect the Code number on the strip. You do not have to check the Code number on the meter display and strip vial.

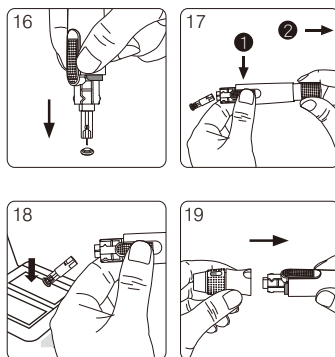
Performing a Blood Glucose Test

12. After inserting a test strip, the " " icon will flash on the screen. Pressing the Left or Right button to choose between the "Before" (before meal), "After" (after meal) and " " (no marker) and then apply the blood sample within 2 minutes (The meter will record the marker when you apply a drop of blood).
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.
15. Countdown Mode will begin on the display window. After 5 seconds, your test result will appear.



Performing a Blood Glucose Test

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 into an appropriate puncture-proof or biohazard container.
19. Replace the depth adjustable cap after finishing the test.

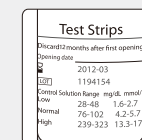


Performing a Blood Glucose Test



CAUTION

- Do not apply your blood drop to the sample port on the strip until you see the " " appear. RIGHTEST Blood Glucose Meter 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 opening date of a new test strip vial.
- 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.
- RIGHTEST Blood Glucose Monitoring System and RIGHTEST Lancing Device are intended for a single user only. Do not share these devices with anyone, including other family members.
- 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 hands thoroughly with soap and water after handling the meter/lancing device, and test strips.
- Please refer to the section "Maintain the Products" for cleaning and disinfecting instructions.




Setting Markers

According to actual life status, you can set meal markers with test result. You have to perform meal marker setting immediately after the meter displays the reading of your test result.

- 1. Before test, the test result is displayed on the screen with time, date and flashing "Before".
- 2. Press the Right or Left button to choose among " " (no marker), "Before" (before meal), "After" (after meal) apply a drop of blood and the system will automatically record the marker.

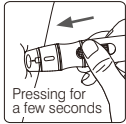
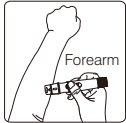
	(Blank) no marker:regular test or definition by user.
Before	Before meal:You execute this blood glucose test before a meal.
After	After meal:You execute this blood glucose test after a meal.

 **NOTE**
If markers has disappeared or not properly displayed, please contact your local distributor.

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.
(For detailed information, refer to the instruction manual for 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 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. (DO NOT test on the palm or forearm if you are testing for hypoglycemia (Low blood glucose).



Alternative Site Testing

CAUTION

- Test results may vary if blood samples are taken from different sites or under certain conditions where glucose levels are changing rapidly such as: following a drink, a meal, an insulin dose or exercise. In these cases, only the fingertip should be used.
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (Low blood glucose).
- Fingertip samples can show the rapid change in glucose faster than palm or forearm samples.
- Consult your healthcare professional before sampling from your palm or forearm.
- Since the blood flow in the forearm and palm is slower than in the fingertip, use the clear cap provided with RIGHTEST Lancing Device when testing sites other than fingertip.
- If you use the normal lancing device for your palm or forearm, the blood sample may not be sufficient for meter operation.
- Periodically compare the test system to a laboratory test system that is known to be well maintained and monitored by a healthcare provider.

Alternative Site Testing

CAUTION

- Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST (alternative site testing) measurements should not be used to calibrate continuous glucose monitors (CGMs).
- AST measurements should not be used in insulin dose calculations.

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 strip.
- Use each RIGHTEST Blood Glucose Test strip immediately after removing it from the vial.
- Do not reuse RIGHTEST Blood Glucose Test strip.
- Do not perform testing immediately after moving from one ambient temperature to another (e.g. after coming indoors from the outside). Allow 45 minutes for the temperature of the meter and the test strips to equilibrate.
- Apply the blood sample only on the sample port of the test strip.

Understanding Test Results and Messages

Blood glucose test results are shown on the meter as mg/dL or mmol/L, depending on the preset of your meter.

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.

You can also run a Quality Control Test with the RIGHTEST Control Solution GC570 to check your RIGHTEST Blood Glucose Meter and RIGHTEST Blood Glucose Test strip (Refer to "Performing a Quality Control Test" on page 46) .

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.

Consult your health care provider for appropriate disposal of used test strips and lancets.

Understanding Test Results and Messages

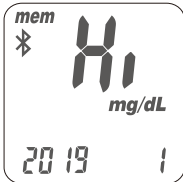
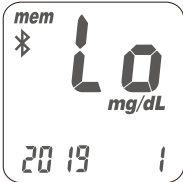
RIGHTEST Blood Glucose Meter displays results between 10 and 600 mg/dL.

If the test result is below 10 mg/dL , " 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, " 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 Solution GC570 when testing your RIGHTEST GT333 Blood Glucose Monitoring System in the Control Solution Mode. If the test result is within the Control Solution Range printed on the strip vial label, RIGHTEST Blood Glucose Monitoring System passes the Quality Control Test and your RIGHTEST Blood Glucose Monitoring System is working properly.

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

Control Solution Range	mg/dL	mmol/L
Low:	28 - 48	1.6 - 2.7
Normal:	107 - 145	5.9 - 8.1
High:	315 - 426	17.5 - 23.7

 NOTE
RIGHTEST Control Solution GC570 are for RIGHTEST GT333 Blood Glucose Monitoring System. If you want to purchase please contact RIGHTEST customer service (printed on manual coverback).

About Quality Control Testing

When should a Quality Control Test Be Performed ?

- To ensure that your RIGHTEST Blood Glucose Meter and RIGHTEST Blood Glucose 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 Blood Glucose Test strip when you open a new vial of strips.
- To check your RIGHTEST Blood Glucose 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 the way you feel.
- To practice testing.

Required Items for Quality Control Tests

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

- RIGHTEST GT333 Blood Glucose Meter
- RIGHTEST GT333 Blood Glucose Test strip
- RIGHTEST Control Solution GC570

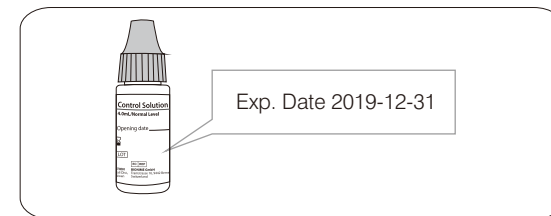
About Quality Control Testing



CAUTION

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

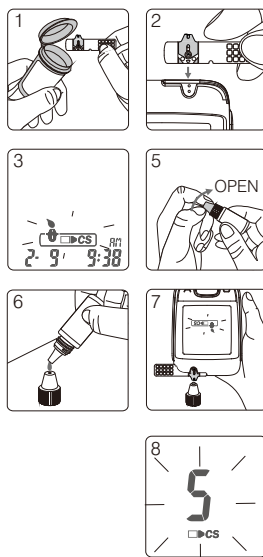
Example



- 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 GC570 Package Insert).
- Keep control solution bottles out of reach of children.

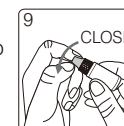
Performing a Quality Control Test

1. Take one RIGHTEST Blood Glucose Test strip from the vial and close the vial cap immediately.
2. Insert RIGHTEST Blood Glucose Test strip horizontally (not vertically) with the colored view window facing up into the test strip port.
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 RIGHTEST Control Solution.
5. Shake the bottle of RIGHTEST Control Solution 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 bottle.
10. The control solution result will appear. Compare your Quality Control Test result to the Control Solution Range printed on RIGHTEST Blood Glucose Test strip 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. RIGHTEST Blood Glucose Meter 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 printed on the test strip vial label. If the results are within the range, the RIGHTEST Blood Glucose Monitoring System is working correctly.

Example of control solution range printed on your test strip vial label

Control Solution Range		
Low	Normal	High
28 - 48 mg/dL	107 - 145 mg/dL	315 - 426 mg/dL

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

- Your RIGHTEST Control Solution is expired or was first opened more than 3 months ago.
- Your RIGHTEST Blood Glucose Test strip 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.
- RIGHTEST Blood Glucose Meter or RIGHTEST Blood Glucose Test strip have malfunctioned.

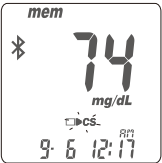
If RIGHTEST Control Solution results are out of range, your RIGHTEST Blood Glucose Monitoring System may not be working properly. Repeat the Quality Control Test. If your control solution results are still out of range, do not use RIGHTEST Blood Glucose Meter to test your blood glucose. Please contact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

Recalling Test Results

RIGHTEST Blood Glucose Meter 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.

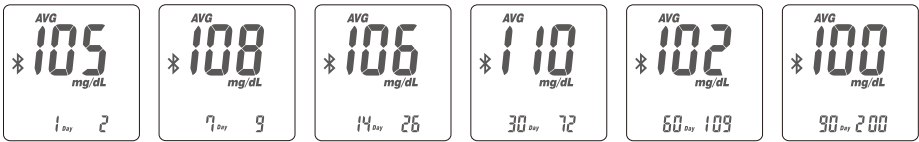
To recall your test memory, start the meter without a test strip inserted.

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 under the data, the test was performed using the RIGHTEST Control Solution. The control solution test result will not be used when recalling test average results.



Recalling Average Test Results


RIGHTEST Blood Glucose Meter 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 < 10°C(50°F), > 40°C(104°F) will be excluded from average calculations.

Maintain the Products

Maintenance

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.

Cleaning Meter

Clean the outside of the meter with disinfecting wipes listed on next page. Do not get the test strip port wet.

Cleaning Test Strip Port

If your test strip port is stained with blood, control solution or any liquid, please use disinfecting wipes listed on next page to clean it immediately. Do not immerse in water. Perform a quality control test to ensure RIGHTEST Blood Glucose Meter is working properly.

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 HBV on the housing materials of the device. The cleaning and disinfecting procedure should be performed at least once per week.

The meter and lancing device should be cleaned before being disinfected.

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.

NOTE: the cleaning procedure can only remove visible contaminants from surfaces.

Only the disinfecting procedure can eliminate non-visible pathogens.

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.

Maintain the Products



NOTE

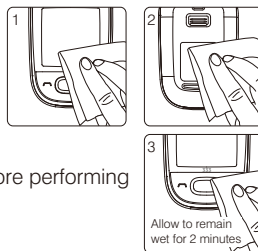
- Clean and disinfect the outside of the device only.
Do not remove battery cover when cleaning and disinfecting.

To clean the meter:

1. Thoroughly wipe the entire surface of the meter, especially port, face/display, housing and buttons 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 minutes.
4. Allow to air dry.



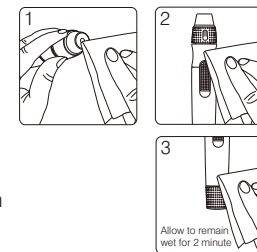
NOTE

- Your RIGHTEST Blood Glucose Meter has been tested to ensure that there is no change in the performance or external materials of the device after 550 cleaning cycles and 550 disinfecting cycles. The testing simulates 2 cleaning and disinfecting cycles per week over the typical life of the meter (5 years).

Maintain the Products

To clean the lancing device:

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



To disinfect the lancing device:

2. Take another disinfecting wipe and wipe the Lancing device thoroughly. (Note: All blood and body fluids should be cleaned from surface before performing disinfecting procedure)
3. Allow the surface to remain wet for 2 minutes.



NOTE

- Your RIGHTEST Lancing Device has been tested to ensure that there is no change in the performance of the device after 550 cleaning cycles and 550 disinfecting cycles. The testing simulates 2 cleaning and disinfecting cycles per week over the typical life of the meter (5 years).

Maintain the Products

CAUTION

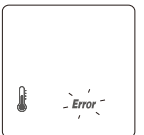
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Please examine your LCD screen, test strip port, buttons and surface of your meter and lancing device after cleaning and disinfecting cycles. Stop using the meter and/or lancing device if any of the following occur:
 - Thin, silver streaks appear on the screen,
 - The screen becomes cracked, soft, dissolved, brittle or swollen.
 - You are unable to turn on/off your meter, operate the left/right button, the lancing device release button or depth adjustable cap.
 - You are unable to enter meter settings, function modes or recall your testing results.

If you have any questions or concerns, please contact your RIGHTEST Blood Glucose Monitoring System authorized representative or call the RIGHTEST Diabetes Support Center.

Error Messages and Troubleshooting



Temperature Error

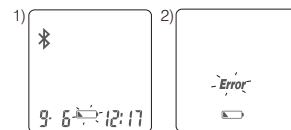
1. In order to get accurate testing results, please test between 10-40°C(50-104°F).
2. When the temperature is below 10°C(50 °F) or over 40°C(104°F), the meter will not function and the "**Error**" symbol will blink.
3. If RIGHTEST Blood Glucose Meter and Test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.





Error Messages and Troubleshooting

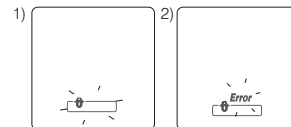
Battery Error

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




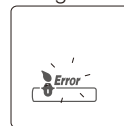
Strip Error

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 (refer to "Handling RIGHTEST Blood Glucose Test strip" for more information).
2. If, after performing the required steps, the "  " and flashing " **Error** " symbols appear on the screen, it means RIGHTEST Blood Glucose Test strip has been inserted incorrectly more than twice. Please, re-insert the unused test strip again after reviewing the steps on how to insert a test strip correctly 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 RIGHTEST Blood Glucose Test strip.



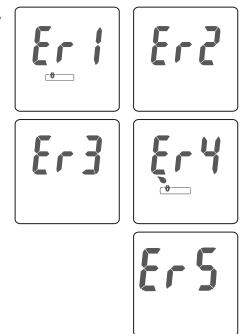
Sampling Error

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 batteries 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 one of the above error messages still appears, please contact your local distributor.

Error Messages and Troubleshooting

Meter Malfunction

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

1. Open the battery cover and remove the batteries.
2. Wait for 5 minutes and reinsert the batteries as described as instructed on "Meter Activation and battery Change."

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

CAUTION

A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and the Meter's screen is showing the image of the test strip and a blood drop flashing symbol. If the blood drop flashing symbol is NOT showing on the screen, do not apply a sample to the test strip. Please re-insert the unused test strip correctly. The screen MUST show the image of the test strip accompanied by the blood drop symbol flashing (this symbol take 3 seconds to show after correctly inserting the test strip) in order for a sample to be applied. Please consult your User Manual and/or contact Customer Service for support on how to correctly insert a RIGHTEST Blood Glucose Test strip.

Rightest CARE App (May not be available in your country)


"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.tw>

Specification

Measurement Technology	Oxidase Electrochemical Sensor
Sample	Capillary whole blood
Measuring Range	10 - 600 mg/dL
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 main button "  " for 3 seconds.
Operating Temperature	10 - 40°C(50 - 104°F)
Operating Relative Humidity	10 - 90%
Meter Storage/ Transportation Conditions	-10 - 60°C(14 - 140°F)

Specification

Power Supply	2 AAA Batteries
Battery Life	Approximately 1000 tests, each test with one data transfer
Meter Dimension	85mm x 57mm x 22.5 mm
Meter Weight	81.0 ± 5g with batteries
Monitor	LCD
Display Area	39 mm x 39.5 mm
Minimum Sample Volume	
Test Strip Storage/ Transportation Conditions	refer to Strip insert
Hematocrit	

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 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.

Please complete and return the enclosed warranty card.

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















 NOTE

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

Customer Service

Please review all of the instructions to make sure you are performing the steps correctly. If you have any questions or in case of problems with the RIGHTEST Products, please contact your local Bionime authorized representative. we will make every effort to provide assistance and solutions for you. If you have questions or need assistance outside the operational days and times, please contact your healthcare provider.)

Description of used symbols

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

Expected Glucose Values Without Diabetes

Expected glucose values without diabetes ⁽¹⁾

Status	Range (mg/dL)
Fasting	<100
Two Hours after meals	<140

References

1) American Diabetes Association: Diabetes Care, January 2015, volume 38 (Suppl. 1) S8-S16.

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.