RIGHTEST™
Blood Glucose Monitoring System

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Max
User's Manual

Indication for use

RIGHTEST Max Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples from capillary. The testing result is calibrated to plasma equivalent with whole blood from capillary, vein, artery and neonates. Capillary whole blood can be sampled from the fingertip, palm or forearm, and in the case of neonates, the heel.

RIGHTEST Max Blood Glucose Monitoring System 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 Max Blood Glucose Monitoring Systems should not be used for the diagnosis of, or screening for diabetes. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

RIGHTEST Max Control Solution is for use with RIGHTEST Max Blood Glucose Meter and RIGHTEST Max Blood Glucose Test Strip 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 Max Blood Glucose Monitoring System provides accurate, reliable test results to help you better manage your diabetes.

You may consult your healthcare professional for instructions on how to use the system correctly. 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 Max Blood Glucose Monitoring System 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

Scan the QR code to view the guide video.

Caution

- Before using RIGHTEST Max Blood Glucose Monitoring System to test your blood glucose, please read all of the info and conduct all of the tests including the quality control test (Refer to page 45).
- Please perform the quality control test regularly to make sure the test results are fine.
- RIGHTEST Max Blood Glucose Meter can only be used with RIGHTEST Max Blood Glucose Test Strip. Other brands' test strips should not be used under any circumstances. The use of other brands' strips may give inaccurate results.
- RIGHTEST Max Blood Glucose Monitoring System is intended for in vitro diagnostic use only. The testing result is calibrated to plasma equivalent with whole blood from capillary, vein, artery and neonates. Capillary whole blood can be sampled from the fingertip, palm or forearm.
- Venous, neonatal or arterial blood testing should be performed by healthcare professionals.
- RIGHTEST Max Blood Glucose Monitoring System is NOT intended for diagnosis of diabetes mellitus.
- If RIGHTEST Meter and Test Strips are exposed to temperature environments out of range for the meter – below 6°C (43°F) or above 44°C (111°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 RIGHTEST Max Blood Glucose Monitoring System 0.75 µL: (•)

Sample Size Example

Blood sample size above 3.0 µL might contaminate the test strip port and the meter.

Sample below 0.75 µL will cause Er4. In this case, repeat the test with a new test strip.

- Please follow the recommendations for follow-up care that have been set by the professional medical staff for critical glucose values in neonates.
- As a matter of good clinical practice, be caution of the interpretation of neonate glucose value below 50 mg/dL (2.8 mmol/L).
- Once patient is suspected as rare disease (e.g. galactosemia), the glucose result should based on laboratory test.

Caution

Important Safety Notes:

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the cleaning and disinfecting procedures. Please refer to the section " Maintain the products " on page 51.
- Users should wash their hands wholly with soap and water before and after touching the meter, lancing device, or test strips.

Limitations

- RIGHTEST Max Blood Glucose Monitoring System is not intended for serum or plasma testing.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Hematocrit levels below 10% may cause falsely high reading. Hematocrit levels over 70% may cause falsely low reading. If you do not know your hematocrit level, consult your doctor or nurse.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- The blood glucose test result may be affected by high blood concentration of interference ingredients, if you need more detail information about interference ingredients, please see RIGHTEST Max blood glucose test strip insert.
- Not for screening or diagnosis of diabetes mellitus.
- These test strips should not be used with meters to test critically ill patients.
- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly), please refer to the (Alternative site testing (AST)) chapter before you perform AST testing.
- Alternative site testing should not be used to calibrate continuous glucose monitoring systems (CGMS).
- To avoid potential electromagnetic or other interference, keep meter away from electromagnetic radiation sources such as X-ray or MRI.

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

The items in RIGHTEST Max Blood Glucose Monitoring System:

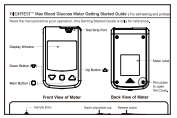
1. User Documents (Getting Started Guide, User's Manual, Log Book, Warranty Card, Emergency Card).
2. RIGHTEST Max Blood Glucose Meter (with battery installed)
3. RIGHTEST Max Blood Glucose Test strips 10 or 25 pcs (with Package Insert)
4. RIGHTEST Max Control Solution (with Package Insert)
5. RIGHTEST 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. Contact distributor for more details.

RIGHTEST Max Blood Glucose Monitoring System

(∗- product sold separately)

1



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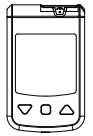

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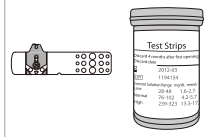

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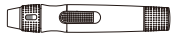

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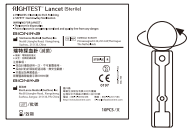
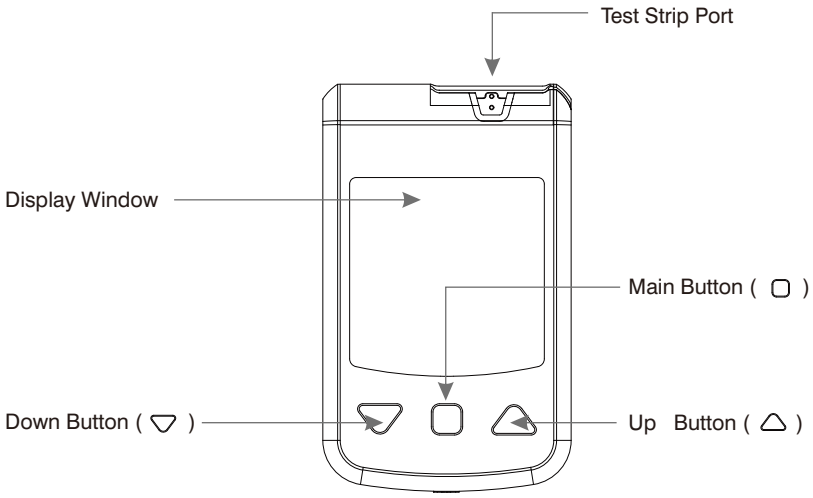
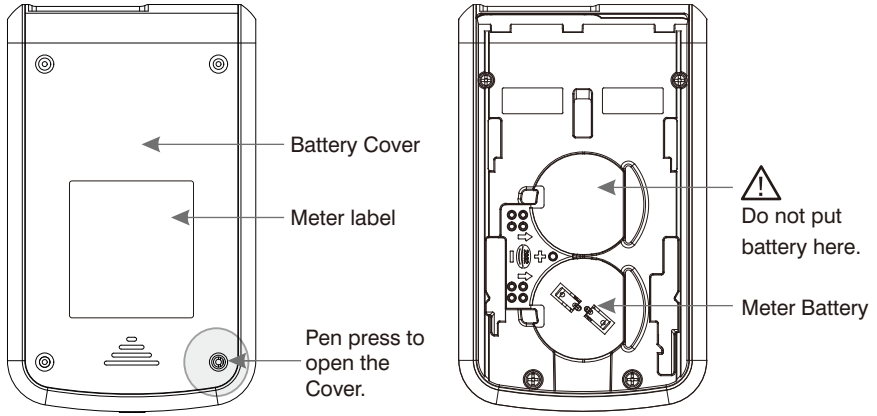
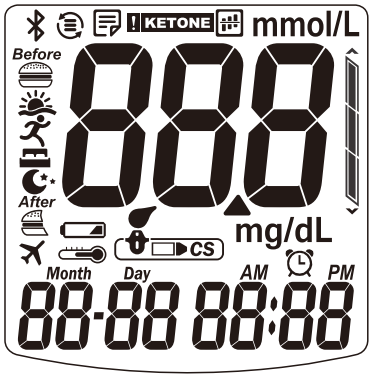


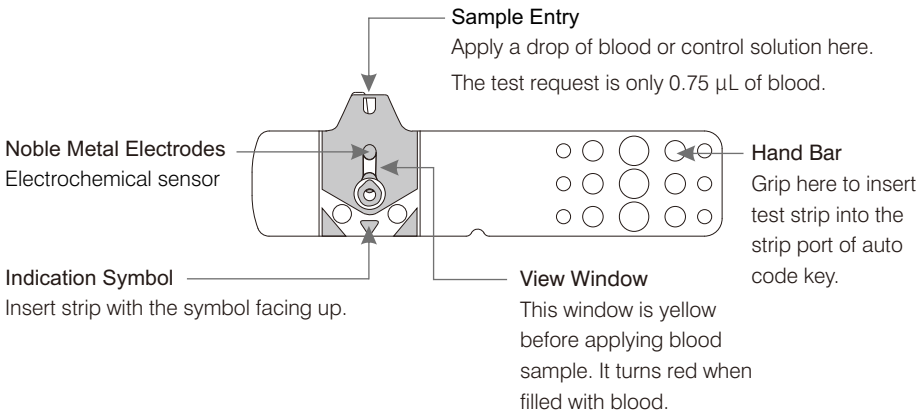

Test Strip Port
Display Window
Main Button ( )
Down Button ( )
Up Button ( )

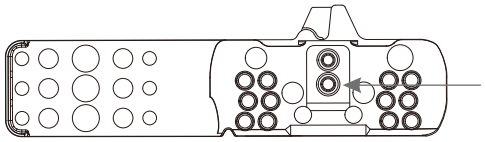

Battery Cover
Meter label
Pen press to open the Cover.
Do not put battery here.
Meter Battery



CS	Indicates a control solution test result.		Indicates when to apply the blood sample.
mmol/L mg/dL	Unit of test result.		Appears after you insert test strip into meter.
KETONE	Appears when a test result is above 240 mg/dL to suggest ketone testing.		Warns when the operational temperature limit is exceeded during testing.
	Warns when the battery is low or must be replaced.	Month Day	Current date under time mode or testing date under memory mode.
Before After	Indicates a meal marker with test result.		Displays current time under time mode or testing time under memory mode.
	Indicates that the Bluetooth is enabled (Bluetooth meter only).	AM PM	Indicates the time format is 12H.
	Test result.		Indicates the average result.
	Indicates a test result stored in memory.		Indicates a testing result is waiting for transmission. (Bluetooth meter only)
	Indicates wake up. exercise marker with test result.		Before sleep marker with test result. Indicates midnight.
	The blood glucose result is within the target range.		The blood glucose result is below the target range. The blood glucose result is above the target range.
	Indicates the alarm setting.		Manufacturing use only.

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



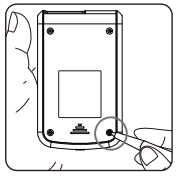


⚠ PRECAUTION

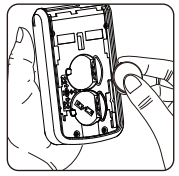
- Close the vial rapidly after taking out a test strip.
- Do not reuse RIGHTEST Test Strip.
- Do not use expired RIGHTEST Test Strip.
- Record the date of opening a new RIGHTEST Test Strip vial for the first time. Discard the vial of test strips after 12 months from opening.
- Store RIGHTEST Test Strip in 4 - 30°C (39 - 86°F) and with < 90% relative humidity. Do not expose to direct sunlight or heat.
- If RIGHTEST Meter and Test Strips are exposed to a temperature environments out of range for the meter – below 6°C (43°F) or above 44°C (111°F) – please wait 30 minutes before testing again.
- For detailed strip information, please refer to RIGHTEST Max Blood Glucose Test Strip Insert.

Meter Activation and Battery Change

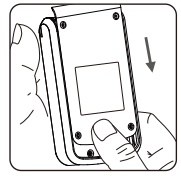
Your RIGHTEST Max Blood Glucose Meter comes with one CR2032, 3 volt, battery installed. One new battery will provide power to perform approximately 1000 tests under normal use. Press the main button or insert a strip to activate your meter.



1. Use a pen point to press the bottom-right spot on the cover, at the same time slide up the cover.



2. Install the battery into the chamber with electrode. Be sure to put the battery in the correct direction (polarity (+)facing up).



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 " on page 20. Test results are still stored in the memory.

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

Set Up Your Meter - Set Up 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. 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.

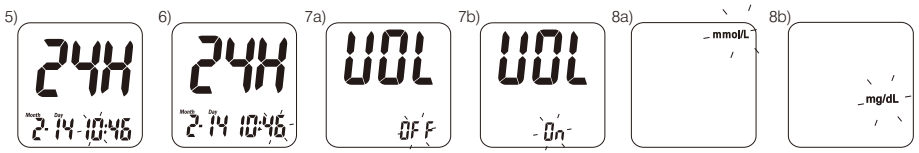
NOTE
- Use the Up or Down buttons to select your setting data and press the main button to confirm each selection. After confirming all of the settings, you will return to the Time Mode.
- After pressing the main button for 3 seconds, the meter will turn off its screen. Please keep press the main button until the meter enter the setup mode.

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

1. Year setting
   When the year blinks, press the Up or Down button to select the current year and press the main button to conform the setup.
2. Month setting
   When the month blinks, press the Up or Down button to select the current month and press the main button to conform the setup.
3. Day setting
   When the day blinks, press the Up or Down button to select the current date and press the main button to conform the setup.
4. 12 or 24-hour format setup
   When the time format blinks, press the Up or Down button to select the preferable time format and press the main button to conform the setup.

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

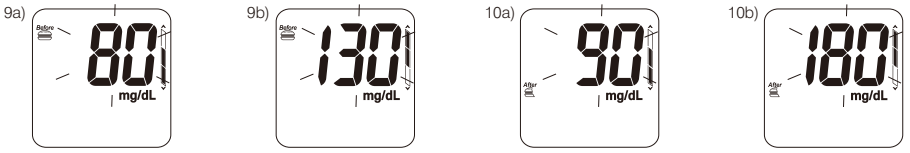
5. Hour setting
   When the hour blinks, press the Up or Down button to select the current hour and press the main button to conform the setup.
6. Minute setting
   When the minute blinks, press the Up or Down button to select the current minute and press the main button to conform the setup.
7. Volume Setting
   When the " OFF " blinks, press the Up or Down button to turn the volume on or off and press the main button to confirm the setup.
8. Measurement Unit Setting
   When the milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L) blinks, press the Up or Down key to select the preferable measurement unit and press the main button to confirm the setup.



Set Up Your Meter - Set Up the Meal Glucose Range

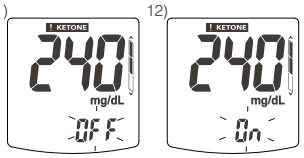
9. Before Meal Blood Glucose Range Setting
   The before meal mark and the lower limit bar will be displayed, and the blood glucose value will blink. Press the up / down button to adjust the value to the target value and then press the main button to confirm. Please follow the same way to set up the upper limit for before meal.
10. After Meal Blood Glucose Range Setting
    The after meal mark and the lower limit bar will be displayed, and the blood glucose value will blink. Press the up / down button to adjust the value to the target value and then press the main button to confirm. Please follow the same way to set up the upper limit for after meal.

NOTE
- The upper / lower limit marker is only for reminding. You may consult your doctor for further assistance.
- Tight blood glucose control for ADA: close to a normal (nondiabetic) blood glucose level as you safely can. Ideally, this means levels between 70 and 130 mg/dL (3.8 and 7.2 mmol/L) before meals, and less than 180 mg/dL (10.0 mmol/L) two hours after starting a meal.



Set Up Your Meter - Ketone Reminder

11) 12)



11. Ketone Reminder Setting
    Ketone test reminder is default set to off. This is only recommended for Type 1 diabetes users.
    By pressing the up / down button to enable the Ketone reminder and press the main button to confirm.

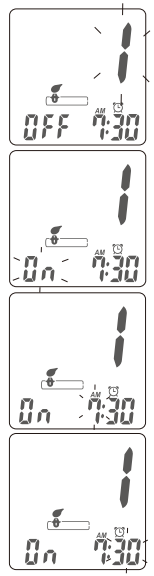
    If your blood glucose test result is more than 240 mg/dL (13.3 mmol/L), the Ketone test reminder well appear when it is on. When " ! KETONE " appears, it means that you may need a ketone test. Please contact your doctor immediately.

12. Setup complete
    After the setup is complete, the meter will beep to notify the user and return to time mode. Please notice that the meter will only beep when the volume is set to on.

NOTE
- When the meter is idle for more than 30 seconds, the meter will leave setting mode and power off automatically.
- Meter default is set according to your local preference.

Set Up Your Meter - Set Up the Time Alarm

This feature reminds the user when to perform a test. There are 8 sets of alarm available per day. The meter will beep when the alarm is triggered and it will be triggered up to 3 times. Insert the test strip or press main button, button will turn off the alarm. The volume must be set to on so that the meter can beep.



1. Enter the reminder setting function
   When the meter is " ON ", long press the up or down button 3 seconds till entering to time alarm setting.
2. Choose the alarm set
   User can set 8 alarms from " 1 " to " 8 ". Choose the number with up or down button when " 1 " flashing, then press the main button to confirm.
3. Turn on / off the alarm
   Choose " On " or " Off " with the up or down button, then press the main button to confirm.
4. Set the alarm clock
   Press the up or down button to adjust when the hour blinking, then press the main button to confirm. Press the up or down button to adjust when the minute blinking,then press the main button to confirm .
5. Finish the alarm setting
   To finish the alarm setting, hold the main key for few seconds, meter will save your setting when exit the setting screen.

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.

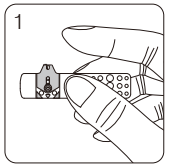
3. Auto Power off
   RIGHTEST Blood Glucose Meter will power off automatically after 30 seconds if no buttons are pressed or no strip is inserted.

Handling RIGHTEST Blood Glucose Test Strip

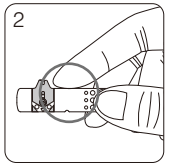
How to handle RIGHTEST Blood Glucose Test Strip.

Inserting RIGHTEST Blood Glucose Test Strip:

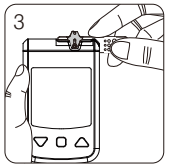
1. Hold RIGHTEST Max Blood Glucose Test Strip between your thumb and middle finger with the view window " " facing up.



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

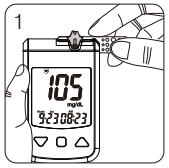


3. Insert RIGHTEST Blood Glucose Test Strip into test strip port until it clicks and firmly stops.

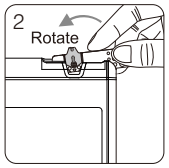


Handling RIGHTEST Blood Glucose Test Strip

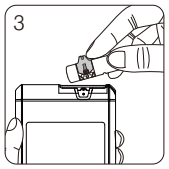
Removing RIGHTEST Blood Glucose Test Strip:
1. Hold RIGHTEST Blood Glucose Test Strip as shown.



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



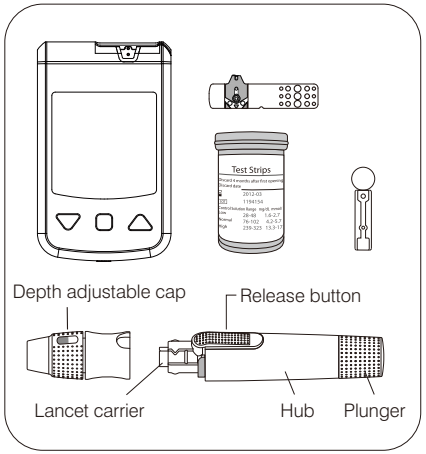
3. Take RIGHTEST Blood Glucose Test Strip out of the test strip port. Please follow your local regulations and discard used strips properly.



Getting Ready for Testing

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

- RIGHTEST Max Blood Glucose Meter
- RIGHTEST Max 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. Wash your hands with warm soapy water and dry thoroughly.

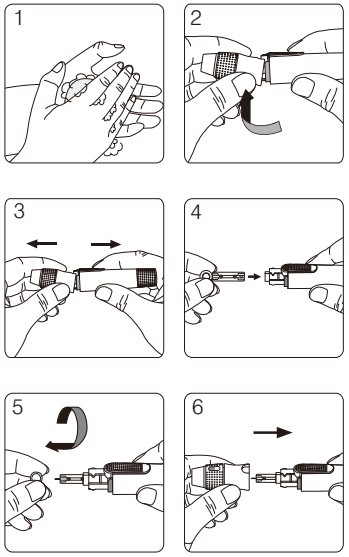
2. Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub.

3. Pull the cap and hub off in opposite directions, remove the cap.

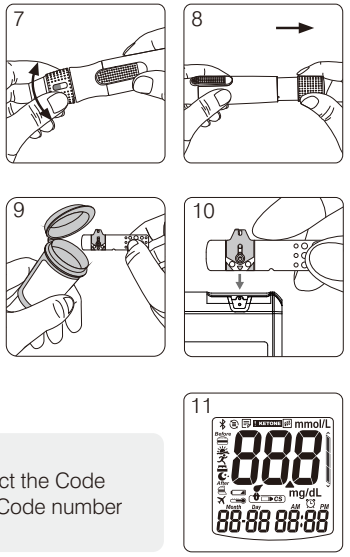
4. Insert a new disposable lancet firmly into lancet carrier.

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

6. Replace the depth adjustable cap.

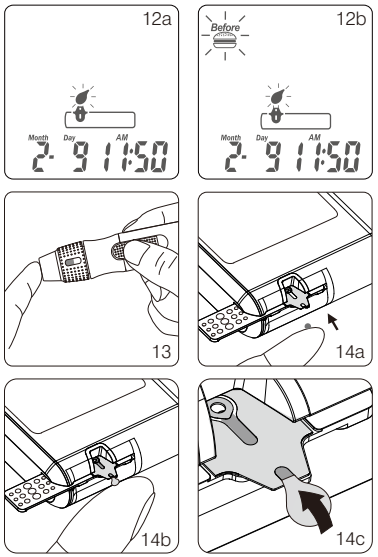


7. The adjustable cap with 7 depth levels allows you to select the depth of penetration by rotating the cap until the preferable depth display in the window, Settings are based on skin type.
   " ▭ " for soft or thin skin; " ▭ " for average skin;
   " ▭ " for thick or calloused skin.
8. Hold the base 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.
9. Take one RIGHTEST Max Blood Glucose Test Strip from the vial. Close the vial cap immediately.
10. Insert the strip into the test strip port of RIGHTEST Max 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).

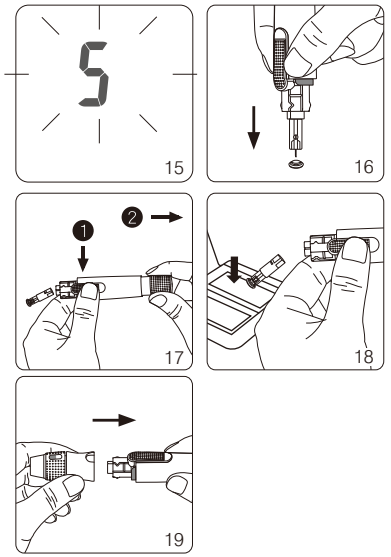


NOTE
- RIGHTEST Blood Glucose Meter will automatically detect the Code number on the test strip. You do not have to check the Code number on the meter display and strip vial.

12. After inserting a test strip, the " " icon will flash on the screen. Pressing the Up or Down button to choose between the " "(before meal), " "(after meal), " "(midnight), " "(bedtime), " "(exercise), " "(wake up) 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 Glucose Test Strip.



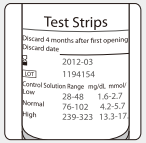
15. Countdown Mode will begin on the display window. After 5 seconds, your test result will appear.
16. Pull off the depth adjustable cap. Without touching the used disposable lancet, insert the lancet tip into the protective lancet cover.
17. Hold the release button in one hand (see picture 17, step 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 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 meter is performing an internal test and will display " " and " Er " 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. Discard the vial of test strips 12 months after first opening.
- Always keep the metal contacts of the test strip port clean. If any dust or dirt is 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 wash hands wholly with soap and water after handling the meter, lancing device, and test strips.
- Please refer to the section " Maintain the Products " on page 51 for surface cleaning.
- Do not reuse lancets. Discard used lancets properly.



Setting Markers

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

1. After inserting a test strip, the " " icon will flash on the screen. Pressing the Up or Down button to choose between the " " (before meal), " " (after meal), " " (midnight), " " (bedtime), " " (exercise), " " (wake up) 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).

Before	Before meal: you test the blood glucose before meal.
After	After meal: you test the blood glucose after meal.
	Regular test or definition by user.
	Midnight: you execute the blood glucose test in midnight.
	Bedtime: you execute the blood glucose test before sleep.
	Exercise: you execute the blood glucose test after exercise.
	Wake up: you execute the blood glucose test when you awake up.

Recalling Test Results

The RIGHTEST Max 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 " " icon in the upper left corner of the display. The latest test result will appear with the number " 1 " .

2. Use either the up or down 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.

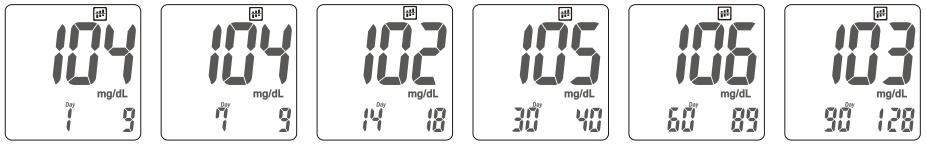
3. The Quality Control Test result can be recalled from the saved data.
   When " CS " appears next to the data, the test was performed by the control solution. The control solution test result will not be used when recalling test average results.

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

Recalling Average Test Results

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

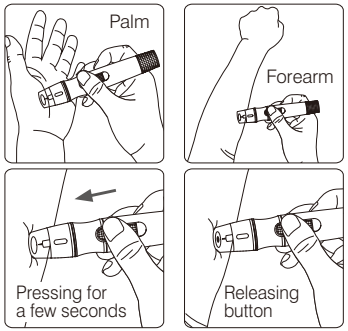


Recalling Average Test Results

NOTE

- The Average function requires that the correct time and date is set. Whenever the battery is changed, the time has to be reset. Otherwise, the average function cannot work normally.
- 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-days 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 CS test result has been automatically removed from the average calculation but it is still searchable in the Memory Mode. The CS test result will show with a blinking " ▭▶CS " icon in the Memory Mode.
- The " Lo ", " Hi " results, control solution test results and test results under abnormal temperature < 6°C (43°F), > 44°C (111°F) will be excluded from average calculations.

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.
- Keep pressing 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).

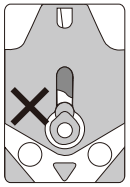
Alternative Site Testing

⚠ CAUTION

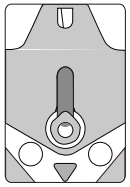
- Consult your healthcare professional before sampling from your palm or forearm.
- Alternate site testing should only be done during steady-state time (when glucose is not changing rapidly), fingertip can show the rapid change in glucose faster than palm or forearm samples.
- Only the fingertip should 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 test strips.
- Use each test strip rapidly after removing it from the vial.
- Do not reuse test strips.
- If RIGHTEST Meter and Test Strips are exposed to temperature environments out of range for the meter – below 6°C (43°F) or above 44°C (111°F) – please wait 30 minutes before testing again.
- 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 test strip.

You can also run a Quality Control Test with RIGHTEST Max Control Solution to check your RIGHTEST Max Blood Glucose Meter and RIGHTEST Max Blood Glucose Test Strip (Refer to " Performing a Quality Control Test " on page 48) .

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

If you feel symptoms that are not consistent with your blood glucose test results and you surely follow all instructions in this manual, contact your healthcare professional rapidly.

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

Understanding Test Results and Messages

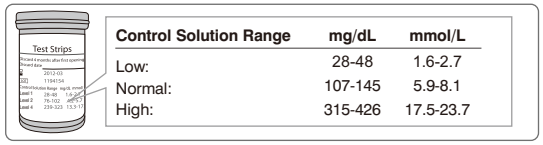
The meter displays results between 10 and 600 mg/dL (0.6 and 33.3 mmol/L).
If the test result is below 10 mg/dL (0.6 mmol/L), " Lo " will appear on the screen. Please repeat your test with by a new test strip.
If you still get a " Lo " result, contact your healthcare professional.
If the test result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

NOTE
- If your blood glucose result is unusually high or low, or if you question the test result, repeat the test with a new test strip. You can also run a Quality Control Test to check your meter and test strip. If the test result 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 surely follow all test instructions of this manual, contact your healthcare professional immediately.

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 RIGHTEST Max Control Solution when testing your RIGHTEST Max 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 Max Control Solution are for RIGHTEST Max Blood Glucose Monitoring System. If you want to purchase please contact Bionime customer service (printed on manual coverback).

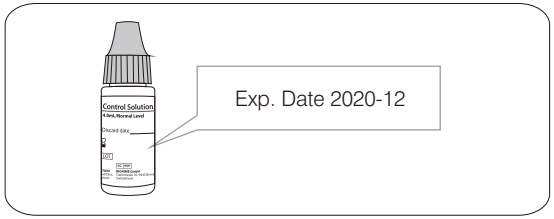
About Quality Control Testing

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 your feeling
- To practice testing.

Required Items for Quality Control Tests
To perform a quality control test, prepare the items below :
- RIGHTEST Max Blood Glucose Meter
- RIGHTEST Max Blood Glucose Test Strip
- RIGHTEST Max Control Solution

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

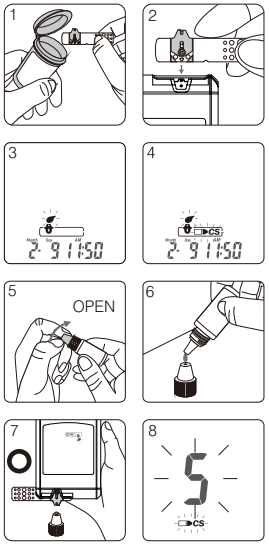
Example



- 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 RIGHTEST Max Control Solution Package Insert).
- Keep control solution bottles out of reach of children.

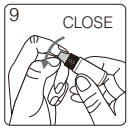
Performing a Quality Control Test

1. Take one RIGHTEST Max Blood Glucose Test Strip from the vial and close the vial cap immediately.
2. Insert the strip into the test strip port of RIGHTEST Max Blood Glucose Meter with the view window facing up.
3. While the test strip icon is flashed on the display window, press and hold the main button for at least 3 seconds until the " CS " symbol appears.
4. You will see " " icon and " CS " icon blinking on the screen, prompting you to apply the corresponding level of RIGHTEST Max Control Solution.
5. Shake the bottle of RIGHTEST Max 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).

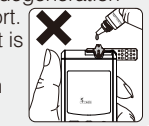


Performing a Quality Control Test

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



⚠ CAUTION
- Your Control Solution Test results will not be included in the average calculations, however, they can still can 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 6 - 44°C (43 - 111°F), relative humidity 10 - 90%.
- 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: " Er " 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, RIGHTEST Blood Glucose Monitoring System is working correctly.

Possible reasons your Control Solution results may be out of 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 Max 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 Bionime customer service (printed on manual coverback).

Maintain the Products

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

The cleaning procedure is to remove dust, blood and body fluid from the surface and should be performed whenever the meter or lancing device is visibly dirty. The disinfecting procedure is necessary to kill pathogens such as HIV, HBV and HCV on the device.
NOTE: the cleaning procedure can only remove visible contaminates from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

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

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

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

Maintaining

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

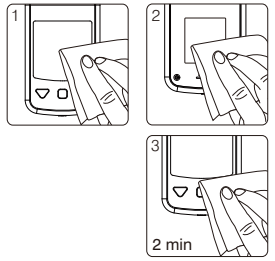
Cleaning and Disinfecting frequency: at least once a week.

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

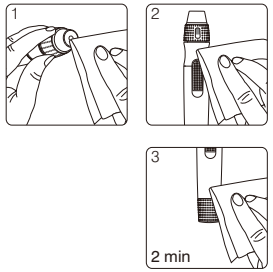
- Clean and disinfect the outside of the device only. Do not remove battery cover when cleaning and disinfecting.

Cleaning and Disinfecting frequency: at least once a week.
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 minute.



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 Max Blood Glucose Monitoring System authorized distributor or contact your local Bionime customer service.

Temperature Error

1. In order to get accurate testing results, please test between 6°C (43°F) and 44°C (111°F).
2. When the temperature is below 6°C (43°F) or over 44°C (111°F), the meter will not function and the " Er " symbol will blink.
3. If RIGHTEST Meter or Test Strips are exposed to temperature environments out of range for the meter – below 6°C (43°F) or above 44°C (111°F) – take the meter and strips back to the environment within the operating temperature of meter and wait 30 minutes before testing again.

Battery Error

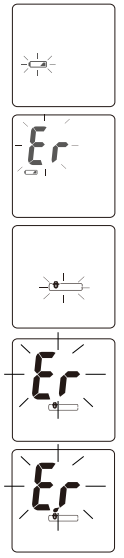
1. The " " symbol is blinking when the battery power is low. Please change battery as soon as you can. You can still do the test.
2. The " " and " Er " symbols appear and the meter will not function when the battery is low. Change the batteries immediately.

Strip Error

1. When the test strip is inserted incorrectly, the meter will beep 4 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“ on page 27 for more information).
2. If, after performing the required steps, the " " and flashing " Er " 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 following the steps of " Handling RIGHTEST Blood Glucose Test Strip " 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.

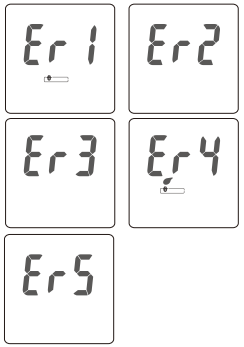
Sampling Error

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 " Er ".



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.



Meter Malfunction
If RIGHTEST Blood Glucose Meter 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 as instructed on page 18, (Meter Activation and Changing the Battery).

The meter should work normally after finishing the above steps. If the meter still does not work, please contact Bionime customer service (printed on manual coverback).

Error Messages and Troubleshooting

⚠ 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 Max Blood Glucose Test Strip.

Specification

Measurement Technology	Dehydrogenase 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 30 seconds after last user action. To turn off manually, press the main button " ▢ " for 3 seconds.
Operating Temperature	6 - 44 °C (43 - 111 °F)
Operating Relative Humidity	10 - 90%
Power Supply	one CR2032 battery

Battery Life	Approximately 1000 standard tests
Meter Dimension	50.0 mm x 82.0 mm x 15.5 mm
Meter Weight	59 ± 5g with batteries
Monitor	LCD
Display Area	40.7 mm x 40.2 mm (2.3")
Meter Storage/ Transportation Conditions	-10 - 60 °C (14 - 140 °F)
Sample	Refer to RIGHTEST Max test 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 RIGHTES Max 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 Max Blood Glucose Monitoring System.

Please complete and return the enclosed warranty card.

Different models have different specifications. This warranty applies only to RIGHTEST Max 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 local regulations to properly dispose of the used RIGHTEST Blood Glucose Monitoring System 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 Rightest customer service (printed on manual coverback).

Description of used symbols

IVD For *in vitro* diagnostic use	Manufacturer	Biological risks
Consult the instruction for use	Expiry date	For single use only
Temperature limitation	WEEE	EC REP EC Representive
CE 0197 CE-mark (with No. of notified body)		LOT Lot number
Caution (consult instructions foruse and warnings)		Direct current
STERILE R Method of sterilization using irradiation		Humidity limitation

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 May 08, 2019 form 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 (CE 0197).
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.