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RIGHTTEST™
Blood Glucose Monitoring System

Max Plus
User's Manual

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

The system can test the glucose concentration in fresh capillary whole blood (drawn from the fingertip, palm or forearm), as well as venous, arterial and neonatal whole blood samples. The glucose result displayed is equivalent to results from plasma glucose testing.

The testing of venous, arterial, and neonatal whole blood samples should only be performed by healthcare professionals.

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

The RIGHTEST Max Plus Blood Glucose Meter is a Bluetooth Low Energy (BLE) device.

Thank you for choosing our product. This manual contains all the information you need to use your product to get accurate blood glucose test results. Please read this entire manual before you get started with any testing.

For people living with diabetes, it is important to regularly monitor blood glucose levels to reduce complications from diabetes. The easy-to-use RIGHTEST Max Plus Blood Glucose Monitoring System provides accurate, reliable test results to help you manage your diabetes better.

You may wish to consult your healthcare professional for further advice on how to use this system.

Our customer service information is on the cover and our staff are also willing to provide you with assistance. Please contact a healthcare professional in an emergency or when our service is not available. Please forward your warranty card to customer support to activate your warranty coverage.

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

- Before using the RIGHTEST Max Plus Blood Glucose Monitoring System to test your blood glucose, please read all of this information and conduct all of the tests including the Quality Control test (p41).
- We recommend you perform the Quality Control test regularly to ensure test results are accurate. The RIGHTEST Max Plus system should be used with RIGHTEST Control Solution GC700.
- The Max Plus Blood Glucose Meter can only be used with extra spacing Max Blood Glucose Test Strips. Test strips from other brands should not be used under any circumstances. The use of test strips from other brands may give inaccurate results.
- If the RIGHTEST Max Plus Blood Glucose Meter or RIGHTEST Max Blood Glucose Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature - below 6°C (43°F) or above 44°C (111°F) - please wait at least 30 minutes before testing again.
- Follow all environmental protection regulations when disposing of batteries, strips and lancets.
- Avoid contact with spilled liquids.

**Important Safety Notes**

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the cleaning and disinfecting procedures. Please refer to the section "Maintaining the Products" on p48.
- Users should wash their hands with soap and water before and after touching the meter, lancing device or test strips.

- The minimum blood sample size to test using the RIGHTEST Max Plus Blood Glucose Monitoring System is 0.75 µL: (•)

Sample Size Example:

Blood sample sizes greater than 3.0 µL may contaminate the test strip port and the meter. Samples smaller than 0.75 µL will cause Er4. If this occurs, 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 cautious when interpreting neonatal glucose values below 50 mg/dL (2.8 mmol/L).
- Once a patient is suspected of having a rare disease (e.g. galactosemia), the glucose result should be based on laboratory testing.

Limitations

- The RIGHTEST Max Plus 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).
- Severe dehydration and excessive water loss may cause inaccurately low results.
- The blood glucose test result may be affected by a high blood concentration of interference ingredients. If you need more detailed information about interference ingredients, please see the RIGHTEST 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.

Limitations

- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly). Please refer to the Alternative Site Testing (AST) chapter before you perform AST.
- DO NOT test on alternative sites (palm, forearm) if you are testing for insulin dose calculations, for Continuous Glucose Monitor (CGM) calibration or hypoglycemia (low blood glucose).
- To avoid potential electromagnetic interference, keep the meter away from electromagnetic radiation sources such as X-rays or MRI.
- Bluetooth is enabled by default when the meter is on. Blood glucose testing is not suggested during flights at any time. This is because the meter, when turning on, will emit electronic signals, which should be restricted at all times aboard aircraft. Please turn off your meter to avoid the auto-enabling of Bluetooth.

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RIGHTEST Max Plus Blood Glucose Monitoring System

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

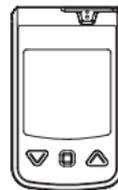
The items in RIGHTEST Max Plus Blood Glucose Monitoring System are:

1. RIGHTEST Max Plus Blood Glucose Meter (with batteries installed)
2. User Documents (User's Manual and Getting Started, Log Book, Warranty Card, Emergency Card).
3. RIGHTEST Max Blood Glucose Test Strips: 10 or 25 pcs (with Package Insert) *
4. RIGHTEST Control Solution GC700 (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. If you want to purchase the items not included in your kit, please contact distributor for more details.

RIGHTEST Max Plus Blood Glucose Monitoring System

1



2



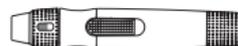
3*



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6*

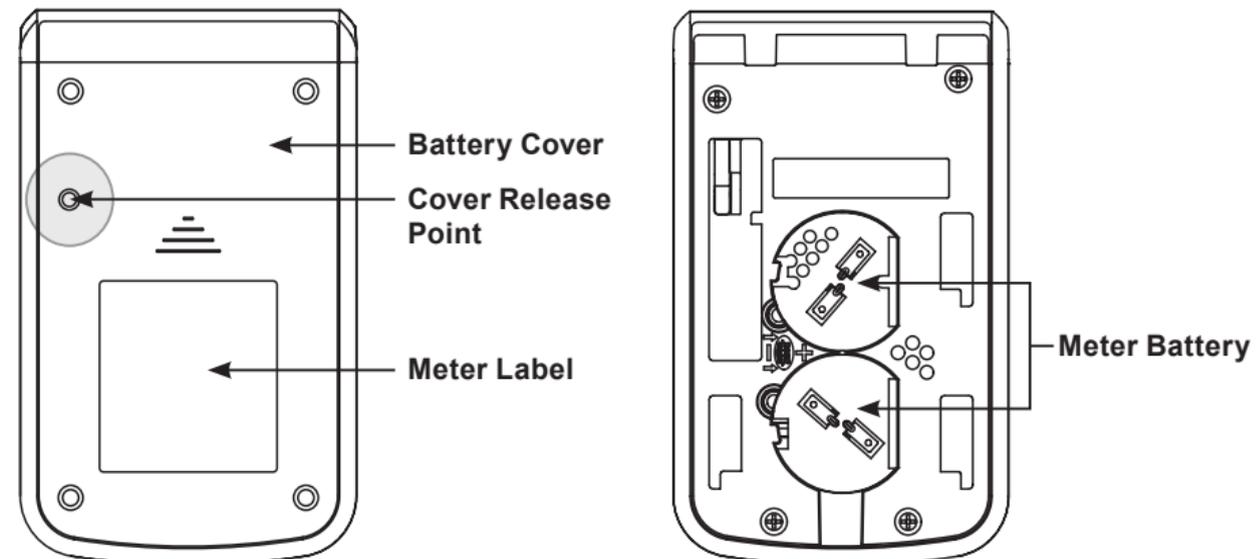
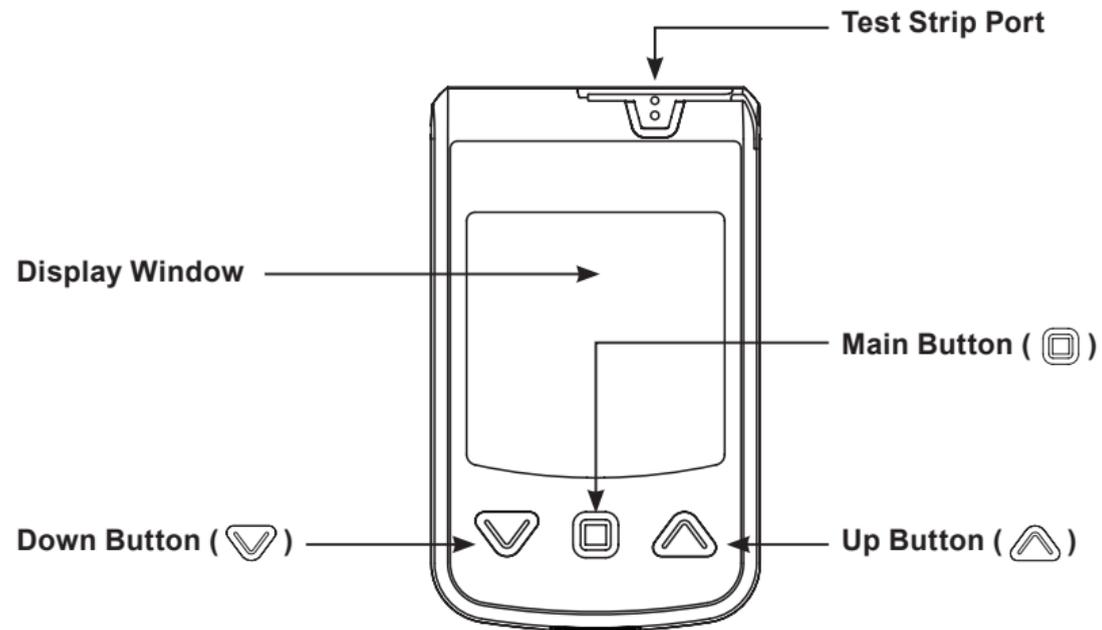


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NOTE

- The RIGHTEST Max Plus Blood Glucose Meter is Bluetooth-compatible and can be connected to the mobile app. Scan the QR code on the package for more details.



RIGHTEST Max Plus Blood Glucose Meter

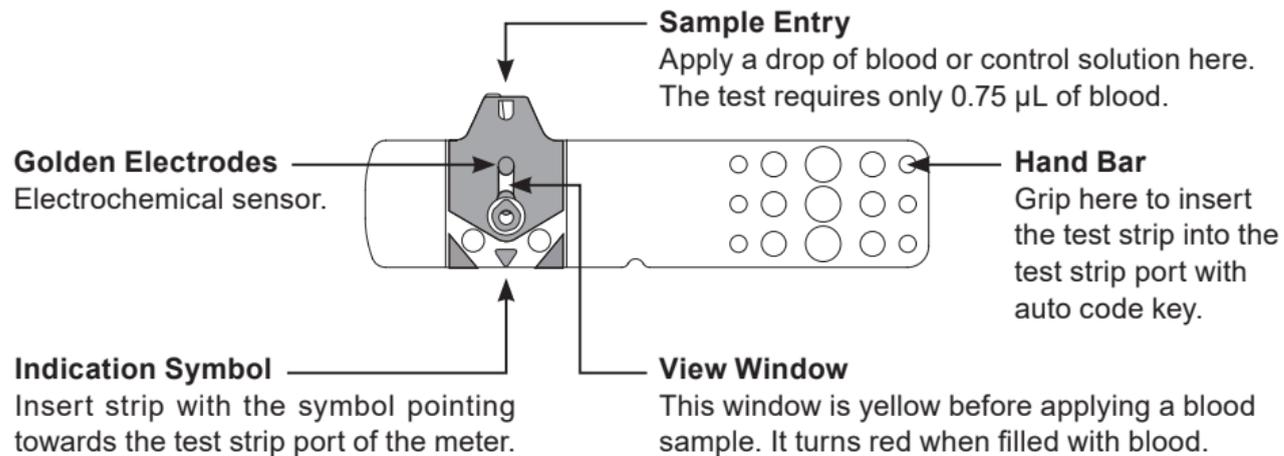


RIGHTEST Max Plus Blood Glucose Meter

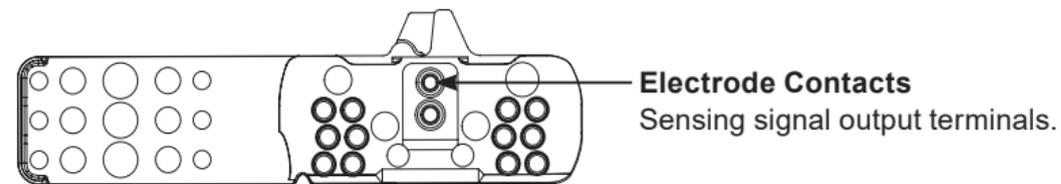
CS	Indicates a control solution test result.		Indicates when to apply the blood sample.
mmol/L mg/dL	Unit of test result.		Appears after you insert test strip into meter.
	Appears when a test result is above 240 mg/dL (13.3 mmol/L) to suggest ketone testing.		Warns when the operating temperature has exceeded its limit during testing.
	Warns when the battery is low or must be replaced.		Current date under time mode or testing date under memory mode.
	Indicates a meal marker with test result.		Displays current time under time mode or testing time under memory mode.
	Indicates that Bluetooth is enabled.		Indicates the time format is 12H.
	Test result.		Indicates the average result.
	Indicates a test result stored in memory.		Indicates a test result is waiting for transmission.
	Indicates wake up marker/exercise marker with test result.		Indicates before sleep marker/midnight marker with test result.
	The blood glucose result is within the target range.		The blood glucose result is above/below the target range.
	Indicates the alarm is activated. (Max only)		Manufacturing use only.

RIGHTEST Max Blood Glucose Test Strip

The RIGHTEST Max Plus Blood Glucose Meter can only be used with RIGHTEST Max Blood Glucose Test Strips and RIGHTEST Control Solution GC700. The use of other test strips or control solutions may lead to incorrect results.



RIGHTEST Max Blood Glucose Test Strip



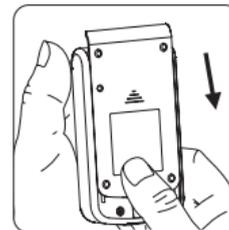
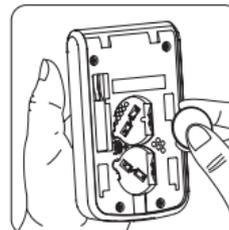
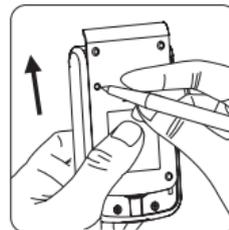
PRECAUTION

- Close the vial immediately after taking out a test strip.
- Do not reuse RIGHTEST Test Strips.
- Do not use expired RIGHTEST Test Strips.
- Write the opening date on the label of each new vial of test strips you open. Use test strips within 4 months of opening or until the expiration date printed on the label, whichever comes first.
- Store RIGHTEST Test Strips at 4 - 30°C (39 - 86°F) and 10 - 90% relative humidity. Do not expose to direct sunlight or heat.
- If the RIGHTEST Meter or Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature – below 6°C (43°F) or above 44°C (111°F) – please wait at least 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 Plus Blood Glucose Meter comes with 2 CR2032, 3V, batteries installed. 2 new batteries provide sufficient power for approximately 1000 tests under normal usage. Press the main button or insert a strip to activate your meter.

Meter Activation and Battery Change



1. Use a pen tip to press the cover release point at the same time slide the cover upwards.
2. Install the batteries. Be sure to put the battery in the correct direction (+ symbol facing up).
3. Slide the battery cover back on until it snaps into place.
4. The RIGHTEST Blood Glucose Meter will enter Self-Testing Mode automatically after the batteries are replaced. All symbols will flash on the screen.
5. Press any button to exit the Self-Testing Mode and enter the Settings Mode.
6. You must set the time and date when replacing the battery. See "Setting Up Your Meter - Setting the Date, Time, Volume and Test Unit." on p20. Test results are still stored in the memory.



CAUTION

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

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

You can enter the Settings Mode in two ways:

1. Replace the Batteries

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

2. With Batteries 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 enter the Settings Mode.



NOTE

- Use the Up or Down buttons to navigate your settings options 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 2 seconds, the screen will turn off. Please keep pressing the main button until the meter enters the Settings Mode.

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

1. Year Setting

When the year blinks, press the Up or Down button to select the current year and press the main button to confirm.

2. Month Setting

When the month blinks, press the Up or Down button to select the current month and press the main button to confirm.

3. Day Setting

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

4. 12 or 24-hour Format Setting

When the time format blinks, press the Up or Down button to select the preferable time format and press the main button to confirm.



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

5. Hour Setting

When the hour blinks, press the Up or Down button to select the current hour and press the main button to confirm.

6. Minute Setting

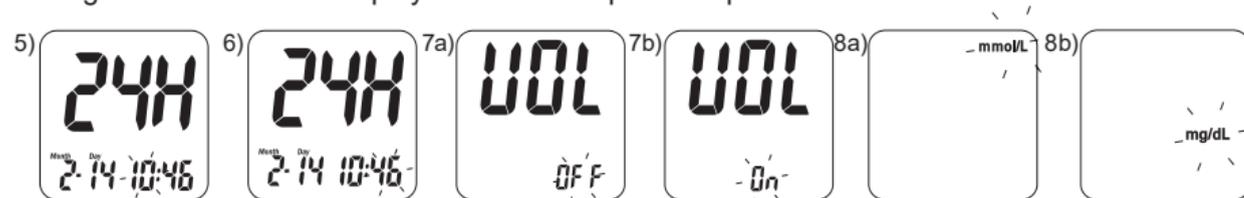
When the minute blinks, press the Up or Down button to select the current minute and press the main button to confirm.

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.

8. Test Unit Setting

When the milligrams per deciliter (mg/dL) or millimoles per litre (mmol/L) blinks, press the Up or Down key to select the preferable test unit and press the main button to confirm. In some countries/regions, regulations may require the test unit to be fixed. In this case, options to change units will not be displayed. Please skip this step.



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

9. Before Meal Blood Glucose Range Setting

The before meal marker and the lower limit bar will be displayed, and the blood glucose value will blink. Press the Up or Down button to adjust the value to the desired value and then press the main button to confirm. Please follow the same method to set the upper limit for before meals.

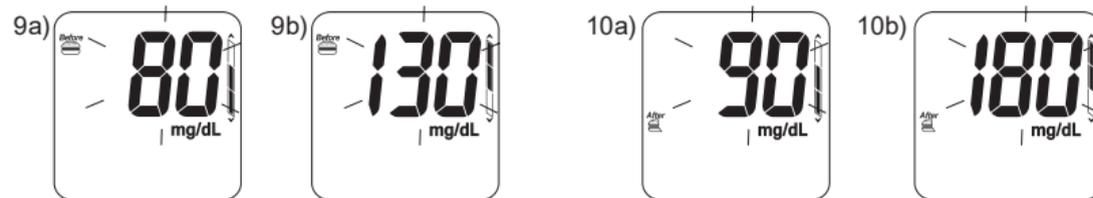
10. After Meal Blood Glucose Range Setting

The after meal marker and the lower limit bar will be displayed, and the blood glucose value will blink. Press the Up or Down button to adjust the value to the desired value and then press the main button to confirm. Please follow the same method to set the upper limit for after meals.



NOTE

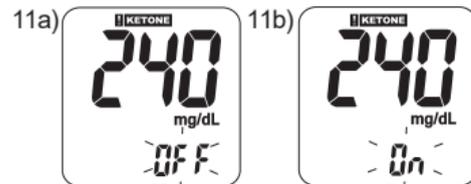
- The upper/lower limit range is only for your reference. Consult your doctor for further assistance.
- Tight blood glucose control as defined by the American Diabetes Association (ADA): keep the blood glucose level as close to normal (non-diabetic) as you safely can. Ideally this means between 80 and 130 mg/dL (4.4 and 7.2 mmol/L) before meals and less than 180 mg/dL (10.0 mmol/L) two hours after starting a meal.⁽¹⁾



11. Ketone Reminder Setting

The Ketone Reminder is set to off by default. This is only recommended for Type 1 diabetes users.

To enable the ketone reminder, press the Up or Down button to switch to 'ON', then press the main button to confirm. If your blood glucose test result is higher than 240 mg/dL (13.3 mmol/L), the Ketone Reminder will appear if it is set to on. When "KETONE" appears, you may need a ketone test. Please contact your healthcare professional immediately.



12. Setup complete

After the setup is complete, the meter will beep to notify the user and return to the Time Mode. Please note that the meter will only beep if the volume is set to on.



NOTE

- When the meter is idle for more than 30 seconds, the meter will leave the Settings Mode and power off automatically.
- Meter defaults are set according to your local preference.
- The date and time will sync with your mobile device when the meter connects to the RIGHTEST Care App.

1. How to turn on the RIGHTEST Max Plus Blood Glucose Meter

Press the main button or insert a test strip.

2. Manual Power off

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

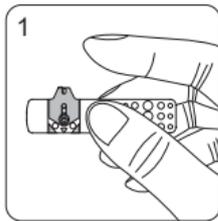
3. Auto Power off

The RIGHTEST Max Plus Blood Glucose Meter will power off automatically after 30 seconds if no buttons are pressed or no strip is inserted.

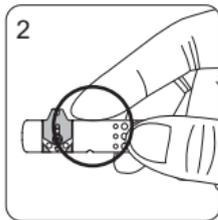
Handling RIGHTEST Max Blood Glucose Test Strips

Inserting a RIGHTEST Max Blood Glucose Test Strip:

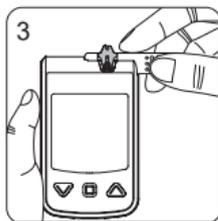
1. Hold the test strip between your thumb and middle finger with the View Window "  " facing up.



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



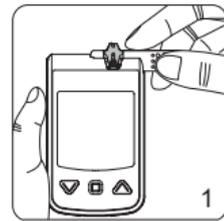
3. Insert the strip into the test strip port until it clicks in securely.



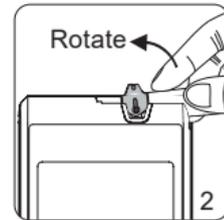
Handling RIGHTEST Max Blood Glucose Test Strips

Removing a RIGHTEST Max Blood Glucose Test Strip:

1. Hold the test strip as shown.

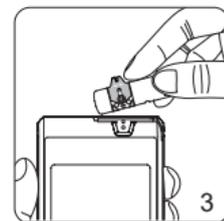


2. Rotate the test strip counterclockwise and pull up at the same time.

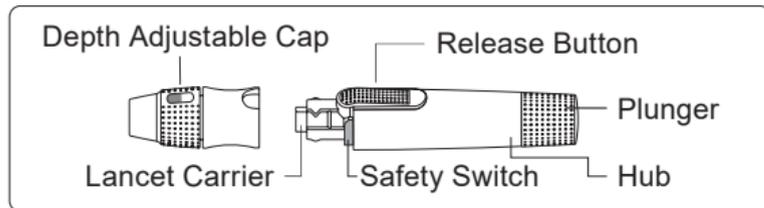


3. Take the strip out of the test strip port.

Please follow your local regulations to discard used strips properly.

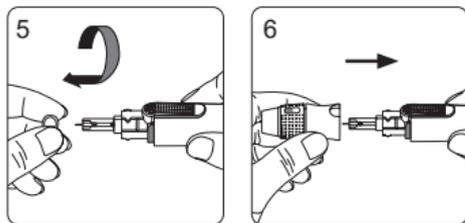
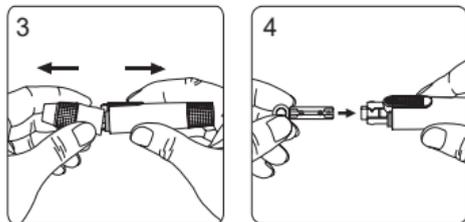
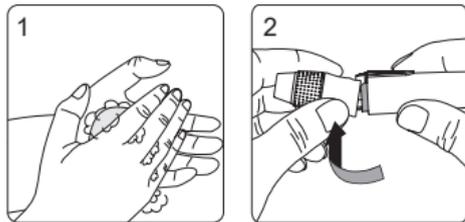


Performing a Blood Glucose Test



Prepare the Lancing Device:

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

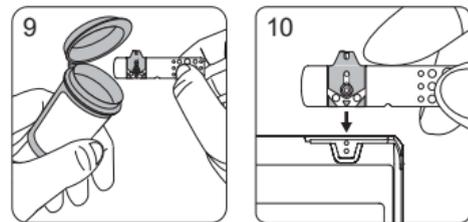
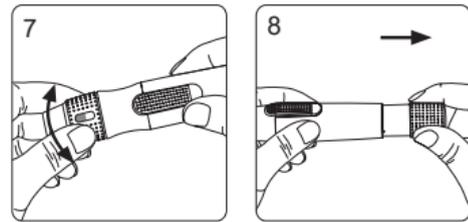


Performing a Blood Glucose Test

7. Rotate the clear top part of the cap to adjust the depth. Check the number of lines visible in the View Window. More lines correspond to a greater depth. Try:
"▣▣▣" for soft or thin skin; "▣▣▣▣" for ordinary skin;
"▣▣▣▣▣" for thick or calloused skin.
8. Pull back the plunger until you hear a click. The device is now primed. Let go of the plunger. It will return to its original position.

Performing a Test:

9. Take one RIGHTEST Test Strip from the vial then immediately close the vial.
10. Insert the strip into the Test Strip Port of the RIGHTEST Meter with the View Window face up.
11. Once inserted, the screen will flash with all possible symbols and emit a beep.

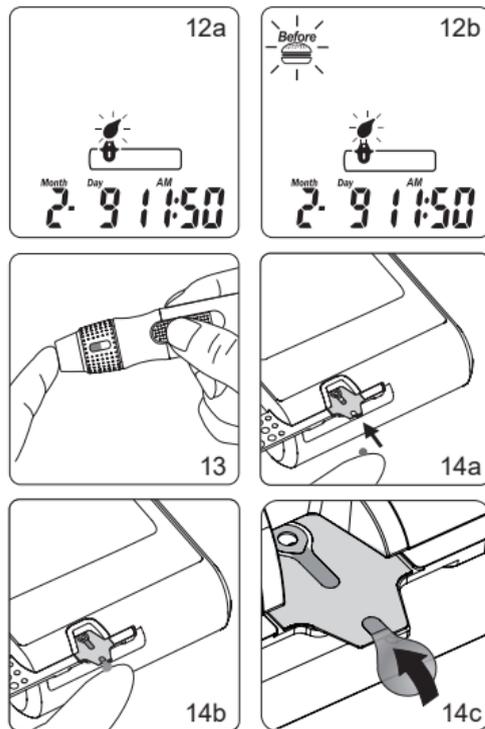


NOTE

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

Performing a Blood Glucose Test

- The "🩸" icon will flash on the screen.
Press the Up or Down buttons to select a status marker. The selected marker will be recorded automatically when you apply the blood sample within 2 min. You do not need to press the main button to confirm.
- Place the lancing device against your fingertip and press the release button.
- Touch the blood drop to the edge of the sample port until the View Window is filled with blood. If the View Window is not filled, the test will not start. In this case, discard the test strip and repeat the test procedure with a new RIGHTEST Test Strip.

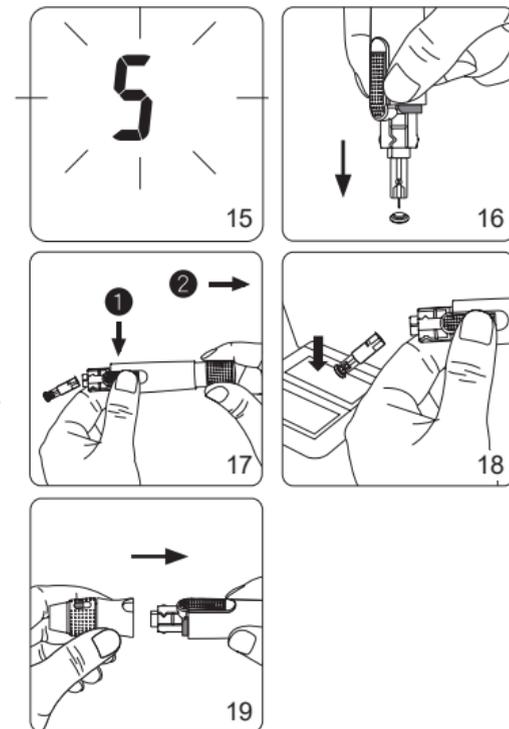


Performing a Blood Glucose Test

- The screen will display a countdown timer. Your test result will be displayed after 5 seconds.

Lancet and Test Strip Disposal:

- Separate the cap from the hub. Press the lancet needle into the side of its original protective cap.
- (1) Hold down the release button and (2) pull back the plunger to eject the lancet.
- Discard the lancet into a suitable biohazard container.
- Replace the Depth Adjustable Cap after finishing the test.





CAUTION

- Do not apply the blood sample to the strip's sample port until you see "  " appear. If you apply blood too soon, the meter will perform an internal test and display "  " and "Er". If this happens, please repeat the test with a new test strip.
- Write the opening date on the label of each new vial of test strips you open. Use test strips within 4 months of opening or until the expiration date printed on the label, whichever comes first.
- Always keep the metal contacts of the test strip port clean. If there is any dust or dirt, please clean it off with a small, soft brush.
- All parts of this kit are considered biohazards and can potentially transmit infectious diseases, even after you have performed the cleaning and disinfecting procedure.
- Users should wash their hands with soap and water after handling the meter, lancing device and test strips.
- Please refer to the section "Maintaining the Products" on p48 for surface cleaning.
- Do not reuse lancets. Discard used lancets properly.



Status markers help you recall when you performed a test.

You must select a marker before you test.

After inserting a test strip, the "  " icon will flash on the screen. Press the Up or Down buttons to choose between "  " (before meal), "  " (after meal), "  " (midnight), "  " (bedtime), "  " (exercise), "  " (wake up) and "  " (no marker) and then apply a blood sample within 2 minutes then the marker will be recorded together with the test result.

	Before meal: You check your blood glucose levels before a meal.
	After meal: You check your blood glucose levels after a meal.
	Regular test or definition by user.
	Midnight: You check your blood glucose levels at midnight.
	Bedtime: You check your blood glucose levels before you sleep.
	Exercise: You check your blood glucose levels after exercise.
	Wake up: You check your blood glucose levels when you wake up.

Uploading Data

RIGHTEST Care App (May not be available in your country)

Bluetooth is set to on by default. When the mobile app is activated, the meter will automatically connect with your mobile device if it has been paired.

Once connected to the app test results will start syncing with the connected mobile device.

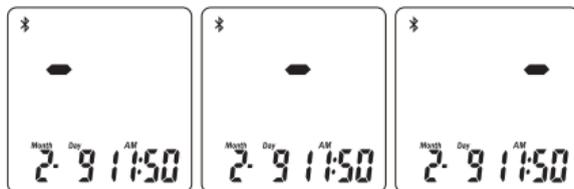
When syncing is complete, the meter will disconnect from the mobile device automatically.



Bluetooth pairing.
The Bluetooth symbol "X" will appear on the screen.



If there are test results waiting for transmission, the data upload icon will appear on the screen to remind the user.



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



CAUTION

- Blood glucose testing is not suggested during flights at any time. This is because the meter, when turning on, will emit electronic signals, which should be restricted at all times aboard aircraft.
- Please turn off your meter to avoid the auto-enabling of Bluetooth.

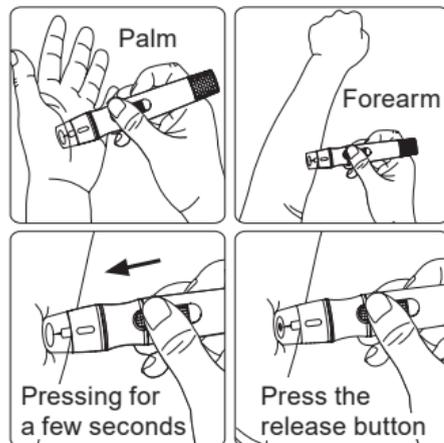
The RIGHTEST Care App is designed to provide people with diabetes with a digital platform for blood glucose analysis, enable quick understanding of results and make glucose management more efficient.

Search "RIGHTEST Care" with on the App Store or Google Play. To get started, simply download the app and pair your phone with meter using Bluetooth. More app instructions can be found by clicking "Learn and Assist" or "Operation Guide" on the app.

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

Alternative site testing: palm or forearm blood sampling

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



CAUTION

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

To obtain an accurate test result, ensure that your blood sample covers the entire area of the View Window. An insufficient blood sample will result in an error message (" Er4 "). If this happens, 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 taking it out from the vial.
- If RIGHTEST Meter or Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature - below 6°C (43°F) or above 44°C (111°F) - please wait at least 30 minutes before testing again.
- Do not reuse test strips.
- Only apply the blood sample to the test strip's sample port.
- Please don't drip or inject these blood sample directly by syringe to the sample entry of test strip except for the medical professionals. However, it's not recommended because this might contaminate the meter or cause damages.

If your blood glucose result is unusually high or low, or if you have any doubts about your test results, repeat the test with a new test strip.

You can also use the RIGHTEST Control Solution GC700 to perform a Quality Control Test on your RIGHTEST Max Plus Blood Glucose Meter and RIGHTEST Max Blood Glucose Test Strip (Refer to "Performing a Quality Control Test" on p44).

If the test result stays unexpectedly high or low, contact your healthcare professional rapidly.

If you experience symptoms that are inconsistent with your blood glucose test results and you have followed all instructions in this manual, contact your healthcare professional immediately.

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

About Quality Control Testing

What is a Quality Control Test ?

We recommend users perform a quality control test on a regular basis to ensure that the blood glucose system is working properly.
Use a bottle of RIGHTEST Control Solution GC700 when testing your RIGHTEST Max Plus Blood Glucose Monitoring System in the Control Solution Mode. If the test result falls within the Control Solution Range printed on the strip vial label, the RIGHTEST Max Plus Blood Glucose Monitoring System has passed the Quality Control Test and is working properly.

Control Solution Range:

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



Control Solution Range	mg/dL	mmol/L
Low:	28 - 48	1.6 - 2.7
Normal:	106 - 146	5.9 - 9.1
High:	315 - 427	17.5 - 23.7



NOTE

- The RIGHTEST Control Solution GC700 is compatible with both the RIGHTEST and the GE Max Plus Blood Glucose Monitoring Systems. If you want to purchase additional supplies please contact Bionime customer service.

About Quality Control Testing

When could a Quality Control Test Be Performed ?

- To confirm that your RIGHTEST 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 first 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 if it has been dropped, damaged or exposed to liquids.
- If you suspect that your test results are inaccurate, or if your test results are inconsistent with how you are feeling.
- To practice testing.

Required Items for Quality Control Tests

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

- RIGHTEST Max Plus Blood Glucose Meter
- RIGHTEST Max Blood Glucose Test Strip
- RIGHTEST Control Solution GC700

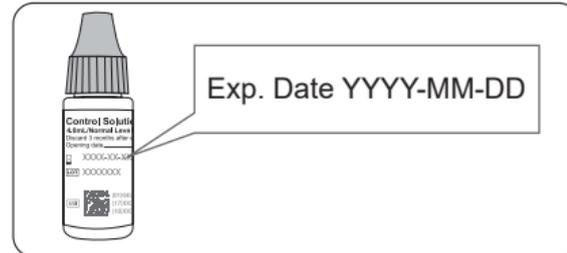
About Quality Control Testing



CAUTION

- Each time you open a new bottle of control solution, write the opening date on the label. RIGHTEST Control Solution GC700 should be used within 3 months of opening or until the expiration date printed on the label, whichever comes first.

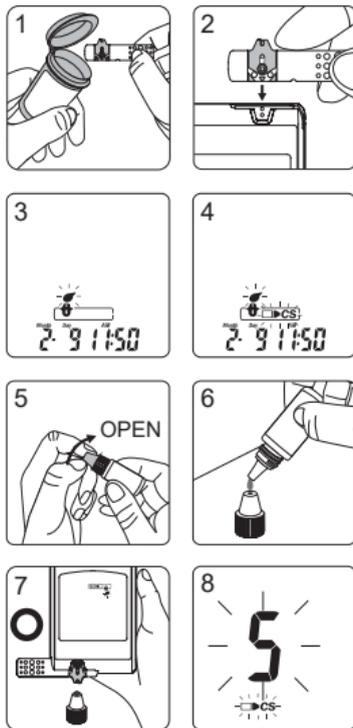
Example



- Wipe the bottle cap with a clean tissue before tightly closing the bottle of control solution.
- Close the bottle tightly immediately after use.
- Check the expiration date before use. Refer to RIGHTEST Control Solution GC700.
- Keep control solution bottles out of the reach of children.

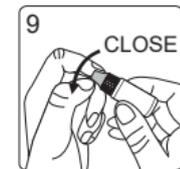
Performing a Quality Control Test

1. Take a test strip from the vial and close the cap immediately.
2. Insert the test strip into the test strip port with the View Window face up.
3. When the test strip icon flashes on the screen, press and hold the main button for 3 seconds until "▣CS" appears.
4. "☉" and "▣CS" will flash on the screen. You are ready to apply Control Solution to the strip.
5. Gently swirl the bottle of RIGHTEST Control Solution GC700 to ensure it is evenly mixed before removing the cap.
6. Place the cap on a flat surface. Squeeze a drop of Control Solution onto the top of the cap.
7. Touch the test strip sample port to the drop. Move the meter, not the cap.
8. The screen will display a 5-second countdown timer. You will hear a beep if the volume is on.



Performing a Quality Control Test

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

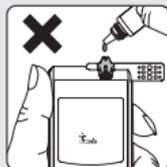


Performing a Quality Control Test



CAUTION

- Your Control Solution Test results will not be included in the average calculations but they can still be recalled and viewed. The Control Solution Test result will be displayed with the " CS " icon on the screen.
- The Control Solution Test should be performed at temperatures ranging from 6 to 44°C (43 to 111°F), with relative humidity ranging from 10 to 90%.
- Do not touch the control solution to the sample port on the strip before "  " and " CS " appear. The meter is performing an internal check. Touching the control solution to the sample port before being prompted will result in an error message: " **Er** " and "  " and be accompanied by beeps (if volume is turned on).
- Do not directly drip the control solution into the test strip's sample port. It is possible that doing so will contaminate the meter or the control solution.
- Keep the test strip port clean and dry. Clean immediately if the test strip port is stained or is overly exposed to moisture.
- Do not touch the tip of the control solution bottle. If the tip is touched, clean with water.



Understanding Control Test Results

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

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

- Your RIGHTEST Control Solution GC700 is expired or was opened more than 3 months ago.
- Your RIGHTEST Blood Glucose Test Strip was expired.
- You left the Blood Glucose Test Strip vial or the Control Solution opened for a long period after use.
- You did not perform the test procedure correctly.
- The RIGHTEST Blood Glucose Meter or RIGHTEST Blood Glucose Test Strip malfunctioned.

If RIGHTEST Control Solution GC700 results are out of range, your RIGHTEST Blood Glucose Monitoring System may be malfunctioning. Repeat the Quality Control Test. If your control solution results are still out of range, do not use RIGHTEST Blood Glucose Meter to test your blood glucose. Please contact Bionime customer service.

Maintaining the Products

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

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

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

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

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

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

Maintaining

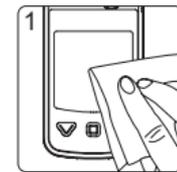
Keep your meter and test strip clean by keeping them free of dust, water, and other liquids. When not in use, keep the meter in its carrying case. Before performing a blood glucose test, perform a quality control test using the control solution if your meter has been dropped or damaged.

Maintaining the Products

Cleaning and disinfection frequency: at least once a week.

To clean the meter:

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



To disinfect the meter:

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



NOTE

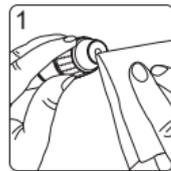
- Clean and disinfect the outside of the device only. Do not remove the battery cover when cleaning and disinfecting.

Maintaining the Products

Cleaning and disinfection frequency: at least once a week.

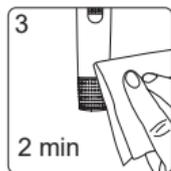
To clean the lancing device:

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



To disinfect the lancing device:

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



Maintaining 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 queries or issues, please contact your local Bionime customer service or the authorized distributor.

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

To recall tests stored in the memory, start the meter without a test strip inserted.

1. Press the Main button to switch from Time Mode to Memory Mode. You will see the "☰" icon in the upper left corner of the display. The most recent test result will appear with the number "1".
2. Use either the Up or Down buttons to review previous results with their date and time. Result order is displayed from most recent (Sequence no. "1") to 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 the symbol "☐▶cs" appears next to the data, the test was performed with the control solution. The control solution test result will not be used when recalling test average results.



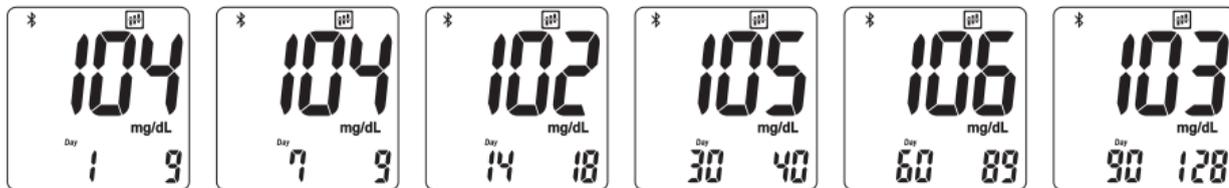
4. Quick Searching

To view test results in sequential order automatically, enter the Memory Mode. Press the Up or Down buttons for 2 seconds. Holding the Up button will scroll through results from most recent to oldest. Holding the Down button will scroll from oldest to most recent. Release the button to stop at any particular test result.

Recalling Average Test Results

The RIGHTEST Max Plus 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 the number of test results calculated.



Recalling Average Test Results



NOTE

- The Average function requires that the correct time and date be entered. Test results must be available during the specific time interval. For example: in order to calculate 14-days average on 1/30, you must have test results dated between 1/17 and 1/30. If no test results are available during that time period you will not be given an average.
- The CS test result is removed from the average calculation but it is still searchable in the Memory Mode. In Memory Mode, the CS test result will be displayed with a blinking "CS" icon.
- The "Lo", "Hi" results, as well as control solution test results and test results under abnormal temperature conditions of $< 6^{\circ}\text{C}$ (43°F), $> 44^{\circ}\text{C}$ (111°F) will be excluded from average calculations.

Error Messages and Troubleshooting

Temperature Error

1. Please test between 6°C (43°F) and 44°C (111°F) in order to obtain accurate test results.
2. The meter will not function if the temperature is below 6°C (43°F) or above 44°C (111°F), the "🔌" will show and the "Er" symbol will blink.
3. If your RIGHTEST Meter or Test Strips have been exposed to temperatures that below 6°C (43°F) or above 44°C (111°F), take the meter and strips back to an environment within the operating temperature of meter and wait at least 30 minutes before testing again.



Battery Error

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



Error Messages and Troubleshooting

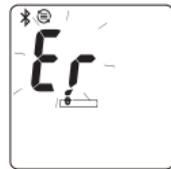
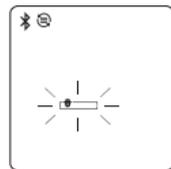
Strip Error

1. The meter will beep four times while the "🔌" sign flashes if the test strip is put in incorrectly. Do not apply a sample on the test strip. Please re-insert the unused test strip correctly (refer to "Handling RIGHTEST Max Blood Glucose Test Strip" on p26 for more information).
2. If the "🔌" and flashing "Er" symbols appear on the screen after completing the proper steps, it signifies the RIGHTEST Test Strip has been inserted incorrectly more than twice. Please follow the steps in "Handling RIGHTEST Max Blood Glucose Test Strip" to re-insert the unused test strip, or contact Customer Service for assistance.

This error notice could mean that you used incorrect test strips. Make sure you are using RIGHTEST Max Blood Glucose Test Strips by checking the test strip vial.

Sampling Error

Please do not apply the blood to the test strip sample port until the meter indicates "👉". Discard the test strip if the meter shows "Er", repeat the test with a new test strip.



Error Messages and Troubleshooting

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

Er2 - The meter has malfunctioned. Reinstall the batteries, and perform a Quality Control Test to check whether the system is working properly. If not, please contact customer service.

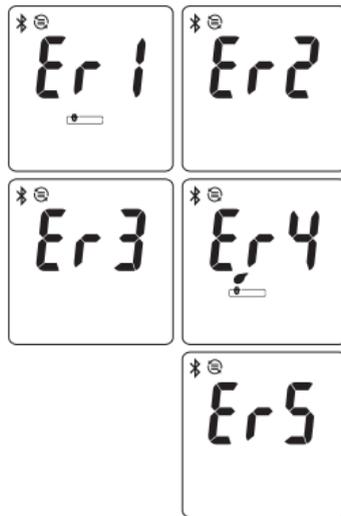
Er3 - The transmission of the signal has been disrupted. Repeat the test with a new test strip.

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

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

- (1) Remove the test strip from the meter.
- (2) Press the Main button for 2 seconds to turn off the meter.
- (3) Press the main button to turn the meter back on.

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



Error Messages and Troubleshooting

Meter Malfunction

If the RIGHTEST 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 instructed in "Meter Activation and Changing the Battery".

After completing the instructions above, the meter should function normally. Please contact your local RIGHTEST Customer Service or email us at info@bionime.com, if the meter is still not working.



CAUTION

A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and the "  " symbol show. If the symbol is NOT showing on the screen, do not apply a sample to the test strip. Please re-insert the unused test strip correctly. It takes about 3 seconds for the symbol to show after the test strip inserting correctly. Please see p26 on the User's Manual and/or contact Customer Service for support on how to correctly insert a RIGHTEST 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 2 seconds.
Operating Temperature	6 - 44°C (43 - 111°F)
Operating Relative Humidity	10 - 90%
Power Supply	2 CR2032 batteries
Battery Life	Approximately 1000 standard tests

Specification

Meter Dimension	50.0 mm x 82.0 mm x 16.5 mm
Meter Weight	52 ± 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	
Minimum Sample Volume	Refer to RIGHTEST Max Test Strip insert
Hematocrit	
Test Strip Storage/Transportation Conditions	

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 Max Plus 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 Plus Blood Glucose Monitoring System.

Please complete and return the enclosed warranty card.

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



NOTE

- During blood glucose test, The RIGHTEST Blood Glucose Meter itself may come into contact with blood. All parts of the 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.

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

Please refer Summary of Safety and Performance at Bionime website. (<http://www.bionime.com>)

Description of used symbols

IVD	<i>In vitro</i> diagnostic medical device	Manufacturer	Caution
i	Consult instructions for use	Date of manufacture	Do not re-use
Temperature limit	Temperature limit	Humidity limitation	Direct current
CE	CE-mark (with No. of notified body)	Biological risks	Importer
UDI	Unique device identifier	Use-by date	LOT Batch code
STERILE R	Sterilized using irradiation (only for lancet)	SN	Serial number
EC REP	Authorized representative in the European Community		

Expected Glucose Values

Expected glucose values without diabetes ⁽²⁾

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) Recommended setting information - American Diabetes Association (ADA) [Electronic Version] Retrieved May 11, 2022 from <https://www.diabetes.org/healthy-living/medication-treatments/blood-glucose-testing-and-control/checking-your-blood-sugar>
- 2) Diabetes Information - Association for Diagnostics & Laboratory Medicine (ADLM)[Electronic Version](2021, Sep. 21) Retrieved Dec. 19, 2023 from <https://www.myadlm.org/science-and-research/scientific-shorts/2021/what-are-the-criteria-for-the-diagnosis-of-diabetes-mellitus-in-2021>