RIGHTEST™
Blood Glucose Monitoring System

BIONIME CORPORATION

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

EC | REP

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

CE
0197

RIGHTEST

mem

105
mg/dL

Day Month   AM
10·10   8:00

GM550
User's Manual

Intended Use

The RIGHTEST Blood Glucose Monitoring System GM550 is designed for *in vitro* diagnostic use (for self-testing outside the body) only, and can be used by home user and healthcare professional.

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

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

Preface

Thank you for choosing the RIGHTEST Blood Glucose Monitoring System GM550. This manual contains all the information you need to use your product to start getting accurate blood glucose test results. Please read this entire manual before you get started with any testing.

It is important for people living with diabetes to regularly monitor their blood glucose levels to reduce complications. The easy-to-use Blood Glucose Monitoring System GM550 provides accurate, reliable test results to help you manage your diabetes better.

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

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

The Blood Glucose Monitoring System GM550 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 RIGHTEST Blood Glucose Monitoring System GM550 to test your blood glucose, please read all of this information and conduct all of the tests including the Quality Control Test (p36).
- We recommend you perform the Quality Control Test regularly to ensure test results are accurate.
- The RIGHTEST Blood Glucose Meter GM550 should only be used with RIGHTEST Blood Glucose Test Strips GS550. Test strips from other brands should not be used under any circumstances. The use of test strips from other brands may produce inaccurate results.
- If the RIGHTEST Meter and RIGHTEST Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature - below 10°C (50°F) or above 50°C (104°F) - please wait at least 30 minutes before testing again.
- Follow all environmental protection regulations when disposing of batteries, strips and lancets.
- Avoid contact with spilled liquids.

> **Important Safety Notes**
> - All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the cleaning and disinfecting procedures. Please refer To the section "Maintaining the Products" on p42.
> - Users should wash their hands with soap and water before and after handling the meter, lancing device, or test strips.

- The minimum blood sample size required for testing using the RIGHTEST System GM550 is 0.75 µL: (•)

Sample Size Example

0.75 µL	1.0 µL	1.5 µL	2.0 µL	3.0 µL
•	•	•	•	•

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

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

Limitations

- The RIGHTEST Blood Glucose Monitoring System GM550 is not intended for serum or plasma testing.

- Do not use at altitudes greater than 10,000 feet (3,048 meters).

- Severe dehydration and excessive water loss may cause inaccurately low results.

- Patients going through oxygen therapy may yield falsely low results.

- The blood glucose test result may be affected by a high blood concentration of interference ingredients. If you need more detailed information about interference ingredients, please see the RIGHTEST Blood Glucose Test Strip GS550 Insert.

- Not for screening or diagnosis of diabetes mellitus.

- These test strips should not be used with meters to test critically ill patients or neonates.

- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly). Please refer to the Alternative Site Testing (AST) chapter before you perform AST.

- DO NOT test on alternative sites (palm, forearm) if you are testing for insulin dose calculations, for Continuous Glucose Monitor (CGM) calibration or hypoglycemia (low blood glucose).

- To avoid potential electromagnetic interference, keep the meter away from electro magnetic radiation sources such as X-rays or MRI.

Table of Contents

Your RIGHTEST Blood Glucose Monitoring System GM550 consists of several items. Please identify each item and make sure you understand how to use them. The items in RIGHTEST Blood Glucose Monitoring System GM550:

1. RIGHTEST Blood Glucose Meter GM550 (with 2 CR2032 batteries installed)

2. Instruction documents (Getting Started and User's Manual (includes Log Book, Warranty Card, Emergency Card)

3. RIGHTEST Blood Glucose Test strips GS550 (10/25 pcs) (with Insert) *

4. RIGHTEST Control Solution GC550 (with Insert) *

5. RIGHTEST Lancing Device GD500 (with Insert) *

6. Clear Cap *

7. Disposable Sterile Lancets (10 pcs) *

8. Carrying Case (not shown) *

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

Test Strip Port
Insert a test strip here until you
hear a click.

Display Window
Shows your test result, messages
and related information.

Main Button (◎)

Left Button (◁)

Right Button (▷)

Battery Cover
Slide cover to
change batteries.

Meter Label

Meter Battery

Backlight Battery

12

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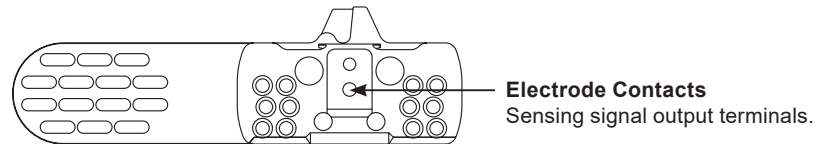| mem	Indicates a test result stored in memory	🌢	Indicates when to apply the blood sample
NO AVG	Indicates a test result will not be included in the Average	▭	Appears after you insert a test strip into the meter
AVG	Indicates the average result	Code Error	Appears when errors occur
CS	Indicates a control solution test result	Day Month 88:88	Current date in time mode or testing date in memory mode
mmol/L mg/dL	Unit of test result	⚷	Warns when the operating temperature is exceeded during testing
88.8	Test result	AM	Indicates the time in 12H format
▭	Warns when the battery is low or must be replaced	88:88	Current time under time mode or testing time under memory mode
OK EN ChecK Key		Manufacturing use only	

RIGHTEST Blood Glucose Test Strip GS550

The RIGHTEST Meter GM550 must only be used with RIGHTEST Test Strip GS550 and RIGHTEST Control Solution GC550.
The use of other test strips or control solutions may lead to incorrect results.

Sample Entry
Apply a drop of blood or control solution here. The test requires only 0.75 μL of blood.

Golden Electrodes
Electrochemical sensor.

Hand Bar
Grip here to insert the test strip into meter.

Indication Symbol
Insert the strip with the indication symbol pointing towards the test strip port of the meter.

View Window
This window is yellow before applying a blood sample. It turns red when filled with blood.

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RIGHTEST Blood Glucose Test Strip GS550

Electrode Contacts
Sensing signal output terminals.

PRECAUTION
- Close the test strip vial immediately after taking out a test strip.
- Do not reuse RIGHTEST Test Strips.
- Do not use expired RIGHTEST Test Strips.
- Write the opening date on the label of each new vial of test strips you open. Use test strips within 12 months of opening or until the expiration date printed on the label, whichever comes first.
- Store RIGHTEST Test Strips at 4 - 30°C (39 - 86°F) and with 10 - 90% relative humidity. Do not expose to direct sunlight or heat.
- If the RIGHTEST Meter or Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the operating range, please wait at least 30 minutes before testing again.
- For detailed strip information, please refer to RIGHTEST Blood Glucose Test Strip GS550 Insert.

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Meter Activation and Battery Change

Your 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.
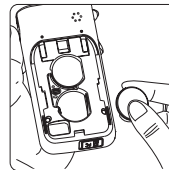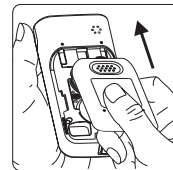

1. Turn the meter over. Press and slide to open the cover.

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

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

4. The meter will perform a self-test.

5. Press any button to exit the self-test and enter the Settings Mode.

6. You must set the time and date when replacing the battery. See "Setting Up Your Meter - Setting the Time, Date, Volume and Test Unit" on p20. Test results are still stored in the memory.

⚠ **PRECAUTION**
Please follow local regulations to properly discard used batteries.

📝 **NOTE**
- If your meter backlight is not functioning, please change the backlight battery (the lower battery).
- When the backlight battery level is low, your meter will continue to work without the backlight function.

You can enter the Settings Mode in two ways:

1. Replace the Battery

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

2. With the Battery Inserted

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

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

1. Year Setting

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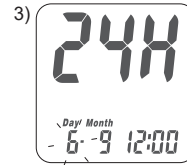
2. Month Setting

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

3. Day Setting

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

4. 12 or 24-hour Format Setting
When the time format blinks, press the Left or Right buttons to select the preferred time format and press the main button to confirm.
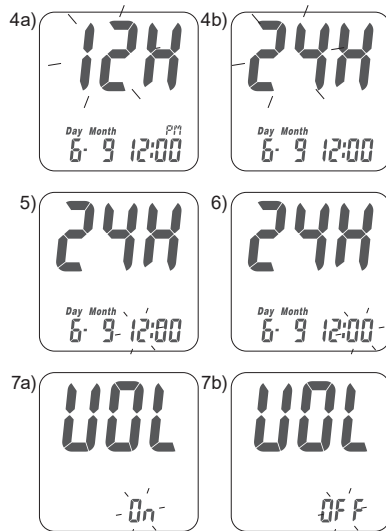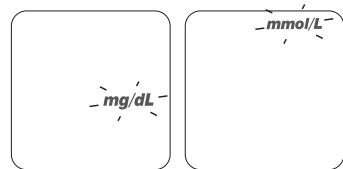
5. Hour Setting
When the hour blinks, press the Left or Right button to select the current hour and press the main button to confirm.

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

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

4a) 12H
Day Month PM
6· 9 12:00

4b) 24H
Day Month
6· 9 12:00

5) 24H
Day Month
6· 9 12:00

6) 24H
Day Month
6· 9 12:00

7a) UOL
-On-

7b) UOL
OFF

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

mmol/L
mg/dL

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

Day Month
6· 9 20:00

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

Turning On / Off the Meter

1. How to turn on the RIGHTEST Meter GM550
   Press the main button or insert a test strip.
2. Manual Power Off
   To power off the meter, press and hold the main button for 4 seconds.
3. Auto Power Off
   The meter will power off automatically after 2 minutes of inactivity.

Turning On / Off the Backlight

1. How to Turn On the Backlight
   Press the main button for 2 seconds.
2. Manually Switch Off the Backlight
   To turn off the backlight, press the main button for another 2 seconds.
3. Auto Backlight Off
   The meter will power off automatically after 10 seconds of inactivity.

Handling the RIGHTEST Blood Glucose Test Strip GS550

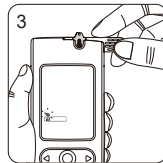**Inserting the RIGHTEST Blood Glucose Test Strip GS550:**
1. Hold the test strip between your thumb and middle finger with the View
   Window " " facing up.
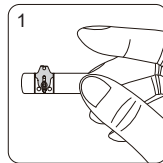
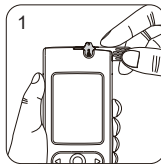2. Put your forefinger on the side of the strip as shown.
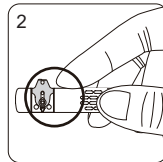
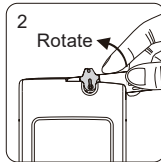3. Insert the test strip into test strip port until it clicks in securely.

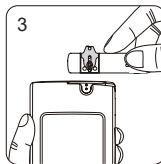**Removing the RIGHTEST Blood Glucose Test Strip GS550:**
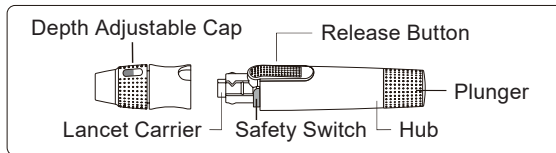
1. Hold the test strip as shown.

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

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

Depth Adjustable Cap   Release Button   Plunger   Lancet Carrier   Safety Switch   Hub

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.
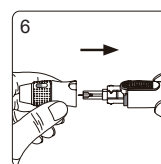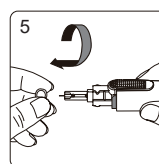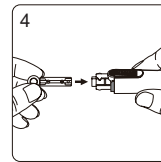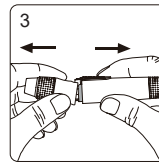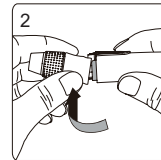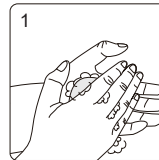
7. Rotate the clear top part of the cap to adjust the depth. Check the number of lines visible in the View Window. More lines correspond to a greater depth. Try: " ⬛️▭ " for soft or thin skin; " ⬛️▭ " for ordinary skin; " ⬛️▭ " for thick or calloused skin.

8. Pull back the plunger until you hear a click. The device is now primed. Let go of the plunger. It will return to its original position.

9. Take one test strip from the vial then immediately close the vial.

10. Insert the strip into the Test Strip Port of the meter with the View Window face up. Once inserted, the screen will flash with all possible symbols and emit a beep (if volume is on).
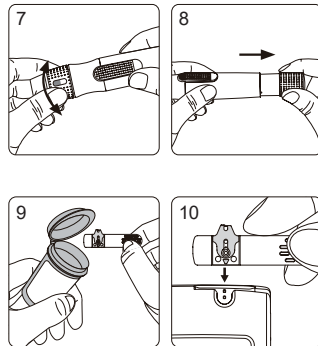

> ✏️ **NOTE**
> The RIGHTEST Meter will automatically detect the Code Number of the test strip. You do not need to check the Code Number on the meter display and strip vial.

11. A blood drop symbol will appear on the screen. Apply a blood sample within 2 minutes.

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

13. Touch the blood drop to the edge of the sample port until the View Window is filled with blood. If the View Window is not filled, the test will not start. In this case, discard the test strip and repeat the test procedure with a new test strip.

14. The screen will display a countdown timer. Your test result will be displayed after 5 seconds.
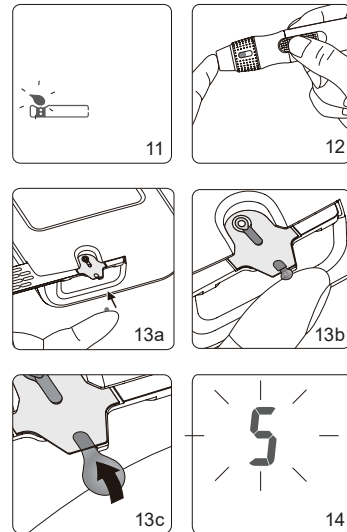
Lancet and Test Strip Disposal:

15. Separate the cap from the hub. Press the lancet needle into the side of its original protective cap.

16. Hold down the release button and pull back the plunger to eject the lancet.

17. Discard the lancet into a suitable biohazard container.

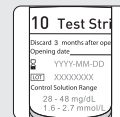18. Replace the depth adjustable cap after finishing the test.
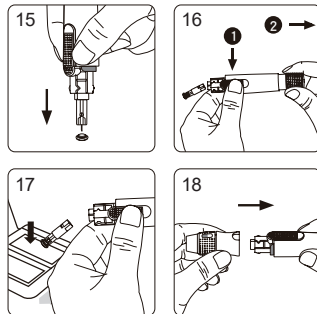

⚠ **PRECAUTION**
- Do not apply the blood sample to the strip's sample port until you see " ◗ " appear. If you apply blood too soon, the meter will perform an internal test and display " ◗ " and " *Error* ". If this happens, please repeat the test with a new test strip.
- Write the opening date on the label of each new vial of test strips you Open. Use test strips within 12 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 p42 for surface cleaning.
- Do not reuse lancets. Discard used lancets properly.

Alternative site testing-palm or forearm blood sampling

- Before performing alternative site testing, please replace the depth adjustable cap of your Lancing Device with the clear cap. (For detailed information, refer to the instruction manual for the RIGHTEST Lancing Device.)

- To increase the blood flow, massage the intended puncture area of your palm or forearm for a few seconds.

- Immediately after massaging the area, press and hold the lancing device against palm or forearm.

- Press the release button.

- Continue pressing the lancing device against your palm or forearm and gradually increase the pressure for a few seconds until the blood sample is of sufficient size.

Palm

Forearm

Pressing for a few seconds

Press the release button
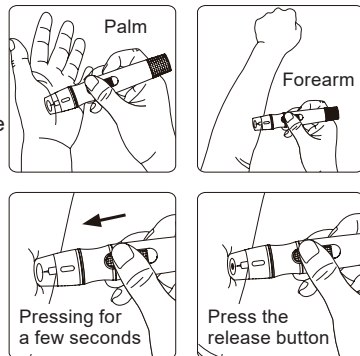
⚠️ **CAUTION**
- Consult your healthcare professional before sampling from your palm or forearm.
- Alternate site testing should be done only during steady-state times (when glucose is not changing rapidly). Fingertip sampling can show rapid changes in glucose faster than palm or forearm samples
- Only 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.

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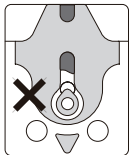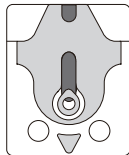
Insufficient blood sample   Enough blood sample

⚠ **CAUTION**
- Check the expiration date printed on the strip vial every time you use a test strip. Do not use expired test strips.
- Use each test strip rapidly after taking it out from the vial.
- Do not reuse test strips.
- If the RIGHTEST Meter or Test Strips are exposed to extreme temperature changes, or environmental temperatures outside of the meter's operating range – below 10°C (50°F) or above 40°C (104°F)– please wait at least 30 minutes before testing again.
- Only apply the blood sample to the test strip's sample port.
- Please don't drip or inject the blood sample directly into the sample Entry of the test strip with a syringe. Doing so may contaminate the meter or cause damage.
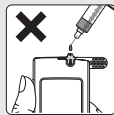
The meter displays results between 10 - 600 mg/dL (0.6 and 33.3 mmol/L).

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

If your test result is above 600 mg/dL (33.3 mmol/L), "Hi" will appear on the screen. Please repeat your test with a new test strip. If you still get a "Hi" result, contact your healthcare professional.
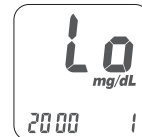
✏ **NOTE**
- If your blood glucose result is unusually high or low, or if you have any doubts about your test results, repeat the test with a new test strip. You can also run a Quality Control Test to check your meter and test strip. If the test result stays unexpectedly high or low, contact your healthcare professional immediately.
- If you experience symptoms that are inconsistent with your blood glucose test results and you have followed all the test instructions in this manual, contact your healthcare professional immediately.

What is a Quality Control Test ?

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

Use a bottle of RIGHTEST Control Solution GC550 when testing your RIGHTEST Blood Glucose Monitoring System GM550 in the Control Solution Mode. If the test result falls within the Control Solution Range printed on the strip vial label, the RIGHTEST Blood Glucose Monitoring System has passed the Quality Control Test and is working properly.

Control Solution Range:

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

Control Solution Range:
28 - 48 mg/dL
1.6 - 2.7 mmol/L

NOTE

RIGHTEST Control Solution GC550 is for the RIGHTEST Blood Glucose Monitoring System GM550. If you want to purchase additional supplies please contact Bionime Customer Service.

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 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 how you are feeling.
- To practice testing.

Required Items for Quality Control Tests
To perform a quality control test, prepare the following items:
- RIGHTEST Blood Glucose Meter GM550
- RIGHTEST Blood Glucose Test Strip GS550
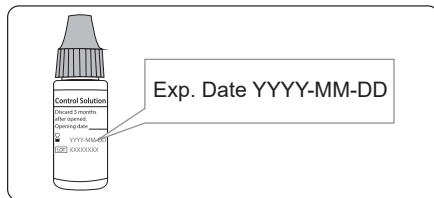- RIGHTEST Control Solution GC550

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

Example

Control Solution

Discard 3 months after opened.
Opening date
YYYY-MM-DD
LOT XXXXXXXX

Exp. Date YYYY-MM-DD

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

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 GC550 to ensure it is evenly mixed before removing the cap.

6. Place the cap on a flat surface. Squeeze a drop of Control Solution onto the top of the cap.

7. Gently touch the sample port of the strip with the control solution from the top of the cap.

8. The screen will display a 5-second countdown timer. You will hear A beep if the volume is on.
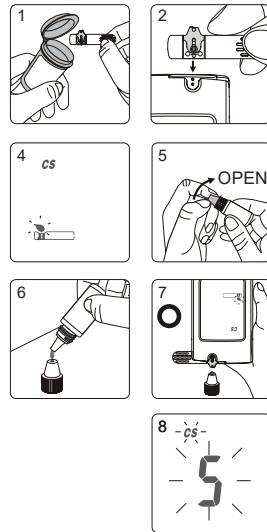
9. Replace the cap and ensure it is screwed on securely.

10. The Quality Control Test Result will appear on the screen. Compare the result with the Control Solution Range printed on the test strip vial label.
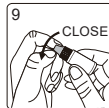
⚠️ **CAUTION**
- Your Control Solution Test results will not be included in the average calculations but they can still can be recalled and viewed. The Control Solution Test result will be displayed with the "*CS*" icon on the screen.
- The Control Solution Test should be performed at temperatures ranging from 15 to 40°C (59 to 104°F), with relative humidity ranging from 10 to 90%.
- Do not touch the control solution to the sample port on the strip before "🌢" and "*CS*" Appear. The meter is performing an internal check. Touching the control solution to the sample port before being prompted will result in an error message: "*Error*" and "🌢" 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.

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

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

- Your RIGHTEST Control Solution GC550 is expired or was opened more than 3 months ago.
- Your RIGHTEST 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 GC550 results are out of range, your RIGHTEST Blood Glucose Monitoring System may be malfunctioning Repeat the Quality Control Test. If your control solution results are still out of range, do not use RIGHTEST Blood Glucose Meter to test your blood glucose. Please contact Bionime customer service.

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.
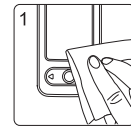
Cleaning and Disinfecting frequency: at least once a week.
To clean the meter:
1. Wipe the whole surface of the meter using the disinfectant wipes listed above to remove any dirt, dust, blood, or other bodily fluids.

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).
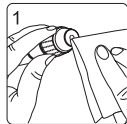3. Allow the surface to remain wet for 2 minutes.
4. Allow to air dry.

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

**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.
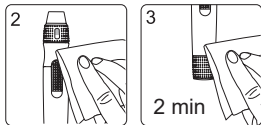
> ⚠ **CAUTION**
> - Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
>
> If you have any questions or concerns, please contact your RIGHTEST Blood Glucose Monitoring System GM550 authorized distributor or contact Bionime Customer Service.

The RIGHTEST Meter GM550 is able to store 500 test results with time and date automatically. If your meter has stored 500 results (which is the maximum) the newest test result will replace the oldest one. To recall results from the memory, start the meter without a test strip inserted.

1. Press the main button to switch from the Time Mode to the Memory Mode. First you will see the "mem" symbol in the upper left corner of the display. When you press the right button, the latest result will be displayed. By pressing the right button sequentially previous test results will be shown in historical order. You will see the sequence number in the lower right corner and the year in the lower left corner of the display followed by the date and time of the measurement.

> 🖉 **NOTE**
> The right button is for reviewing the tests with sequence number increasing, and the left button is for reviewing tests with sequence number decreasing. The sequence no "1" is the latest result while sequence no "500" is the oldest test result.

2. Quick Searching: To view test results in sequential order automatically, enter the Memory Mode. Press the Left or Right button for 2 seconds. Hold the Right button to scroll through results from most recent to oldest. Hold the Left button to scroll from oldest to most recent. Release the button to stop any particular test result.
3. View Reading Immediately After Test: If you just finished a test, press the main button to enter the memory and review the latest test result.
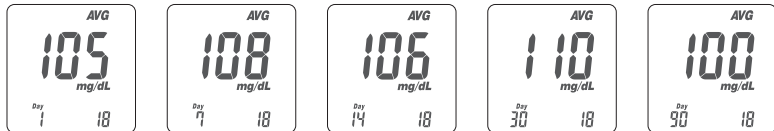
4. To finish reviewing tests from the memory, press main button again. You will enter the Average Screen. By pressing the right button, the display shows "AVG" on the upper right corner of the display and the average value for the actual day. By pressing the right or left button you will get to the 1-day, 7-days, 14-days, 30-days and 90-days average of your blood glucose values. You will see the number of the calculated days on the lower left corner and the number of the calculated readings on the lower right corner.

5. All test results (besides CS test) are default included in the average calculation. Sometimes, you may want to exclude a test result from the average calculation.

Note: You could only exclude/include a test from the average calculation right after you finish the test in the test mode. Once leave the test mode, you will not be able to change the exclusion/inclusion settings of the test results.

After finishing a test and the result is displayed on the screen, press and hold the right button until the "NO AVG" symbol appears in the upper right corner of the screen, press the main button to confirm. The result is now excluded from the average calculation.

To cancel the exclusion, press and hold the right button until "NO AVG" changes to "AVG", press the main button to confirm. This result is now included in the calculation of the average again.
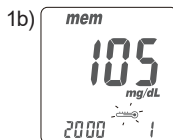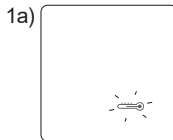
⚠ **PRECAUTION**
- You have to set the time and date to activate the average function.
- The Average function requires that the correct time and date be entered. Test results must be available during the specific time interval. For example: in order to calculate the 14-day average on 1/30, you must have 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.
- You could only adjust the exclude/include settings for a test result in the test mode. Not in the memory mode.
- Control Solution test results are not included in the Average but are still searchable in test memory. In Memory Mode, Control Solution test results will be displayed with a "*CS*" symbol.
- "*Lo*" and "*Hi*" results, Control Solution results and test results tested under abnormal temperatures < 10°C (50°F), > 40°C (104°F) will be excluded from average calculations.

Temperature Error

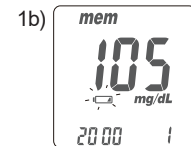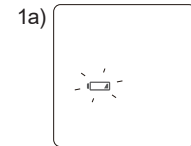In order to get accurate test results, perform testing between 10 - 40°C (50 - 104°F).

1. When the ambient temperature is 0 - 9°C (32 - 49°F) or 41 - 50°C (105 - 122°F) the " 🔑 " warning symbol will blink (1a). You still can do the test but the test result is only for reference because test results in these ranges may be inaccurate. In the memory screen this value will be flagged with " 🔑 " (1b). Repeat the test in an area within operating range (10 - 40°C or 50 - 104°F).

2. If the RIGHTEST Blood Glucose Meter GM550 and Test Strips are exposed to a substantial change in temperature or are outside the recommended operating temperature - below 10°C (50°F) or above 40°C (104°F) - return them to an environment within the operating temperature and wait at least 30 minutes before testing again.

3. When the temperature is below 0°C (32°F) or over 50°C (122°F) the meter cannot do a test and the " *Error* " symbol will blink with " 🔑 " displayed on the screen. Please move the meter to an environment with a temperature between 10 - 40°C (50 - 104°F) and repeat the test after 30 minutes.

1a)

1b)

3)

Battery Error

1. The " 🔋 " symbol blinks when the battery power is low. Please change the meter battery (upper battery) as soon as you can. You can still do a test.

2. The " 🔋 " and " *Error* " symbols blink when the battery is too low. You will not be able to do a test. Please change the meter battery (upper battery) immediately.
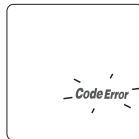
1a)

1b)

2)

Sampling Error

Please do not apply a blood sample to the sample entry port of the test strip before the meter displays " 🝔 ". If you do so, the meter will display " *Error* " and " 🝔 " accompanied by beeps (if volume is turned on). Please discard the test strip and repeat the test with a new test strip.

Code Error

Occurs if the strip is not inserted correctly or in the proper position. Please reinsert the strip according to the instructions. If Code Error occurs again, you may be using incorrect test strips. If you have checked you are using the correct test strip for your meter and are inserting it correctly but the Code Error persists, please contact Bionime Customer Service.

Er1 - The inserted test strip has been used or damp. Please use a new test strip from the vial.

Er2 - The meter has malfunctioned. Reinstall the batteries and do a Quality Control Test to check if the meter works properly.

Er3 - Signal transmission is disrupted, repeat the test with a new test strip.

Er4 - The blood sample volume is insufficient. Please repeat the test with a new test strip.

If error messages persist, please contact Bionime Customer Service.

Error Messages and Troubleshooting

Meter Malfunctionl

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

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

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

⚠️ A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and the " 🕳 " symbol show.
If the symbol is NOT showing on the screen, do not apply a sample to the test strip.
Please re-insert the unused test strip correctly.
It takes about 3 seconds for the symbol to show after the test strip inserting correctly.
Please see p25 on the User's Manual and/or contact Customer Service for support on how to correctly insert a RIGHTEST Test Strip.

Specification

Measurement Technology	Oxidase Electrochemical Sensor
Measuring Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Test Time	5 seconds
Memory Capacity	500 blood glucose test results with date and time
Power Saving	Turn off automatically 2 minutes after last user action / Press the " ◎ " button for 4 seconds.
Operating Temperature	10 - 40°C (50 - 104°F)
Operating Relative Humidity	10 - 90%
Power Supply	2 CR2032 batteries
Meter Battery Life	About 1,000 tests
Meter Dimension	90.6 mm x 46 mm x 16.5 mm

Specification

Meter Weight	53.0g ± 5g with batteries
Monitor	LCD display
Display Area	46.6 mm x 33 mm
Meter Storage Conditions	-10 - 60°C (14 - 140°F)
Test Strip Storage Conditions	4 - 30°C (39 - 86°F), 10 - 90% relative humidity
Sample	
Minimum Sample Volume	Refer to RIGHTEST test strip GS550 insert
Hematocrit	
Test Strip Storage/Transportation Conditions	

Customer Service

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

Description of used symbols

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

Warranty

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

This warranty does not apply to the performance of a RIGHTEST Blood Glucose Meter GM550 that has been altered, misused, tampered with or abused in any way.
This warranty applies only to the original purchaser of RIGHTEST Blood Glucose Monitoring System GM550.

Please complete and return the enclosed warranty card.

Different models have different specifications. This warranty applies only to the RIGHTEST Blood Glucose Monitoring System GM550; 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.

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
Diabetes Information - American Association for Clinical Chemistry (AACC)[Electronic Version] (2021, Sep. 21) Retrieved Apr. 26, 2023 from https://auth.aacc.org/science-and-research/scientific-shorts/2021/what-are-the-criteria-for-the-diagnosis-of-diabetes-mellitus-in-2021