



|____ | | | Thank you for selecting RIGHTEST GT200 Blood Glucose Monitoring System. This manual provides all the information you need to operate this product for accurate test results. Please read this entire manual before you start any testing.

For people living with diabetes, it is important to regularly monitor blood glucose levels to effectively reduce complications from the disease. The easy-to-use RIGHTEST GT200 Blood Glucose Monitoring System provides accurate, reliable test results to help you better manage your diabetes.

RIGHTEST GT200 Blood Glucose Monitoring System is designed for *in vitro* diagnostic use only (for self-testing by a single user outside the body). Testing requires only a small amount of fresh capillary whole blood from either the fingertip, palm or forearm.

The testing result is calibrated to be plasma equivalent for test with fresh capillary, venous, arterial and neonatal whole blood samples.

RIGHTEST GT200 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 or email to rightest@bionime.com .

RIGHTEST GT200 Blood Glucose Monitoring System is a personal blood glucose monitoring system to be used for self-testing only. It is not recommended for multiple users.

A healthcare professional should be contacted when Customer Service is not available.

Please forward your warranty card to customer support to activate your warranty coverage.

Preface

Caution

- Before using the RIGHTEST Blood Glucose Monitoring System to test your blood glucose, please read all of the instructions and conduct all of the tests including the quality control test.
- Please perform the quality control test regularly to make sure the test results are accurate.
- RIGHTEST GT200 Blood Glucose Meter can only be used with RIGHTEST GT200 Blood Glucose Test Strips. Other brands' test strips should not be used under any circumstances. The use of other brands' strips may give inaccurate results.
- RIGHTEST Blood Glucose Monitoring System is intended for in vitro diagnostic use only.
 RIGHTEST Blood Glucose test results using fresh capillary whole blood samples from the fingertip, palm and forearm are calibrated to be the equivalent to that of plasma testing.
- RIGHTEST Blood Glucose Monitoring System is intended for self-testing. It should not be used to diagnose diabetes mellitus.
- Wait to test at least 30 minutes after entering another location of a different ambient temperature.Follow all environmental protection regulations when disposing of batteries.
- Keep the test strips, control solution or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your physician immediately.
- Prevent water from entering the meter. Never immerse the meter or hold it under running water.
- A drop of blood is required to perform a blood glucose test. Capillary blood can be used, while venous, neonatal or arterial blood may also be used only if drawn by healthcare professionals.

- The system has been tested with neonatal blood. As a matter of good clinical practice, be caution
 of the interpretation of neonate glucose value below 50 mg/dL (2.8 mmol/L). Please follow the
 recommendations for follow-up care that have been set by your intuition for critical glucose values
 in neonates. Once patient is suspected as rare disease (galactosemia), the glucose result should
 based on laboratory test.
- The minimum blood sample size to test using RIGHTEST Blood Glucose Monitoring System is 0.75 $\mu\text{L}:$ (\bullet)



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

Caution

3.0 µL

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RIGHTEST Blood Glucose Monitoring System

Contents

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

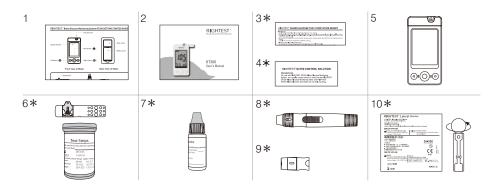
Below are the items included in your RIGHTEST Blood Glucose Monitoring System:

- 1. Getting Started Guide
- 2. User's Manual (includes Log Book, Warranty Card, Emergency Card)
- 3. RIGHTEST GT200 Blood Glucose Test Strip Package Insert *
- 4. RIGHTEST Control Solution GC700 Package Insert *
- 5. RIGHTEST GT200 Blood Glucose Meter (with 2 CR2032 batteries installed)
- 6. RIGHTEST GT200 Blood Glucose Test strips (10/25 pcs)*
- 7. RIGHTEST Control Solution GC700 * (Level 2 is provided in your starter kit)
- 8. Lancing Device *
- 9. Clear Cap *

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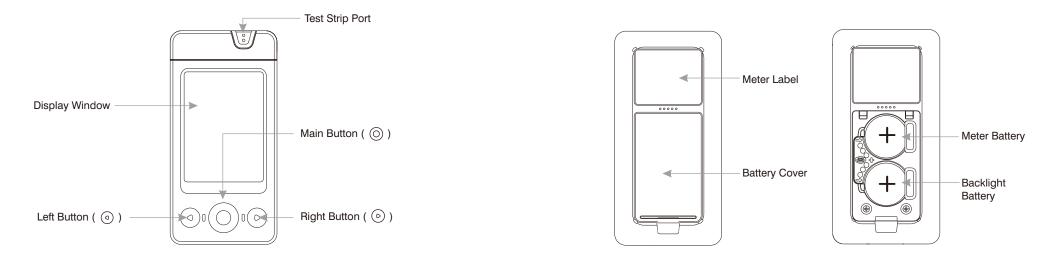
- 10. Disposable Sterile Lancets (10 pcs) *
- 11. Carrying Case (not shown) *
- 12. Instruction for the lancing device (not shown)*
- (* Different packages have different bundled items. Some of packages might not include * items.)

RIGHTEST Blood Glucose Monitoring System



RIGHTEST Blood Glucose Meter

RIGHTEST Blood Glucose Meter



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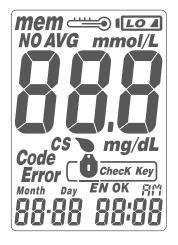
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RIGHTEST Blood Glucose Meter

RIGHTEST Blood Glucose Meter



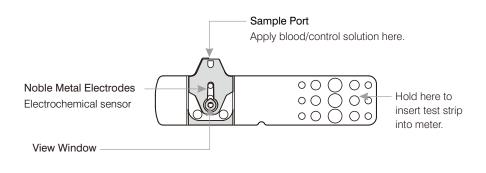
mem	Indicates a test result stored in memory			Indicates when to apply the blood sample
NO AVG	Indicates a test result not included into the average results of the meter		(<u>ð</u>)	test strip
AVG	Indicates the average result		Error	Appears when an error occurs
CS	Indicates a control solution test result		Month Day 88-88	Current date under time mode or testing date under memory mode
mmol/L mg/dL	Unit of test result			Warns when the operational temperature limit is exceeded during testing
888	Test result		RM	Indicates the time in 12H format
LO A	Warns when the batteries are low or must be replaced		88:88	Displays current time under time mode or testing time under memory mode
OK EN Code ChecK Key Manufacturing use only				

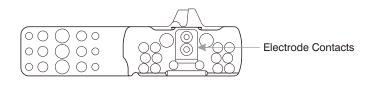
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RIGHTEST Blood Glucose Test Strip

RIGHTEST Blood Glucose Test Strip

RIGHTEST GT200 Blood Glucose Meter can only be used with RIGHTEST GT200 Blood Glucose Test Strips and RIGHTEST Control Solution GC700. The use of other test strips or control solutions can lead to incorrect results.



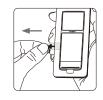


Λ	PRECAUTION
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- Close the RIGHTEST Blood Glucose Test Strip vial immediately after removing a test strip.
 Do not reuse RIGHTEST Blood Glucose Test Strips.
 - Do not use expired RIGHTEST Blood Glucose Test Strips.
 - Use each test strip immediately after removing from the vial.
 - For detailed information as validity period after open and storage environment, please refer to RIGHTEST Test Strips Insert.

Meter Activation and Battery Change

Your RIGHTEST Blood Glucose Meter comes with 2 CR2032, 3 volt, batteries installed. New batteries will provide power to perform approximately 1000 tests under normal use. Press the main button or insert a strip to activate your meter.



NOTE

For some meter please pull off the plastic tape and press the main button to activate the meter.

1. Turn the RIGHTEST Blood

Glucose Meter over. Press

and slide the battery cover



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



Meter Activation and Battery Change

- 3. Put the battery cover back until it snaps into place.
- 4. RIGHTEST Blood Glucose Meter will enter Self-Testing Mode automatically when replacing the battery (all symbols will appear on the screen).
- 5. Press any button to exit the self-test and enter Setting Mode.
- 6. You must set the time and date when replacing the battery. See Chapter "Setting Up Your Meter -Setting the Date, Time, and Volume" on page 18. Test results are still stored in the memory.

PRECAUTION

to open.

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

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

You can enter the Setting Mode two ways.

1. Replace the Battery

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

2. With Battery Inserted

Press the main button to turn on RIGHTEST Blood Glucose Meter. Hold down the main button for 7 seconds. During this time the screen will go blank until you hear a beep. After the beep, the meter will turn on into the Setting Mode. The display screen will show setting data.

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

1. Year setting

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



2. Month setting

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



// NOTE

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

3. Day setting

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



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

4. Time format 12/24H selection

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

5. Hour setting

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

6. Minute setting

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

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

7. Volume Setting

Month Day 6-9 12:00

6. 9. 12:00

6. 9 12:00

6. 9 12:00

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

8. Setting the Unit of Measurement

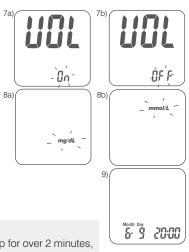
With milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L) blinking, press the Left or Right button to switch. Then press the Main button to confirm it and finish the settings.

9. Ending setting

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

/ NOTE

- If you do no change any settings during Meter Set-up for over 2 minutes, RIGHTEST Blood Glucose Meter will leave setting mode and power off automatically.





Turning On / Off the Meter

Turning On / Off the Backlight

- 1. How to turn on RIGHTEST Blood Glucose Meter Press the Main button or Insert a test strip.
- 2. Manual Power off

To power off RIGHTEST Blood Glucose Meter, press and hold the Main button for 4 seconds.

3. Auto Power off

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

- 1. Turn on the backlight Press and hold the Main button for 2 seconds.
- 2. Manually turn off the backlight With the backlight on, press and hold the Main button for another 2 seconds.
- Auto shutoff RIGHTEST Blood Glucose Meter backlight will turn off automatically after 10 seconds if no buttons are pressed.

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Handling RIGHTEST Blood Glucose Test Strip

How to handle RIGHTEST Blood Glucose Test Strip.

Inserting RIGHTEST Blood Glucose Test Strip:

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

2

(3

- 2. Put your forefinger on the side of the strip as shown.
- 3. Insert RIGHTEST Blood Glucose Test Strip into test strip port until it clicks and firmly stops.



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

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

Handling RIGHTEST Blood Glucose Test Strip

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



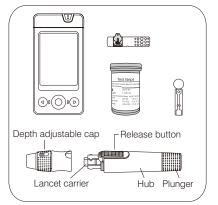




Getting Ready for Testing

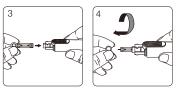
Before performing a blood glucose test, prepare the items below :

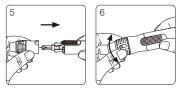
- RIGHTEST Blood Glucose Meter
- RIGHTEST Blood Glucose Test Strips
- (Please check the expiration date on the test strip vial. Do not use expired test strips)
- RIGHTEST Lancing device
- Sterile lancet
- Alcohol swab (optional)



- 1. Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub.
- 2. Pull the cap and hub off in opposite directions, remove the cap.
- 3. Insert a new disposable lancet firmly into lancet carrier.
- 4. Twist off and set aside the protective cover of the disposable lancet.
- 5. Replace the depth adjustable cap.
- 6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until your desired setting is visible in the window. Settings are based on skin type
 " " or soft or thin skin; " or average skin;
 " " or average skin;

Performing a Blood Glucose Test



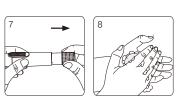


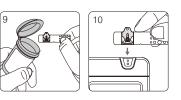
Performing a Blood Glucose Test

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

/ NOTE

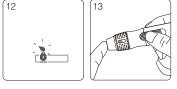
- RIGHTEST Blood Glucose Meter will automatically detect the Code number on the strip. You do not have to check the Code number on the meter display and strip vial.



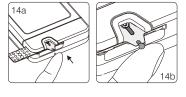


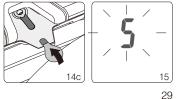


- A blood drop icon will appear on the display window and will be accompanied by a beep (if volume is turned on).
 Apply the blood sample within 2 minutes.
- 13. Place the lancing device against your fingertip and press the release button.
- 14. Touch and hold the blood drop to the edge of sample port until the view window is filled with blood. If the view window is not completely filled with blood the test will not start. If the blood sample was insufficient, discard the test strip and repeat with a new RIGHTEST Blood Glucose Test Strip.
- 15. Countdown Mode will begin on the display window. After 5 seconds, your test result will appear.



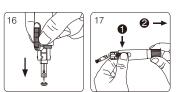
Performing a Blood Glucose Test

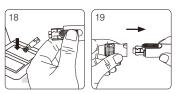




Performing a Blood Glucose Test

- Pull off the depth adjustable cap. Without touching the used disposable lancet, insert the lancet tip into the protective lancet cover.
- 17. Hold the release button in one hand (see picture 17, step1) and pull on the plunger with the other hand (see picture 17, step 2) to safely eject the used disposable lancet.
- 18. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
- 19. Replace the depth adjustable cap after finishing the test.





Performing a Blood Glucose Test

- Do not apply your blood drop to the sample port on the strip until you see the " " " appear. The screen will display " " " and " *Error* " if you apply blood too soon. If this occurs, please use a new test strip to test.
- Record the opening date of a new test strip vial. Discard the vial of test strips 12 months after opening.
- Always keep the metal contacts of the test strip port clean. If any dust or impurities are present, please clean with a small, soft brush.



- All parts of this kit are considered biohazards and can potentially transmit
- infectious diseases, even after you have performed the cleaning and disinfecting procedure.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, and test strips.
- Please refer to the section "Maintain the Products" for more cleaning information.

Alternative Site Testing

Alternative site testing: palm or forearm blood sampling

- To perform alternative site testing, install the clear cap for your RIGHTEST Lancing Device. (For detailed information, refer to the instruction 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 intended puncture area, press and hold the lancing device with the clear cap against palm or forearm.
- Press the release button.

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- Continue holding the lancing device against your palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient. See caution before alternative site testing.









CAUTION

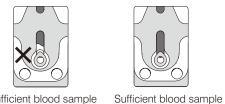
- CAUTION
 Fingertip samples can show the rapid change in glucose faster than palm or forearm samples.
 - Test results may vary when user's glucose level is changing rapidly after condition as: drinking, eating, insulin dosing or exercise. In these cases, only the fingertip should be used.
 - DO NOT test on the palm or forearm if you are testing for hypoglycemia (Low blood glucose).
 - Consult your healthcare professional before sampling from your palm or forearm.
 - As the blood flow taken from forearm is slower than fingertip or palm, we recommend using the RIGHTEST lancing device with Clear Cap for testing sites other than fingertip.
 - Periodically compare the test system to a laboratory test system that is known to be well maintained and monitored by a healthcare provider.



Alternative Site Testing

View Window Appearance

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



Insufficient blood sample

CAUTION Ŵ

- 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 immediately after removing it from the vial.
- Do not reuse Test Strips.
- Apply the blood sample only on the sample port of the test strip.
- Please don't drip or inject the blood sample directly by syringe to the sample entry of test strip. Doing this might contaminate the meter or cause damages and is not recommended



Understanding Test Results and Messages

Blood glucose test results are shown on RIGHTEST Blood Glucose Meter as mg/dL or mmol/L.

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

You can also run a Quality Control Test with the RIGHTEST Control Solutions GC700 to check your RIGHTEST GT200 Blood Glucose Meter and RIGHTEST GT200 Test Strip.

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

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

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

Understanding Test Results and Messages

RIGHTEST Blood Glucose 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) , " L a" will appear on the screen. Please repeat your test with by a new test strip.

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

If the test result is above 600 mg/dL (33.3 mmol/L), " H_1 " will appear on the screen. Please repeat your test again with a new test strip.

If you still get a " H_1 " result, contact your healthcare professional.



About Quality Control Testing

What is a Quality Control Test?

To ensure proper monitoring function, it is necessary to regularly perform a quality control test. Use one of the RIGHTEST Control Solutions when testing your RIGHTEST Blood Glucose Monitoring System in the Control Solution Mode. If the test result is within the Control Solution Range printed on the strip vial label, RIGHTEST Blood Glucose Monitoring System passes the Quality Control Test and your RIGHTEST Blood Glucose Monitoring System is working properly.

Control Solution Range:

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

Test Strips	Control Solution Rang	je mg/dL	mmol/L
Pical & contra alter first spearing Named date 2012-01 201 1194154	Normal (Level2):	88 - 120 mg /dL	4.9 - 6.7 mmol/L
500536005600 rogs rogs inel 23-52 inel 235-102 125-57 inel 4 225-323 15.5-17	Hing (Level4):	250 - 340 mg/dL	13.9 - 18.9 mmol/L

/ NOTE

- If you want to purchase new control solutions, please contact your local Bionime distributor or email to rightest@bionime.com .

About Quality Control Testing

When should a Quality Control Test Be Performed ?

- To ensure that your RIGHTEST Blood Glucose Meter and RIGHTEST Blood Glucose Test Strip are working properly.
- To confirm that you are following the correct testing procedures.
- To prepare for your initial blood glucose test.
- To check the RIGHTEST Blood Glucose Test Strip when you open a new vial of strips.
- To check your RIGHTEST Blood Glucose Meter after it has been dropped, damaged or exposed to liquids.
- If you suspect that your test results are inaccurate, or if your test results are not consistent with the way you feel.
- To practice testing.

Required Items for Quality Control Tests

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

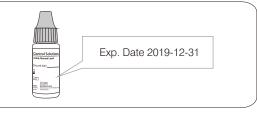
- RIGHTEST Blood Glucose Meter
- RIGHTEST Blood Glucose Test Strips
- RIGHTEST Control Solution

About Quality Control Testing

CAUTION

Each time you open a new bottle of control solution, write the expiration date on the label. RIGHTEST Control Solution GC700 is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first.



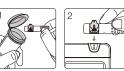


- Wipe the bottle cap with a clean tissue before tightly closing the bottle of control solution.

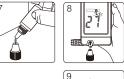
- Close the bottle of control solution tightly immediately after using.
- Check the expiration date before use. (Refer to the RIGHTEST Control Solution GC700 Insert).
- Keep control solution bottles out of reach of children.

Performing a Quality Control Test

- 1. Take one Test Strip from the vial and close the vial cap immediately.
- 2. Insert the Test Strip horizontally (not vertically) with the colored view window facing up into the test strip port.
- 3. While the blood drop icon is flashing on the display window, press and hold the Main button for at least 3 seconds until the " CS " and " L2 " symbol appears.
- 4. Keep pressing the main button for another 3 seconds to select the "CS" level you want test (Level 2-Normal, Level 4-High) Ensure that the control solution level on the control solution bottle matches the level you are testing.
- 5. You will see the blinking " " icon and " *CS* " icon on the screen, prompting you to apply the corresponding level of RIGHTEST Control Solution.
- 6. Shake the bottle of RIGHTEST Control Solution well before opening the cap. Place the cap on a flat surface.
- 7. Drip a drop of control solution onto the top of the cap.
- 8. Gently touch the sample port of the strip with the control solution from the top of the cap.
- 9. The screen will display the count time starting from 5 (you will hear a beep if the volume is turned on).







10. Tightly replace the cap on the Control Solution bottle.

stained or is overly exposed to moisture.

11. The control solution result will appear. Compare your Quality Control Test result to the Control Solution Range printed on RIGHTEST Blood Glucose Test Strip vial label.



- Your Control Solution Test results will not be included in the average calculations, however, they can still can be recalled and viewed. The Control Solution Test result will be shown with the " *cs* " icon on the screen.
- The Control Solution Test should be conducted between 6 44°C (43 111°F).
- Before " > " and " *cs* " appear, do not touch the control solution to the sample port on the strip. RIGHTEST Blood Glucose Meter is performing an internal check. Touching the control solution to the sample port before prompted will result in an error message:
- " *Error* " and " " " and be accompanied by beeps (if volume is turned on).
- Do not drip the control solution on to the sample port of the test strip directly. The reagent on the strip might leak into the bottle of control solution and may cause the degeneration
- of the control solution. This could contaminate the meter via the test strip port. - Keep the test strip port clean and dry. Clean immediately if the test strip port is

liately if the test strip port is

Performing a Quality Control Test

- Do not touch the tip of the control solution bottle. If the tip is touched, clean with water.



Understanding Control Test Results

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

	Control Solution Range		
Example of control	L2 = Level 2 (Normal)	L4 = Level 4 (High)	
solution range printed on your test strip vial label	88 - 120 mg/dL	250 - 340 mg/dL	
	4.89 - 6.67 mmol/L	13.89 - 42.5 mmol/L	

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

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

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

RIGHTEST Blood Glucose Meter is able to automatically store a maximum of 1,000 test results with time and date. If your meter has stored 1,000 results, the newest test result will replace the oldest one.

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

1. Press the Main button to switch from the Time Mode to Memory Mode. You will see the "mem" icon in the upper left corner of the display. The latest test result will appear with the number "1".



Recalling Test Results

- Use either the Left or Right button on the side to review all previous results with date and time. Results display from the most recent (Sequence no. "1") to the oldest (Sequence no. "1000") in the lower right hand corner of the screen.
- The Quality Control Test result can be recalled from the saved data. When
 " *cs* " appears next to the data, the test was performed using the RIGHTEST
 Control Solution. The control solution test result will not be used when
 recalling test average results.



Recalling Average Test Results

RIGHTEST Blood Glucose meter provides several average test results. View the 1-day, 7-days, 14-days, 30-days, 60-days and 90-days average test results for better blood glucose monitoring.



- 1. Press the Main button to switch the screen to Average Mode.
- 2. On the average screen, use either the Left or Right button to view 1-day, 7-days, 14-days, 30-days, 60-days or 90-days averages.
- 3. The number shown in the lower right hand corner indicates how many test results have been calculated.
- 4. Excluding test results from the average calculation:

Mark "exclusion": After the your in-time testing result pop out, Press the Right or Left button until the symbol "NO AVG" appears in the upper Left of the screen. The test result is now excluded from averaging.

∧ PRECAUTION

 $^{\Delta}$ - Set the time and date to activate the average function.

Recalling Average Test Results

Cancel "exclusion": Stay in the display of "NO AVG". Press the Right or Left button until the symbol "NO AVG" changes to "AVG". Keep pressing the Right or Left button and while simultaneously pressing the Main button until "AVG" appears. The test result is now included into the average calculation.

5. Quick Searching:

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

NOTE

- The Average function requires that the correct time and date is set. Test results must exist during the desired time interval. For example: To get a 14-day average on 1/30/11, you must have test results dated between 1/17 and 1/30. If no test results exist during that time frame you will not receive an average.
- To exclude test results from average calculation, you need to remain in Test Mode and perform the exclusion right after you get the test result.
- The "Lo", "Hi" results, control solution test results and test results at abnormal temperatures $< 6^{\circ}C (43^{\circ}F)$ and $> 44^{\circ}C (111^{\circ}F)$ will be excluded from average calculations.

Maintain the Products

Maintenance

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

Cleaning Meter

Clean the outside of the meter with a damp cloth and mild soap/detergent. Do not get the test strip port wet.

Cleaning Test Strip Port

If your test strip port is stained with blood, control solution or any liquid, please use a dry tissue or alcohol swab to clean it immediately. Do not use anything wet to clean it. Perform a quality control test to ensure RIGHTEST Blood Glucose Meter is working properly.

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 the shared use of fingerstick (lancing) devices and point of care blood testing devices.

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

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person. NOTE: the cleaning procedure can only remove visible contaminates from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

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.

Maintain the Products

Maintain the Products

NOTE

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

To clean the meter:

- Throughly wipe the entire surface of the meter with disinfecting wipes listed above to clean any possible dirt, dust, blood and other body fluids.
- To disinfect the meter:
- Take another disinfecting wipe and wipe the meter thoroughly. (Note: All blood and body fluids should be cleaned from surface before performing the disinfecting procedure)
- 3. Allow the surface to remain wet for 2 minute.
- 4. Allow to air dry.

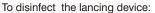
// NOTE

 Your RIGHTEST Blood Glucose Meter has been tested to ensure that there is no change in the performance or external materials of the device after 10,000 cleaning cycles and 10,000 disinfecting cycles. The testing simulates high frequency of cleaning and disinfecting cycles around 5 years..

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To clean the lancing device:

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



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



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

Maintain the Products





Maintain the Products

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

- You are unable to enter meter settings, function modes or recall your testing results. If you have any questions or concerns, please contact your RIGHTEST Blood Glucose Monitoring System authorized representative or contact your local Bionime distributor or email to rightest@bionime.com.

Error Messages and Troubleshooting

Temperature Error

1. In order to get accurate testing results, please test between 6 - 44 $^{\circ}\text{C}$ (43-111 $^{\circ}\text{F}).$



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- 2. When the temperature is below 6°C (43°F) or over 44°C (111°F), the meter will not function and the " *Error* " symbol will blink.
- 3. If the RIGHTEST Blood Glucose Meter and Test Strips are exposed to a substantial change in temperature, please wait 30 minutes before measurement.

Error Messages and Troubleshooting

Battery Error

1. The " — " and " *Error* " symbols appear and the meter will not function when the battery is low. Change the batteries immediately.

// NOTE

- The backlight function operates off of its own battery source. If the backlight is no longer functioning, replace the backlight battery (Refer to page 11 to find the location of the backlight battery)
- When the backlight no longer operates, the meter will still function for testing purposes until the " and " *Error*" symbols appear as described above.

Strip Error

When a test strip is not inserted correctly, "Strip Error" will flash on the screen. Please reinsert the strip following the instructions on page 27 (Performing a Blood Glucose Test). If after following the instructions, "Strip Error" appears again, you may be using the wrong test strip. Please check to make sure you are using a RIGHTEST Test Strip.

Sampling Error

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



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Error Messages and Troubleshooting

- **Er1** The inserted test strip has been used or damaged. Please use a new test strip.
- Er2 The meter has malfunctioned. Do a Quality Control Test or reinstall the batteries to check if the meter works properly.
- **Er3** The signal transmission is disrupted. Repeat the test using a new test strip.
- **Er4** The blood sample volume is insufficient. Repeat the test using a new test strip.
- **Er5** An issue calibrting the Meter has occurred.Please follow the steps below:
 - 1. Remove the test strip from the meter.
 - 2. Turn off the meter.

3. Press the mailn button to turn ON the meter. If after turning on the Meter, you do not see Er5, your meter is functioning properly and able to perform a test.



Er3

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Meter Malfunction

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

- 1. Open the battery cover and remove the batteries.
- 2. Wait for 5 minutes and reinsert the batteries as described as instructed on page 16, (Meter Activation and Changing the Battery).

The meter should work normally after finishing the above steps. If the meter still does not work, please contact your local local Bionime distributor or email to rightest@bionime.com .

Limitations

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

- Inaccurate test results may be obtained at altitudes greater than 3,048 meters(10,000 feet) above sea level.

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

- The glucose test may be invalid in the presence of abnormally high concentration: Ascorbic acid \geq 5 mg/dL (0.28 mmo/L)

Uric acid \geq 20 mg/dL (1.19 mmol/L)

Xylose \geq 20 mg/dL (1.33 mmol/L).

- Not for screening or diagnosis of diabetes mellitus.

- Regarding potential electromagnetic or other interference, keep meter out of electromagnetic radiation sources.

Measurement Technology	Dehydrogenase Electrochemical Sensor	
Measuring Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)	
Test Time	5 seconds	
Memory Capacity	1,000 blood glucose test results with date and time	
Power Saving	Turns off automatically 2 minutes after last user action. To turn off manually, press the button " \bigcirc " for 4 seconds.	
Operating Temperature	6 - 44°C (43 - 111°F)	
Operating Relative Humidity	10 - 90%	
Power Supply	2 CR2032 Batteries (3 Voltage)	
Battery Life	Approximately 1,000 standard tests	

Specification

Meter Dimension	96 mm x 46 mm x 17.5 mm
Meter Weight	$65 \pm 5g$ with batteries
Monitor	LCD
Display Area	55 mm x 37 mm
Sample	
Minimum Sample Volume	
Hematocrit	 Refer to RIGHTEST GT200 Strip insert
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 Blood Glucose Meter that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the original purchaser of the RIGHTEST Blood Glucose Monitoring System.

Please complete and return the enclosed warranty card.

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



 During blood glucose measurement, 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 batteries.

Customer Service

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

Description of used symbols

IVD	For in vitro diagnostic use	-	Manufacturer
LOT	Lot number Expiry date	====	Direct current
	Temperature limitation	8	For single use only
CE 0197	CE-mark (with No. of notified body)	&	Biological risks
EC REP	EC Representive	Ì	humidity limitation
STERILE R	Method of sterilization using irradiation	Ĩ	Consult the instruction for use
\land	Caution (consult instructions foruse and w	/arnings)	

Expected Glucose Values Without Diabetes

Expected values⁽¹⁾

Fasting Blood Glucose	
GLUCOSE LEVEL	INDICATION
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
From 100 to 125 mg/dL (5.6 to 6.9 mmol/L)	Pre-diabetes (Impaired fasting glucose)
126 mg/dL (7.0 mmol/L) and above on more than one testing occasion	Diabetes

References

1) Diabetes Information - American Association for Clinical Chemistry (AACC) (Electronic Version) Retrieved Aug 21, 2015 form www.labtestsonline.org/understanding/analytes/glucose/test.html

Component Manufacturer Information

Blood Glucose Meter, Test Strip, Control Solution

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

Lancing Device

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

Disposable Sterile Lancets

Manufacture information is as package printed.