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EC REP

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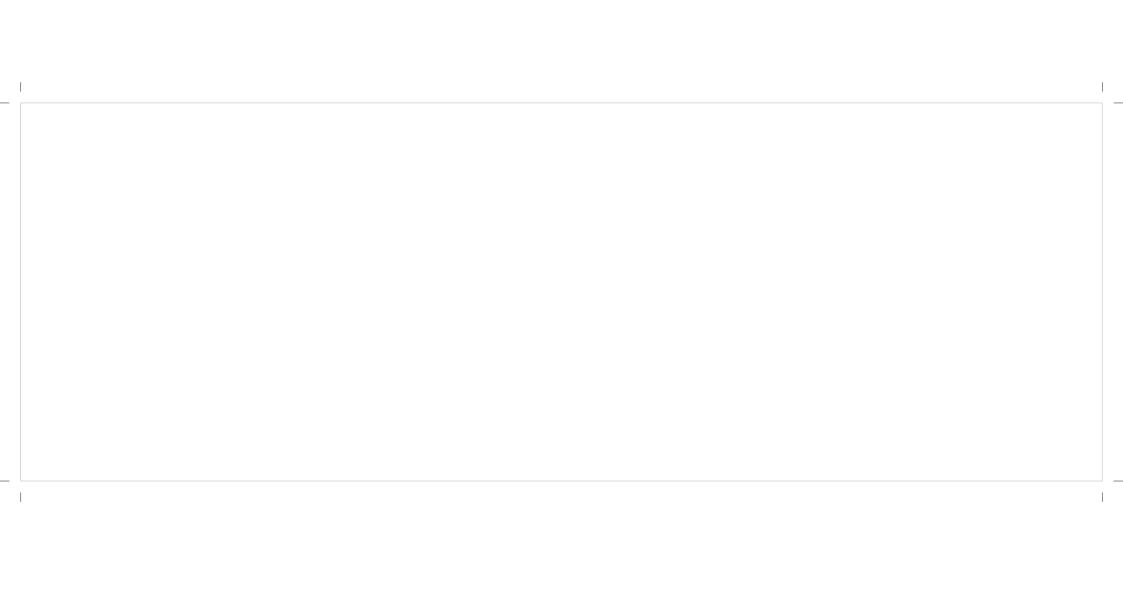
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GT100 User's Manual



Preface Preface

Thank you for selecting the GT100 Blood Glucose Monitoring System. This manual provides all the information you need to operate this product for accurate test results. Please read the 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 GT100 Blood Glucose Monitoring System provides accurate, reliable results to help you better manage your diabetes.

The GT100 Blood Glucose Monitoring System is perfect for both self-testing and professional use. Designed for in vitro diagnostic use only, testing requires just a small amount of fresh capillary whole blood from either the fingertip, palm or forearm. If you have any questions regarding the GT100 Blood Glucose Monitoring System or testing procedures, contact our Customer Support staff or your healthcare professional.

The GT100 Blood Glucose Monitoring System was manufactured and supported by Bionime Corporation and its authorized representative. If you have any questions or concerns, please contact your local Bionime Customer Service or email to rightest@bionime.com.

Healthcare professional should be contacted when Customer Service is not available.

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

Caution Precaution

- Before using RIGHTEST Blood Glucose Monitoring System to test your blood glucose, please read all the instructions and conduct all the tests including quality control test (Refer to page 36.)
- Please do the quality control test regularly to make sure the test results are accurate
- The RIGHTEST GT100 Blood Glucose Meter can only be used with the RIGHTEST GT100 Blood Glucose Test Strips. The use of any other brand strips should not be used under any circumstances. The use of other brands of strips may give inaccurate results.
- RIGHTEST Blood Glucose Monitoring System is intended for in vitro diagnostic use only. The testing result is calibrated to be plasma equivalent for test with fresh capillary whole blood samples from the fingertip, palm and forearm.
- RIGHTEST Blood Glucose Monitoring System is intended for self-testing. It should not be used to diagnose diabetes mellitus.
- RIGHTEST Blood Glucose Monitoring System has not been validated for use on neonates. Therefore, it's not intended for use of neonates.
- RIGHTEST Blood Glucose Monitoring System has not been used for arterial blood testing yet, so it is still not suitable to be used for arterial blood testing.
- Wait at least 30 minutes before testing after entering another site with a different ambient temperature.
- Follow all environmental protection protocol when disposing of batteries.

- Use this appliance in tropical and / or temperate climates only.
- Avoid contact with dripping or splashing liquids.
- The minimum blood sample size to test using RIGHTEST Blood Glucose Monitoring System is 0.75  $\,\mu$ L.

Sample Size Example



A minimum of  $0.75~\mu L$  of blood is needed to test on the RIGHTEST Blood Glucose Monitoring System. Blood sample size above  $3.0~\mu L$  might contaminate the test strip port and the meter. Blood sample size below  $0.75~\mu L$  might cause inaccurate test result or might not start the meter. In this case, repeat the test with a new test strip.

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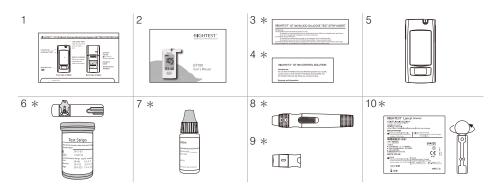
# **RIGHTEST Blood Glucose Monitoring System**

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:

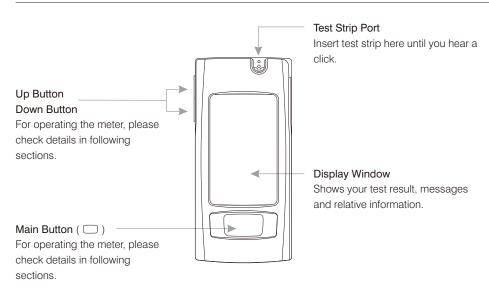
- 1. Getting Started Guide
- 2. User's Manual (includes Log Book, Warranty Card, Emergency Card)
- 3. RIGHTEST GT100 Blood Glucose Test Strip Package Insert \*
- 4. RIGHTEST GC550 Control Solution Package Insert \*
- 5. RIGHTEST GT100 Blood Glucose Meter (with one CR2032 battery installed)
- 6. RIGHTEST GT100 Blood Glucose Test Strip (10/25 pcs) \*
- 7. RIGHTEST GC550 Control Solution \*
- 8. RIGHTEST Lancing Device \*
- 9. Clear Cap \*
- 10. Disposable Sterile Lancets (10 pcs) \*
- 11. Carrying Case (not shown) \*
- 12. Instruction for the lancing device (not shown) \*
- (\* Different packages have different bundled items. Some of packages might not include \* items.)

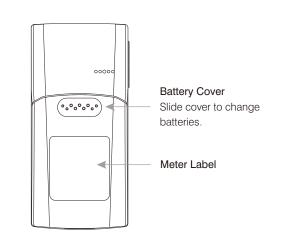
# RIGHTEST Blood Glucose Monitoring System

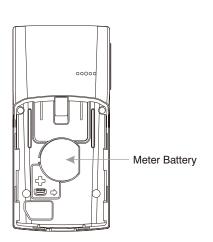


# **RIGHTEST Blood Glucose Meter**

# **RIGHTEST Blood Glucose Meter**





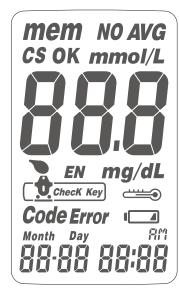


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# **RIGHTEST Blood Glucose Meter**

# RIGHTEST Blood Glucose Meter

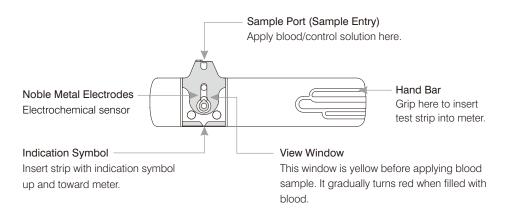
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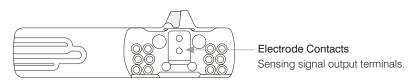
mem	Indicates a test result stored in memory		Indicates when to apply the blood sample
NO AVG	Indicates a test result not included into the Average function of this meter	( <u>\$</u>	Test strip
AVG	Indicates the average result	Error	Appears when an error occurs
CS	Indicates a control solution test result	Month Day	Current date under time mode or testing date under memory mode
mmol/L mg/dL	Unit of test result		Indicates if the environmental temperature limit is exceeded during testing
888	Test result	AM	Indicates the time in 12H format
1	Warns when the battery is low or must be replaced	88:88	Current time under time mode or testing time under memory mode

# **RIGHTEST Blood Glucose Test Strip**

RIGHTEST GT100 Blood Glucose Meter can only be used with RIGHTEST GT100 Blood Glucose Test Strips. The application of other Test Strips or control solutions can lead to incorrect results.



# RIGHTEST Blood Glucose Test Strip



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### CAUTION

- 4 Close RIGHTEST Blood Glucose Test Strip vial immediately after taking out a test strip.
- Do not reuse RIGHTEST Blood Glucose Test Strips.
- Do not use expired RIGHTEST Blood Glucose Test Strips .
- Record the date of opening a new RIGHTEST Blood Glucose Test Strip vial for the first time.
- Discard the vial of test strips after 3 months from opening.
- Store RIGHTEST Blood Glucose Test Strips in a cool (4 30°C or 39 86°F) and dry location (< 90% relative humidity). Do not expose to direct sunlight or heat.
- For detailed information, please refer to RIGHTEST GT100 Blood Glucose Test Strip Package Insert.
- If the RIGHTEST Blood Glucose Meter and Test Strips are exposed to a high temperature difference, please wait 30 minutes before measurement.

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# Meter activation and Battery change

Your RIGHTEST Blood Glucose Meter comes with 1 CR2032, 3 volt, battery installed. New battery will provide power to perform about 1000 tests under normal use. Press the main button or insert a strip to activate your meter.



Turn the Meter over.
 Press and push battery cover to open.



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



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

- 4. The RIGHTEST Blood Glucose Meter will perform a self test.
- 5. Press any button to exit the self-test and enter Setting Mode.
- Set the time and date when the battery is replaced. See Chapter "Setting Up Your Meter Setting the Time, Volume and Date". Test results are still stored in the memory.



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

You can enter Setting Mode two ways.

- 1. Reload 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 load batteries. RIGHTEST Blood Glucose Meter performs a self test. Press the main button to exit the self test and enter Setting Mode.

Meter activation and Battery change

2. With Battery inserted

Press the main button first to turn on RIGHTEST Blood Glucose Meter. Then press and hold the main button for 7 seconds (NOTE: Prior to the setting mode, the meter will turnoff) until you hear a beep, indicating you have successfully entered Setting Mode. The display screen will show setting data.



#### NOTE

- After pressing the main button for 3 seconds, screen display will turn off. Keep pressing the main button to enter the setting data.
- Continue to press the main button allows you to change settings. To return to the time mode, quickly press the main button to reach the desired setting.

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# Setting Up Your Meter- Setting the Time, Volume and Date

### 1. Year setting

With the year format blinking, press the Up or Down 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 Up or Down button until you see the current month. Press the Main button to confirm. Once the month is confirmed, the Day setting will appear.



#### 3. Day setting

With the day blinking, press the Up or Down button until you see the current day. Press the Main button to confirm. Once the day is confirmed, the Time setting will appear.



# Setting Up Your Meter- Setting the Time, Volume and Date

#### 4. Time format 12/24H selection

With the time format blinking, press the Up or Down button to switch between 12H and 24H. Press the Main button to confirm your hour setting. Once confirmed, the hour setting will appear.

#### 5. Hour setting

With the hour blinking, press the Up or Down 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 minute blinking, press the Up or Down button until you see the current minute. Press the Main button to confirm. Once the minute is confirmed, the volume setting will appear.

#### 7. Volume setting

With the volume blinking, press the Up or Down button to turn it on or off. Press the Main button to confirm and finish the settings.









# Setting Up Your Meter- Setting the Time, Volume and Date

# Turning On / Off the Meter

8. Setting the Unit of Measurement With milligrams per deciliter(mg/dL) or milnimol per litter(mmol/L) blinking, press the Up or Down button to switch. Then press the main button to confirm it and finish the settings.



9. Ending setting After the setting, you will hear a beep (if volume is turned on) to confirm your changes were saved. Once completed you will return to time screen.



- 1. How to turn on RIGHTEST Blood Glucose Meter Press the Main button or insert a test strip.
- 2. Manual Power off If you want to turn off RIGHTEST Blood Glucose Meter, press and hold the Main button for 3 seconds.
- 3. Auto Power off RIGHTEST Blood Glucose Meter will power off automatically after 2 minutes.

### 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.

# Easily Handling RIGHTEST Test Strip

How to handle RIGHTEST Blood Glucose Test Strip

Inserting RIGHTEST Blood Glucose Test Strip:

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



- This is the easiest way to insert the strip.
- 3. Insert RIGHTEST Blood Glucose Test Strip into test strip port until it snaps and firmly stops.







# Removing RIGHTEST Blood Glucose Test Strip:

- 1. Hold RIGHTEST Blood Glucose Test Strip as shown in insertion instructions.
- 2. Rotate RIGHTEST Blood Glucose Test Strip counterclockwise and pull up simultaneously.



### NOTE

- Pulling the strip in a counterclockwise direction will make it easier to remove it from the meter.
- Rotate

Easily Handling RIGHTEST Test Strip

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



#### NOTE

- Test Strip Port will not be contaminated by blood if you follow the steps correctly.

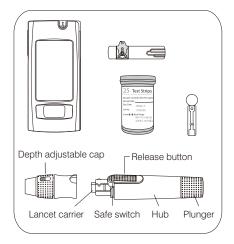


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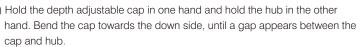
# **Getting Ready for Testing**

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

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



1) Hold the depth adjustable cap in one hand and hold the hub in the other





Performing a Blood Test

- 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.









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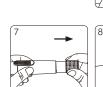
# Performing a Blood Test

- 6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until your desired depth setting is visible in the window. Settings are based on skin type: " up " for soft or thin skin; " up " for average skin; " for thick or calloused skin.
- 7. Hold the hub 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 strip port of the RIGHTEST Blood Glucose Meter with the indication symbol facing up. The meter confirms the insertion of the strip with a beep (if volume is turned on).



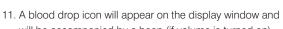
### NOTE

- RIGHTEST Blood Glucose Meter will automatically detect the Code number on the strip. You don't have to check the Code number on the meter display or strip vial

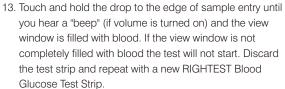


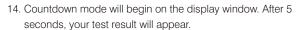




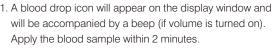


12. Place the lancing device against your fingertip and press the release button.





# Performing a Blood Test







completely filled with blood the test will not start. Discard









# Performing a Blood Test

- 15. Pull off the depth adjustable cap. Without touching the used disposable lancet, insert the lancet tip into the protective cover.
- 16. Hold the release button in one hand (see picture 16, step 1) and pull on the plunger with the other hand (see picture 16, step 2) to safely eject the used disposable lancet.
- 17. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
- 18. Replace the depth adjustable cap after finishing the test.









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- Do not apply your blood drop to the sample entry on the strip until you see the
- " > " appear. RIGHTEST Blood Glucose Meter is performing an internal test and will display " > " and " *Error*" if you apply blood too soon. Please repeat the test with a new RIGHTEST Blood Glucose Test Strip.
- Record the opening date of a newRIGHTEST Blood Glucose Test Strip vial. Discard the vial of test strips 12 months after opening.



# Performing a Test in Order

Alternative site testing: palm or forearm blood sampling

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









## Performing a Test in Order

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#### CAUTION

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

# **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

Enough blood sample

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#### CAUTION

- Check the expiration date printed on the package every time you use the strip. Do not use expired RIGHTEST Blood Glucose Test Strips.
- Use each RIGHTEST Blood Glucose Test Strip immediately after taking it from the vial.
- Do not reuse RIGHTEST Blood Glucose Test Strips.
- Wait at least 30 minutes to test after entering another location with a different ambient temperature.

# **Understanding Test Results and Messages**

Blood glucose test results are shown on RIGHTEST Blood Glucose Meter as mg/dL or mmol/L, based on your setting (for unit setting, refer to page 18 - 20).

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 RIGHTEST GC550 Control Solutions to check your RIGHTEST Blood Glucose Meter and Test Strip (Refer to page 36). 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.

# **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 your test result is below 10 mg/dL or 0.6 mmol/L, " Lo" will appear on the screen. Please repeat your test again with a new strip.

If you still get "  $L_0$  " result, you should immediately contact your healthcare professional.

If your test result is above the high end of the system's detective range (600 mg/dL or 33.3 mmol/L), " \( \mathbb{H}\_1 \)" will appear on the screen. Please repeat your test again with a new strip. If you still get " \( \mathbb{H}\_1 \)" result, you should immediately contact your healthcare professional.



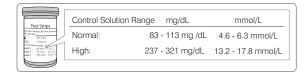


# **Quality Control Test**

Use RIGHTEST Control Solutions when testing your RIGHTEST GT100 Blood Glucose Monitoring System under 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. That means your RIGHTEST Blood Glucose Monitoring System is working correctly.

### Control Solution Range:

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



### When should a Quality Control Test be performed?

- To ensure that your RIGHTEST Blood Glucose Meter and Test Strip are working together properly.
- To confirm that you are following the correct procedure.
- 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 liauids.
- When you suspect that your test results are inaccurate, or if your test results are not consistent with the way you feel.

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# **Quality Control Test**



#### NOTE

- If you want to purchase new RIGHTEST Control Solutions, please contact customer service.

Possible reasons your Control Solution results are out of range

- Your RIGHTEST Control Solution is expired or has been opened more than 3 months ago.
- Your RIGHTEST Blood Glucose Test Strip has expired.
- You left the cap of RIGHTEST Blood Glucose Test Strip vial or the GC550 Control Solution off for a period of time.
- You didn't perform the test procedure correctly.
- Malfunction of RIGHTEST Blood Glucose Meter or Test Strip.

If control solution test 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 outside the range still exist, do not use RIGHTEST Blood Glucose Monitoring System to test your blood glucose and contact Bionime Customer service.



## **↑** CAUTION

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

### Example of Expiration Date:



# Performing a Quality Control Test

- 1. Take one RIGHTEST Blood Glucose Test Strip from the vial and close the vial cap immediately.
- 2. Insert RIGHTEST Blood Glucose Test Strip with view window facing up, into test strip port.
- 3. While the blood drop icon is flashing on the display window, press and hold the Main button for at least 3 seconds until the " cs " symbol appears.
- 4. You will see the blinking " > " icon and " *cs* " icon on the screen, prompting you to the apply RIGHTEST Control Solution.
- 5. Shake the bottle of RIGHTEST Control Solution well before opening the cap. Put cap off to side.
- 6. Place a drop of RIGHTEST Control Solution into the cap.
- 7. Gently touch the sample entry of the strip with RIGHTEST Control Solution from the top of the cap.
- 8. When you hear a beep (if volume is turned on), the screen will display the test countdown from 5.















# **Performing a Quality Control Test**

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



### **↑** CAUTION

- Your Control Solution results will not be calculated for average reading but can still be recalled. The Control Solution Test result will be shown with " cs " symbol on the screen.
- Control Solution Test should be conducted between 15 40°C (59 104°F).
- Before " " and " cs " appears, don not touch RIGHTEST Control Solution to the sample entry on the strip. The GT100 Blood Glucose Meter is preforming an internal check, touching the Control Solution to the sample entry before prompted will result in an error message: "Error" and RIGHTEST be accompanied by beeps (if volume is turned on).
- Don't drip RIGHTEST Control Solution into the sample entry of the strip directly. The reagent on the strip might leak into the bottle of RIGHTEST Control Solution and may cause the degeneration of RIGHTEST Control Solution. Doing this could also contaminate the meter via the test strip port.
- Don't touch the tip of RIGHTEST Control Solution bottle. If you have touched it, please clean with water.



# **Recalling Test Result and Average**

RIGHTESTBlood Glucose Meter is able to automatically store a maximum of 500 test results with time and date. If your meter has stored 500 results, the newest test result will replace the oldest one. To recall your test memory, start the meter without a test strip inserted.

1. Press the Main button to switch from the time mode to the Memory screen. You will see the "MEM" symbol in the upper left corner of the display. When you press the Down button, the latest result will be displayed. By pressing the Down button sequentially, former 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 date and time of the measurement.



- Note: The Up button is for reviewing the tests with the sequence number increasing, and the Down button is for reviewing tests with sequence number decreasing. The sequence "1" is the latest result while sequence "500" is the oldest test result.
- 2. To finish reviewing memory tests, press the Main button again. This will bring you to the Average screen. By pressing the Down button, the display shows "AVG" in the upper right corner of the display and the average value for the actual day. By sequencely pressing the Up or Down 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 in the lower left corner and the number of the calculated readings in the lower right corner.

# Recalling Test Result and Average











3. Non-Averaging set and canceled:

You may exclude unwanted or doubtful test results from the average calculation. After you finished your test in the test mode, you can exclude the unwanted result. Keep pressing the Down button until you see the symbol "NO AVG" in the top right corner of the screen. Press the Down button and the Main button simultaneously to confirm the value as "Non average".

Now this value is flagged by the symbol "NO AVG" in the upper right corner of the screen. to cancel a non-averaging setting. Keep pressing the Down button until the "NO AVG" symbol changes to "AVG" in the upper right corner of the screen. To confirm this original status, simultaneously press the Main button to confirm the "AVG" status. The value will be stored as a regular value and included in the average values.



#### NOTE

- The average function is related to the time setting. You must set the time correctly and have enough time intervals on the basis of current inquiry time to make sure that the average test results will show. For example, take the 14-day average; if your current inquiry time is 1/30, you must check that you have tested blood glucose in the past 14 days before 1/30, including today. If not, the 14-day average will show no will not show a figure.
- The Non-averaging/re-averaging function only works in test mode and when you get a value. This action cannot be performed in mem mode.

# **Recalling Test Result and Average**

- 4. Quick Searching: If you want to see all values automatically displayed in sequence, enter the memory mode. Press and hold the Up or Down button for 2 seconds. (Down button is for searching the latest test value to the oldest one; Up button scrolls from the oldest to the latest one). Anytime you want to stop, just release the pressed button. It will stop and display the current value. Use this to check a particular reading.
- 5. Reading right after test: Press the Main button to enter the MEM (memory) screen and review the latest test result.



### NOTE

Your Control Solution results will be automatically non-averaged without selecting, but still
can be recalled. The Control Solution Test results will show with "CS" symbol under memory
screen.

## ♠ CAUTION

- You have to set the time and date to activate the average function.
- The "Lo" and "H<sub>1</sub>" results the Control Solution results and test results made out of normal temperature range: <10°C (50°F), > 40°C (104°F) will not be calculated in the average.

### 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.

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### Maintain the Products

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



#### 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.







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#### NOTE

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

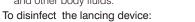
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### Maintain the Products

## Maintain the Products

### 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.





### // No

#### NOTE

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

### **⚠** CAUTION

- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Please examine your LCD screen, test strip port, buttons and surface of your meter and lancing device after cleaning and disinfecting cycles. Stop using the meter and/or lancing device if any of the following occur:
- Thin, 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 GT200 Blood Glucose Monitoring System authorized representative or contact your local local Bionime distributor or email to rightest@bionime.com .

# Error messages and Trouble shooting

- Er1 The inserted test strip has been used or damaged. Please use a new test strip from vial.
- Er2 Meter has malfunctioned. Do the Quality Control Test or reinstall the battery to check if the meter works properly.
- Er3 Signal transmission is disrupted, repeat the test.
- Er4 Applied blood volume is insufficient, repeat the test with a new test strip.
- Er5 An issue calibrating the Meter has occurred. Please follow the steps below:
  - 1. Remove the test strip from the meter.
  - 2. Turn off the meter (press and hold the Main button for 3 seconds).
  - 3. Press the main button to turn ON the meter.

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

If one of the above error messages still appears, please contact local Bionime distributor or email to rightest@bionime.com.











- 1. The " ysymbol is blinking when the battery power is low Please change the meter battery as soon as you can. You can still do the test
- The " and " Error" symbols are blinking when the battery is too low. Meter can not do the strip test. Please change the meter battery immediately.

#### Strip Error

Battery Error

- 1. When the test strip is inserted incorrectly, the meter will beep 4 times while the " meter will beep 4 times while the meter will be a sample on the test strip. Please re-insert the unused test strip correctly (refer to "Easily Handling RIGHTEST Test Strip" on Page 23 for more information).
- 2. If, after performing the required steps, the " " and flashing " Error" symbols appear on the screen, it means Test Strip has been inserted incorrectly more than twice. Please, re-insert the unused test strip again after reviewing the steps on how to insert a test strip correctly on p.22 or contact Customer Service for support. This error message can also indicate that you may have used the wrong test strips. Please check the test strip vial to ensure you are using RIGHTEST Test Strips.



Error messages and Trouble shooting









# Error messages and Trouble shooting

### **∴** CAUTION

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

# Error messages and Trouble shooting

### Temperature Error

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

1. When the ambient temperature is 0 - 9°C (32 - 48°F) or 41 - 50°C (106 - 122°F) the " - " warning symbol will blink (1a). You can still do the test but the test result is for reference. Tests in the memory screen this value will be flagged with " symbol (1b). Repeat the test in an area with temperature ranges between operating range (10 - 40°C or 50 - 104°F).



- 2. When you move from an area with temperature outside the operating range to another area with temperature inside operating range, please wait for 30 minutes before you test.
- 3. When the temperature is below 0°C (32°F) or over 50°C (122°F), RIGHTEST Blood Glucose Meter will blink the " Error " symbol with the thermograph symbol displaying on screen.





# Error messages and Trouble shooting

#### Sampling Error

Do not apply the blood drop to the sample entry of the strip before RIGHTEST Blood Glucose 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 RIGHTEST Blood Glucose Test Strip.



#### Meter Malfunction

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

- 1. Open the battery cover and remove the battery.
- 2. Wait for 5 minutes and reinsert the battery as described " Meter activation and Battery change " on page 16 17.

RIGHTEST Blood Glucose Meter should work normally after finishing the above steps. If not, please contact customer service.

# Limitations

- Store RIGHTEST Blood Glucose Test Strips in the original capped vial at temperatures between 4°C to 30°C (39°F to 86°F) and relative humidity below 90%. Do not freeze.
- RIGHTEST Blood Glucose Test Strips are designed for using with capillary whole blood samples. Do not use serum or plasma samples.
- Inaccurate test results may be obtained at high altitude more than 3,048 meters (10,000 feet) above sea level.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- RIGHTEST Blood Glucose Monitoring System has not been validated for use on neonates.
- Test result may be interfered in the presence of abnormally high concentration of interferences or HCT, please refer to strip insert for the detail.

# Specification

# Specification

Oxidase Electrochemical Sensor	
Plasma	
10 - 600 mg/dL (0.6 - 33.3 mmol/L)	
5 seconds	
500 blood glucose test results with date and time	
Turn off automatically 2 minutes after last user action or press the " _ " button for 3 seconds.	
10 - 40°C (50 - 104°F)	
10 - 90%	
one CR2032 battery	
About 1000 tests	

Meter Dimension	98 mm x 46 mm x 17.5 mm		
Meter Weight	$53.0 \pm 5g$ with battery		
Monitor	LCD display		
Display Area	32 mm x 53 mm		
Meter Storage Conditions	-10 - 60°C (14 - 140°F)		
Sample			
Minimum Sample Volume	Refer to RIGHTEST GT100 Strip insert		
Hematocrit	— neier to night izst at 100 strip insert		
Test Strip Storage Conditions			

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Warranty

# **Customer Service**

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

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

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

Please complete and return the enclosed warranty card.

Different models have different specifications. Some of the models are not included with the warranty card.

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 concerns, please contact your Bionime authorized representative. We will make every effort to provide assistance and solutions for you.

### Description of used symbols

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

# Expected glucose values without diabetes

# Parts of Critical Component

### Expected glucose values without diabetes(1)

Status	Range
Fasting	70 - 99 mg/dL (3.9 - 5.5 mmol/L)

#### References

Diabetes Information - American Association for Clinical Chemistry (AACC) [Electronic Version]
 Retrieved June 15, 2010 from www.labtestsonline.org/understanding/analytes/glucose/test.html

### RIGHTEST Blood Glucose Meter, Test Strip, Control Solution

Manufacturer: Bionime Corporation

No. 100, Sec. 2, Daging St., South Dist., Taichung City 40242, Taiwan

Product complied with In Vitro Diagnostic Medical Device Directive 98/79/EC. (CE0197)

EC-Rep: Bionime GmbH, Tramstrasse 16, 9442 Berneck / Switzerland

E-mail: info@bionime.ch

### Lancing device

Manufacturer: Bionime Corporation

No. 100, Sec. 2, Daging St., South Dist., Taichung City 40242, Taiwan

Product complied with Medical Device Directive 93/42/EEC

EC-Rep: Bionime GmbH, Tramstrasse 16, 9442 Berneck / Switzerland

E-mail: info@bionime.ch

### Disposable Sterile Lancets

Manufacture information is as package printed.

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