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Preface

Thank you for selecting the *Rightest***™** Blood Glucose Monitoring System. Please read this manual thoroughly before you start testing. It provides all the information you need to use the product. You will get a correct test result by the following instruction of this manual.

It is quite important for you to monitor blood glucose regularly. A derived complication can thus be effectively reduced. Through the assistance of *Rightest***™** Blood Glucose Monitoring system, which provides considerate design and accurate results, your diabetes management can become more reliable and ease-to-use.

The **Rightest™** Blood Glucose Monitoring System is intended for *in vitro* diagnostic use (For self-testing & professional use) only (outside the body). The testing result is calibrated to be plasma equivalent for test with fresh capillary whole blood samples from the fingertip, palm and forearm. You may consult your healthcare professional for instructions on how to use the system correctly. Our Customer Support staff is available to assist you as well.

The **Rightest™** 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 Bionime authorized representative or call us by toll free at 1 (888) 481-8485 (Monday through

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Preface

Friday 8:00 AM to 5:00 PM PST). We will make every effort to provide assistance and solutions for you.

Healthcare professional should be contacted when the authorized representatives are not available.

Please forward your warranty card to Bionime authorized representative to activate your warranty coverage.

Precaution

- Before using the **Rightest™** System to test your blood glucose, please read all the instructions and practice 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[™]** Blood Glucose Meter GM550 can only be used with the **Rightest[™]** Blood Glucose Test Strips GS550. 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.
- The **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.
- The **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 Meter hasn't been used for arterial blood testing yet, so it is still not suitable to be used for arterial blood testing so far.
- Do the test at least 30 minutes after while entering another site with different ambient temperature.
- Pay attention to the environment protection when disposal of batteries.
- Using appliance in tropical and / or temperate climate.

- Not to be exposed dripping or splashing.
- The minimum blood sample size of **Rightest™** Glucose Monitoring System is 1.0µl :(•)

Sample Size Example	1.0µL	1.5µL	2.0µL	3.0µL	4.0µL
	•	•	٠	•	

Please take a minimum of 1.0μ I to do the test on glucose monitoring system. Blood sample size above 3.0μ I might contaminate the test strip port and the meter.

Blood sample size below 1.0μ I might cause inaccurate test result or might not start on meter measurement. In this case, repeat the test with a new test strip.



The meter will be set to mg/dL by default when sold in the United States. When your display shows " mmol/L " during setting or test, please contact customer service. Use of the wrong unit of measure may cause you to incorrect treatment.

Precaution

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The Rightest[™] Blood Glucose Monitoring System

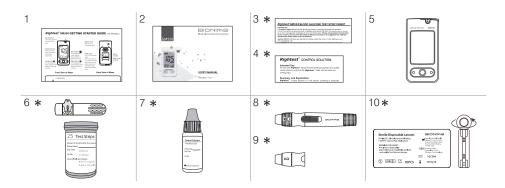
Package of System Kit

Your **Rightest™** Blood Glucose Monitoring System consists of several items. Please identify each item of your system and learn what they're called and how they're used.

These items are 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™ Blood Glucose Test Strip Package Insert *
- 4. Control Solution Package Insert *
- 5. Rightest™ Meter (with 2 CR2032 batteries installed)
- 6. *Rightest*[™] Test strips (0/10/25 pcs) *
- 7. Rightest™ Control Solution *
- 8. Rightest™ GD500 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.)

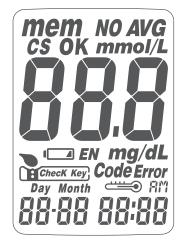
The *Rightest*[™] Blood Glucose Monitoring System



The Rightest[™] Meter The Rightest[™] Meter Test Strip Port Insert test strip here until you hear a click. 1:1 ° ° ° ° ° ° BIONIMO GM550 Battery Cover Slide cover to change Display Window Show your test result, messages batteries. Meter Battery and relative information. BIONIME Product name Main Button (🔘) Rightest" GM55 For operating the meter, please -> Backlight Battery check details in following sections. Meter Serial Number Manufacturer: Bionime Corporation Left Button (Right Button (\triangleright) \bowtie \triangleright For operating the meter, please For operating the meter, please check details in following sections. check details in following sections.

The Rightest[™] Meter

The Rightest[™] Meter

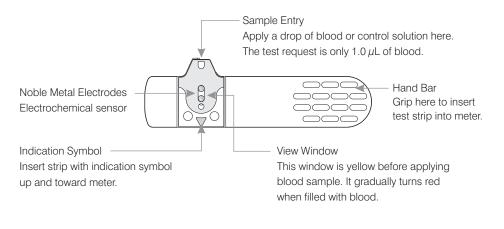


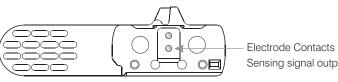
mem	Indicates a test result stored in memory		Tell when to apply the blood sample
NO AVG	Indicates a test result, not joining into the Average function of this meter		Test strip
AVG	Indicates with the average result	Code Error	Warns when using the strip, not suitable for your region test, or strip error
CS	Indicates a control solution test result	Day Month	Current date under time mode or Testing date under memory mode
mmol/L mg/dL	Unit of test result		Indicates if the environmental temperature is exceeded during testing
888	Test result	8M	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

The *Rightest*[™] Test Strip

The **Rightest™** Blood Glucose Meter GM550 can only be used with the **Rightest™** Blood Glucose Test Strips GS550.

The application of other Test Strips or control solutions can lead to incorrect results.





Sensing signal output terminals.

The *Rightest*[™] Test Strip

PRECAUTION

- \angle Re-cap the test strip vial immediately after taking out a test strip.
 - Do not reuse test strips.
 - Do not use expired test strips.
 - Record the date of opening a new test strip vial for the first time. Discard the vial of test strips after 3 month from opening.
 - Store the test strips in a cool (39-86°F or 4-30°C) and dry location (< 90% relative humidity). Do not expose to direct sunlight or heat.
 - For detailed information, please refer to the *Rightest*[™] Test Strips Package Insert.
 - If the **Rightest[™]** meters and strips are exposed to a high temperature difference, please wait 30 minutes before measurement.

Meter activation and Battery change

Your meter comes with two CR2032, 3volt, batteries installed. Two new batteries will provide power to perform about 1000 tests under normal use. You can press the main button or insert a strip to activate your meter.

4. The meter performs a self test.





setting the time, volume and date". Test results are still stored in the memory.

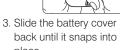
 \bigwedge - PRECAUTION - Please follow the local regulation and discard a used battery properly.

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

1. Turn the meter over. Press and push batteries cover to open.

6. Set the time and date when the batteries are replaced. See Chapter "Setting up your meter -

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



back until it snaps into place.

Meter activation and Battery Change

- NOTE
 - When meter backlight has no function, you cannot see the backlight, please change your backlight battery.
 - When the backlight battery is running out of power, your meter still works properly but without backlight function.

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

You can enter Setting Mode by below two ways.

1. Reload battery

After removing the battery, please press the main button for several times until no signal on screen, then follow the battery installation steps to load batteries. The meter will do self test. Press the main button to exit the self test and enter Setting Mode.

2. With Battery inserted

Press the main button first to turn on the meter. Then press and hold the main button for 7 seconds (the meter will first show backlight, then be turned off during this period, please keep pressing) until you hear a beep, indicating you have successfully entered Setting Mode. The display screen will show setting data.

// NOTE

- When you keep pressing the main button for 2 seconds, the display on screen will show backlight. Keep pressing the main button till display is off.
- When you keep pressing the main button for 4 seconds, the display on screen will turn off. Please don't care it. Keep pressing the main button till entering setting data.
- Quick press the main button allows you to change setting. However, if you want to return to the time mode, you need to go through all the settings first by pressing quickly the main button.

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

1. Year setting

With the year format blinking, press the Left or Right button to adjust it. Then press the Main button to confirm it. Meantime, it will shift to next digit for setting. Repeat the above action until the year setting is completed. Then it will move to Month setting.



2. Month setting

With the month blinking, press the Left or Right button until the current month appears. Then press the Main button to confirm it and move Day setting.

Day setting

With the day blinking, press the Left or Right button until the current day appears. Then press the Main button to confirm it and move to Time format setting.





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

4. Time format 12/24H selection

With the time format blinking, press the Left or Right button to adjust it. Then press the Main button to confirm it and move to hours setting.

5. Hour setting

With the hour blinking, press the Left or Right button until the current hour appears. Then press the Main button to confirm it and move to minute setting.

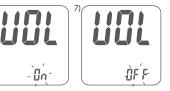
6. Minute setting

With the minute blinking, press the Left or Right button to adjust it. Then press the Main button to confirm it. Meantime, it will shift to next digit for setting. Repeat the above action until the minute setting is completed. Then it will move to volume setting.

7. Volume setting

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





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

8. Ending setting

After volume settings, 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".)

Day N	lonth 9	20:	пп

/ NOTE

- When you do not do any settings of meter for over 2 minutes, the meter will leave setting mode and power off automatically.

Turning On/Off the Meter

1. How to turn on the Meter Press the Main button or Insert a test strip.

- 2. Manual Power off If you want to turn off the meter, please keep pressing the Main button for 4 seconds.
- 3. Auto Power off

The meter will power off automatically if you don't operate it over 2 minutes.

1. How to turn on the Backlight Keep pressing the Main button for 2 seconds.

2. Manual Backlight off If you want to turn off the backlight, please keep pressing the Main button for another 2 seconds.

Turning on /off the Backlight

3. Auto Backlight off The meter backlight will turn off automatically if you don't operate it over 10 seconds.

Easily Handling the *Rightest*[™] Test Strip

How to easily handle the Rightest[™] test strip ?

Inserting the test strip:

1. Hold the test strip between thumb and middle finger with indication symbol " $\langle \!\!\!\!\!\!\!\!\!\rangle$ " facing up.

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

NOTE This is the easiest way to insert the strip.

3. Insert the test strip into test strip port until it snaps and firmly stops.

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Removing the test strip: 1. Hold the test strip same as insert it.



NOTE

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

Easily Handling the *Rightest*[™] Test Strip

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

Please follow the local regulation and discard used strip properly.

NOTE

Test Strip Port will not be contaminated by blood, if you follow the step correctly.



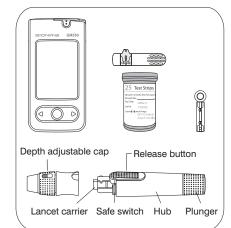




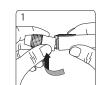
Getting Ready for Testing

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

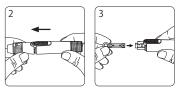
- Rightest™ Blood Glucose Meter
- Rightest[™] Blood Glucose Test Strips
- (Please check the expired date on the vial. Don't use the expired test strip)
- Lancing device
- Sterile lancet
- Alcohol swab (optional)

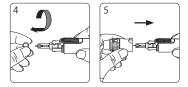


- Performing a Blood Test
- 1. Hold the adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side. When a gap appears between the cap and hub, pull them off in opposite directions.



- 2. Pull off the depth adjustable 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.





Performing a Blood Test

6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type " are " for soft or thin skin; " are " for average skin; " are " for thick or calloused skin.



1

- 7. Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, 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 strip from the vial. Re-cap the vial cap immediately.
- 10. Insert the strip into the strip port of the meter with the indication symbol facing up. The meter confirms the insertion of the strip with a beep 9if volume is turned on).

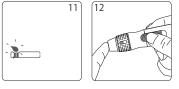
// NOTE

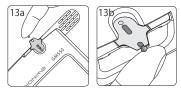
The meter will automatically detect Code number on strip. You don't have to check the Code number on the meter display and strip vial.

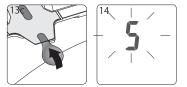


- 11. A blood drop symbol appears and is accompanied by a further beep (if volume is turned on). Now you can apply the blood sample within 2 minutes.
- 12. Place the lancing device against your fingertip and press the release button.
- 13. Touch and hold the drop to the edge of sample entry until you hear a " beep " (if volume is turned on) and the View Window is totally filled with blood. If the View Window is not totally filled with blood or the test does not start, please discard the test strip and repeat the test with a new test strip.
- 14. You will see the countdown mode on the screen. After 5 seconds, the test result appears.







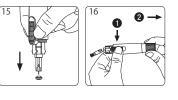


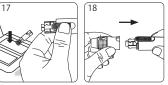
Performing a Blood Test

- 15. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.
- 16. Holding the release button in one hand I (see picture 16, step 1) and pulling on the plunger in the other hand (see picture 16, step 2) will 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.

PRECAUTION \wedge

- Do not apply your blood drop to the sample entry on the strip until you see the
- " 🝗 " appear. The meter is performing an internal test and will display " 🍗 " and " Error " if you apply blood too soon. Please repeat the test with a new test strip. - Record the date of opening a new test strip vial for the first time. Discard the vial of
- test strips after 3 months from opening.







Performing a Test in Order

Alternative site testing-palm or forearm blood sampling

- To do the alternative site testing, please install the clear cap for your lancing device. (For detailed information of lancing device, please check the instruction manual for the lancing device.)



- To increase the blood flow, please massage the puncture area of palm or forearm for a few seconds.
- Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
- Then press the release button.
- Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient.



Releasi

button

Performing a Test in Order

♠ PRECAUTION

- The glucose test results of blood samples taken from different sites might be varied in certain conditions such as your glucose is changing rapidly following a drink, a meal, an insulin dose or exercise. In these cases, only 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 the rapid change of glucose faster than palm or forearm samples.
- Consult with your healthcare professionals whenever you want to conduct a sampler from palm or forearm.
- As the blood flow taken from forearm is slower than fingertip or palm, we recommend using a special lancing device with Clear Cap for testing sites other than finger.
- If you use normal lancing device for palm or forearm the blood sample might be not enough for meter.
- Please periodically compare the test system to a laboratory test system known to be well maintained and monitored by a healthcare provider.

View Window Appearance





Insufficient blood sample

Enough blood sample

PRECAUTION

- Check the expiration date printed on the package every time you use the strip. Do not use expired test strips.

- Use each test strip immediately after taking it out from the vial.
- Do not reuse test strips.

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.

- Do the test at least 30 minutes after while entering another site with different ambient temperature.

Comprehending Test Results and Messages

Blood glucose test results are shown on the meter as mg/dL.

If your blood glucose result is unusually high or low, or if you question your testing results, repeat the test with a new test strip. You can also run a QUALITY CONTROL TEST with your *Rightest***[™]** Control Solutions to check your meter and 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 of this manual, contact your healthcare professional immediately.

Comprehending Test Results and Messages

The **Rightest™** Meter displays results between 20 and 600 mg/dL. If your test result is below 20 mg/dL, " *L o* " will appear on the screen. Please repeat your test again by a new strip.

If you still get " Lo~ " 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), " H_{I} " will appear on the screen. Please repeat your test again by a new strip. If you still get " H_{I} " result, you should immediately contact your healthcare professional.



20.09

mg/dL

Quality Control Test

Please use normal or high level control solutions tested with *Rightest***[™]** Blood Glucose Monitoring System under Control Solution Mode. If the test result is within the Control Solution Range printed on the strip vial label, the *Rightest***[™]** Blood Glucose Monitoring System passes 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 meter and test strips are working together properly.
- To confirm that you are following the correct procedure.
- To prepare for your initial blood glucose test.
- To check the test strips when you open a new vial of strips.
- To check your meter after it has been dropped, damaged or exposed to liquids.
- 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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NOTE

- If you want to purchase new normal or high level control solutions, please contact your authorized Bionime representative.

The possible reasons your Control Solution results are out of the range :

- Your Control Solution has expired or has been opened 3 months ago.
- Your test strip has expired.
- You left the cap of the tst strip vial opened or the control solution off for a long time.
- You didn't perform the test procedure correctly.
- Malfunction of the meter or the test strip.

If 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 outside the range still exist, do not use the Blood Glucose Monitoring System to test your blood glucose and contact your Bionime Customer service. Example of Expiration Date:

▲ PRECAUTION

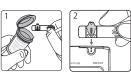
Each time you open a new bottle of Control Solution, write the discard date on the label. Control Solution is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first.

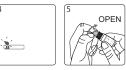


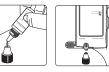
Quality Control Test

Performing a Quality Control Test

- 1. Take one test strip from vial and Re-cap the vial cap immediately.
- 2. Insert the test strip with view window, facing up, into test strip port.
- 3. While the blood drop symbol flashing, press and hold the main button for over 3 seconds until the " *CS* " symbol appears.
- 4. You will see blinking "> " symbol and " *Cs* " symbol symbol on the screen, prompting you to apply Control Solution.
- 5. Shake the bottle of Control Solution well before opening the cap. Then open the bottle and put the cap on the table.
- 6. Drip a drop of Control Solution on the top of the cap.
- 7. Gently touch sample entry of the strip with the Control Solution on the top of the cap.
- 8. When you hear a beep (if volume is turned on) please wait for the test result. The screen will display the countdown number from 5.









- 9. Tightly replace the cap on the Control Solution bottle.
- 10. The Control Solution result appears. Compare your Quality Control Test result to the Control Solution Range printed on the test strip vial label.



Performing a Quality Control Test

A PRECAUTION

- Your Control Solution results will not be calculated for average reading but still can be recalled. The Control Solution Test result will be shown with "*Cs* " symbol on the screen.
 Our suggestion environment for Control Solution Test is 59-104°F (15-40°C).
- Before " > " and " *Cs* " appears, please don't touch the Control Solution to the sample entry on strip because the meter is still in an internal check. If you do so, the meter will show " > " and " *Error* ". Accompanied by beeps (if volume is turned on)
- Don't drip the Control Solution to sample entry of the strip directly. The reagent on strip might be sucked into the bottle of Control Solution and might cause the degeneration of Control Solution. Doing this might contaminate the meter via the test strip port as well.



- Don't touch the tip of the control solution bottle. If you have touched it, please clean up with water.

Recalling Test Result and Average

The **Rightest**[™] GM550 Meter is able to store 500 test results with time and date automatically. If your meter has stored 500 results, which is the maximum memory of the meter, the newest test result will replace the oldest one. To recall your test memory, start the meter without test strip inserted.

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



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

2. To finish reviewing memory tests, press main button again, and you will enter the Average screen. By pressing the right button, the display shows "AVG" on the upper right corner of the display and the average value for the actual day. By sequencely pressing the right or left button you will get to the 1-days, 14-days, 30-days and 90-days average of your blood glucose values. You will see the number of the calculated days on the lower left corner and the number of the calculated readings on the lower right corner.

Recalling Test Result and Average



3. Non-Averaging set and canceled:

You may select the unwanted or doubtful test results, to exclude them from the average calculation, after your every test. After you finished your test in the test mode, you can exclude the unwanted result. Keep pressing the right butten until you see the symbol "NO AVG" in the top right cornet of the screen. By keeping the right button pressed and pressing the main button simultaneously to confirm the value as "Non average". Now this value is flaqued by the symbol "NO AVG" in the up per right corner of the screen.

If you want to cancel this non-averaging setting, you have to stay in the test mode. First keep pressing the right button until the "NO AVG" symbol changes to "AVG" in the up per right corner of the screen. To confirm this original status you again simultaneously press the main button to confirm the "AVG" status. Now 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 right and have enough time intervals on the basis of current inquiry time, to make sure that the average test results will show. Use the 14-day average for example; if your current inquiry time is 2008/1/30, then that 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 figure.
- The Non-averaging/re-averaging function only works in the test mode and when you get the value. In the MEM mode, you can not perform this action.

Recalling Test Result and Average

- 4. Quick Searching: If you want to see all values automatically displayed in sequence, first enter the memory mode. Then keep pressing the right or left button for 2 seconds. (right button is for searching the tests the latest value to the oldest one; by using the left button you can scroll from the oldest to the latest one). Anytime you want to stop just release the pressed button. It will stop and display the current displayed value. You can use this way to find a particular reading you want to check.
- 5. Reading right after test: If you just finish the 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.

A PRECAUTION

You have to set the time and date to activate the average function.
 The "L₀", " H_I " results, the Control Solution results and the test result made out of normal temperature range <50°F (10°C), >104°F (40°C) are not calculated in the average.

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Caring for Your Meter

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 meter is dropped or damaged, perform a quality control test with the control solution before doing a blood glucose test.

Cleaning Meter

Clean the outside of the meter with a damp cloth and mild soap/detergent. Keep the test strip port from getting 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 up immediately. Do not use any thing wet to clean it. Perform a quality control test to ensure the system is working properly.

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 batteries to check if the meter works properly.
- Er3 Signal transmission is disrupted, repeat the test.
- **Er4** Applied blood volume is insufficient, please repeat the test with a new test strip.

Above, if error screen still appears contact your local Bionime Customer Service.

Er 1 Er 2

Er3 Er4

Battery Error

Error messages and Trouble shooting

2. The " I and " *Error* " symbols are blinking when the battery is too low. Meter can not do the strip test. Please change the meter battery immediately.



// NOTE

- When meter backlight has no function, you cannot see the backlight, please change your backlight battery.
- When the backlight battery is runnign out of power, your meter still works properly but without backlight function.

Error messages and Trouble shooting

Temperature Error

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



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- 2. When you move from the area with temperature outside the operating range of test strip to another area with temperature inside operating range of test strip, please wait for 30 minutes before you do the test.
- 3. When the temperature is below 32°F (0°C) or over 122°F (50°C), Meter can not do the test and the "*Error* " symbol will blink with thermograph symbol displaying on screen in this condition. Please move the meter to environment with temperature between 50~104°F (10~40°C) and repeat the test after 30 minutes.



Sampling Error

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



Meter Malfunction

If the meter can not be started, please follow the steps below:

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

Error messages and Trouble shooting

The meter should be working normally after finishing above steps. If not, please contact your local Bionime customer service.

Limitations

- Store the strips in the original capped vial at temperatures between 39°F to 86°F (4°C to 30°C) 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 about 10000 feet (3048 meters) above sea level.
- Hematocrit below 30% may cause higher results, and hematocrit above 60% may cause lower results.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Rightest™ Blood Glucose Monitoring System has not been validated for use on neonates.
- The glucose test may be interfered under abnormal concentration of Uric acid \geqq 10.0 mg/dL

// NOTE

Acetaminophen, Ascorbic acid (Vitamin C), Dopamine, Ibuprofen, L-Dopa, Methyldopa, Salicylic Acid, Tetracycline, Tolbutamide, Bilirubin-conjugated, Cholesterol, Creatinine, Triglyceride, Maltose, Xylose, Galactose and Lactose (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate results.

Measurement Technology	Oxidase Electrochemical Sensor
Measurement Calibration	Plasma
Sample	Capillary whole blood
Minimum Sample Volume	1.0 microliters
Measuring Range	20-600 mg/dL
Test Time	5 seconds
Memory Capacity	500 blood glucose test results with date and time
Power Saving	Turn off automatically 2 minutes after last user action Press the " \bigcirc " button for 4 seconds.
Operating Temperature	$50 \sim 104^{\circ}\text{F} (10 \sim 40^{\circ}\text{C})$
Operating Relative Humidity	10 - 90%

Specification

Specification

Hematocrit	30-60%
Power Supply	2 CR2032 batteries
Meter Battery Life	About 1000 tests
Meter Dimension	90.6 mm x 46 mm x 16.5 mm
Meter Weight	53.0 \pm 5g with batteries
Monitor	LCD display
Display Area	47 mm x 33.5 mm
Meter Storage Conditions	14 ~ 140°F (-10 ~ 60°C)
Test Strip Storage Conditions	$39 \sim 86^\circ$ F (4 $\sim 30^\circ$ C), < 90% relative humidity

Bionime Corporation warrants that your *Rightest***™** Meter 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™** Meter that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the original purchaser of the meter.

Please complete and return the enclosed warranty card to Bionime authorized representative.

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

Warranty

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 concerns, please contact your Bionime authorized representative or call us by toll free at 1 (888) 481-8485 (Monday through Friday 8:00 AM to 5:00 PM PST). We will make every effort to provide assistance and solutions for you.

Expected glucose values without diabetes

			(1	١
Expected glucose	values	without	diabetes	′

Status	Range (mg/dL)
Fasting	70 – 99

References

1) Diabetes Information - American Association for Clinical Chemistry (AACC) (Electronic Version) Retrieved February 08, 2006 from www.labtestsonline.org/understanding/analytes/glucose/test.html

Parts of Critical Component

Blood Glucose Meter, Test Strip and Control Solution

Manufacturer : Bionime Corporation Product complied 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 Product complied with Medical Device Directive 93/42/EC EC-Rep: Bionime GmbH, Tramstrasse 16, 9442 Berneck / Switzerland

Disposable Sterile Lancets

Manufacturer : SteriLance Medical (Suzhou) Inc. Product complied with Medical Device Directive 93/42/EEC. (CE0197) EC-Rep: Emergo Europe; Molenstraat 15, 2513 BH The Hague, The Netherlands

Address:		
Home Phone:	Work Phone	
Doctor:	Doctor's Phone	
Pharmacy:	Pharmacy Phone	
Insulin/Pills:	Log book date From:	To:
In case of emergency contact:		

Log Book

Log Book

	DATE	Μ	Т	W	Т	F	S	S
	Blood							
Breakfast	Glucose							
	Insulin/							
	Medication							
	Blood							
Lunch	Glucose							
Lunch	Insulin/							
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	Medication							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
Dural (ant	Blood Glucose							
Breakfast	Insulin/ Medication							
	Blood Glucose							
Lunch	Insulin/ Medication							
Dinner	Blood Glucose							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
	Blood							
Breakfast	Glucose							
Dicariasi	Insulin/							
	Medication							
	Blood							
Lunch	Glucose							
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Dinner	Glucose							
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Bedtime	Glucose							
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	DATE	Μ	Т	W	Т	F	S	S
Breakfast	Blood Glucose							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
Dural (ant	Blood Glucose							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
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Breakfast	Insulin/ Medication							
	Blood Glucose							
Lunch	Insulin/ Medication							
Dinner	Blood Glucose							
Dinner	Insulin/ Medication							
Bedtime	Blood Glucose							
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	DATE	Μ	Т	W	Т	F	S	S
Breakfast	Blood Glucose							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
Dural (ant	Blood Glucose							
Breakfast	Insulin/ Medication							
	Blood Glucose							
Lunch	Insulin/ Medication							
Dinner	Blood Glucose							
Dinner	Insulin/ Medication							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
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Breakfast	Insulin/ Medication							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
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	Medication							
	Blood							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
	Blood							
Breakfast	Glucose							
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Log Book

	DATE	Μ	Т	W	Т	F	S	S
	Blood Glucose							
Breakfast	Insulin/ Medication							
Lunch	Blood Glucose							
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Dinner	Blood Glucose							
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	DATE	Μ	Т	W	Т	F	S	S
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Other	Blood Glucose							
Other	Insulin/ Medication							
Comments								

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Warranty Card

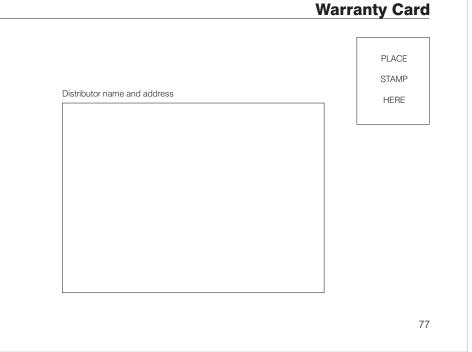
Name	Tel	Distributor name and address
Address		
Serial No	Model	
Date of purchase		

(Please present this card for replacement purpose)

×

Limited warranty:

- Bionime corp warrants the original purchaser only, that the **Rightest**[™] Monitor shall be free of any defects in materials or workmanship and, provided it is not modified, altered or misused, will perform in accordance with specifications for a period of five (5) years from the original date of purchase.
- 2. Bionime guarantees the performance of the **Rightest™** Monitor only if used as directed and provided that the failure to perform or misperformance of the **Rightest™** Monitor has not been caused in whole or in part by the use of test strips that are not **Rightest™** Test Strips manufactured by Bionime. Use only **Rightest™** Test Strips in your **Rightest™** Monitor.
- 3. The sole obligation of Bionime under this warranty shall be to replace any defective **Rightest™** Monitor. No other warranties, express or implied, are made. Bionime shall not be responsible for any incidental or consequential damages.
- 4. Activation of this warranty shall be conditioned upon completion and return of the warranty registration card to your local authorized Bionime distributor.
- 5. You must contact your local authorized Bionime distributor for assistance and/or instructions for obtaining a replacement monitor.



Rightest™ Blood Glucose Monitoring Syste Name	Male/Female	Date of Birth	
Āddress			
City		Country	Postal Code
Phone Number			
Healthcare Professional Who Recommended	City	Country	
Store/Pharmacy Name Where Purchased	City	Country	
Date of Purchase	Model No:	Serial/Lot No.	
Do you have Type I Type II G Have you owned a blood glucose monitor b Which brand/s were you most recently using			
Will the Rightest™ meter be your primary m		1	
How often do you test your blood glucose ? Do you use insulin ? Yes No How did you hear about the Rightest [™] Bloo	Oral medication ?	week es No	
Thank you for answering these questions ar Blood Rightest™ Glucose Monitoring Syste	, ,		BIONIME
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EMERGENCY CARD Blood Glucose Monitoring System	BIONIME
User Name:	
User Phone No.:	
• Blood Type:	I am a diabetes patient. If you
Doctor/Hospital:	find me in a coma or stupor, please take me to the hospital on left side. Or call :
* Please fill this card and carry with you	
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Emergency Card

Warranty Card