BIONIME

Blood Glucose Monitoring System
Instructions for Use
Rightest® GM100

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 manufactured by Bionime Corporation and supported by its authorized representative. If you have any questions or concerns, please contact your authorized distributor, in the USA and Canada please contact Bionime USA toll-free at 1 (888) 481-8485 (Monday through Friday 8:00 AM to 5:00 PM PST).

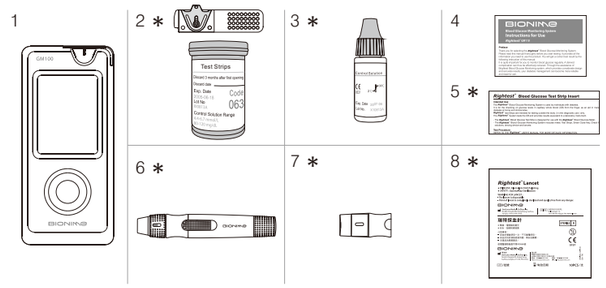
1. Intended Use

The ***Rightest®*** Blood Glucose Monitoring System is intended for **In Vitro** diagnostic use (for self-testing) only (outside the body) and **coding is not required**. The testing result is calibrated to be plasma equivalent for test with fresh capillary whole blood samples from the fingertip, palm or 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.

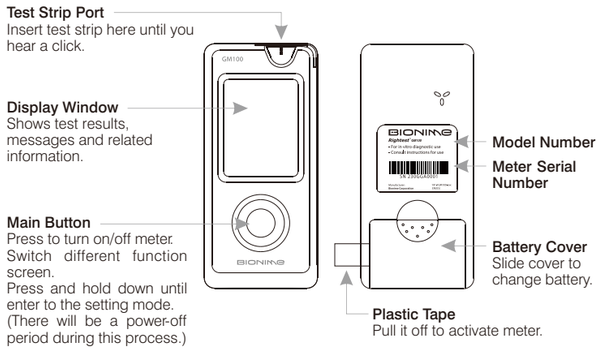
2. Package of Meter Kit

1. ***Rightest®*** Meter
2. ***Rightest®*** Test Strips (0/10/25 pcs) *
3. ***Rightest®*** Control Solutions (Normal Level) *
4. ***Rightest®*** Instructions for Use
5. ***Rightest®*** Blood Glucose Test Strip Package Insert *
6. ***Rightest®*** Lancing Device *
7. Clear Cap *
8. Disposable Sterile Lancets (10pcs) *
9. Instruction for the lancing device *
10. Log Book
11. Warranty Card + Emergency
12. CR2032 Battery (Inserted into the meter)
13. Carrying Case *

(Different packages have different bundled items. Some of packages might not include * items.)



3. The *Rightest®* Meter



4. Precautions

- Before using the ***Rightest®*** System to test your blood glucose, please read all the instructions and practice performing a test including a quality control test.
- Please do the quality control test regularly to make sure the test results are accurate.
- The ***Rightest® GM100*** Blood Glucose Meter can only be used with the ***Rightest® GS100*** 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 produce inaccurate results.
- 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 on neonates.
- This meter can be only tested with capillary whole blood. Please don't test with arterial blood.
- Do the test at least 30 minutes after moving into a different location with significant change in temperature.
- Dispose of used batteries properly.
- Please note the meter kit contains small parts like test strips which could result in a choking hazard for children.
- Prevent water from entering the meter. Never immerse the meter or hold it under running water.
- The minimum blood sample size for testing is 1.4μL :(●)

Sample Size Example

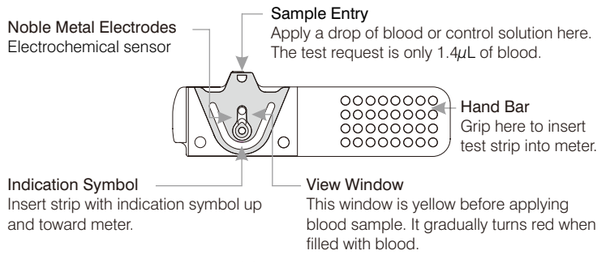
1.0μL	1.4μL	2.0μL	3.0μL	4.0μL
●	●	●	●	●

Please take a minimum of 1.4μl to do the test on glucose monitoring system.
Blood sample size above 4.0μL might contaminate the test strip port.
Blood sample size below 1.4μL might cause inaccurate test result or might not start on meter measurement. In this case, repeat the test with a new test strip.

⚠ PRECAUTION
The unit of measure must be fixed to " mg/dL ". 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.

5. The *Rightest®* Test Strip (GS100 Test Strip)

Rightest® GM100 is designed to use with ***GS100*** strip only. Please note that misuse of other strips might cause unexpected damage or produce inaccurate test results.

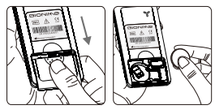


⚠ PRECAUTION
- Re-cap the test strip vial immediately after removing a test strip.
- Do not reuse test strips.
- Do not use expired test strips.
- Record the date of opening a new strip vial for the first time. Discard the vial of strips after 3 month from opening.
- Store the test strips in a cool and dry location. Do not expose to direct sunlight or heat.
- For detailed information, please refer to the ***Rightest® GS100*** Test Strip Package Insert.

6. Battery Installation

Your meter comes with one CR2032, 3volt, battery installed. One new battery will provide power to perform about 1000 tests under normal use. Before using it, please pull off the plastic tape and press the main button to activate the meter. The low battery symbol " " will keep appearing on your display if your battery runs low. Please keep spares on hand and replace the battery soon when a battery symbol appears.

1. 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 meter performs a self-test and all symbols on the display will blink.
5. Press any button to exit the self-test and enter Setting Mode.
6. Set the time and date when the batteries are replaced. See Setting the Date, Time and Unit section. Prior test results are still stored in the memory.

⚠ PRECAUTION
- Danger of explosion might happen if the battery is incorrectly replaced.
- Please follow the local regulation and discard a used battery properly.

7. Setting Up Your Meter-Setting the Date, Time

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 battery. The meter will do self test. Press the main button to close the 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 5 seconds (the meter will 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.

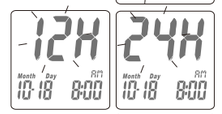
NOTE
- When you keep pressing the main button for 2 seconds, the display on screen will turn off. Please don't care it. Keep pressing the main button till entering setting data.
- Quick press the main button allows you to change setting while hold it for 2 seconds will confirm the setting. However, if you press and hold the main button over 5 seconds it will escape from setting mode and return to time screen.

1. Year setting
With the year format blinking, press the main button to adjust it. Then hold the same button for 2 seconds 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 main button until the current month appears. Then hold the same button for 2 seconds to confirm it and move to day setting.

3. Day setting
With the day blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it. Meantime, it will shift to next digit for setting. Repeat the above action until the day setting is completed. Then it will move to time format setting.

4. Time format 12/24H selection
With the time format blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it and move to hours setting.



5. Hour setting
With the hour blinking, press the main button until the current hour appears. Then hold the same button for 2 seconds to confirm it and move to minute setting.

6. Minute setting
With the minute blinking, press the main button to adjust it. Then hold the same button for 2 seconds 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 average-day setting.

7. Ending setting
After confirm the Average-day setting, you'll hear a sound of " beep ". All the settings are saved and completed and will return to time screen.

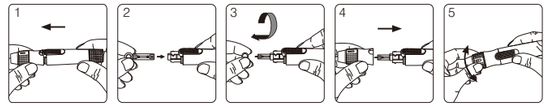
NOTE
- When you do not do any settings of meter for over 2 minutes, the meter will leave setting mode and power off automatically.
- Any time you would like to escape from the setting mode, please press and hold the main button for over 5 seconds. Meantime, all the current settings will be saved.

Turning on /off the Meter
1. Auto Power off
The meter will power off automatically if you don't operate it over 2 minutes.
2. Manual Power off
If you want to turn off the meter, please keep pressing the main button for 2 seconds.
3. How to turn on the Power
1) Press the main button.
2) Insert one piece of test strip.

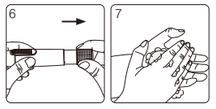
8. Performing a Blood Test

The ***Rightest®*** blood glucose monitoring system gives you an opportunity to obtain blood samples from fingertip, palm or forearm.

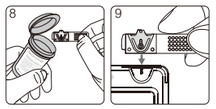
1. Pull off the depth adjustable cap.
2. Insert a new disposable lancet firmly into lancet carrier.
3. Twist off and set aside the protective cover of the disposable lancet.
4. Replace the depth adjustable cap.
5. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type " " for soft or thin skin; " " for average skin; " " for thick or calloused skin.



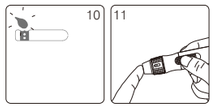
6. Hold the hub in one hand and pull on the plunger in the other hand. The device is now loaded. Release the plunger, it will automatically move back to its original position near the hub.
7. Wash your hands with warm soapy water and dry thoroughly.



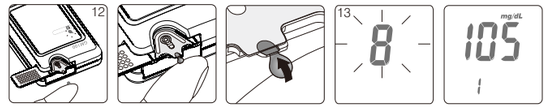
8. Take one strip from the vial. Re-cap the vial cap immediately.
9. Insert the strip into the strip port on meter with the indication symbol facing up.



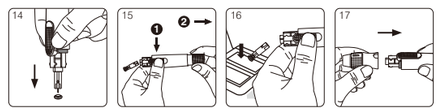
10. While the blood drop symbol flashing, you are ready to apply the blood sample.
11. Place the lancing device against the pad of your fingertip and press the release button. The best puncture sites are on the middle or ring fingers. Press the release button.



12. Touch and hold the drop to the edge of sample entry until you hear a " beep " 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.
13. You will see the countdown mode on the screen. After 8 seconds, the test result appears.



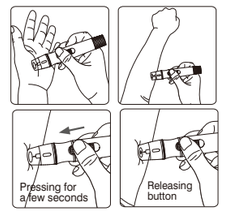
14. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.
15. Hold the release button in one hand and pull on the plunger in the other hand. This will safely eject the used disposable lancet.
16. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
17. Replace the depth adjustable cap after finishing the test.



⚠ PRECAUTION
- For detailed information of installing clear Cap of lancing device, please check the instruction manual for the lancing device.
- Be careful to load the lancing device to avoid being pierced by the needle.
- Do not touch 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. Then you will waste a test strip.

Alternative site testing-palm or forearm blood sampling

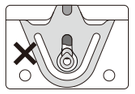
1. Using the clear cap, follow the above listed steps 1 through 4.
2. Massage the puncture area of palm or forearm for a few seconds.
3. Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
4. Then press the release button.
5. Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient.
(Refer to Instruction manual for the lancing device)

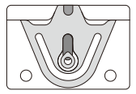


⚠ PRECAUTION
- The glucose test results of blood samples taken from different sites might be varied in certain conditions such as your glucose is changing rapidly following a drink, a meal, an insulin dose or exercise. In these cases, only fingertip should be used.
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (Low blood glucose).
- Fingertip samples can show the rapid change of glucose faster than palm or forearm samples.
- 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.

9. View window appearance

Make sure your blood sample covers the whole area of the View Window to get an accurate test result. Insufficient blood sample will cause inaccurate test result. Repeat the test with a new test strip.


Insufficient blood sample


Enough blood sample

⚠ PRECAUTION
- Check the expiration date printed on the package every time you use a strip. Do not use expired test strips.
- Use each test strip immediately after removing from the vial.
- Do not reuse test strips.
- Do the test at least 30 minutes after moving into a different location with significant change in temperature.
- Place the blood drop only on the sample entry of the strip.
- Please don't drip or inject the blood sample directly by syringe to the entry port of test strip. Doing this might contaminate the meter or cause damage and is strongly not recommended.

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 ***Rightest®*** Control Solutions to check your meter and 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 steps of this instruction, contact your healthcare professional immediately.

The ***Rightest®*** Meter displays results between 20 and 600 mg/dL. If your test result is below 20 mg/dL, " Lo " 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 detection range 600 mg/dL, " Hi " will appear on the screen. Please repeat your test again by a new strip. If you still get " Hi " result, you should immediately contact your healthcare professional.

10. Recalling Test Result & Average

The GM100 meter is able to store 150 test results with time and date automatically. If your meter has stored 150 results, which is the maximum memory of the meter, the newest test result will replace the oldest one.
To recall your test memory, start with the meter without test strip inserted.

1. Press the main button to switch to screen to memory function, you will see "**AVG**" symbol on the up left corner of the screen. The display sequence will be 1-day, 7-day,14-day, 30-day, 90-day average, and then memory 1 reading, memory 2 reading,…until memory 150 reading which will show "**MEM**" on the up right corner of the screen.
2. Under average screen, the number on the down right corner of the screen means how many days of readings have been calculated as the average while the number on the down left corner of the screen means how many readings have been counted in. Under memory screen, it will show the sequence number on the down left corner and then display date and time.
3. Quick Searching: you could also quick press the main button twice, and then it will automatically display the average and memory by sequence. Anytime you want to stop it, you could just press the main button again. It will stop and display the reading right at the moment you press the main button. You could just apply the way above; especially when you find a particular reading you want to check with.
4. Reading right after test: if you just finish the test and press the main button to review. The display sequence will be the latest reading, 1-day, 7-day, 14-day, 30-day, 90-day average, and the memory 2 reading until the oldest one (memory 150 reading).

⚠ PRECAUTION
- You have to set the time and date to activate the average function.

11. Quality Control Test

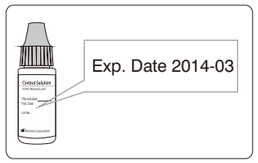
To make sure that your blood glucose monitoring system works properly, you must perform quality control testing.

1. Entering Control Solution Mode
Insert the strip into the strip port on meter. While the blood drop symbol flashing, press and hold the main button for over 5 seconds. Then you will see " CS " symbol blinking on the screen indicating that you've successfully entered the Control Solution Mode.

2. Control Solution Test
A control solution test ensures that the meter and test strips are functioning properly together. Once you enter control solution mode, you are ready to perform a control solution test.

When should perform a Quality Control Test ?
Before doing a blood glucose test with your meter for the first time.
When you open and start using a new test strip vial.
When your meter is dropped or splashed with liquids.
Whenever you think your test result does not consistent with the way you feel.
Whenever you want to check if your system is working properly or not.
Whenever you want to practice testing and check correct procedure.

⚠ 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.



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

Understanding Control Test Results
Your control solution test results should fall within the control solution range.
That means your ***Rightest®*** System is working correctly.

Control Solution Range
79-107 mg/dL
4.4-5.9 mmol/L

Example of control solution range printed on your test **strip vial label**.

If control solution test results are out of control solution range, your ***Rightest®*** 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 ***Rightest®*** System to test your blood glucose. And contact Bionime authorized distributor or Bionime Customer Service.

The reason your control solution results are out of the range :
- Your Control Solution has expired or after 3 months since opened.
- Your test strip has expired.
- You leave the cap off the vial of test strips or Control Solution for a long time.
- You didn't perform the test procedure correctly.
- Malfunction of the meter.

12. Performing a Quality Control Test

Use with Control Solution

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 5 seconds until the " CS " symbol appears.
4. You will see blinking " " symbol and " CS " 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 cap and put it on the table.

6. Drop 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, leave the meter on the table while waiting for the test result.
The screen will display the countdown.
9. Tightly replace the cap on the Control Solution bottle.

10. The control solution result appears. Compare your control test result to the range printed on the test strip vial label.

⚠ PRECAUTION
- Your quality control test result by control solution test 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.
- 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 " Error " and " ".
- 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 Control Solution. If the control solution has touched you, wash the area with water.

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 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.

13. Error Message and Trouble Shooting

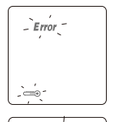
Er1 - The inserted strip has been used or damaged. Please use a new test strip from vial.

Er2 - Meter has malfunctioned. Do the quality control test or reinstall the battery to see if the meter works properly. If error screen still appears, contact Bionime Customer Service.

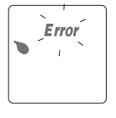
Er3 - Signal transmission is disrupted, repeat the test.

Battery Error
1. The " " symbol is blinking when the battery power is low. Please change battery as soon as you can. You can still do the test.
2. The " " and " ***Error*** " symbols are blinking when the battery is too low. Meter can not do the strip test. Please change the battery immediately.
3. After changing the battery, perform a quality control test.

Temperature Error
In order to get accurate test result, perform testing between 10~40℃ (50~104℉).
1. When the ambient temperature is 0~9℃ (32~48℉) or 41~50℃ (106~122℉) the " " warning symbol will be blinking, you still can do the test but the test result is only for reference because the test result under these ranges of temperature might not be correct. Repeat the test at an area with temperature between operating range. (10~40℃ or 50~104℉)
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 0℃ (32℉) or over 50℃ (122℉), Meter can not do the test and the " ***Error*** " symbol will blink in this condition. Please move the meter to environment with temperature between 10~40℃ (50~104℉) and repeat the test after 30 minutes.



Sampling Error
Before " " appears. Please don't apply the blood to the entry of the strip because the meter is still doing internal check. If you do so, the meter will show " ***Error*** " and " ". Please remove the strip and insert a new one to do the test again.



Meter Malfunction
If you find the meter can't be switched on, please follow the steps below for quick inspection.
1. Open the battery cover, take out the battery.
2. Wait for 5 minutes and reload the new battery.

The meter should be work normally after finishing above steps. If not, please contact Bionime authorized distributor or Customer Service Center.

Specification

Measurement Technology	Oxidase Electrochemical Sensor
Sample	Capillary whole blood
Minimum Sample Volume	1.4 microliter
Measuring Range	20-600 mg/dL
Test Time	8 seconds
Memory Capacity	150 blood glucose test results with date and time
Power Saving	Turn off automatically after 2 minutes no use Press the " ◎ " button for 2 seconds.
Operating Temperature	10 ~ 40℃ (50 ~ 104℉)
Operating Relative Humidity	10 - 90%
Hematocrit	30 - 55%
Power Supply	one CR2032 battery
Battery Life	About 1000 tests
Meter Dimension	95.0 mm x 43.8 mm x 13.0 mm
Meter Weight	43.0 g with batteries
Monitor	LCD display
Display Area	39.0 mm x 38.0 mm
Meter Storage Conditions	-10 ~ 60℃ (14 ~ 140℉)
Test Strip Storage Conditions	4 ~ 30℃ (39 ~ 86℉), < 90% relative humidity

Limitations
- ***Rightest®*** Blood Glucose Test Strips are designed for useing with capillary whole blood samples. Do not use serum or plasma samples.
- Inaccurate test results may be obtained at high altitude more than about 10,000 feet (3048 meters) above sea level.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- ***Rightest®*** Blood Glucose Monitoring has not been validated for use on neonates.
- The glucose test may be interfered under abnormal concentration of
Uric acid≧9.0 mg/dL Cholesterol≧500 mg/dL

NOTE
Acetaminophen, Ascorbic acid (Vitamin C), Dopamine, Ibuprofen, Salicylic Acid, Tetracycline, Bilirubin-conjugated, Creatinine, Triglyceride, Maltose, Xylose, Galactose and Lactose (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results (the bias of interference is below 10%). However, abnormally high concentrations of these interferents in blood may cause inaccurate results.
In addition when blood glucose concentration drops below 70mg/dL, the bias of interference with the presence of L-dopa and methyldopa may be slightly higher than 10%.

Customer Service
Bionime is committed to providing you with the highest quality of Customer Service. If you have any questions, please contact your authorized distributor, in the USA and Canada please contact Bionime USA toll-free at 1 (888) 481-8485 (Monday through Friday 8:00 AM to 5:00 PM PST). Or e-mail at info@bionime.com
For 24 hour assistance please contact your healthcare provider. Review the instructions to ensure that the correct testing procedure has been followed.

Warranty
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.

Expected values for normal glucose level (1)

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, Control Solution and Lancing Device
Manufacturer: Bionime Corp.
Product complied with In Vitro Diagnostic Medical Device Directive 98/79/EC. (CE0197)
EU Rep: Klaus Ellensohn, Tschuetschgasse 8, 6833 Klaus / Vlbg., Austria

Disposable Sterile Lancets
Manufacturer: SteriLance Medical (SuZhou) Inc.
EU Rep: EMERGO EUROPE, Molenstraat 15, 2513 BH The Hague, The Netherlands.
(CE0197)

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