GM300

BIONIME

Blood Glucose Monitoring System

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USER'S MANUAL

Rightest™ GM300

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. 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

Preface

your Bionime authorized representative or email to rightest@bionime.com.
We will make every effort to provide assistance and solutions for you.

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 46.)

- Please do the quality control test regularly to make sure the test results are accurate .

- The ***Rightest***™ Blood Glucose Meter can only be used with the ***Rightest***™ 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.

- 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 by finger stick.

- 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.

Precaution

- ***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.

- Perform blood glucose testing between10～40°C(50～104°F).

- Keep your meter and test strip free of dust, water or any other liquid.

- The minimum blood sample size of ***Rightest***™ Glucose Monitoring System is 1.4μl :(●)

We suggest you to take 1.4～2.5μl to do the test on glucose monitoring system. Blood sample size above 4.0μl might contaminate the Smart Code Key.
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.

Table of Contents

Table of Contents

Package of Meter 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.

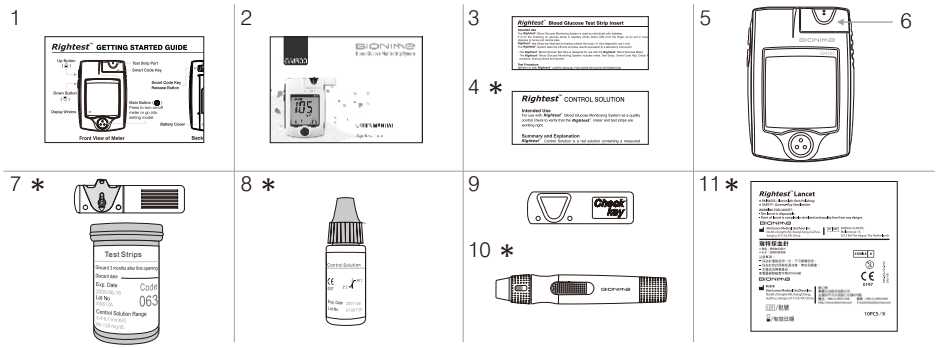
These items are included in your ***Rightest***™ Blood Glucose Monitoring System :

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
6. ***Rightest***™ Dummy Code Key (for the package without strip) or Smart Code Key pre-installed (for the package with strip)
7. ***Rightest***™ Test strips (0/10/25 pcs) ∗
8. ***Rightest***™ Control Solution ∗
9. ***Rightest***™ Check Key
10. Lancing Device ∗
11. Disposable Sterile Lancets (10 pcs) ∗
12. Carrying Case (not shown) ∗

The *Rightest*™ Blood Glucose Monitoring System

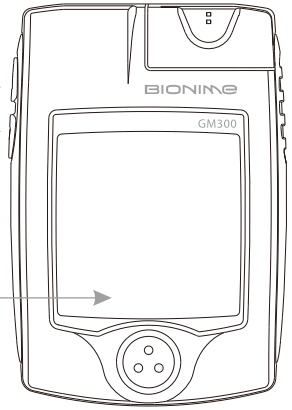
13. Two AAA Batteries (not shown) ∗
14. Instruction for the lancing device (not shown) ∗

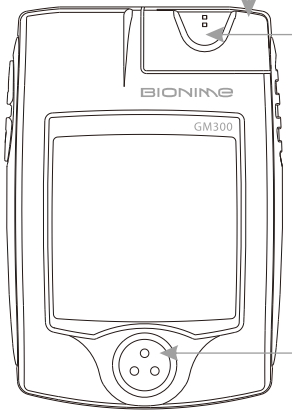
(∗ Different packages have different bundled items. Some of packages might not include ∗ items.)



Up Button (△)
Down Button (▽)
Press to review stored test value in memory and average.
Select the function mode.

Display Window
Show your test result, messages and relative information.



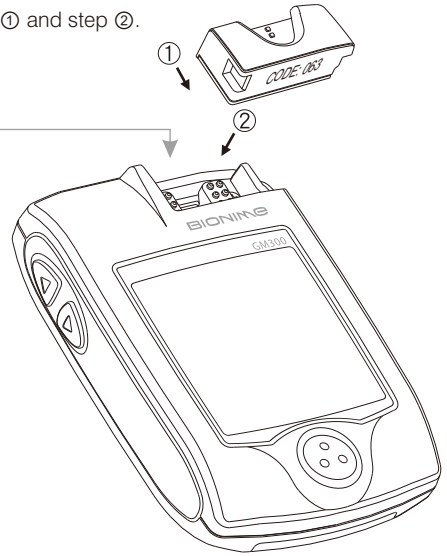


Smart Code Key
For calibrating your meter. New one comes with every box of test strips. (Refer to page 17)
Contain the test strip port for inserting strip.
Assemble Smart Code Key into code key base.

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

Main Button (⊙)
Press to turn on/off meter.
Switch different function screen.
Press and hold down until enter to the setting mode.
(There will be a power-off period during this process.)

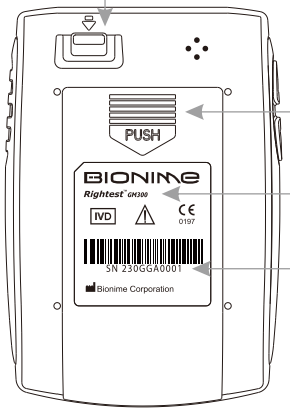
Please follow the step ① and step ②.



Smart Code Key Base

Assemble Smart Code Key here

The *Rightest*™ Meter



Smart Code Key Release Button

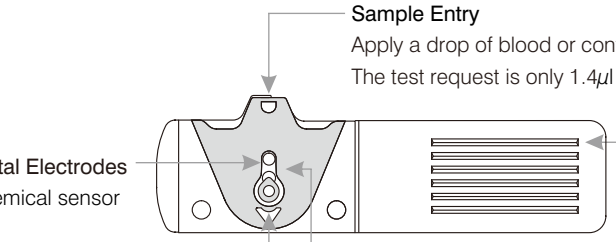
Press down to release and switch the Smart Code Key.

Battery Cover

Slide cover to change batteries.

Model Number

Meter Serial Number



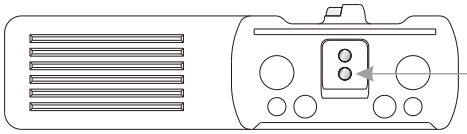
Sample Entry
Apply a drop of blood or control solution here.
The test request is only 1.4μl of blood.

Noble Metal Electrodes
Electrochemical sensor

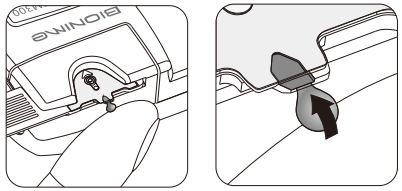
Hand Bar
Where you can easily hand the strip to do the test.

Indication Symbol
Insert strip with indication symbol up and toward meter.

View Window
This window is originally yellow before applying blood sample. It will gradually become red after filled with blood drop.



Electrode Contacts
Sensing signal output terminals.

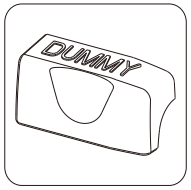


The blood sample will be drawn into sample entry by capillarity automatically.

⚠ PRECAUTION
- Re-cap the vial cap immediately and close tightly after taking test strip out from the vial.
- Do not reuse test strips.
- Do not use expired test strips.
- Check the discard date you wrote on the vial label every time you use the strip.
- Store the test strip in a cool, dry place and avoid the exposure of direct sunlight and heat.
- For detailed information, please refer to the ***Rightest***™ Test Strip Package Insert.

Dummy Code Key

For package without test strip, not for package with test strip



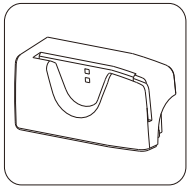
A Dummy Code Key will be installed on the new ***Rightest***™ meter in the package without test strip. This Dummy Code Key is not intended to be used for testing.

When you open a new box of test strips, you have to replace the Dummy Code Key by new Smart Code Key in the box.

Do not throw away this Dummy Code Key. It can be used to keep the Smart Code Key Base clean while the Smart Code Key is not installed.

The *Rightest*™ Smart Code Key

What is Smart Code Key ?



Smart Code Key is designed to calibrate your meter to make each lot of strips have the same performance. Each new box of strips contains its new Smart Code Key. The Smart Code Key stores calibrated information that your meter needs to give you accurate blood glucose results. You must change your Smart Code Key with each new box of ***Rightest***™ Test Strips.

Smart Code Key also contains the test strip port. Although you can still review the memory and other settings, it's necessary to assemble the Smart Code Key into meter before actually starting your test. This procedure makes sure you do calibrate the meter and assures you of getting accurate test results.

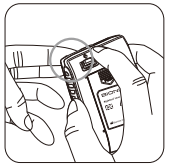
Smart Code Key Installation

How to switch Smart Code Key ?

Every new box of test strips should come with a Smart Code Key inside. Before you install the Smart Code Key, please check that the code number on the strip vial and the code number on the bottom of Smart Code Key should be the same.

If you find they are not the same, please return them to the store where you bought from.

1. Turn the meter over. Remove old Smart Code Key by pressing down Smart Code Key release button if one is installed.



2. With the Meter off, follow ① and ② direction to put the new Smart Code Key into the track on code key base.

Smart Code Key Installation

3. Push down the Smart Code Key until it snaps into the Smart Code Key base.

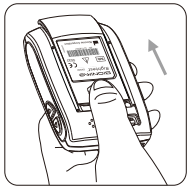
⚠ PRECAUTION

- Assemble the Smart Code Key into your meter is necessary before starting your test.
- Be sure to change the Smart Code Key with each new box of ***Rightest***™ Test Strips.
- Use only the Smart Code Key that is packaged with the box of strips you are using.
- Please don't remove this Smart Code Key before you run out of these new strips.

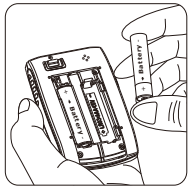
Batteries Installation

Your meter kit comes with two AAA, 1.5volt, batteries uninstalled. New set of batteries will provide power to perform about 1000 tests under normal use. The low battery symbol " LO " will keep appearing on your display if your batteries run low. Please keep spares on hand and replace the batteries soon when a battery symbol appears.

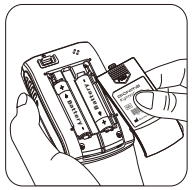
The meter will automatically turn off after 3 minutes of nonuse to save battery power. Your test memories are still saved.



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



2. Install both batteries at once. Be sure to put battery in correct direction.

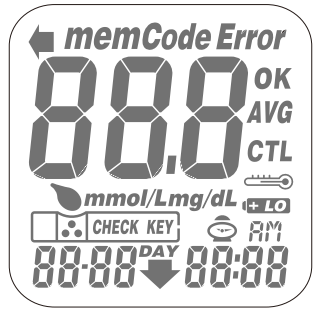


3. Slide the battery cover back until it snaps into place.

4. Meter will do the self test and the whole screen will keep blinking as soon as the batteries are installed.

5. Press any button to close the running-test of the meter, and enter setting mode.

6. Please set time and date when the batteries are replaced. See Setting the Time, Date and Unit on page 23.



⚠ PRECAUTION

- Danger of explosion might happen if battery is incorrectly replaced; replace only with the same or equivalent type.
- Please follow the local regulation and discard used battery properly.

Entering Setting Mode

You can enter Setting Mode by below two ways.

1. Reload batteries: After removing the battery, please press " ⊛ " button for several times until no signal on screen, then follow the steps of page 20～21 to load batteries.

2. With batteries: Press " ⊛ " button for 5 seconds till hearing a sound of " beep ". The display screen will show setting data.

⚠ PRECAUTION
When you keep pressing " ⊛ " button for 2 seconds, the display on screen will turn off. Please don't care it. Keep pressing the " ⊛ " button till entering Setting Mode.

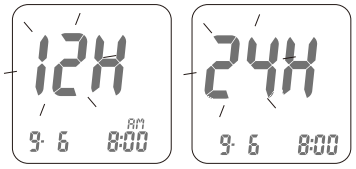
Setting the Time, Date and Unit

1. Year setting
   With the year format blinking, press the " △ " or " ▽ " button on the side to adjust it. Then press the " ⊛ " button to confirm the year adjustment and move to month setting.

2. Month setting
   With the month blinking, press the " △ " or " ▽ " button until the current month appears. Then press the " ⊛ " button to confirm it and move to day setting.

3. Day setting
   With the day blinking, press the " △ " or " ▽ " button until the current day appears. Then press the " ⊛ " button to confirm it and move to time format setting.

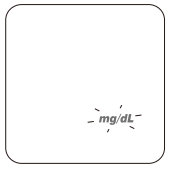
4. Time Format 12H/24H Selection
   With the time format blinking, press the " ▲ " or " ▼ " button on the side to adjust it. Then press the " ● " button to confirm it and move to hour setting.

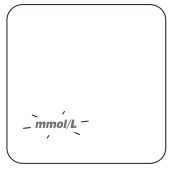


5. Hour Setting
   With the hour blinking, press the " ▲ " or " ▼ " button until the current hour appears. Then press the " ● " button to confirm it and move to minute setting.

6. Minute setting
   With the minute blinking, press the " ▲ " or " ▼ " button until the current minute appears.
   Then press the " ● " button to confirm it and move to the setting mode of measurement unit.

7. Setting the Unit of Measurement
   With milligrams per deciliter (mg/dL) or millimol per liter (mmol/L) blinking, press the " ▲ " or " ▼ " button on the side to switch.





8. Ending Setting
   Then press the " ● " button to complete the setting and go back to time screen. The settings you have entered are saved.

9. When you do not do any settings of meter for over 3 minutes, the meter will leave setting mode and power down automatically.

NOTE
Fast Settings :
When you do the settings, you can press the " ▲ " or " ▼ " buttons and hold them for two seconds to select or adjust faster.

Turning On/Off the Meter

1. Auto Power Off

   The Meter will power off automatically if you don't operate it for over 3 minutes.

2. Manual Power Off

   If you want to turn off the Glucose Meter, please keep pressing the " ⊛ " button for 2 seconds.

3. How to turn on the Power

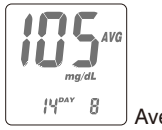
   1) Press the " ⊛ " button.

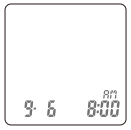
   2) Insert one piece of strip.

Function Screens and Button Operations

Switching the Function Screens

1. Press the " ⊛ " button to switch function screens including Memory, Average and Time in sequence.

Memory


Average


Time

2. Under Memory function, press the " △ " or " ▽ " button to search your memorized testing data.

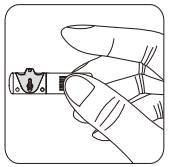
3. Under Average function, press the " △ " or " ▽ " button to search your average data of 1 day, 7 days, 14 days or 30 days in sequence.

4. When the display on meter screen shows time, memory or average, keep pressing " ⊛ " button for 5 seconds to enter setting mode.

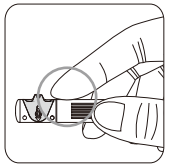
How to easily handle the *Rightest*™ test strip ?

Inserting the test strip:

1. Hold the test strip between thumb and middle finger with indication symbol " " facing up.

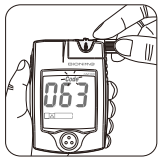


2. Put forefinger on the side of strip as shown.



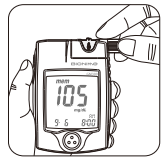
NOTE
This is the easiest way to insert the strip.

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

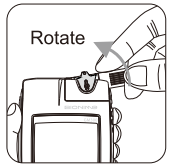


Removing the test strip:

1. Hold the test strip same as insert it.



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



NOTE
Pull the strip in counterclockwise direction will be easier to remove it from the meter.

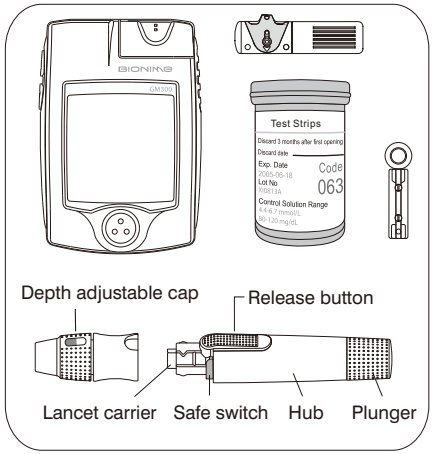
3. Take the test strip out of test strip port totally.
Please follow the local regulation and discard used strip properly.

NOTE
Code key 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***™ Meter (with ***Rightest***™ Smart Code Key installed)
- ***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)



⚠ PRECAUTION

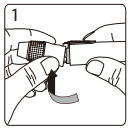
- Assembling the Smart Code Key into your meter is necessary before starting your test.

Performing a Test in Order

Each time of using a new box of test strip, you have to assemble the Smart Code Key from the new strip package.

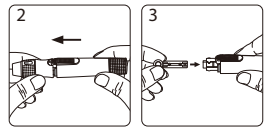
Cleaning your hands

Before starting your test, use warm soapy water to wash your hands and dry thoroughly. Warm water helps to increase the blood flow to your fingertips. You can also use alcohol swab to clean your finger to get accurate measurement.



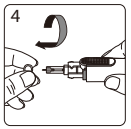
1) Hold the adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side. When a gap appears between the cap and hub, pull them off in opposite directions.

2) Pull off the depth adjustable cap.

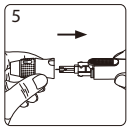


3) Insert a new disposable lancet firmly into lancet carrier.

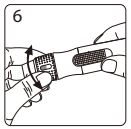
4) Twist off and set aside the protective cover of the disposable lancet.



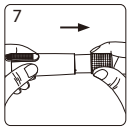
5) Replace the depth adjustable cap.



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
"▭" for soft or thin skin;
"▭" for average skin;
"▭" for thick or calloused skin.



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.

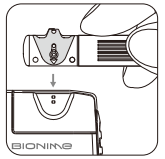


⚠ PRECAUTION
- Load the lancing device (Refer to Instruction manual of the lancing device)
- Be careful to load the lancing device to avoid being pierced by the needle.

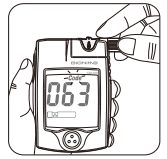
Performing a Test in Order

Preparing your meter and strip

1. Remove new test strip from vial and ***re-cap the vial cap immediately.***

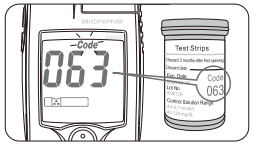


2. Insert the test strip with indication symbol, facing up, into test strip port.



3. Push the test strip in until it snaps and stops. The meter turns on automatically. When you put the strip into the strip port, you will hear a sound of " beep ".

4. Check that the code number blinking on your meter matches the code highlighted on the vial of test strips currently in use.

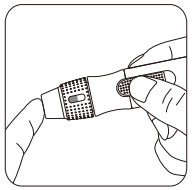


5. While the " " symbol flashing, you are ready to apply the blood sample. The code number will appear on the right down corner of the screen.

⚠ PRECAUTION
- Before " " appearing, please don't touch your blood drop to the sample entry on strip because meter is doing a internal test. If you do so, the meter will show " " and " ***Error*** " and you will waste a strip.

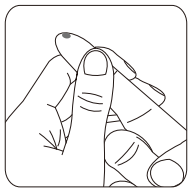
⚠ PRECAUTION
- To ensure accurate test results, make sure the code number on your meter matches the code highlighted on the vial of test strips you are using.
- If the code number does not match, change the Smart Code Key to the right one and redo a test.
- If the meter turns off before you apply the blood sample, take out the unused test strip and reinsert it. You have three minutes to apply the blood sample before the meter turns off automatically.
- Please follow the local regulation and discard the used strips properly.

Obtaining blood sample



1. Hold the lancing device to the soft side of your fingertip and press the release button to get a tiny blood sample.

⚠ PRECAUTION
Before you take the blood sample, please make sure your fingertip for sampling is dry thoroughly. Water or alcohol might affect the accuracy of testing.



2. Obtain a small blood drop on your finger
In order to get a more accurate measurement, suggest to discard the first drop of blood. (The first drop of blood from your fingertip might include some body liquid which might affect the testing accuracy.)

3. You can start measurement by the second drop of blood.

4. The minimum blood sample size of ***Rightest***™ Glucose Monitoring System is 1.4μl :(●)

Sample Size Example

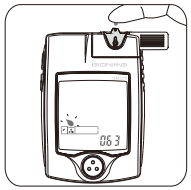
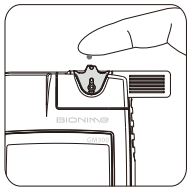
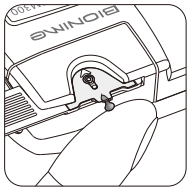
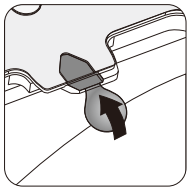
1.0μl	1.4μl	2.0μl	3.0μl	4.0μl
●	●	●	●	●

We suggest you to take 1.4～2.5μl to do the test on glucose monitoring system. Blood sample size above 4.0μl might contaminate the Smart Code Key.

⚠ PRECAUTION
- Don't take too much blood sample, such as 4.0μl (please see how much it is in the example picture) or more, to do the test. Too much blood might contaminate the Smart Code Key.
- Please clean it up right away if your Smart Code Key gets blood stain or moisture. (Refer to page 55 for cleaning Smart Code Key)
- 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.

Performing a Test in Order

Applying blood sample to test strip

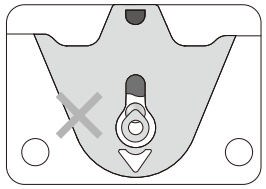
1. Touch the blood drop to the sample entry of the strip. The blood will be drawn into the strip automatically.

2. Hold your finger on the 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 and/or the test does not start, discard the test strip and repeat the test with a new test strip. When you repeat the test, you may want to obtain the blood sample from a different finger if the first attempt did not produce enough blood sample.

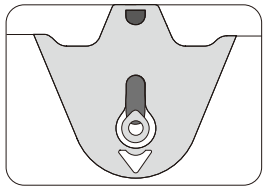
⚠ PRECAUTION
- When you do a test, please pay attention not to squeeze too much blood to pollute Smart Code Key.

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 might 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 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.
- Assemble the Smart Code Key into your meter is necessary before starting your test.
- Be sure to change the Smart Code Key with each new box of ***Rightest***™ Test Strips.
- Do the test at least 30 minutes after while entering another site with different ambient temperature.

- To ensure accurate test results, make sure the code number on your meter matches the code number highlighted on the vial of test strips you are using.
- Only place the blood drop to the sample entry of the strip.
- Keep your Smart Code Key dry and clean. Please clean it up right away if your Smart Code Key gets blood stain or moisture. (Refer to page 55 for cleaning)
- Pose the finger and the strip to the way you feel most comfortable.
- Please follow the local regulation and discard the used strip and lancet properly.

Appearance of result

1. When blood is applied to the strip, you see the countdown mode appearing on your screen. This means the meter is measuring your glucose value.

2. Your blood glucose result appears after the measurement is completed. The result is displayed in mmol/L or mg/dL. At the same time, the result will be memorized with time and date.

Performing a Test in Order

3. The testing result with time and date is automatically stored in your meter's memory. You may also record the glucose value in your Log Book.

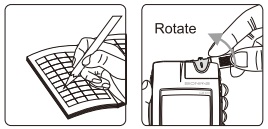
4. Rotate to remove the test strip. Please follow the local regulation and discard the used strip properly.

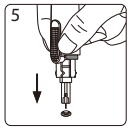
5. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.

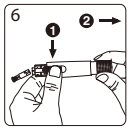
6. Hold the release button in one hand and pull on the plunger in the other hand will safely eject the used disposable lancet.

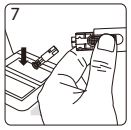
7. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.

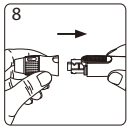
8. Replace the depth adjustable cap after finishing the test.











⚠ PRECAUTION
- The meter will power off automatically after 3 minutes no use. You can also turn off the meter by pressing the main button for 2 seconds.

Comprehending Test Results and Messages

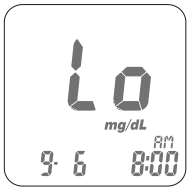
Blood glucose test results are shown on the meter as mmol/L or mg/dL, depending on which unit of measurement you have chosen. Consult your healthcare professional before making any changes to your diabetes medication program.

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***™ Check Key and ***Rightest***™ Control Solutions to check your meter and strip. (Refer to page 46.)
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 0.6 and 33.3 mmol/L or 10 and 600 mg/dL. If your test result is below 0.6 mmol/L (10 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 detective range (33.3 mmol/L or 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.

Recalling Your Test Result

The ***Rightest***™ meter is able to store 300 test results with time and date automatically. If your test results are up to 300 sets, which is the max memory of the meter, your newest test results will replace the old ones starting from the oldest one.
To recall your test memory, start with the meter without test strip inserted.

1. Press the main button " ⊛ " to switch the screen to memory function, it will show the latest testing result with time and date. The latest result is with sequence number, " 1 "

2. Under the memory screen, use either the " △ " or " ▽ " button on the side to review all previous results with date and time. You will see results from the most recent (Sequence no, " 1 ") to the oldest (Sequence no, " 300 ") at the down right corner of the screen.

Recalling Your Test Result

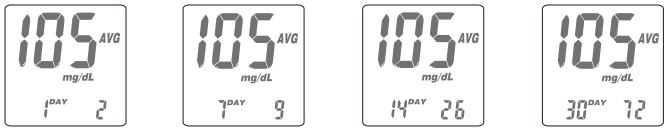
3. If a test result is not yours or you think it is not suitable to be calculated by average, you can mark it as non-average data by pressing and firmly holding the " ▲ " or " ▼ " button for over 2 seconds until the " AVG " and " no " appears on the screen, then press the " ● " button to confirm it.

4. The quality control solution test result can be recalled from the memorized data. When you see data with the " CTL ", it is testing data with control solution. The result will not be used for average calculation.

5. If the ambient temperature is 0℃～9℃ or 41℃～50℃ (32℉～48℉ or 106℉～122℉), the test result will show with " ⚠ " symbol blinking. The test result under these range of temperature will not be used for average calculation because the test result may not be correct. It is for reference only.

Recalling Your Average Test Result

The ***Rightest***™ meter provides you several average test results. You can view the 1-day, 7-day, 14-day and 30-day average of test results for better blood monitoring of your blood glucose .



1. Press the main button " ● " to switch the screen to average function.
2. Under the average of screen, use either the " ▲ " or " ▼ " for the option of 1-day, 7-day, 14-day or 30-day average of test results.
3. The number showed on the down right corner means how many test results are calculated.
4. The " Lo " , " Hi " results, the control solution results, the non-average test results and the test result made out of normal temperature range (0～9℃ and 41～50℃) are not calculated in the average.

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

What is quality control test ?

To make sure the monitoring system will work properly. It is necessary to do two kinds of quality controls.

1. Check Key Test
   Please check your meter function by check key, the detail is shown in " Starting with Check Key " section on page 49.

2. Control Solution Test
   If you finish the check key test without error, that only makes sure the meter is working properly. You still have to use control solution to check if the strip and meter work together properly.

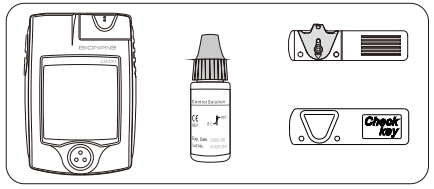
⚠ PRECAUTION
- The complete quality check should include check key test and control solution test. Before you do control solution test, you have to do check key test first.

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 vial of test strips.
- When you replace a new Smart Code Key, please check your meter by " CHECK KEY ".
- 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.

Required items for quality control tests

To perform a quality control test you have to prepare the items below :
- ***Rightest***™ Meter (with Smart Code Key installed)
- ***Rightest***™ Blood Glucose Test Strips
- ***Rightest***™ Control Solution
- ***Rightest***™ Check Key

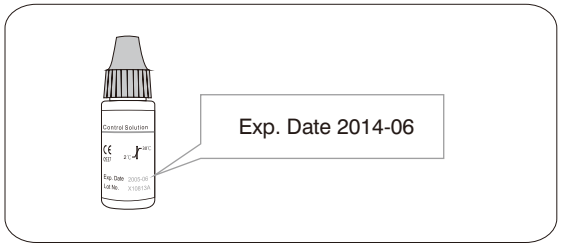


About Quality Control Test

⚠ PRECAUTION

- When you open a new bottle of ***Rightest***™ Control Solution, please write the discard 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



- Replace the vial cap of control solution and close tightly right away after using of control solution sample.
- Check the expiration date before you use the control solution. (Refer to Control Solution Package Insert.)

Performing a Quality Control Test

Starting with Check Key

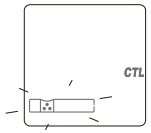
1. Insert the ***Rightest***™ Check Key with " Check Key " word, facing up, into test strip port. The meter quickly goes through a series of internal checks.
2. The check key allows you to make sure your meter is functioning well. You can see " CHECK KEY " symbol and " ***OK*** " symbol blinking on the screen.
   The check key also allows your meter proceeding quality control test with control solution.

NOTE
The check key is only for functional testing of meter. If you want to make sure strip and meter work properly, please use control solution for the test (see page 50 for detail.)

3. If both " CHECK KEY " symbol and " ***Error*** " symbol blinking appear, remove check key and insert it again. If error screen appears again, your meter is not working correctly. Please contact Bionime authorized distributor or Customer Service Center.
4. If you don't want to conduct the control solution test after the test of check key, please press " ⊛ " to leave " ***CTL*** " mode first. Then start the blood test procedure. Otherwise, your test resuit will be recorded as " ***CTL*** " data which will not be counted in average data.

Performing test with control solution

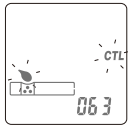
1. Please run check key test first. After see " CHECK KEY " symbol and " **OK** " appear on the screen. Remove check key from meter. The screen shows the " " symbol blinking and " **CTL** " appears. Then you need to put a new strip into the meter.



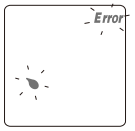
2. Remove test strip from vial and Re-cap the vial cap immediately.

3. Insert the test strip with view window, facing up, into test strip port. The code number will appear.

4. The test strip symbol stops blinking. You will see blinking " " symbol and " **CTL** " symbol on the screen. Then you need to approach your control solution to the meter.



PRECAUTION
- Before you do control solution test, you have to do check key test first.
- Before " " appears, please don't touch the control solution to the sample entry on strip because meter is stilling in a internal test. If you do so, the meter will show " ***Error*** " and " ".

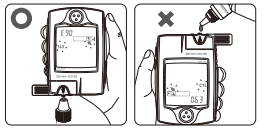


5. Shake the bottle of control solution well before opening the cap. Then open the cap and put it on the table.

6. Drip a drop of control solution on the top of the cap.

NOTE
- Don't drip the control solution to sample entry of strip directly.
- Don't touch the control solution. If you have touched it, please clean up with water.

7. Gently touch sample entry of the strip with the control solution on the top of the cap.

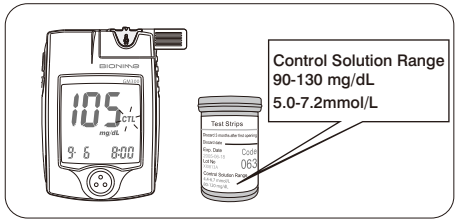


8. When you hear a sound of " beep " , leave the meter on the table while waiting the test result. The screen will show the countdown mode.

9. Tightly recap the cap of control solution.

10. The control result appears after the measurement is completed. Compare your control test result to the range printed on strip vial label.

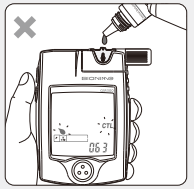
Example



Your result should fall within the control solution range printed on the label of strip vial. If result is not within the control range, please refer to Understanding Control Test Results on page 54. Please follow the local regulation and discard the used strip properly.

⚠ 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 " CTL" symbol on the screen.
- You have to do check key test before control solution test. If you only use the control solution to do the quality control test, your test result will be memorized and calculated for average same as real blood test.
- Please don't touch the control solution by approaching the vial to the sample entry on strip (see drawing). The reagent might be sucked into the vial of control solution which alteration or degeneration might happen. If you approach the control solution vial to the sample entry on strip for 3~5 times, you will find that the measurements might lower down for 10-20%.



- Keep your Smart Code Key dry and clean. Please clean it up right away if your Smart Code Key gets stain or moisture.

(Refer to page 55 for cleaning)

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 Soultion Range
90-130 mg/dL
5.0-7.2 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.

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 check key and control solution before doing a blood glucose test.

Cleaning Meter

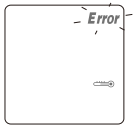
Clean the outside of the meter with a damp cloth and mild soap/detergent. Keep the test strip port and Smart Code Key base from getting wet.

Cleaning Smart Code Key

If your Smart Code Key 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 check key and quality control test to ensure the system is working properly.

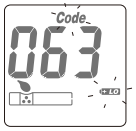
About Temperature Error

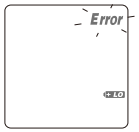
1. In order to get accurate testing, please do testing between 10～40℃ (50～104℉).
2. When the ambient temperature is 0～9℃ (32～48℉) or 41～50℃ (106～122℉) , the " " warning symbol will blinking, you still can do the test but the result obtained is only for reference because the test result under these range of temperature might not be correct. Repeat the test at an area with temperature between operating range. (10～40℃ or 50～104℉)
3. When you move from the area with temperature outside the operating range of test strip to another area with temperature under operating range of test strip, please wait for 30 minutes before you do the test.
4. 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 redo the test after 30 minutes.



About Battery Error

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



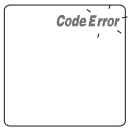


About Check Key Error

When you see " CHECK KEY " and " ***Error*** " symbols showing on screen, please do the check key test again. If this error message appears again, it would be Meter or Check Key defect.
Please return your Meter and Check Key to the store where you bought.

About Smart Code Key Error

The Smart Code Key is faulty or not assembled well to the meter. Reinsert the Smart Code Key. If the error screen appears again, contact Bionime Customer Service.



Error Messages and Trouble Shooting

About early applying blood sample or control solution

The blood sample or control solution are applied before the meter is ready. Repeat the test with a new test strip. Add sample after the " " symbol appears.

About Strip Error - Er1

Test strip inserted has been used or damaged. Please use a new test strip from vial.

About Meter Error - Er2

Meter has malfunctioned. Do the quality control test or reinstall the batteries to see if the meter works properly.

If error screen still appears, contact Bionime Customer Service.

About Signal Error - Er3

When you do the test, the meter find the signal is unreasonable. Please do a new test again.

Limitations

- Store the strips in the original capped vial at temperatures between 4℃ to 30℃ (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 and venous 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 55% 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 > 0.54 mmol/L (> 9.0 mg/dL)
  L - Dopa > 0.076 mmol/L (> 1.5 mg/dL)
  Methyldopa > 0.071 mmol/L (> 1.5 mg/dL)
  Cholesterol > 6.5 mmol/L (> 250 mg/dL)

Specification

Measurement Technology	Oxidase Electrochemical Sensor
Sample	Capillary whole blood
Minimum Sample Volume	1.4 μL (microliters)
Measuring Range	10-600 mg/dL (0.6-33.3 mmol/L)
Test Time	8 seconds
Memory Capacity	300 blood glucose test results with date and time
Power Saving	Turn off automatically after 3 minutes no use Press the " ⏻ " button for 2 seconds.
Operating Temperature	10 ～ 40℃ (50 ～ 104℉)
Operating Relative Humidity	10 - 90%

Specification

Hematocrit	30 - 55%
Power Supply	Two 1.5V (AAA) batteries
Battery Life	About 1000 tests
Meter Dimension	85.0 mm x 58.0 mm x 22.0 mm
Meter Weight	80.0 g ± 5 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

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.

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. You are always welcome to contact us by call: 886 4 23692388 (GMT+08:00, 08:30~17:30), or by e-mail at rightest@bionime.com If you have any question or advice.

IVD	For in vitro diagnostic use		Manufacturer
LOT	Lot number		Use by
	Temperature limitation		Do not reuse
STERILE R	Method of sterilization using irradiation		WEEE
			Biological risks

Parts of Critical Component

Blood Glucose Meter, Test Strip, Control Solution
Manufacturer: Bionime Corporation
No. 100, Sec. 2, Daqing 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, Daqing 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

Disposable Sterile Lancets
Manufacturer: SteriLance Medical (SuZhou) Inc.
No.68 LiTangHe RD, XiangCheng, SuZhou, JiangSu 215133, P.R. China
Product complied with Medical Device Directive 93/42/EEC. (CE0197)
EC- Rep: EMERGO EUROPE, Molenstraat 15, 2513 BH The Hague, The Netherlands

Log Book

NAME

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

	DATE	M	T	W	T	F	S	S
Breakfast	Blood Glucose							
	Insulin/ Medication							
Lunch	Blood Glucose							
	Insulin/ Medication							
Dinner	Blood Glucose							
	Insulin/ Medication							
Bedtime	Blood Glucose							
	Insulin/ Medication							
Other	Blood Glucose							
	Insulin/ Medication							
COMMENTS								

Log Book

	DATE	M	T	W	T	F	S	S
Breakfast	Blood Glucose							
	Insulin/ Medication							
Lunch	Blood Glucose							
	Insulin/ Medication							
Dinner	Blood Glucose							
	Insulin/ Medication							
Bedtime	Blood Glucose							
	Insulin/ Medication							
Other	Blood Glucose							
	Insulin/ Medication							
COMMENTS								

Log Book

	DATE	M	T	W	T	F	S	S
Breakfast	Blood Glucose							
	Insulin/ Medication							
Lunch	Blood Glucose							
	Insulin/ Medication							
Dinner	Blood Glucose							
	Insulin/ Medication							
Bedtime	Blood Glucose							
	Insulin/ Medication							
Other	Blood Glucose							
	Insulin/ Medication							
COMMENTS								

Log Book

	DATE	M	T	W	T	F	S	S
Breakfast	Blood Glucose							
	Insulin/ Medication							
Lunch	Blood Glucose							
	Insulin/ Medication							
Dinner	Blood Glucose							
	Insulin/ Medication							
Bedtime	Blood Glucose							
	Insulin/ Medication							
Other	Blood Glucose							
	Insulin/ Medication							
COMMENTS								

Log Book

	DATE	M	T	W	T	F	S	S
Breakfast	Blood Glucose							
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	Insulin/ Medication							
Bedtime	Blood Glucose							
	Insulin/ Medication							
Other	Blood Glucose							
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COMMENTS								

Log Book

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Bedtime	Blood Glucose							
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Other	Blood Glucose							
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COMMENTS								

Log Book

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	Insulin/ Medication							
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	Insulin/ Medication							
Other	Blood Glucose							
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	Insulin/ Medication							
Other	Blood Glucose							
	Insulin/ Medication							
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Log Book

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	Insulin/ Medication							
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Other	Blood Glucose							
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	Insulin/ Medication							
Dinner	Blood Glucose							
	Insulin/ Medication							
Bedtime	Blood Glucose							
	Insulin/ Medication							
Other	Blood Glucose							
	Insulin/ Medication							
COMMENTS								

Warranty Card

(Please present this card for replacement purpose)

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

Limited warranty:

1. 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.

BIONIME

Warranty Card

PLACE

STAMP

HERE

Distributor name and address

Warranty Card

Thank you for purchasing our product. Please complete and mail this warranty card within 30 days of purchase of your ***Rightest***™ Blood Glucose Monitoring System.

Name | Male/Female | Date of Birth

Address

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 ☐ Gestational Diabetes?

Have you owned a blood glucose monitor before? ☐ Yes ☐ No

Which brand/s were you most recently using?_____

Will the ***Rightest***™ meter be your primary monitor? ☐ Yes ☐ No

How often do you test your blood glucose? Times per day_____ per week_____

Do you use insulin? ☐ Yes ☐ No Oral medication? ☐ Yes ☐ No

How did you hear about the ***Rightest***™ Blood Glucose meter? _____

Thank you for answering these questions and for your purchase of the ***Rightest***™ Blood Glucose Monitoring System.

BIONIME

Emergency Card

EMERGENCY CARD

Blood Glucose Monitoring System

BIONIME

- User Name:
- User Phone No.:
- Blood Type:
- Doctor/Hospital:

I am a diabetes patient. If you 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 at anytime.