

Version 2 Date: 3.17.2016

iGlucose™ Blood Glucose Monitoring System

GM291 User Manual

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iGlucose™ Blood Glucose Monitoring System User Manual

iGlucose™ is a trademark of Smart Meter Corporation

iGlucose Blood Glucose Monitoring System is manufactured by Bionime Corporation, No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan (R.O.C)

Preface

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

For people living with diabetes, it is important to regularly monitor blood glucose levels to effectively reduce complications from the disease. The easy-to-use iGlucose Blood Glucose Monitoring System provides accurate, reliable test results. It can be connected to web portals by GSM technology to help you better manage your diabetes.

The iGlucose Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The iGlucose Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The iGlucose Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iGlucose Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

The iGlucose Blood Glucose Test Strips are for use with the iGlucose Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The iGlucose Blood Glucose Monitoring System is manufactured and supported by Bionime Corporation. If you have any questions or concerns, please contact the iGlucose Diabetes Customer Support Center toll free at 1-555-555-5555 (Monday through Friday 8:00 AM to 5:00 PM PST).. We will make every effort to assist you.

The iGlucose Blood Glucose Monitoring System is a personal blood glucose monitoring system to be used for self-testing only. The glucose meter and lancing device are for single patient use. Do not use on multiple patients. Do not share meter or lancing device with anyone including other family members.

A healthcare professional should be contacted when Customer Service is not available. Please forward your warranty card to iGlucose Diabetes Customer Support Center.

iGlucose Diabetes Customer Support Center
12345 Main Street
Any town AA, 12345

Caution

- Before using the iGlucose Blood Glucose Monitoring System to test your blood glucose, please read all of the instructions and conduct all of the tests including the quality control test (Refer to page XX).
- Please perform the quality control test regularly to make sure the test results are accurate.
- The iGlucose Blood Glucose Meter can be used with iGlucose Blood Glucose Test Strips. Other test strips should not be used under any circumstances. The use of other test strips may give inaccurate results.
- The iGlucose Blood Glucose Monitoring System is intended for in vitro diagnostic use only. The Blood Glucose test results using fresh capillary whole blood samples from the fingertip are calibrated to be equivalent to that of plasma samples..
- The iGlucose Blood Glucose Monitoring System is intended for self-testing. It should not be used to screen for or diagnose diabetes mellitus.
- If the iGlucose Blood Glucose meter and Test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.
- Follow all environmental protection regulations when disposing of batteries.
- The iGlucose Blood Glucose meter will be set as mg/dL by default when sold in United States. If meter display shows "mmol/L" during setting or test, please contact iGlucose Diabetes Customer Support Center. Use of the wrong unit of measurement may cause incorrect treatment.
- The iGlucose Blood Glucose Monitoring System is not for use on neonates and should not be used in the critically ill.
- The minimum blood sample size to test using the iGlucose Blood Glucose Monitoring System is 0.75µL:

Sample Size Example



Blood sample size above 3.0µL might contaminate the test strip port and the meter.

Blood sample size below 0.75µL may cause an inaccurate result or may prevent a meter reading. An Er4 reading will be displayed if the sample size is too small. In this case, repeat the test with a new test strip.

Important Safety Notes:

- The iGlucose Blood Glucose meter and iGlucose Lancing Device are for single patient use. Do not share them with anyone including other family members.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after following the cleaning and disinfecting procedures. Please refer to the section "Cleaning and Disinfecting Procedures" on page XX.

- Users should wash their hands thoroughly with soap and water before and after handling the meter, lancing device, or test strips.

Please see the following references for further information.

1. "FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

2. "CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk or Transmitting Bloodborne Pathogens" (2010)

<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

Limitations

- Blood glucose meter readings may be significantly lower than "true glucose levels" in a hyperglycemic- hyperosmolar state, with or without ketosis.
- Caution is advised when glucose values are below 50 mg/dL or above 250 mg/dL. Consult a Physician as soon as possible, if values in this range are obtained.
- Healthcare professionals should evaluate their patients' technique regarding the use of the iGlucose Blood Glucose Monitoring System regularly. To accomplish this, it is recommended that blood glucose monitoring results be compared with a concurrently obtained laboratory measurement on the same blood sample. A proven clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- The results of blood glucose measurements are different for measurements with whole blood and plasma.
- Storage of strips near bleach as well as bleach containing products will affect the results of the iGlucose Blood Glucose Test Strips.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3,048 meters) above sea level.
- Hematocrits below 20% may cause higher results. Hematocrits above 60% may cause lower results.
- High concentrations of Uric acid ≥ 10 mg/dL, Cholesterol ≥ 600 mg/dL, and Ascorbic acid (Vitamin C) ≥ 5 mg/dL may interfere with the glucose test causing inaccurate test results.
- Do not perform the blood glucose test at temperatures below 10°C (50°F) or above 40°C (104°F), nor below 10% or above 90% relative humidity.
- iGlucose Blood Glucose Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Not for screening or diagnosis of diabetes mellitus.

- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Not for neonatal use.

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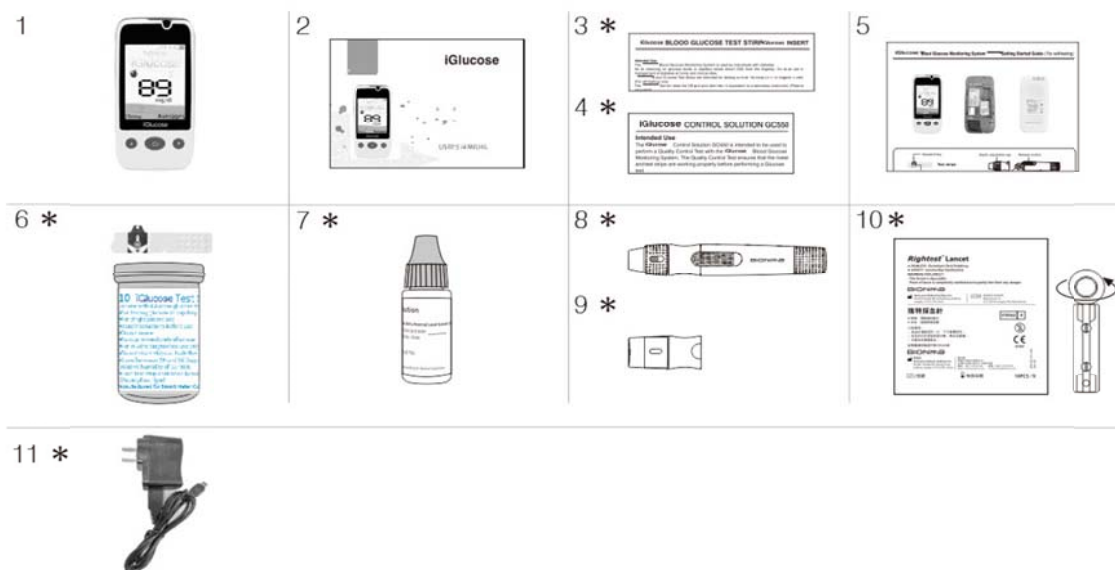
The iGlucose Blood Glucose Monitoring System

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

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

1. iGlucose Blood Glucose meter (with a Li rechargeable battery installed)
2. User's Manual (includes Log Book, Warranty Card, Emergency Card)*
3. iGlucose Blood Glucose Test Strip Package Insert*
4. Rightest® Control Solution GC550 Package Insert*
5. Getting Started Guide*
6. iGlucose Blood Glucose Test strips (10/25 pcs)*
7. Level 2 of Rightest Control Solution GC550*
(Level 2 and Level 4 of Rightest Control Solution GC550 are available for the iGlucose Blood Glucose Monitoring System but must be purchased separately.)
8. iGlucose Lancing Device*
9. Clear Cap*
10. Disposable Sterile Lancets (10 pcs)*
11. Meter charger and Meter cable (Input: DV5V, 0.5A ;Output:DC5V, 0,5A)

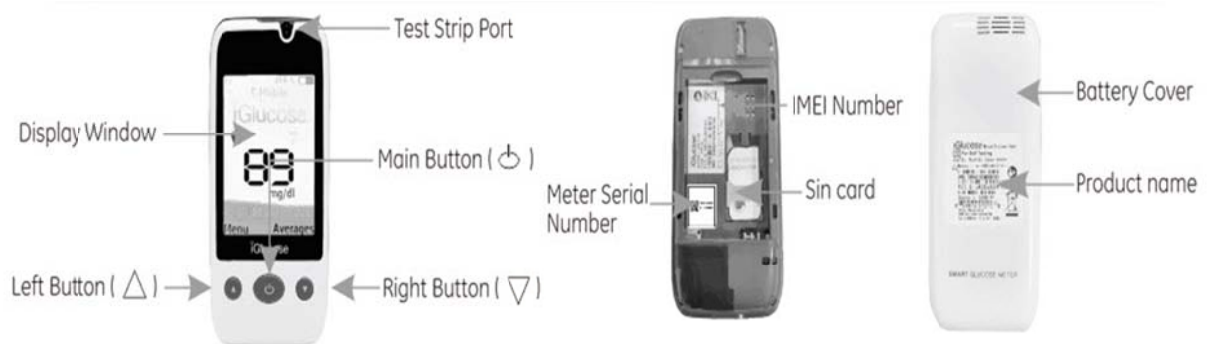
(* Different packages have different bundled items. Some of packages might not include * items)



(By the need to use the product specifications for the input and authentication iec60950-1 AC100-240V, 50 / 60Hz 0.2A, output DC5V, 0.5A of charging transformer)

(IEC62133 certified by the need to use the product, specifications for DC3.7V, 1000mAh Li-Ion battery of lithium)

The iGlucose Blood Glucose Meter

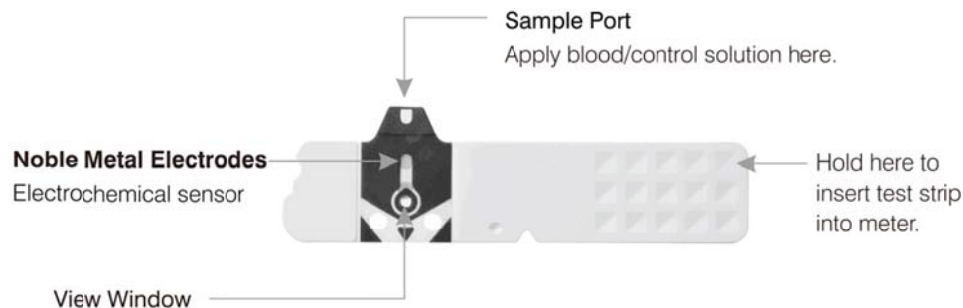


The iGlucose Blood Glucose Meter Icons

Spelled out on display	Average result
	Indicates a control solution test result
mg/dL	Unit of test result
109	Test result
	Warns when the batteries are low or must be recharged
	Indicates a meal marker with test results
	Indicates that the GSM is turned on
	Indicates when to apply the blood sample
"Strip Inserted"	Appears after you insert test strip into meter
"Er # (Number)"	Appears when an error occurs
Spelled out on display	Current date and time
	Warns when the operational temperature limit is exceeded during testing

The iGlucose Blood Glucose Test Strip

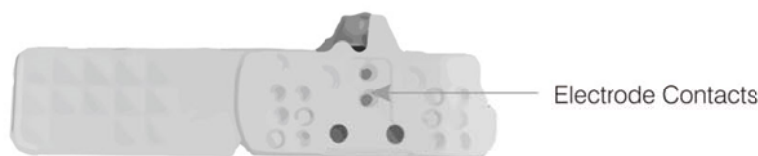
The iGlucose Blood Glucose meter can only be used with the iGlucose Blood Glucose Test Strips and Rightest® Control Solution GC550. The use of other test strips or control solutions can lead to incorrect results.



The iGlucose Blood Glucose Test Strip

PRECAUTION

- Close the iGlucose Blood Glucose Test Strip vial immediately after removing a test strip.
- Do not reuse iGlucose Blood Glucose Test Strips
- Do not use expired Blood Glucose Test Strips.
- When you open a new vial of iGlucose Blood Glucose Test Strips, record the date on the vial. Discard the vial of test strips after 3 months from opening.
- Store the iGlucose Blood Glucose Test Strips, between 39-86°F (or 4-30°C) and in a location 10-90% relative humidity. Do not expose to direct sunlight or heat.
- If the iGlucose Meter and test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.
- For detailed information, please refer to the iGlucose Blood Glucose Test Strip, Package Insert.
- The use of other test strips may cause strip error. Please refer to page XX for troubleshooting.



Meter Activation and Battery Charge

Your iGlucose Blood Glucose meter comes with an installed Li rechargeable battery. When fully charged this battery will provide power to perform approximately 500 tests under normal use. Press the main button to activate your meter or insert a strip.

Connect the charging adapter and the cable.

Insert the battery

1. Take the battery out of the plastic bag.
2. Open the back cover of the device by inserting your thumbnail into the small groove on the right-hand side near the bottom of the back cover and lifting up the cover.
3. Remove the old battery
4. Install a new battery inside the battery compartment so that the small metal contacts on the bottom of the battery touch the small metal pins in the battery compartment.
5. Replace the back cover of the device.

Charge the battery

1. Connect the Meter Charger to its adapter cable
2. Plug the pin into the port at the bottom of unit
3. Plug the Charger into a power outlet. When the unit begins charging, the charging light illuminates and a charging battery icon flashes on the screen for a short while. Charging takes between 2-3 hours to complete.
4. When charging is complete, the battery icon on the device screen appears solid green.
5. Unplug the adapter from the socket.

CAUTION

- Please follow the local regulation to properly recycle rechargeable battery.
- Risk of explosion if battery is replaced by an incorrect type.

Setting Up Your Meter - Setting the Date, Time.

Synchronizing the date and time

To synchronize the date and time manually:

1. Press the “up” (Menu) button on the device. The Menu appears.
2. Select the “Date and Time” option. The “Date and Time” menu appears.
3. Select the “Synch Time” option. A confirmation message appears after a few seconds.

Setting the Time and Date Manually

To set the time and date manually:

1. Press the “up” (Menu) button on the device. The Menu appears.
2. Select the “Date and time” option. The “Date and time” menu appears.
3. Select the “Set Date” option. The year appears. Use the up or down buttons to change the year as needed. Press the “home” button to move on to the month.
4. Press the up or down buttons to change the month as needed. Press the “home” button to move to the day.
5. Press the up or down buttons to change the day as needed. Press the “home” button finish and return to the “Date and time” menu.
6. To exit the menu, press the up or down button to scroll to the “Back” option. Select the “Back” option to exit the menu.

Setting the Date or Time format

To select your format for date or time:

1. Press the “up” (Menu) button on the device. The Menu appears.
2. Select the “Date and Time” option. The “Date and Time” menu appears.
3. Select the “Date Format” option. Press the up or down button to scroll to the desired date format. Press the home button to select. A confirmation message appears.
4. Select the “Time Format” option. Press the up or down button to scroll to the desired time format. Press the home button to select. A confirmation message appears.
5. To exit the menu, press the up or down button to scroll to the “Back” option. Select the “Back” option to exit the menu.

Turning On / Off the Meter

1. How to turn on the iGlucose Blood Glucose Meter
Press the Main button or Insert a test strip.
2. Manual Power off
To power off the iGlucose Blood Glucose Meter, press and hold the Main button for 3 seconds.
3. Auto Power off
The iGlucose Blood Glucose Meter will power off automatically after 2 minutes if no buttons are pressed or no strip is inserted.

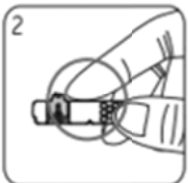
Handling the iGlucose Blood Glucose Test Strip

Inserting the iGlucose Blood Glucose Test Strip

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



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



3. Insert the iGlucose Blood Glucose Test Strip into test strip port until it clicks and firmly stops.

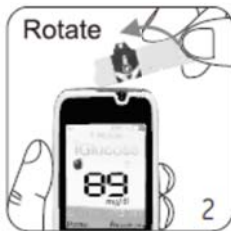


Removing the iGlucose Blood Glucose Test Strip

1. Hold the iGlucose Blood Glucose Test Strip as shown.



2. Rotate the iGlucose Blood Glucose Test Strip counterclockwise and pull up simultaneously.



3. Take the iGlucose Blood Glucose Test Strip out of the test strip port.



Please follow your healthcare professional's instructions and discard used strips properly.

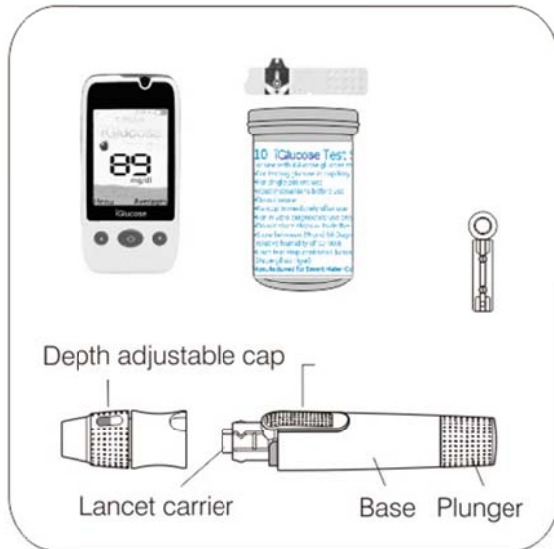
Getting Ready for Testing

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

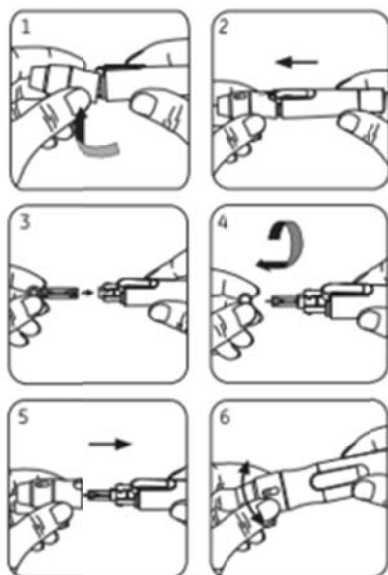
- iGlucose Blood Glucose Meter
- iGlucose Blood Glucose Test Strips

(Please check the expiration date on the test strip vial. Do not use expired test strips)

- iGlucose Lancing device
- Sterile lancet

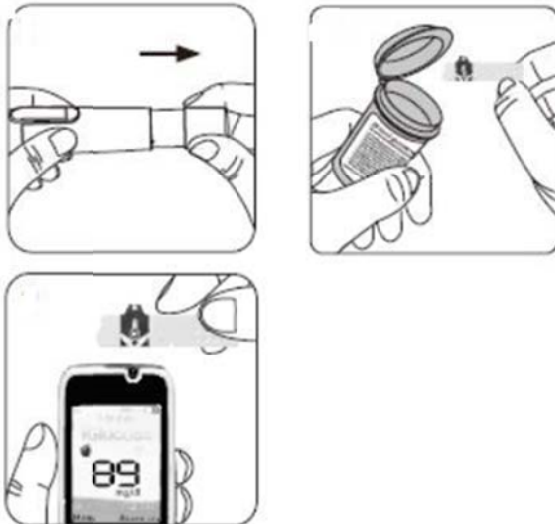


1. Hold the adjustable depth cap of the lancing device in one hand while holding the base in the other hand. Slightly force downward.
2. Pull the two parts in opposite directions to remove the adjustable depth cap.
3. Insert a new disposable lancet firmly into lancet carrier.
4. Twist off and set aside the protective cover of the disposable lancet.
5. Replace the depth adjustable cap.
6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until your desired setting is visible in the window. Settings are based on skin type "  " for soft or thin skin; "  " for average skin; "  " for thick or calloused skin.



Performing a Blood Glucose Test

1. Wash your hands thoroughly with soap and water and dry well
2. Hold the base of the lancing device in one hand and pull on the plunger with the other hand. The device will be cocked. Release the plunger and it will automatically move back to its original position near the base.
3. Take one iGlucose Blood Glucose Test Strip from the vial. Close the vial cap immediately.
4. Insert the strip into the test strip port of the iGlucose Blood Glucose meter with the view window facing up. Once the strip is inserted, your meter will be automatically turn on.

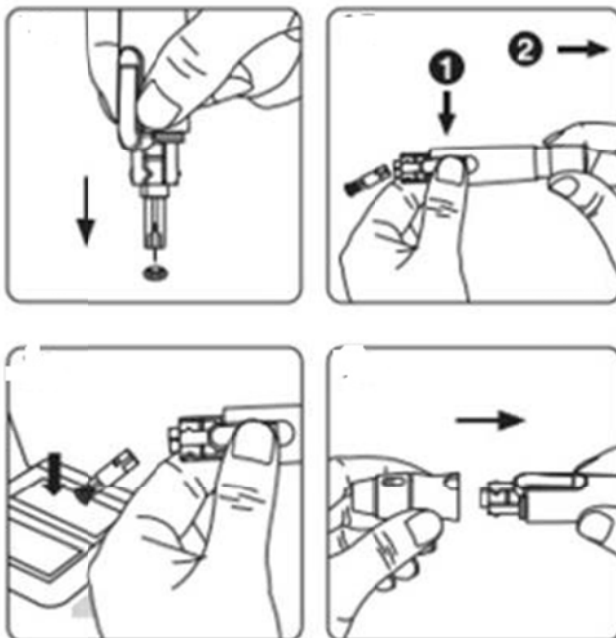


5. A blood drop icon will appear on the display window. Apply the blood sample within 2 minutes.
6. Place the lancing device against your fingertip and press the release button.
7. Touch and hold the blood drop to the edge of sample port until the view window is filled with blood. If the view window is not completely filled with blood the test will not start. If the blood sample was insufficient, discard the test strip and repeat with a new iGlucose Blood Glucose Test Strip.
8. Countdown Mode will begin on the display window. After 5 seconds, your test result will appear.





9. Pull off the depth adjustable cap. Without touching the used disposable lancet, insert the lancet tip into the protective lancet cover.
10. Hold the release button in one hand and pull on the plunger with the other hand to safely eject the used disposable lancet.
11. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
12. Replace the depth adjustable cap after finishing the test.



CAUTION

- Do not apply your blood drop to the sample port on the strip until you see the "Apply a drop of blood " appear.

The iGlucose Blood Glucose Meter is performing an internal test and will display an error message if you apply blood too soon. If this occurs, please repeat the test with a new test strip.

- Record the opening date of a new test strip vial. Discard the vial of test strips 3 months after opening.

- Always keep the metal contacts of the test strip port clean. If any dust or impurities are present, please clean with a small, soft brush.

- The iGlucose Blood Glucose Monitoring System and iGlucose Lancing Device are intended for a single user only. Do not share these devices with anyone, including other family members.
- All parts of this kit are considered biohazards and can potentially transmit infectious diseases, even after you have performed the cleaning and disinfecting procedure.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, and test strips.
- For cleaning and disinfecting please refer to the section "Cleaning and Disinfecting Procedures" on page XX.

View Appearance of Blood on the strip

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



Insufficient
blood sample



Sufficient
blood sample

CAUTION

- Check the expiration date printed on the strip vial every time you use a test strip. Do not use expired iGlucose Blood Glucose Test Strips.
- Use each iGlucose Blood Glucose Test Strip immediately after removing it from the vial.
- Do not reuse iGlucose Blood Glucose Test Strips.
- Do not perform testing immediately after moving from one ambient temperature to another (e.g. after coming indoors from the outside). Allow 45 minutes for the temperature of the meter and the test strips to equilibrate.
- Apply the blood sample only on the sample port of the test strip.

Understanding Test Results and Messages

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

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

You can also run a Quality Control Test with the Rightest® Control Solution GC550 to check your iGlucose Blood Glucose meter and iGlucose Blood Glucose Test Strip (Refer to "Performing a Quality Control Test" on page XX) .

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

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

Consult your healthcare provider for appropriate disposal of used test strips and lancets.

The iGlucose Blood Glucose meter displays results between 20 and 600 mg/dL.

If the test result is below 20 mg/dL, “LO” will appear on the screen. Please repeat your test with by a new test strip.

If you still get a “LO” result, contact your healthcare professional.



If the test result is above 600 mg/dL, “HI” will appear on the screen. Please repeat your test again with a new test strip.

If you still get a “HI” result, contact your healthcare professional.



Setting Meal Markers:

Press the main button to choose among before meal  and after meal, 



Before meal: You execute this blood glucose test before a meal.



After meal: You execute this blood glucose test after a meal.

Select the appropriate test mode: “Before Meal” or “After Meal” in one of the following ways:

Using the menu:

- Press the “up” (Menu) button on the device. The Menu appears.
- Select the “Test Mode” option.
- Scroll to the “Before Meal” or “After Meal” option as required.
- Press the middle button. A confirmation message appears.

Using the middle button from the home screen (when no menu is selected):

- Press the “middle button on the device to toggle the Test Mode icon (#8 in Figure 1 above) on the display.
- For “Before Meal” toggle to the whole apple icon; for “After Meal” toggle to the partially eaten apple icon.
- Note: Do not use the “Control Solution” setting (represented by the solution bottle



icon) for a blood test, as the result will not be calculated into averages.

About Quality Control Testing

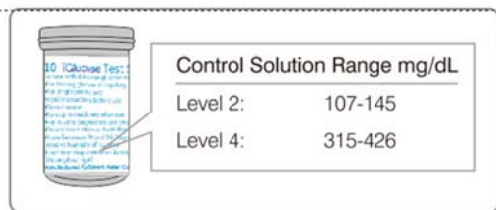
What is a Quality Control Test?

To ensure proper monitoring function, it is necessary to regularly perform a quality control test.

Use one of the Rightest® Control Solution GC550 when testing your iGlucose Blood Glucose Monitoring System in the Control Solution Mode. If the test result is within the Control Solution Range printed on the strip vial label, the iGlucose Blood Glucose Monitoring System passes the Quality Control Test and your iGlucose Blood Glucose Monitoring System is working properly.

Control Solution Range:

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



NOTE

- Level 2 and Level 4 of Rightest® Control Solution GC550 are available for iGlucose Blood Glucose Monitoring System but must be purchased separately. If you want to purchase Level 2 or Level 4, please contact the iGlucose Diabetes Customer Support Center.

When should a quality control test be performed?

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

- To practice testing.

Required Items for Quality Control Tests

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

- iGlucose Blood Glucose Meter
- iGlucose Blood Glucose Test Strips
- Rightest® Control Solution GC550

CAUTION

- Each time you open a new bottle of control solution, write the expiration date on the label. The Rightest® Control Solution GC550 is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first.

Example



- Wipe the bottle cap with a clean tissue before tightly closing the bottle of control solution.
- Close the bottle of control solution tightly immediately after using.
- Check the expiration date before use. (Refer to the Rightest® Control Solution GC550 Package Insert).
- Keep control solution bottles out of reach of children.

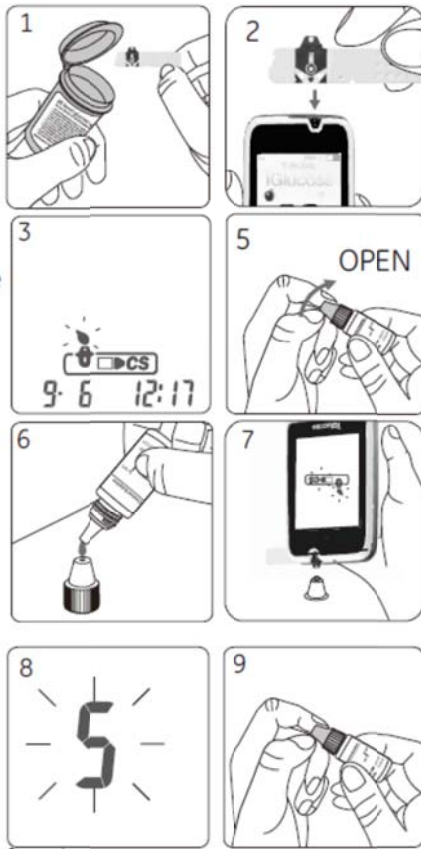
Performing a Quality Control Test

1. Take one iGlucose Blood Glucose Test Strip from the vial and close the vial cap immediately.
2. Insert the iGlucose Blood Glucose Test Strip horizontally (not vertically) with the colored view window facing up into the test strip port.
3. Press the "up" (Menu) button on the device and the Menu will appear. .
4. Select the "Test Mode" option. The "Test Mode" menu appears.
5. Select the "Control Solution" option. A confirmation message appears.

Note: When a test mode is set for a Control Solution, the result will not be calculated into averages. It is important to set the Test Mode to "Control Solution" to ensure this when performing a control test.

5. Shake the bottle of Rightest® Control Solution GC550 well before opening the cap. Place the cap on a flat surface.

6. Place a drop of control solution onto the top of the cap.
7. Gently touch the sample port of the strip with the control solution from the top of the cap.
8. The screen will display the count time starting from 5.



9. Tightly replace the cap on the Rightest® Control Solution GC550 bottle.
10. The control solution result will appear. Compare your Quality Control Test result to the Control Solution Range printed on the Blood Glucose Test Strip vial label.

CAUTION

- Your Control Solution Test results will not be included in the average calculations, however, they can still be recalled and viewed. The Control Solution Test result will be shown with the  control solution icon on the screen.
- The Control Solution Test should be conducted between 59-104°F (15-40°C) and in a location with 10-90% RH.
- Before "Apply a drop of blood ", do not touch the control solution to the sample port on the strip. The iGlucose Blood Glucose meter is performing an internal check. Touching the control solution to the sample port before prompted will result in an error message.
- Do not drip the control solution on to the sample port of the test strip directly. The reagent on the strip might leak into the bottle of control solution and may cause the degeneration of the control solution. This could contaminate the meter via the test strip port.

- Keep the test strip port clean and dry. Clean immediately if the test strip port is stained or is overly exposed to moisture.
- Do not touch the tip of the control solution bottle. If the tip is touched, clean with water and pour out 2 drops of control solution.



Understanding quality Control Test Results

Your control solution test results should fall within the control solution range printed on the test strip vial label. If the results are within the range, the Blood Glucose Monitoring System is working correctly.

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

Control Solution Range	Level 2	Level 4
	88-120 mg/dL	250-340 mg/dL

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

- Your Rightest® Control Solution GC550 is expired or was first opened more than 3 months ago.
- Your Blood Glucose Test Strip has expired.
- You left the cap of the iGlucose Blood Glucose Test Strip vial or the control solution off for a period of time.
- You did not perform the test procedure correctly.
- The iGlucose Blood Glucose meter or Blood Glucose Test Strip have malfunctioned.

If Rightest® Control Solution GC550 results are out of range, your iGlucose Blood Glucose Monitoring System may not be working properly. Repeat the Quality Control Test. If your control solution results are still out of range, do not use Blood Glucose Meter to test your blood glucose. Please contact the iGlucose Diabetes Customer Support Center.

Recalling Test Results

The iGlucose Blood Glucose meter is able to automatically store a maximum of 500 test results with time and date. If your meter has stored 500 results, the newest test result will replace the oldest one.

Obtaining Readings Averages

iGlucose maintains the averages of your blood glucose readings for the last 7, 14, 30 and 90 days in memory on the device.

To obtain glucose reading averages:

1. Press the “down” button on the right side of the device. The “Averages” menu appears.
2. Select the desired option:
 - a. Last 7 Days
 - b. Last 14 Days
 - c. Last 30 Days
 - d. Last 90 Days
3. The average blood glucose reading for the selected period appears. Press the middle button to return to the “Averages” menu. Select another item from the menu that you wish to view, or select the “Back” button to exit the menu. Please note “control solution” readings do not count in calculating the averages.

Obtaining Readings History

iGlucose maintains a record in memory on the device of each blood glucose reading for up to 500 readings.

To obtain the list of previous blood glucose readings:

1. Press and hold (“long press”) the “down” button on the right side of the device OR
From the “Averages” menu (see above), select the “Previous Readings” option.

The “History” list appears showing previous readings. Press the “up” or “down” buttons to scroll through the list. Press the middle button to exit the list.



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

Cleaning Meter

Clean the outside of the meter with disinfecting wipes listed on next page. Do not get the test strip port wet.

Cleaning Test Strip Port

If your test strip port is stained with blood, control solution or any liquid, please use disinfecting wipes listed on next page to clean it immediately. Do not immerse in water. Perform a quality control test to ensure the iGlucose Blood Glucose meter is working properly.

Cleaning and Disinfecting Procedures

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

The cleaning procedure is to remove dust, blood and body fluid from the surface and should be performed whenever the meter or lancing device is visibly dirty. Performing the cleaning procedure once per week is recommended. The disinfecting procedure is necessary to kill pathogens such as HBV on the housing materials of the device. The cleaning and disinfecting procedure should be performed at least once per week. The meter and lancing device should be cleaned before being disinfected.

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

CaviWipes Disinfecting Towelettes has been tested and may be used to clean and disinfect the meter and lancing device. Users may purchase the disinfecting wipes from the manufacturer (Metrex), distributors or major on line Users may purchase the disinfecting wipes from the manufacturer (Metrex), distributors or major on line retail sites such as www.amazon.com and www.ebay.com. You can contact Metrex customer service at 1-800-841-1428 and info@metrex.com. (Monday through Friday, between 6 AM and 4 PM PST)

Please see the following references for further information:

-FDA Public Health Notification: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010).

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

- CDC Clinical Reminder: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

NOTE

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

To clean the meter:

1. Thoroughly wipe the entire surface of the meter, especially port, face/display, housing and buttons with disinfecting wipes listed above to clean any possible dirt, dust, blood and other body fluids.

To disinfect the meter:

2. Take another disinfecting wipe and wipe the meter thoroughly. (Note: All blood and body fluids should be cleaned from surface before performing the disinfecting procedure)

3. Allow the surface to remain wet for 2 minutes.

4. Allow to air dry.



NOTE

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

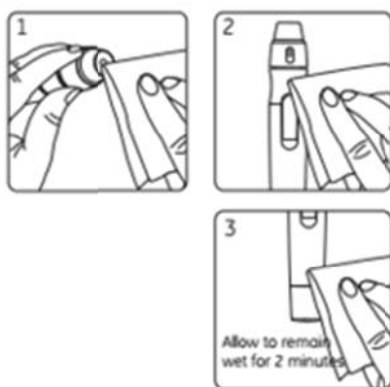
To clean the iGlucose lancing device:

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

To disinfect the iGlucose lancing device:

2. Take another disinfecting wipe and wipe the iGlucose Lancing device thoroughly. (Note: All blood and body fluids should be cleaned from surface before performing disinfecting procedure)

3. Allow the surface to remain wet for 2 minutes.



NOTE

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

- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device or test strips.

- Please examine your LCD screen, test strip port, buttons and surface of your meter and lancing device after cleaning and disinfecting cycles. Stop using the meter and/or lancing device if any of the following occur:

- Thin, sliver streaks appear on the screen,

- The screen becomes cracked, soft, dissolved, brittle or swollen.

- You are unable to turn on/off your meter, operate the left/ right button, the lancing device release button or depth adjustable cap.

- You are unable to enter meter settings, function modes or recall your testing results.

If you have any questions or concerns, please contact your Blood Glucose Monitoring System authorized representative or call the GE Diabetes Support Center.

Error Messages and Troubleshooting

Trouble Shooting

Potential problems and the recommended solution(s) are listed below:

Problem	Possible reason	Solution(s)
Cannot turn on device	No battery Battery not charged Battery connection error	Check battery is inserted correctly. Recharge battery. Replace battery.
Cannot turn off device by pressing middle button	Software error	Press and hold “up” button, select “Shutdown”.
Part of the display is not working	Device is damaged	Contact customer support at 1-844-IGLUOSE (1-555-555-5555)
Cannot insert strips	Strip inserted incorrectly. Damaged strip. Incorrect make of strip. Damaged strip slot.	Insert the strip in the correct way. Use a different strip. Use correct make of strip. Repair or replace device.
No response when strip is	Battery is dead.	Charge the battery.

inserted into the device.	Strip was inserted incorrectly. Wrong strip was inserted. Device is damaged.	Insert the test strip in the correct way. Insert the right test strip. Contact customer support.
No response when blood sample is applied to the strip	Blood sample is not sufficient. Strip is has been used or is damaged. Device is damaged.	Repeat the test with a sufficient blood sample. Repeat the test with a new strip. Check the device with a Control Solution test.
Cannot send data	Weak signal or network error	Retry later or in different location. All unsent data will be sent together with data for next test
Cannot synchronize time	Network error	Set manually from device menu: Date & Time

Contact customer support at (1-555-555-5555) for any unresolved issues.

Display Messages and Problem-Solving Guide

When any of the following messages appears, there is a problem that requires your attention.

Display	Description	Action to Take
HI	Blood glucose result may be higher than 600 mg/dL.	Review proper testing procedure and perform a quality check with control solution. Repeat blood test; if "HI" still appears, call your doctor or seek medical attention immediately.
LO	Blood glucose result may be lower than 20 mg/dL.	Review proper testing procedure and perform a quality check with control solution. Repeat test; if "LO" still appears, call your doctor or seek medical attention immediately.
Temperature out of range	Temperature is above or below the operating range of test strips or the device.	The result you have obtained may not be accurate. Move to an area with temperature between 50°F - 104°F (10°C to 40°C). Do not artificially heat or cool the device. Repeat the test with a new test strip.
Low Battery	Battery is low on charge.	Charge the battery.
Unknown strip	Test strip unknown or may be damaged.	Perform the test with new test strip.
Discarded strip	Test strip is used or test was not performed correctly.	Discard the strip and repeat the procedure with a new strip from the vial or package Perform the test with a new test strip and follow the test procedure correctly.

If error messages appear that are not listed above, or for any unresolved issues, contact customer support at (1-555 555 5555).

1. In order to get accurate testing results, please test between 50-104 °F (10-40 °C).
2. When the temperature is below 50 °F (10 °C) or over 104 °F (40 °C), the meter will not function and the " " symbol will blink.
3. If the iGlucose Blood Glucose meter and Test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.

Sampling Error

Please do not apply the blood to the sample port of the test strip before the meter displays: “apply a drop of blood”. Otherwise, the meter will display an error message. Please discard the test strip and use the new one.

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

Er2- The meter has malfunctioned. Do a Quality Control Test or reinstall the batteries to check if the meter works properly.

Er3- The signal transmission is disrupted. Repeat the test using a new test strip.

Er4- The blood sample volume is insufficient. Repeat the test using a new test strip.



Insufficient
blood sample



Sufficient
blood sample

Er5- An issue calibrating the Meter has occurred. Please follow the steps below:

- (1) Remove the test strip from the meter.
- (2) Turn off the meter (press and hold the Main button for 3 seconds).
- (3) Press the main button to turn ON the meter.

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

If one of the above error messages still appears, please contact iGlucose Diabetes Customer Service at 1-55-555-5555.

Meter Malfunction

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

1. Open the battery cover and remove the batteries.
2. Wait for 5 minutes and reinsert the batteries as described as instructed on page 19, (Meter Activation and Changing the Battery).

The meter should work normally after finishing the above steps. If the meter still does not work, please contact iGlucose Diabetes Customer Support Center.

CAUTION

A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and the Meter's screen is showing the image of the test strip and a blood drop flashing symbol. If the blood drop flashing symbol is NOT showing on the screen, do not apply a sample to

the test strip. Please re-insert the unused test strip correctly. The screen MUST show the image of the test strip accompanied by the blood drop symbol flashing (this symbol take 3 seconds to show after correctly inserting the test strip) in order for a sample to be applied. Please consult your User Manual and/or contact Customer Service for support on how to correctly insert a Blood Glucose Test strip.

FEDERAL COMMUNICATIONS COMMISION (FCC) STATEMENT

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference and
- 2) this device must accept any interference received, including interference that may cause undesired operation of the device.

Specifications

GSM	GSM Platform	MT6260
	Mode	GSM+GPRS
	Frequency	GSM 850/900/1800/1900
	Antenna	Interior on the bottom
Glucose	Type	Module mounted
	IC	Fujitsu MB95F378E

	Test Sample	Fresh capillary whole blood
	Test Result	Plasma / Serum glucose
	Sample Size	Less than 0.5 µL
	Measuring Time	Less than 5 seconds
	Measuring Range	20mg/dL~600mg/dL
	Hematocrit Range	20% ~ 60%
	Working temp	10°C ~ 40°C,
General	LCM	Size - 2.4" QVGA
		Hi contrast TFT
		Colors 260K
		Resolution - 320 * 240 pixels
	Button pad (3 Buttons)	Left - Menu, information menu
		Middle - ON/OFF; Enter, test mode change
		Right - Averages, readings history
	Meter Dimension	100* 49.8 * 16.5mm
	Meter weight	85g+/-5g With battery
	meter input	DC5V, 0.5A
	Port	Micro USB - Charging, software download
	Speaker	15MM mini-speaker as buzzer or vocal reminding
	Battery	Capacity
	Battery	3.7V, 1,000mAh Li-Ion
		Life - 25-30 days for normal use (2-3 tests per day)
	Data entry	500 Entries
	Main standby page	GSM signal strength, battery level, carrier name, date/time
	Languages	English
	software name and version	Bionime X.X

Warranty

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

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

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

Please complete and return the enclosed warranty card.

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

iGlucose is a trademark of Smart Meter Corporation.

NOTE

- During blood glucose measurement, the iGlucose Blood Glucose meter itself may come into contact with blood. All parts of the iGlucose Blood Glucose Monitoring System are considered biohazardous and can potentially transmit infectious diseases. Please follow your healthcare professional's direction to properly dispose of the used iGlucose Blood Glucose Monitoring System after removing the batteries.

Customer Service

Please review all of the instructions to make sure you are performing the steps correctly. If you have any questions or concerns, please contact the iGlucose Diabetes Support Center toll free at 1-555-555-5555 or visit our web site:

www.gediabetes.com. (Monday through Friday 8:00 AM to 5:00 PM PST. If you have questions or need assistance outside the operational days and times, please contact your healthcare provider.)

Expected glucose values for persons without diabetes ⁽¹⁾

Status	Range (mg/dL)
Fasting	< 100 mg/dL
Two hours after meals	< 140 mg/dL

References

1) American Diabetes Association: Diabetes Care, January 2015, volume 38 (Suppl. 1) S8-S16.

Component Manufacturer Information

iGlucose Blood Glucose Meter, Test Strip, Control Solution

Manufacturer: Bionime Corporation

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

Lancing Device

Manufacturer: Bionime Corporation

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

Disposable Sterile Lancets

Warranty Card

Distributor name and address

PLACE

STAMP

HERE

Warranty Card

Name:	Tel:	Distributor name and address
Address:		
Serial No.:	Model	
Date of Purchase:		

(Please present this card for product replacement)

Limited warranty:

1. Bionime warrants to the original purchaser only, that the iGlucose Blood Glucose meter 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 iGlucose Blood Glucose meter only if used as directed and provided that the failure to perform has not been caused in whole or in part by the use of test strips that are not iGlucose Blood Glucose Test Strips manufactured by Bionime. Use only iGlucose Blood Glucose Test Strips in your iGlucose Blood Glucose Meter.
3. The sole obligation of Bionime under this warranty shall be to replace any defective iGlucose Blood Glucose Meter. No other warranties, express or implied, are made. Bionime shall not be responsible for any incidental or consequential damages.
4. You must contact your distributor for assistance and/or instructions for obtaining a replacement iGlucose Blood Glucose meter is a trademark of Smart Meter Corporation.

Emergency Card

iGlucose Blood Glucose Monitoring System

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

I am a person with diabetes. If you find me in a coma or stupor, please contact nearest emergency services immediately. Or call:

* Please fill out this card and carry with you at all times.

Description of used symbols

	For in vitro diagnostic use		Manufacturer
	Lot number		Expiry date
	Temperature limitation		For single use only
	Method of sterilization using irradiation		Consult the instruction for use
	Biological risks		WEEE
	Caution (consult instructions for use and warnings)		