iGlucose®

Blood Glucose Monitoring System

Owner's Booklet

iGlucose® Blood Glucose Monitoring System User Manual

iGlucose® is a trademark of Smart Meter LLC.
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 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 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 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 System is intended to be used by a single person and should not be shared.

The iGlucose 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 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.

WARNING:

The device is not intended for use in multi-patient facilities such as hospitals, physicians offices or long term care facilities. It has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B

Virus (HBV), or other blood borne pathogens. The iGlucose® Blood Glucose Monitoring System is supported by Smart Meter, LLC. We will make every effort to assist you. If you have any questions or concerns, please contact the iGlucose Diabetes Customer Support Center Mon - Fri, 8am - 5pm EST at 1-844-IGLUCOSE (1-844-445-8267) or email us at support@ iglucose.com. Please contact your healthcare provider after normal business hours.

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

CAUTION

- The iGlucose Blood Glucose Meter and iGlucose Lancing Device are for single patient use. Do not use on multiple patients. Do not share meter with anyone including other family members.
- Do not use the lancing device for assisted blood draws by healthcare providers or at healthcare provision sites and do not share it with anyone else, even a family member.
- Before using the iGlucose System to test your blood glucose, please read all of the instructions.
- Please perform a quality control test with control solution regularly to make sure the test results are accurate. (See "Performing a Quality Control Test").
- The iGlucose Meter can only be used with the 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 plasma samples.
- The iGlucose Monitoring System should not be used to screen for or diagnose diabetes mellitus.
- If the iGlucose Blood Glucose Meter and iGlucose Test Strips are exposed to a substantial change in temperature, please wait 45 minutes before measurement.
- The iGlucose System is not for use on neonates.
- 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."
- Users should wash their hands thoroughly with soap and water before and after handling the meter, lancing device, or test strips.

LIMITATIONS

- This device is not for use on anyone in a hyperglycemic hyperosmolar state, with or without ketosis.
- Not for use with critically ill patients.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3,048 meters) above sea level.
- Hematocrit levels outside the 20-60% range may yield inaccurate results.
- High concentrations of Uric acid >9 mg/dL, Cholesterol >600 mg/dL, and Ascorbic acid (Vitamin C) >5 mg/dL may interfere with the glucose test causing inaccurate test results. Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. This means that when the uric acid concentration in your blood is greater than 9 mg/dL you may get inaccurate and unreliable glucose results. Please check with your doctor before using the iGlucose® Blood Glucose Monitoring System.
- Do not perform the blood glucose test at temperatures below 50°F (10°C) or above 104°F (40°C), 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.
- For over-the-counter use. Single patient use only. For in vitro diagnostic use only.
- Not for use on neonates or the critically ill.

Please see the following references for further information.

1. FDA Public Health Notification: Use of Fingerstick 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 Fingerstick Devices on More than One Person Poses Risk or Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-Devices-BGM.html

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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.

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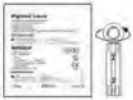

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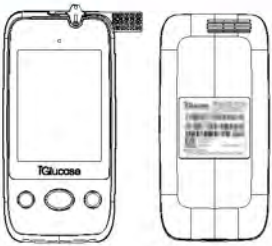
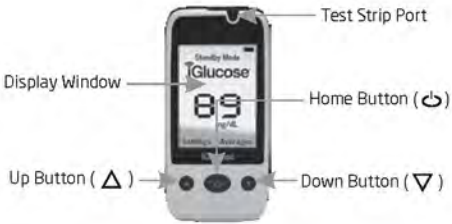
1. iGlucose® Blood Glucose Meter
2. iGlucose® Blood Glucose Test Strips
3. Rightest® Control Solution GC550
4. Meter Charger
5. Disposable Sterile Lancets (10 pcs)
6. Lancing Device
7. Owner's Booklet
8. iGlucose® Blood Glucose Test Strip Package Insert
9. Rightest® Control Solution GC550 Package Insert
10. Quick Reference Guide - Meter, Test Strip and Lancing Device
11. Quick Reference Guide - Website Portal, Text Messages and Circle of Care

The iGlucose Blood Glucose Monitoring System consists of the iGlucose Blood Glucose Meter, the iGlucose Test Strips as well as Rightest® Control Solution. The iGlucose Meter is a cellular device.

When used with its corresponding iGlucose Test Strips, it measures glucose in a small drop of fresh capillary whole blood (minimum 0.75 µL). The blood drop is placed on the test strip where it interacts with chemicals to produce an electrical current which is read by the meter and is converted to the corresponding glucose level in the sample. The glucose result is then displayed on the meter within 5 seconds.

THE IGLUCOSE BLOOD GLUCOSE MONITORING METER

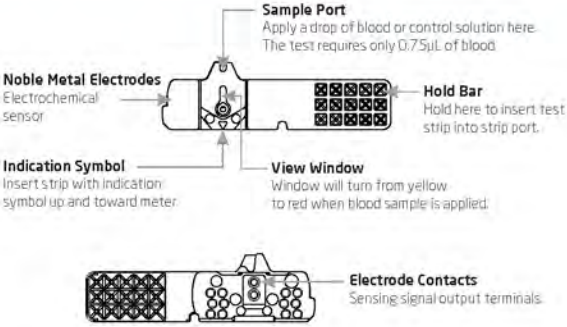




THE iGLUCOSE BLOOD GLUCOSE METER ICONS

	• Indicates a control solution test result
mg/dL	• Unit of test result
109 mg/dL	• Test result
	• Battery fully charged
	• Battery is low and must be recharged
	• Indicates a meal marker. A full apple for "Before Meal" and an eaten apple for "After Meal"
	• Indicates that there is a connection to a cellular network
	• Indicates when to apply a blood drop
	• Indicates when to apply a control solution drop

THE iGLUCOSE BLOOD GLUCOSE TEST STRIP



CAUTION

- The iGlucose® Blood Glucose Meter can only be used with the iGlucose Blood Glucose Test Strips and the Rightest® Control Solution GC550. The use of other test strips or control solutions can lead to incorrect results.
- Close the iGlucose Test Strips vial immediately after removing a test strip.
- Test strips should not be kept outside the capped vial. Strips removed from the vial for practice purposes should not be used for testing and should be discarded.
- Do not reuse iGlucose Test Strips.
- Do not use expired iGlucose Test Strips (See expiration date on Test Strip vial.).

• 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 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.
• Storage of strips near bleach as well as bleach containing products will affect the results of the iGlucose 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. The need to wait 45 minutes is required when for example, a meter is kept for a while in a car on a hot afternoon and then brought into an air conditioned room for testing or when a meter is kept outside on a snowy day and then brought into a warm room.
• For more information, please refer to the iGlucose Test Strips Package Insert.
• The use of other test strips may cause strip error.

AUTO CODE

The iGlucose Blood Glucose Meter will automatically detect the code number on the strip. You do not have to manually enter a code number.

TURNING THE METER ON / OFF

• To power on the iGlucose Meter, press and hold the "Home" button until the meter turns on. The display will light up. In the next few seconds the meter will display "Searching" while the date and time automatically synchronize. When done, a message "Date & Time Synchronized" will appear and the meter will enter "Standby Mode."

• After turning the meter on, the iGlucose® Blood Glucose Meter will remain lit for 60 seconds. After 60 seconds, it will go dark and into "Standby Mode". The meter can be awakened by pressing any button or inserting a test strip.
• To power off the iGlucose Meter, make sure the screen is lit by pressing any button and then press and hold the "Home" button for 3 seconds.

METER BATTERY CHARGE

Your iGlucose Meter comes with an installed lithium rechargeable battery. When fully charged this battery will provide power to perform approximately 500 tests under normal use.

CHARGING THE BATTERY

• Connect the meter charger to the mini usb port on the bottom of the meter.
• Plug the charger into a power outlet. When the unit begins to charge, the screen illuminates, a blue light appears above the screen, a charging battery icon appears on the screen along with the message "Charging. Cannot Perform Glucose Test". The blue light remains on while charging continues. It may take 2-3 hours to fully charge.
• When charging is complete, the battery icon on the device screen appears solid green.
• Before using, unplug the charger from the power outlet and from the meter.

REPLACING THE BATTERY WHEN NEEDED

- Take the new battery out of its plastic bag.
- Open the back cover of the device by inserting your thumbnail into the small groove on the side of the meter near the bottom of the cover and lift the cover up.

- Remove the old battery.
- Install the 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.
- Replace the back cover of the device and close tightly.
- Charge the battery following the instructions above.

CAUTION

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

SYNCHRONIZING THE DATE AND TIME AUTOMATICALLY

The date and time are synchronized automatically when the meter is turned on and when the message "Date and Time Synchronized" appears.

SETTING THE DATE AND TIME MANUALLY

1. Press the "Δ" button on the device.

2. Scroll to the "Date and time" option by using the "Δ" or "∇" button and press the "Home" button to select. The "Date and Time" menu appears.
3. Scroll to the "Set Date" option by using the "Δ" or "∇" button and

press the "Home" button to select. The year appears. Use the "Δ" or "∇" button to change the year as needed. Press the "Home" button to select and move on to the month.
4. Scroll using the "Δ" or "∇" button to change the month as needed. Press the "Home" button to select and move to the day.
5. Scroll using the "Δ" or "∇" button to change the day as needed. Press the "Home" button. A "Done" confirmation message appears.
6. To set the time, in the "Date and Time" menu scroll to "Set Time" by using the "Δ" or "∇" button and press the "Home" button to select. The hour appears. Use the Settings "Δ" or "∇" button to change the hour as needed. Press the "Home" button to select and move on to the minute.
7. Scroll using the "Δ" or "∇" button to change the minute as needed. Press the "Home" button. A "Done" confirmation message appears.
8. To exit the Settings menu, press the "Δ" or "∇" button to scroll to the "Back" option and press the "Home" button to select and exit the menu.

SETTING THE FORMAT FOR THE DATE OR TIME

1. Press briefly the "Δ" button on the device. The Settings menu appears.
2. Scroll to the "Date and time" option by using the "Δ" or "∇" button and press the "Home" button to select. The "Date and Time" menu appears.

3. Scroll to the "Date Format" option by pressing the "Δ" or "∇" button and press the "Home" button to select.
4. Press the "Δ" or "∇" button to scroll to the desired date format. Press the "Home" button to select. A "Done" confirmation message appears.
5. Scroll to the "Time Format" option by using the "Δ" or "∇" button and press the "Home" button to select.
6. Press the "Δ" or "∇" button to scroll to the desired time format. Press the "Home" button to select. A "Done" confirmation message appears.
7. To exit the Settings menu, press the "Δ" or "∇" button to scroll to the "Back" option and press the "Home" button to select and exit the menu.

SETTING PREFERRED METER SOUND VOLUME

1. Press briefly the "Δ" button on the device. The Settings menu appears.
2. Scroll to the "Volume" option using the "Δ" or "∇" button and press the "Home" button to select. The "Volume" menu appears.
3. Select the level of sound volume you prefer between "Silent" and "Level 5" by using the "Δ" or "∇" button. Level 5 provides the highest volume. Press the "Home" button to select. A "Done" confirmation message appears.
4. To exit the Settings menu, press the "Δ" or "∇" button to scroll to the "Back" option and press the "Home" button to select and exit the menu.

CHOOSING A BLOOD TESTING MODE

To provide a better understanding of your blood glucose results the iGlucose® Blood Glucose Meter can help you record your results as "Before Meal" represented by a full apple icon or "After Meal" represented by an eaten apple icon .

You select this icon for a blood glucose test done before a meal.

You select this icon for a blood glucose test done after a meal.

The iGlucose Meter provides two ways to set this up:

- From the home screen: Turn the meter on by pressing and holding the "Home" button. One of the two apple icons will appear on the screen, either the "Before Meal" or the "After Meal" icon. If the icon shown is not what you desire, press the "Home" button again to switch and select the other icon.
- From the Settings menu: Press the "Δ" button on the device. The Settings menu appears. Scroll to the "Blood Testing" option using the "Δ" or "▽" button and then press the "Home" button to select. The "Blood Testing" menu appears and you can select between "Before Meal" and "After Meal" using the "Δ" or "▽" button. Press the "Home" button to select. The home screen will appear with the chosen icon of either "Before Meal" or "After Meal".

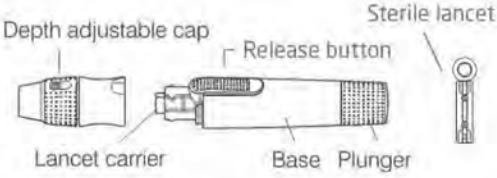
CONFIRMING SIGNAL QUALITY

1. The iGlucose Meter is a cellular device. Each time you perform a blood glucose test, the device will automatically connect to the cellular network and then transmit the test result to your online Electronic Logbook. In the rare instance that you experience difficulty with the cellular connection then please contact the iGlucose® Diabetes Customer Support Center at 1-844-445-8267. A Customer Support Center representative may assist you in the use of the Signal Quality function as part of a troubleshooting process in order to assure that your device is functioning 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

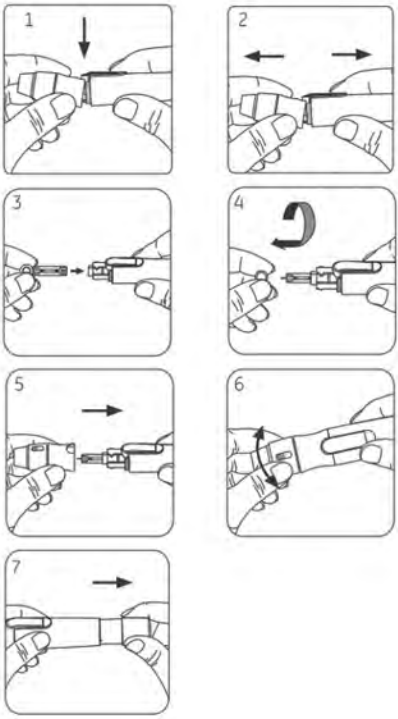


PREPARING THE LANCING DEVICE

1. Hold the adjustable depth cap of the lancing device in one hand while holding the base in the other hand. Slightly force downward to separate the two parts. Please see drawing below.
2. Pull the two parts in opposite directions to remove the adjustable depth cap.
3. Insert a new disposable lancet firmly into lancing device.
4. Twist off and set aside the protective cover of the disposable lancet. This round piece will be used later to dispose of the used lancet.
5. Replace the depth adjustable cap firmly.
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:

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

7. Prepare (cock) the lancing device for a finger stick by holding the base of the lancing device in one hand and pulling on the plunger with the other hand, please see drawing #7 below. The device will be cocked. Release the plunger and it will automatically move back to its original position near the base.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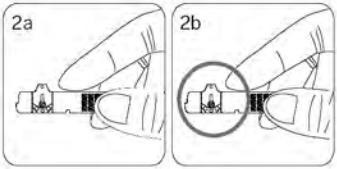
PERFORMING A BLOOD GLUCOSE TEST

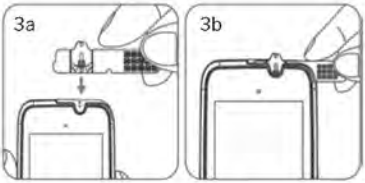
- Wash your hands thoroughly with soap and water and dry well.
- Set your meter test mode to "Before Meal" or "After Meal" by turning the meter on (pressing and holding the "Home" button). Press the "Home" button to get to the desired "Before Meal" or "After Meal" icon on the screen.
- Take one iGlucose® Blood Glucose Test Strip from the vial. **Close the vial cap immediately.**

INSERTING THE TEST STRIP

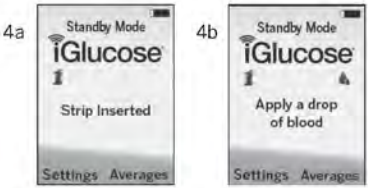
1. Hold the iGlucose Test Strip between your thumb and middle finger with the view window facing you (dark side of the sample port facing you).
2. Put your forefinger on the side of the strip as shown.



3. Insert the iGlucose Test Strip into the test strip port straight downwards with the strip view window facing you until it clicks and firmly stops.
If in Standby Mode, your meter will automatically turn on once the strip is inserted and the message "Strip Inserted" will be displayed.



4. The meter goes through an internal check that takes 3 seconds. **Wait until a blood drop icon and "Apply a drop of blood" message appears** on the display window. Once the message appears, apply the blood sample within 120 seconds.



APPLYING A BLOOD SAMPLE

- Place the lancing device against your fingertip and press the release button as indicated in the drawing below.

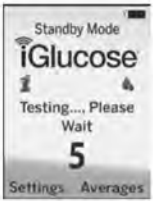
Note: The blood sample should come out by gently squeezing.

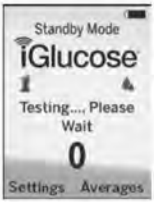
The minimum blood sample size to test using the iGlucose® Blood Glucose Monitoring System is 0.75 µL:

Sample Size Example

Blood sample size above 3.0 µL might contaminate the test strip port and the meter while blood sample size below 0.75 µL may cause an inaccurate result or may prevent a meter reading. An error code will be displayed if the sample size is too small. In this case, repeat the test with a new test strip.

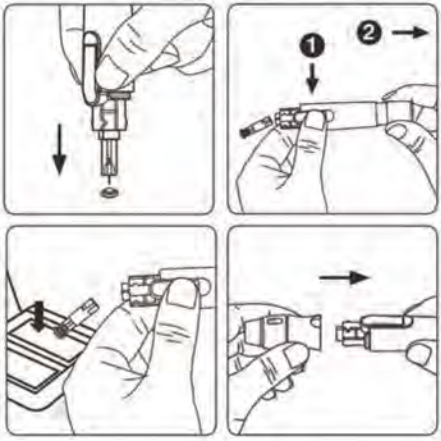
- Touch and hold the blood drop to the edge of sample port until the view window is filled with blood. Please see above drawing.
- If the view window is not completely filled with blood the test will not start. Discard the used test strip and repeat with a new iGlucose® Blood Glucose Test Strip. Please see section below on "View Appearance of Blood on the Strip".
- The meter will now count down from 5 to 0 and will display your blood glucose result. A "No Service" message may appear which does not impact the meter's function. It means that the cellular service has not made a connection. The glucose result will still be displayed and will still get recorded in the system's memory.





REMOVING THE USED LANCET

- Pull off the depth adjustable cap. Locate the protective lancet cover and place it on a flat surface. Without touching the used disposable lancet, securely insert the sharp lancet tip into the protective lancet cover. See drawing below.
- Hold the release button of the lancing device in one hand and pull on the plunger with the other hand to safely eject the used disposable lancet. See drawing below.
- Discard the used disposable lancet into a "Sharps" container.
- Clean and disinfect the lancing device (see section on Cleaning and Disinfecting Procedures). Replace the depth adjustable cap after finishing the test.



REMOVING THE iGLUCOSE BLOOD GLUCOSE TEST STRIP

• Hold the iGlucose® Blood Glucose Test Strip by its right edge as shown.
• Rotate the iGlucose Test Strip upwards (counterclockwise) and pull up simultaneously.
• Take the iGlucose Test Strip out of the test strip port.

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

• 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.

STUDY RESULTS OF TYPICAL iGLUCOSE USERS

• Like all commercially available blood glucose meters, your iGlucose® Blood Glucose Meter result may vary slightly from your actual blood glucose value. This may be due to slight **differences in technique and the natural variation in the test** technology. The table below shows the results of a study where 153 typical users used the iGlucose Meter to test their blood glucose level. When glucose results were below 75 mg/dL the iGlucose Meter gave results within 15 mg/dL of their true blood glucose level 6 out of 6 times.

Difference range between the true blood glucose level and the iGlucose Meter result	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
The percent (and number) of meter results that match true bloodglucose level withinx mg/dl	33.3% 2/6	83.3% 5/6	100% 6/6

• When the users' results were equal or greater than 75 mg/dL in this study, the iGlucose Meter gave results within 15% of their true blood glucose level 140 out of 147 times.

Difference range between the true blood glucose level and the iGlucose Meter result	Within ±5%	Within ±10%	Within ±15%
The percent (and number) of meter results that match true bloodglucose level withinx mg/dl	43.5% 64/147	81.6% 120/147	95.2% 140/147

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.
- The iGlucose Test Strip should be stored capped in their vial. Use each iGlucose Test Strip immediately after removing it from the vial to avoid exposure to light and humidity. Test strips that are left out of the vial should not be used for testing.
- Do not reuse iGlucose Test Strips.
- Apply the blood sample to the sample port of the test strip only.
- A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and the meter's screen shows both a blood drop icon and the message "Apply a drop of blood". This takes 3 seconds from the time a test strip is inserted. During this time the iGlucose Blood Glucose Meter performs an internal check. If the blood drop icon and the message are NOT showing on the screen, do not apply a sample to the test strip as it will result in an error message.
- 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 section "Cleaning and Disinfecting Procedures.

VIEW WINDOW APPEARANCE

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

Insufficient blood sample

Sufficient blood sample

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.

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.

You can also run a quality control test with the Rightest® Control Solution GC550 to check your iGlucose Meter and iGlucose Test Strip (Refer to "Performing a Quality Control Test").

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 600mg/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.

ABOUT QUALITY CONTROL TESTING

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

Use 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 test strip vial label, the iGlucose Monitoring System passes the quality control test and your iGlucose System is working properly.

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

Control Solution Range mg/dL	
Level 2:	93-125
Level 4:	N/A

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 Test Strip or when opening a new vial of test strips.
- To check your iGlucose 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 glucose 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 of the control solution, **whichever comes first.**

Example

- After use, wipe the top of the bottle cap with a clean wet tissue and then with a dry one to remove any residue of the control solution.
- Close the bottle of control solution tightly immediately after using.
- Keep control solution bottles out of reach of children.

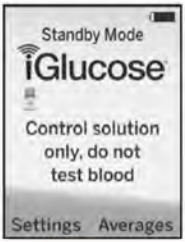
WARNING

Do not apply blood when testing in the "Control Solution" mode and when this icon is displayed. Testing blood in this test mode will produce inaccurate blood results.

PERFORMING A QUALITY CONTROL TEST

1. Press briefly the "△" button on the device and the Settings menu will appear.

2. Scroll to the "Control Solution" by using the "△" or "▽" button and press the "Home" button to select.



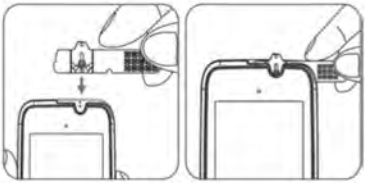
The Control solution screen appears with the message "Control solution only, do not test blood".

3. Take one iGlucose® Blood Glucose Test Strip from the vial and **close the vial cap immediately.**

INSERTING THE TEST STRIP

1. Hold the iGlucose Test Strip between your thumb and middle finger with the view window facing you (colored side of the sample port facing you).

2. Insert the iGlucose® Test Strip into the test strip port straight downwards with the strip view window facing you until it clicks and firmly stops. If not on yet, your meter will automatically turn on once the strip is inserted and the message "Strip Inserted" will be displayed.



3. The meter goes through an internal check that takes 3 seconds. Wait until a Control Solution drop icon and "Apply a drop of control solution" message appears on the display window. Once the message appears, apply the control solution sample within 120 seconds.

Note: When a test mode is set for a Control Solution, the result will not be calculated into averages.

a. Shake the bottle of Rightest® Control Solution GC550 well before opening the cap. Remove the bottle cap and place it on a flat surface.

b. Place a drop of control solution onto the top of the cap. See drawing below.

c. Gently touch the sample port of the strip to the control solution on top of the cap. See drawing below.

d. The meter will now count down from 5 to 0 and will display the control solution test result.

e. The control solution result will appear on the display for a few seconds and the meter will then revert to the home screen. You can recall and view your Control Solution test results by pressing the "▽" button to select the "Averages" menu. Scroll with the "△" or "▽" key to the "Prior Readings" and select it with the "Home" button. The Control Solution test result will be shown with the control solution icon next to it.

Compare your quality control test result to the control solution range printed on the iGlucose® Blood Glucose Test Strip vial label.

f. Wipe any residue of the control solution from the top of the cap with a wet tissue and then with a dry one. Tightly replace the cap on the Rightest® Control Solution GC550 bottle.

g. Remove test strip from meter. See removing the iGlucose Test Strip.

CAUTION

• The control solution test should be conducted between 59-104°F (15-40°C) and in a location with a relative humidity of 10-90%.

• Do not touch the control solution to the sample port on the strip before seeing the message "Apply a drop of control solution". The iGlucose® Blood Glucose Meter performs an internal check that takes 3 seconds. 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 as this could flood and 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 a wet tissue, then with a dry one and pour out 2 drops of control solution.

Understanding 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 iGlucose® Blood Glucose Monitoring System is working correctly.

Example of control solution range printed on your test strip vial label. These ranges may vary depending on the test strip lot that is in use.

Control Solution Range	Level 2	Level 4
	88-120 mg/dL	N/A

Possible reasons why your Control Solution results are out of range:
• Your Rightest® Control Solution GC550 is expired or was first opened more than 3 months ago.
• Your iGlucose Blood Glucose Test Strip has expired.
• You left the cap of the iGlucose 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 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 the 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

The iGlucose Blood Glucose System maintains in the device memory the averages of your blood glucose readings for the last 7, 14, 30, 60 and 90 days.

To obtain glucose readings averages:

- Press the "▽" button on the right side of the device.
The "Averages" menu appears.
- Scroll to the desired option by using the "△" or "▽" button then press the "Home" button to select:
    - Last 7 Days
    - Last 14 Days
    - Last 30 Days
    - Last 60 Days
    - Last 90 Days

• The average blood glucose reading for the selected period appears. Press the "Home" button to return to the "Averages" menu. Select another item from the menu that you wish to view, or scroll to the "Back" button by using the "Δ" or "∇" button and press the "Home" button to select and exit the "Averages" menu. Please note control solution readings do not count in calculating the averages.

Obtaining Test Results History

The iGlucose® Blood Glucose System maintains a record in the device memory of each blood glucose reading for up to 500 readings. To obtain the list of previous blood glucose readings.

Press the "∇" button on the right side of the device. The "Averages" menu appears. Scroll to the "Prior Readings" by using the "Δ" or "∇" button and press the "Home" button to select.

The "History" list appears showing previous readings. Press the "Δ" or "∇" button to scroll through the list. Results of control solution testing are also stored and identified by the control solution Icon next to them. Press the "Home" button to exit the list.

To exit the "Averages" menu, scroll to the "Back" button by using the "Δ" or "∇" button and press the "Home" button to select and exit the menu.

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 the clean damp cloth or disinfecting towelettes. Do not get the test strip port wet.

Cleaning Test Strip Port

If your test strip port is stained with blood, control solution or any liquid, please use a clean damp cloth listed below 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 Lancing Device

Use a clean damp cloth or the disinfecting towlettes listed below to wipe the outside of the lancing device. To avoid rusting the internal spring, do not submerge the device in water or wash the device in the dishwasher.

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. 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 contaminates from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

CaviWipes™ Disinfecting Towelettes 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 online retail sites such as www.amazon.com.

To purchase the disinfecting wipes from Metrex, please contact their customer service department at 1-800-841-1428 or email at info@metrex.com.

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.

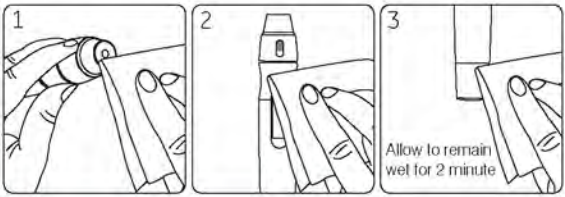
To clean the iGlucose Blood Glucose Meter:

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

To disinfect the iGlucose Blood Glucose Meter:

1. 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).
2. Allow the surface to remain wet for 2 minutes.
3. 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:

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:

1. 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).

2. 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, silver 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 "△" or "▽" 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 call the iGlucose® Diabetes Customer Support Center, 1-844-445-8267.

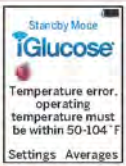
Troubleshooting

If problems remain, please contact the iGlucose® Customer Support Center at 1-844-445-8267, or email us at support@iglucose.com.

Problem	Possible reason	Solution(s)
Cannot turn on device	No battery. Battery not charged. Battery connection error.	Open the battery cover and check that the battery is inserted correctly. If so, remove the batteries, wait for 5 minutes and reinsert the battery as described in the Changing the Battery section. Recharge battery. Replace battery.
Part of the display is not working.	Device is damaged.	Contact customer support.
Cannot turn off device by pressing middle button	Software error.	Press and hold "Δ" button, select "Shutdown".
Cannot insert strips	Strip inserted incorrectly. Damaged strip. Incorrect brand of strip. Damaged strip sample port.	Insert the strip in the correct way. **Use a different strip.** Use correct brand of strip. Repair or replace device.
Meter does not produce sounds	Sound Volume is set to "silent".	Follow instructions for setting sound volume.
No response when charging meter	**Battery is insufficient to** show charging light.	Wait several minutes and a blue light should appear above the screen.
No response when strip is inserted into the device	Battery is dead. Strip inserted incorrectly. Incorrect brand of strip. Device is damaged.	Charge the battery. Insert the test strip in the correct way. Use correct brand of strip.
No response when blood sample is applied to the strip	Blood sample is not **sufficient.** Strip has been used or is damaged. Device is damaged.	Repeat the test with a new test strip **and 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 Settings menu: Date and time. See section on Date and Time Settings.

Display Messages and Problem-Solving Guide

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

Message	Possible reason	Solution(s)
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.
Low battery shutdown	Battery is low.	Charge the battery.
	Temperature is above or below the operating range for the device.	The glucose test result you may have obtained may be inaccurate. Move to an area with temperature between 50°F to 104°F (10°C to 40°C) and **wait 45 minutes. Do not artificially** heat or cool the device. Repeat the test with a new test strip.
	A blood sample was applied to the test strip before the meter displayed "Apply a drop of blood". Or, when testing a control solution, a drop of control solution was applied to the test strip before the meter displayed "Apply a drop of control solution".	Please discard the used test strip and retest using a new strip.
	The inserted test strip has been used or damaged.	Please use a new test strip.

Standby Mode iGlucose Device malfunction, please test with control solution Settings Averages	The meter has malfunctioned.	Do a Quality Control Test or reinstall the battery to check if the meter works properly.
Standby Mode iGlucose Signal failure, please insert new strip Settings Averages	Meter detects an abnormal signal while testing.	Repeat the test using a new test strip.
Standby Mode iGlucose Strip error, please check strip and re-insert Settings Averages	Meter senses that strip code may be affected.	Remove strip, check it and reinsert. If unsuccessful, discard the strip and use a new one.
Standby Mode iGlucose Low blood volume, please insert new strip and retest Settings Averages	The applied blood sample volume is insufficient.	Discard the used strip and repeat the test using a new test strip. Insufficient blood sample Sufficient blood sample
Standby Mode iGlucose Auto-coding error, please call customer service Settings Averages	An issue calibrating the Meter has occurred.	Remove the test strip from the meter. **Turn off the meter (press and hold the** "Home" button for 3 seconds). Press and hold the "Home" button again to turn the meter on and insert the test strip. If you do not see the error message again your meter is functioning properly and able to perform a test.
Standby Mode iGlucose BGM Voltage Error! Settings Averages	The meter has malfunctioned.	Restart the meter and test.

If one of the above error messages still appears, pleasecontact the iGlucose® Diabetes Customer Support Center at 1-844-445-8267.

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

Measurement Technology	Oxidase Electrochemical Sensor
Sample	Capillary Whole Blood
Sample Volume	**0.75 µL minimum**
Measuring Range	20-600 mg/dL
Test Time	5 seconds
Memory Capacity	500 blood glucose results with date and time
Power Saving	Automatically turns to Standby mode
Operating Temperature	50-104°F (10-40°C)
Operating Relative Humidity	10-90%
Operating Altitude	Up to 10,000 ft
Power Supply	Rechargeable battery **(3.7V, 1,000mAh Li-Ion)**
Battery Life	About 500 tests per battery charge without use of data transmission. Number of uses is reduced and varies when data is transmitted.
Meter Dimensions	104 mm × 49.8 mm × 16.5 mm
Meter Weight	85.0 ± 5 g with battery
Monitor	Color LCD
Monitor Display area	36.6 mm × 49 mm
Meter Storage/ Transportation Conditions	14-140°F (-10-60°C)
Test Strip Storage/ Transportation Conditions	39-86°F (4-30°C), 10-90% relative humidity
Interferences	Ascorbic acid > 5 mg/dL Cholesterol > 600 mg/dL Uric acid > 9 mg/dL
Hematocrit Range	20-60%
Shelf Life After Opening **the Test Strip Vial**	3 months
Coding	Auto Coding
Control Solution	Rightest® Control Solution GC550
Data Transmission	4G LTE CAT-M1
Backlight	Meter features a backlight.
Error Messages	Spelled out on meter display

Warranty

Smart Meter LLC 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 LLC.

Note: During blood glucose measurement, the iGlucose Meter itself may come into contact with blood. All parts of the iGlucose 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 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® Customer Support Center Mon - Fri, 8am - 5pm EST at 1-844-445-8267, or email us at support@iglucose.com. If you have questions or need emergency assistance outside normal business hours, 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. Standards of medical care in diabetes-2016. 2016;39 (supp. 1 diabetes Care):S16.

Component Manufacturer Information

iGlucose Blood Glucose Meter, Test Strip, Control Solution, Lancing Device
Manufacturer: Bionime Corporation. No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan.
Disposable Sterile Lancets Manufacturer: Please refer to the package.

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:

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								

Warranty Card

PLACE
STAMP
HERE

Name: Tel:

Address:

Distributor name and address:

Serial No.: Model

Date of Purchase:

(Please present this card for product replacement)

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.

Manufactured for:
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www.iglucose.com

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