125*85mm

MANUFACTURED FOR:
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Contact Smart Meter Customer Support Monday-Friday
9:00AM-5:00PM EST 844-445-8267
Please contact your healthcare provider for assistance
after normal business hours.

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iGlucose® Touch

Blood Glucose Monitoring System

Owner's Manual

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

The iGlucose Touch 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, forearm, or palm. It is intended to be used by a single person and should not be shared.

The iGlucose Touch Blood Glucose Monitoring System is intended for self- testing outside the body (*in vitro* diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The iGlucose Touch Blood Glucose Monitoring System is comprised of the iGlucose Touch Meter and the iGlucose Touch Blood Glucose Test Strips.

Preface

Thank you for selecting the iGlucose Touch 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 Touch Monitoring System provides accurate, reliable test results. It can be connected to web portals by GSM technology to help you better manage your diabetes.

You may wish to consult your healthcare professional for further advice on how to use this system. Our customer service information is on the cover and our staff are also willing to provide you with assistance. Please contact a healthcare professional in an emergency or when our service is not available

The iGlucose Touch 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 Customer Support Mon - Fri, 9am - 5pm EST at 844-IGLUCOSE (844-445-8267) or email us at support@iglucose.com. Please contact your healthcare provider after normal business hours.

Caution

- Before using the iGlucose Touch Blood Glucose Monitoring System to test your blood glucose, please read all of this information and conduct all of the tests including the Quality Control test.
- We recommend you perform the Quality Control test regularly to ensure test results are accurate. The iGlucose Touch Blood Glucose Monitoring System should be used with iGlucose Touch Control Solution GC700.
- The iGlucose Touch Meter can only be used with iGlucose Touch Test Strips. Test strips from other brands should not be used under any circumstances. The use of test strips from other brands may give inaccurate results.
- If the iGlucose Touch Blood Glucose Meter or iGlucose Touch Test Strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature - below 43°F (6°C) or above 111°F (44°C) - please wait at least 30 minutes before testing again.
- Follow all environmental protection regulations when disposing of batteries, strips and lancets.
- Avoid contact with spilled liquids.

Caution

- The minimum blood sample size to test using the iGlucose Touch Blood Glucose Monitoring System is 0.75 µL: (•)

Sample Size Example

Blood sample sizes greater than 3.0 µL may contaminate the test strip port and the meter. Samples smaller than 0.75 µL will cause Er4. If this occurs, repeat the test with a new test strip.

Important Safety Notes

- 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 "Maintaining the Products".
- Users should wash their hands with soap and warm water and dry thoroughly before touching the meter, lancing device or test strips. Please wash your hands after touching the products.
- This system may cause radio interference in the operation of nearby equipment. To reduce the interference, please relocate the meter or shield the product with a metal board.
- Please do not use any other cables or accessories which are not provided by Smart Meter, or it may have problems with electromagnetic compatibility.

Limitations

- The iGlucose Touch Blood Glucose Monitoring System can only use with capillary whole blood samples.
- Not for use on neonates.
- Not for screening or diagnosis of diabetes mellitus.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Hematocrit range is 10 - 70%. Check with your healthcare provider if you do not know your hematocrit level.
- Not for use on critically ill patients, severely hypotensive individuals, patients in shock,dehydrated patients, or in a hyperglycemic-hyperosmolar state with or without ketosis.
- 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 bloodborne pathogens.
- The iGlucose Touch Blood Glucose Monitoring System is for over-the-counter use and single patient use only.
- Alternative site sample results may be different from fingertip sample results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).

- Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the following applies:
  • you think your blood sugar is low.
  • you are not aware of symptoms when you become hypoglycemic.
  • the results do not agree with the way you feel.
  • after a meal.
  • after exercise.
  • during illness.
  • during times of stress.
- DO NOT use the results from alternative site testing (palm, forearm) to calibrate Continuous Glucose Monitoring (CGM) devices.
- DO NOT use the results from alternative sites (palm, forearm) for insulin dose calculations.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients
- The iGlucose Touch Blood Glucose Meter is a cellular-connected device using a 4/5G LTE network.
- Communication through cellular connectivity is not recommended during flights. Therefore, when you are on an airplane you should turn on the flight mode (airplane mode). This will turn off the cellular function.

NOTE

To make the owner's manual straightforward and easy to read, the product name will be abbreviated as follow in subsequently sections.

- iGlucose Touch Blood Glucose Monitoring System as the system.
- iGlucose Touch Blood Glucose Monitoring Meter as the meter.
- iGlucose Touch Blood Glucose Test Strips as the test strips.
- iGlucose Touch Control Solution GC700 as the control solution.

All products mentioned in this manual are under the iGlucose brand unless otherwise stated.

- If you have a condition, such as kidney disease or gout, that may cause your blood levels of uric acid to rise to more than 12 mg/dL, the results from your meter may not be correct.
- If you are taking a high level of vitamin C (ascorbic acid level in your blood > 3 mg/dL), your blood glucose results may not be reliable. If you are unsure, ask your doctor.
- If you have a condition, such as jaundice, that may cause your blood levels of Conjugated Bilirubin to rise to more than 30 mg/dL, the results from your meter may not be correct.
- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.

The following is a summary of safety information which must be observed before using the iGlucose Touch. WARNING indicates potential danger to user. PRECAUTION indicates potential injury to the user or damage to the system. To minimize risks, read the following safety information before using the system. Improper use and maintenance may damage the system resulting in failure or user injury. It is important to understand that the safety information is not exhaustive. It is meant to keep the user safe while using the system.

⚠ **WARNING**

- **Modification of the System is Not Allowed:** Do not modify or tamper with any components or accessories of the iGlucose Touch. All components of the iGlucose Touch are not allowed to be used with any product not in this system. Otherwise, you could damage the integrity of the system and put yourself at risk especially when you have a severe low or high glucose event.
- **Choking Hazard:** The iGlucose Touch contains small components that may be dangerous if swallowed.

PRECAUTION

- **Use as Directed:** The AC power adapter, USB cable and USB charger to be used with the iGlucose Touch comply with safety regulations for medical devices. Use only these components when charging your meter. Otherwise, it could damage the system or cause fire. Make sure the access to the power adapter is not blocked and it can be easily unplugged due to the potential risk of electrical shock.
- **Do NOT Use If It Could Fall into Water.** Do not spill liquids on meter or submerge it in water or other liquids. If the meter has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the meter while it is wet could result in electric shock or no glucose results.
- **Traveling by Air.** Always check and follow flight rules or regulations before departure.
- **Trouble Shooting** If any situation not mentioned in this owner's manual occurs, please contact your healthcare professional or contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.

About the iGlucose Touch Blood Glucose Monitoring System	
iGlucose Touch Blood Glucose Monitoring System	16
iGlucose Touch Blood Glucose Meter	18
iGlucose Touch Blood Glucose Test Strip	22
Before Testing	
Before Getting Started	24
Turning On/Off the Meter	26
Meter Setting	27
Turn On/Off Flight Mode	30
Handling iGlucose Touch Blood Glucose Test Strips	31
Testing Procedure	
Performing a Blood Glucose Test	33
Setting Markers	38
Uploading Data	39
Alternative Site Testing	40

View Window Appearance	42
Understanding Test Results and Messages	43
Quality Control	
About Quality Control Testing	45
Performing a Quality Control Test	48
Understanding Control Test Results	51
Other Information	
Maintaining the Products	52
Recalling Test Results	56
Recalling Average Test Results	57
Error Messages and Troubleshooting	59
Specification	64
FCC STATEMENT	67
Warranty	69
Customer Service	71

Accuracy for Home Use by Lay-Users	72
Precision for Home Use	73
Expected Glucose Values	74
Cybersecurity	75
Operating Bands	77
Manufacturer’s declaration	78
Log book	85
Warranty card	87
Emergency card	88

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

1. iGlucose Touch Blood Glucose Meter (with Li-polymer battery, type C cable, 5V adapter)
2. User Documents

A. iGlucose Touch Blood Glucose Test Strips, B. iGlucose Touch Control Solution GC700, C. iGlucose Touch Lancing Device, and D. Disposable Sterile Lancets should be purchase independently.

* If you have any questions, please contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.

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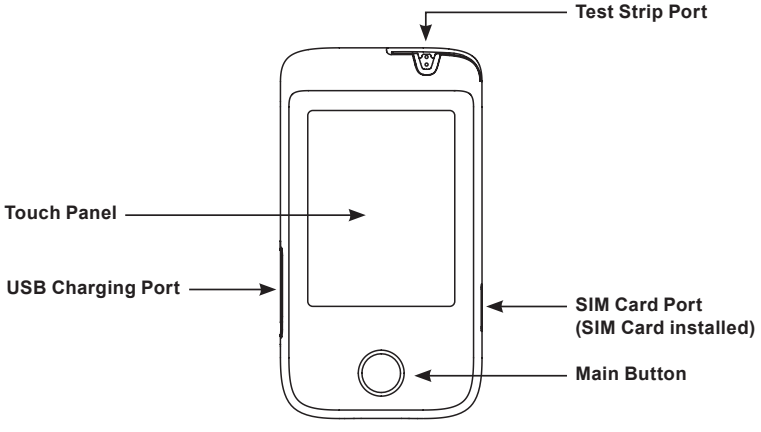
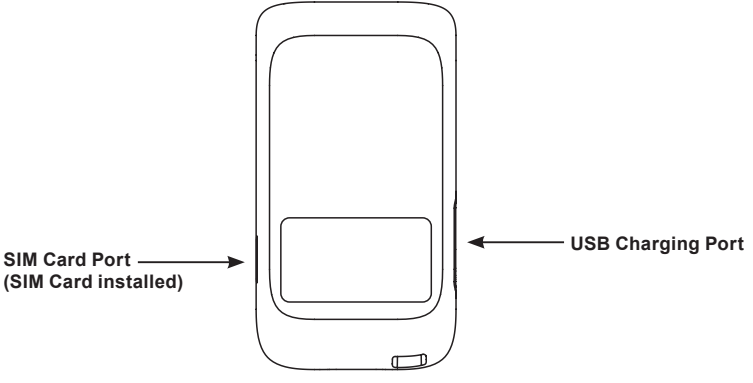
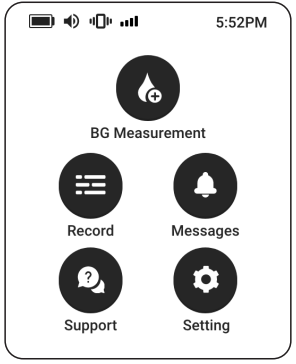
iGlucose Touch Blood Glucose Meter GETTING STARTED GUI


Test Strip Port
Touch Panel
USB Charging Port
SIM Card Port
(SIM Card installed)
Main Button

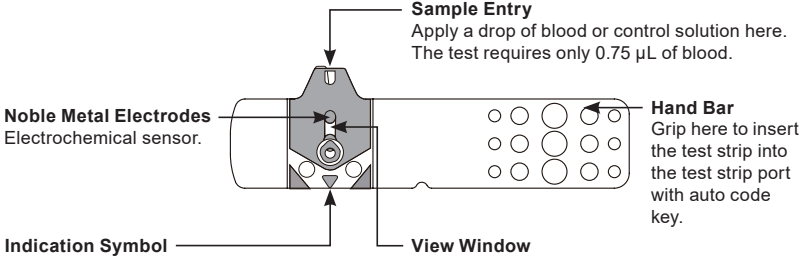

SIM Card Port
(SIM Card installed)
USB Charging Port

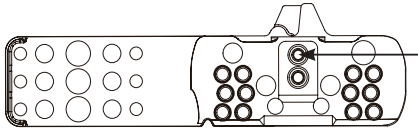
Home Screen



	Indicates that the current battery status. A larger black area indicates a higher battery charge. When the black area shrinks or disappears, please charge your meter.		
	Indicates that the battery is actively charging. When the black area becomes full, your meter is fully charged.		
	Indicates there is a cellular network signal available and ready for data uploading.		Indicates the meter vibration is turned on.
	Indicates there is no cellular network signal available for data uploading.		IIndicates the flight mode (airplane mode) is on.
	Indicates the meter sound is turned on.		Indicates the measurement record has uploaded.
	Indicates the meter sound is turned off.		Indicates the measurement record hasn't uploaded.

The iGlucose Touch Blood Glucose Meter can only be used with iGlucose Touch Blood Glucose Test Strips and iGlucose Touch Control Solution GC700. The use of other test strips or control solutions may lead to incorrect results.





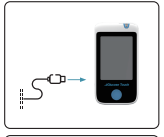
Electrode Contacts
Sensing signal output terminals.

PRECAUTION
- Close the vial immediately after taking out a test strip.
- Do not reuse the test strip.
- Do not use expired test strip.
- Write the opening date on the label of each new vial of test strips you open. Use test strips within 4 months of opening or until the expiration date printed on the label, whichever comes first.
- Store the test strip at 39 - 86°F (4 - 30°C) and 10 - 90% relative humidity. Do not expose to direct sunlight or heat.
- If the meter or the test strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature – below 43°F (6°C) or above 111°F (44°C)
- Please wait at least 30 minutes before testing again. The test strips should not be stored at below 39°F (4°C) or above 86°F (30°C) temperatures.
- For detailed strip information, please refer to iGlucose Touch Blood Glucose Test Strip Insert.

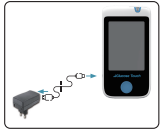
Charging Basics
Before using the system for the first time, charge the meter for a complete charging cycle without interruption.
A complete charging cycle of the meter takes about 3 hours when using the supplied USB adapter plugged into a standard household electrical outlet (100 to 240V AC, 50/60 Hz). It is recommended to use only the supplied USB cable and USB power adapter.

Charging the Meter
PRECAUTIONS :
- Use as Directed: The AC power adapter, USB cable and USB charger provided with the iGlucose Touch comply with safety regulations for medical devices. Use only these components when charging your meter. Otherwise, it could damage the system or cause fire. Make sure the access to the power adapter is not blocked and it can be easily unplugged due to the potential risk of electrical shock.
- Do not test while the meter is charging.
- Use the battery status icon (displayed on top-left corner of meter screen) to check the charging status. When the meter is charging, you will see lightning bolt in the middle of the battery icon. When the meter is closed and is plugged in, you will see battery status showed in the middle of the battery icon.

1. Connect the USB-C Plug of the charging cable to the USB-C input of the receiver.



2. Connect the USB plug to the USB port of the AC power adapter supplied with your system and connect the adapter to the power source.



Battery Life Indicator On the Meter
On the meter display, the battery level and the battery status icon (charging or discharging) is displayed in the top-left corner of the screen. When the meter is charging, you will see lightning bolt in the middle of the battery icon. When the meter is closed and is plugged in, you will see battery status showed in the middle of the battery icon. The meter utilizes an intelligent battery charging technology that prevents overcharging.

Turning On/Off the Meter

1. How to turn on the meter

Press and hold the main button for about 2 seconds or insert a test strip.

2. How to turn off the meter

Press and hold the main button for about 2 seconds and a box will pop up asking for confirmation to power off the meter.

3. Power saving

To save power, if the meter is idle for more than 30 seconds in non-test mode; or more than 2 minutes in test mode, the meter will switch to sleep mode, and turn off the screen automatically.

The screen-off time in non-test mode can be set by the user, please refer to the "Meter Settings" section.

To manually switch the meter to sleep mode, or to "wake up" the meter from sleep mode, press the main button once.

Meter Setting

Initial setting set-up

When the meter is turned on for the first time, it will automatically begin the setting set-up process. Follow the on-screen instructions to complete and save your settings. The meter will then return to the home screen and you can begin using the device.

Settings menu

You can go into the setting menu by tapping the "Setting" icon on the home screen. In the setting menu, features of the meter (e.g.Notification, Display, Date/Time, Target Range, CS Mode, Flight Mode, Language) can be set by the user.

Tap the item you want to set, and follow the on screen instructions to adjust the setting to fit your preferences. You could also find the CS mode (control solution testing mode) and the System Info (system information) in the setting menu.

For more detail about CS mode, please refer to the section "Performing a Quality Control Test". In the "System Info" menu option, you can find the Device S/N, IMEI number and firmware version.

In the "Set Target Range" menu option, you can set target blood glucose range for the before meal and after meal markers, and adjust the value to your target value. The upper and lower range limit bar will be displayed next to the measurement value.

NOTE
- The test unit of the meter is mg/dL by default and cannot be changed.
- The upper / lower limit marker is to be used as a reminder. Consult your doctor if you need further assistance with your limit range.

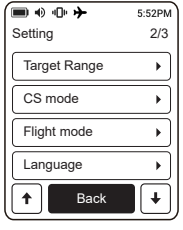
The date and time
- The date and time will be auto-set according to the cellular signal. It can also be manually set up by the user.
- Please check that the date and time are correct when using the meter.
- If you are to change time zones, the meter's date and time will not automatically update. You are still able to test your blood glucose, but please set the date and time manually if you are to travel. The correct date and time are necessary to correctly track your measurement data.

Cellular connectivity

The iGlucose Touch meter is a cellular device. Each time you perform a blood glucose test, the meter will automatically connect to the cellular network and transmit your test result back to your healthcare provider or care team. The SIM card in the iGlucose Touch is equipped with the capability to scan and connect to multiple cellular carrier networks and will allow the device to operate on the strongest available network in the device's geographic area.

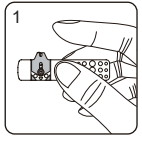
In the event there is a service interruption, the SIM card will switch to another available network, maintaining an uninterrupted connection. In the rare instance where your meter is not connecting to a cell network, you can call Smart Meter Customer Support at 844-445-8267, and they will assist you in the use of the signal quality function.

Turn on/off flight mode
Turn on/off "Flight Mode" in "Setting."

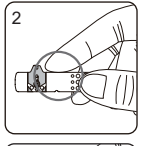


NOTE
- This device uses cellular connectivity for data uploading to cloud service, the cellular service is provided by Smart Meter.
- Please turn on flight mode (airplane mode) while using airplane travel when instructed. User can still perform blood glucose testing while flight mode is on, and the reading will be stored in the device memory and automatically transmitted once flight mode is turned off and a cellular connection is reestablished. Please follow all airplane travel policies for cellular connected devices.

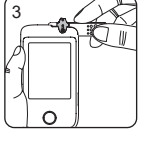
Inserting a test strip:
1. Hold the test strip between your thumb and middle finger with the View Window " " facing up.



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

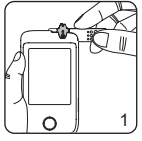


3. Insert the strip into the test strip port until it clicks in securely.

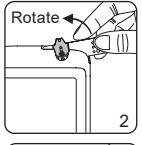


Removing a test strip:

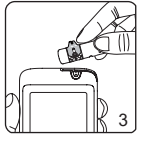
1. Hold the test strip as shown.



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



3. Take the strip out of the test strip port.
   Discard the used disposable lancet into an appropriate puncture-proof or bioharzard container.

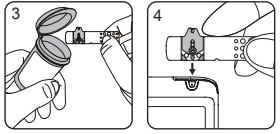


Prepare the Lancing Device:

1. Wash and dry your hands. Users should wash their hands with soap and warm water and dry thoroughly before touching the meter, lancing device or test strips.
2. Please check the sampling step on the lancing device insert carefully.

Performing a Test:

3. Take one test strip from the vial then immediately close the vial.
4. Insert the strip into the Test Strip Port of the meter with the View Window face up.



NOTE

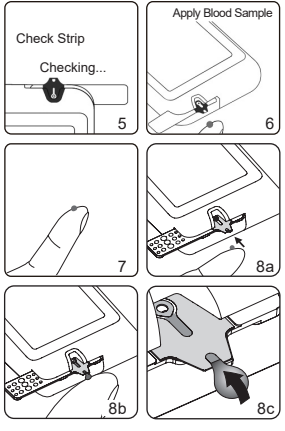
- The meter will automatically detect the Code Number of the test strip. You do not need to check the Code Number on the meter display and strip vial.

5. Once the strip is inserted, the meter will switch to the testing mode, the screen will display with "Checking" and emit a beep.

6. "Apply Blood Sample" will display on the screen, please apply the sample within 2 minutes.

7. Using the lancing device for pricking the finger.

8. Touch the blood drop to the edge of the sample port until the View Window is filled with blood. If the View Window is not filled, the test will not start. If this occurs, discard the test strip and repeat the test procedure with a new test strip.



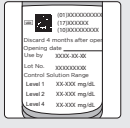
9. The screen will display a countdown timer. Your test result will be displayed after 5 seconds.

Lancet and Test Strip Disposal:

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

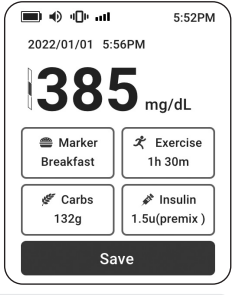
CAUTION

- Do not apply the blood sample before you see "Apply Blood Sample" appear. The meter is performing an internal check. Applying the blood sample too early will result in an error and "Sampling Error" will appear on the meter screen. This will be accompanied by beeps if volume is turned on. If this occurs, please repeat the test with a new test strip.
- Write the date opened on the label of each new vial of test strips you open. Use test strips within 4 months of opening or until the expiration date that is printed on the label, whichever comes first.



- Always keep the metal contacts of the test strip port clean. If there is any dust or dirt, please clean it off with a small, soft brush.
- All parts of this kit are considered a biohazard and can potentially transmit infectious diseases, even after you have performed the cleaning and disinfecting procedure.
- Users should wash their hands with soap and warm water and dry thoroughly before touching the meter, lancing device or test strips. Please wash your hands after touching the products.
- Please refer to the section "Maintaining the Products" for surface cleaning instructions.
- Do not reuse lancets. Discard used disposable lancets into an appropriate puncture-proof or bioharzard container.

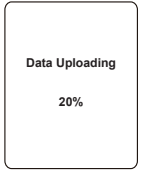
After 5 seconds countdown, the test result and test date and time will be displayed, along with 4 status markers below the result.
By tapping the marker you want to set, different options will be displayed, and you can use them to record the status and events of this test result.
After marked, tap Save to complete the test process. You can find the the result at a later time by going to your home screen and tapping the "Record" section.

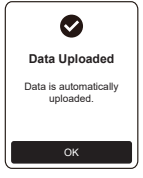


NOTE
You can only set the markers after each test result is shown. Once the result saved, the markers can no longer be changed.
If the meter is left idle for more than 2 minutes after the test result shows, the meter will automatically save the results without any marker.

The cellular network is set to on by default.
After saving test results, the meter will automatically transmit the test results.

If the iGlucose Touch is not connected to a cellular network when the result is saved, the result will be stored in the meter memory.
The next time you perform a test with a cellular connection, your results stored in the device memory will transmit with the test you just performed.





CAUTION
- Data transmission via a cellular network is not suggested during flights at any time. The meter, while connected to a cellular network, will emit electronic signals.
- Follow flight crew and airline instructions for turning on flight mode (airplane mode) on your device.

Alternative site testing: palm or forearm blood sampling

Please use medical device which can support the alternative site blood sampling, when you have the need for alternative site blood sampling.

Alternative Site Testing

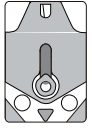
CAUTION

- Consult your healthcare professional before sampling from your palm or forearm.
- Alternative site sample results may be different from fingertip sample results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
- Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the following applies:
  - You think your blood sugar is low.
  - You are not aware of symptoms when you become hypoglycemic.
  - The results do not agree with the way you feel.
  - After a meal.
  - After exercise.
  - During illness.
  - During times of stress.
- DO NOT test on the palm or forearm if you are testing for insulin dose calculations or hypoglycemia (low blood glucose).
- AST results should not be used to calibrate Continuous Glucose Monitors (CGM).
- Use the clear cap provided with the lancing device when testing sites other than fingertips. The depth adjustable cap may not produce a blood droplet of sufficient size when testing on the palm or forearm.

View Window Appearance

To obtain an accurate test result, ensure that your blood sample covers the entire area of the View Window. 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 test strips.
- Use each test strip immediately after removing it from the vial.
- If the meter or test strips are exposed to extreme temperature changes, or environmental temperatures outside the meter operating temperature - below 43°F (6°C) or above 111°F (44°C) - please wait at least 30 minutes before testing again.
- Do not reuse the test strips.
- Only apply the blood sample to the test strip's sample port.
- Please don't drip or inject the blood sample directly into the sample entry of the test strip with a syringe. Doing so may contaminate the meter or cause damage.

Understanding Test Results and Messages

If your blood glucose result is unusually high or low, or if you have any doubts about your test results, repeat the test with a new test strip.

You can also use the control solution to perform a Quality Control Test on your meter and test strip (Refer to "Performing a Quality Control Test").

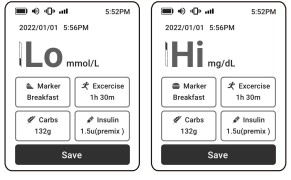
If the test result stays unexpectedly high or low, contact your healthcare professional immediately.

If you experience symptoms that are inconsistent with your blood glucose test results and you have followed all instructions in this manual, contact your healthcare professional immediately.

Consult your health care provider for details on how to properly dispose of used test strips and lancets.

The meter displays results between 20 and 600 mg/dL (1.1 and 33.3 mmol/L).
If the test result is below 20 mg/dL (1.1 mmol/L), **"Lo"** will appear on the screen. Please repeat your test with a new test strip. If you still get a **"Lo"** result, contact your healthcare professional.

If the test result is above 600 mg/dL (33.3 mmol/L), **"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.



NOTE
- If your blood glucose result is unusually high or low, or if you have any doubts about your test results, repeat the test with a new test strip. You can also run a Quality Control Test to check your meter and test strip. If the test result stays unexpectedly high or low, contact your healthcare professional immediately.
- If you experience symptoms that are inconsistent with your blood glucose test results and you have followed all the test instructions in this manual, contact your healthcare professional immediately.

What is a Quality Control Test ?
Users are to perform a quality control test on a regular basis to ensure that the blood glucose system is working properly.
When performing a Control Test, go to the control solution mode (CS mode) on your meter and use iGlucose Touch Control Solution when testing the device. If the test result falls within the Control Solution Range printed on the strip vial label, the system has passed the Quality Control Test and is working properly.

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

Control Solution Range	mg/dL
Level 1	28 - 48
Level 2	106 - 146
Level 4	315 - 427

NOTE
- The iGlucose Touch Control Solution GC700 is compatible with the iGlucose Touch Blood Glucose Monitoring Systems. If you need additional supplies, please contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.

When should a Quality Control Test Be Performed ?

- To confirm that your meter and test strip are working properly.
- To confirm that you are following the correct testing procedures.
- To prepare for your first blood glucose test.
- To check the test strip when you open a new vial of strips.
- To check your meter if it has been dropped, damaged or exposed to liquids.
- If you suspect that your test results are inaccurate, or if your test results are inconsistent with how you are feeling.
- To practice testing.

Required Items for Quality Control Tests

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

- iGlucose Touch Blood Glucose Meter
- iGlucose Touch Blood Glucose Test Strip
- iGlucose Touch Control Solution GC700

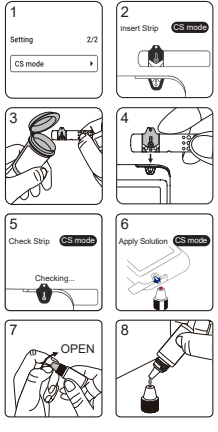
CAUTION

- Each time you open a new bottle of control solution, write the opening date on the label. The control solution should be used within 3 months of opening or until the expiration date printed on the label, whichever comes first.

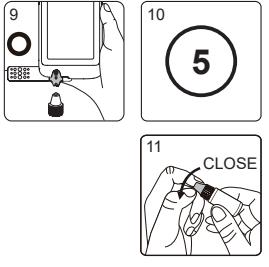
Example

- Wipe the bottle cap with a clean tissue before tightly closing the bottle of control solution.
- Close the bottle tightly immediately after use.
- Check the expiration date before use.
- Keep control solution bottles out of the reach of children.

1. To perform a quality control test, tap the "Setting" on the home page, and tap the "CS mode" to enter the mode.
2. Wait until screen displays "Insert Strip" and a CS mode icon on the top left of screen.
3. Remove a test strip from the vial and close the cap immediately.
4. Insert the test strip into the test strip port with the View Window face up.
5. Once inserted, the screen will display with "Checking" and emit a beep.
6. "Apply Solution" will display on the screen. You are ready to apply control solution to the strip.
7. Gently swirl the bottle of the control solution to ensure it is evenly mixed before removing the cap.
8. Place the cap on a flat surface. Squeeze a drop of control solution onto the top of the cap.



9. Touch the test strip sample port to the drop. Move the meter, not the cap.
10. The screen will display a 5-second countdown timer. You will hear a beep if the volume is on.
11. Place the cap back on the control solution bottle and ensure it is screwed on securely.
12. The Quality Control Test Result will appear on the screen. Compare the result with the Control Solution Range printed on the test strip vial label.



CAUTION

- Your Control Solution Test results will not be included in the average calculations but they can still can be recalled and viewed. The Control Solution Test result will be displayed with the "CS Mode" icon on the screen.
- The Control Solution Test should be performed at temperatures ranging from 43 to 111°F(6 to 44°C), with relative humidity ranging from 10 to 90%.
- Do not apply the control solution before "Apply Solution" and "CS Mode" appear. The meter is performing an internal check. Apply the control solution too early will result in "Sampling Error" to appear on the screen. It will be accompanied by a beep if the device volume is turned on. If this occurs, please repeat the CS test with a new test strip.
- Do not directly drip the control solution into the test strip's sample port. Doing so may contaminate the meter or the control solution.
- 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.

The control solution tests should fall within the control solution range printed on the test strips label, which means the system is functioning properly.

If the control solution test results were out of range, it may be due to:
- Your control solution is expired or was opened more than 3 months ago.
- Your test strips were expired.
- You left the test strips vial or the control solution opened for a long period after use.
- You did not perform the test procedure correctly.
- The meter or test strips malfunctioned.

If any level of the Quality Control test result is out of range, your system may be malfunctioning. Repeat the Quality Control Test. If any level of the Quality Control test result is still out of range, STOP using the system and contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.

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 sharing of lancets, lancing devices, and blood glucose meters.

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 HIV, HBV and HCV on the device.

NOTE: The cleaning procedure can only remove visible contaminates from surfaces. Only the disinfecting procedure can eliminate non-visible pathogens.

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 decontaminated prior to use by the second person.

The following disinfecting wipe has been tested and may be used to clean and disinfect the meter.

Users may purchase these disinfecting wipes from the manufacturer, their distributors or major

online retail sites such as www.amazon.com and www.walmart.com.

CAVIWIPES DISINFECTING TOWELETTES, manufacturer: Metrex. It is with Isopropanol as the active ingredient, have been shown to be safe for use with the meter and lancing device.

Maintaining the Products

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 ransmitting Bloodborne Pathogens: Initial Communication" (2010). https://wayback.archive-it.org/7993/20170111013014/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

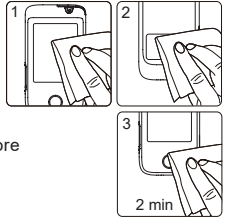
Maintaining

Keep your meter and test strip clean by keeping them free of dust, water, and other liquids. When not in use, keep the meter in its carrying case. Before performing a blood glucose test, perform a quality control test using the control solution if your meter has been dropped or damaged.

Cleaning and disinfection frequency: at least once a week.

To clean the meter:

1. Wipe the whole surface of the meter using the disinfectant wipes listed above to remove any dirt, dust, blood, or other bodily fluids.



To disinfect the meter:

2. Take a new disinfecting wipe to wipe the meter thoroughly (**Note:** All blood and body fluids should be cleaned from surfaces before performing the disinfecting procedure).
3. Allow the surface to remain wet for 2 minutes.
4. Allow to air dry.

NOTE

- Clean and disinfect the outside of the device only. Do not remove the Charging Port or Sim Port cover when cleaning and disinfecting.
- Your 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).
- For instructions on how to clean and disinfect the Lancing Device, refer to the Lancing Device insert.

Maintaining the Products

CAUTION

- Users should wash their hands with soap and warm water and dry thoroughly before touching the meter, lancing device or test strips. Please wash your hands after touching the products.
- If there is any cracking, swelling or dissolving, please stop using the meter and contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.

Recalling Test Results

The iGlucose Touch Blood Glucose Meter can automatically store up to 1000 test results with the time and date. If your meter has 1000 stored results, the most recent test result will take the place of the oldest.

To recall tests stored in the memory, tap "Record" on the home page.
Tap the "Results" icon, the previous test results will show in a list. The newest result will be on the top, followed by the older results.
Use "up" and "down" icon to turn the page. Tap "back" to return to the home page.

Recalling Average Test Results

The iGlucose Touch Blood Glucose Meter provides several average test results. View the 1-day, 7-days, 14-days, 30-days, 60-days and 90-days average test results for better blood glucose monitoring.

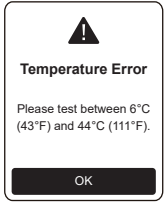
To check the average test results, tap "Record" on the home page.
Use the "up" and "down" icon to change the interval of average you want to view.
Tap "back" to return to the home page.

NOTE

- The averaging function requires the correct time and date to be set. Test results must exist within that specific time interval.
  Example: If you want to know the 14-day average of 1/30, you must have test results between 1/17 and 1/30. If you did not perform any test in the interval, the average won't be shown.
- The CS test result will be excluded the average calculation but it is still searchable in the "Record". In Results page of the "Record", the control solution test result will be displayed with a "CS Mode" icon.
- The "**Lo**" and "**Hi**" results, and test results under abnormal temperature conditions of < 43°F (6°C), > 111°F (44°C) will be excluded from average calculations.

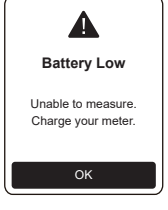
Temperature Error

1. Please test between 43°F (6°C) and 111°F (44°C) in order to obtain accurate test results.
2. The meter will not function if the temperature is below 43°F (6°C) or above 111°F (44°C).
3. If your iGlucose Touch Meter or Test Strips have been exposed to temperatures that below 43°F (6°C) or above 111°F (44°C), take the meter and strips back to an environment within the operating temperature of meter and wait at least 30 minutes before testing again.



Battery Low

The battery power is too low and can't support the test. Please charge the meter immediately.



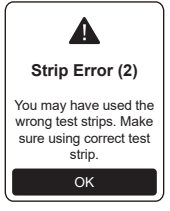
Strip Error

Strip error (1)

The meter will show this error notice if the test strip is inserted incorrectly. Do not apply a sample when you see this error. Please re-insert the unused test strip correctly. Please follow the steps in the Test Strip insert to re-insert the unused test strip, or contact Customer Support for assistance.

Strip error (2)

This error notice could mean that the incorrect test strip was used. Make sure you are using iGlucose Touch Blood Glucose Test Strip by checking the test strip vial.



Sampling Error

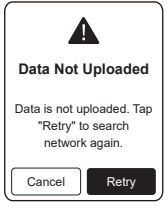
Please do not apply the blood to the sample port of the test strip before the meter is ready. Discard the test strip If the meter shows this error message.

LTE Not Connected

Find a location with a better cellular signal and tap "Retry".
Once you skip the connection, you need to turn off the meter and then turn on the meter to reconnect to the network.

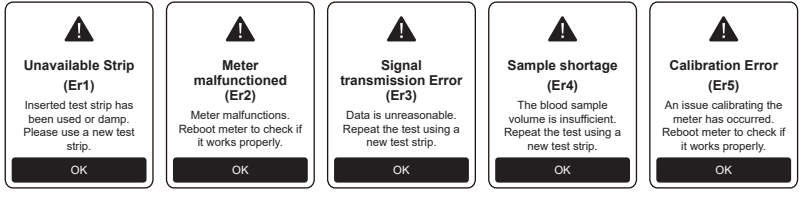
Data Not Uploaded

Tap "Retry" to search the network again.
If you tap "Cancel", the result will be stored in the meter. The next time you perform a test with a cellular connection, stored results that may not have been uploaded will be uploaded with the most recent reading.



Testing Mode Error code

Error codes on this page are errors that may happen while performing a test.



Er1 - The test strip was used or damp. Please try again with a new strip.

Er2 - The meter has malfunctioned. (1)Remove the test strip from the meter. (2)Tap the "Reboot" on screen or press and hold the main button for about 2 seconds to turn off the meter. (3) If the meter did not reboot after step 2, or the screen does not pop out the power off confirmation, please press and hold the main button for at least 10 seconds to power off the meter. Then press and hold the main button for about 2 seconds to turn on the meter.

Er3 - The glucose conduct has problem, repeat the test with a new test strip.

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

Error Messages and Troubleshooting

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

(1) Remove the test strip from the meter.

(2) Tap the "Reboot" on screen or press and hold the main button for about 2 seconds to turn off the meter.

(3) If the meter did not reboot after step 2, or the screen does not pop out the power off confirmation, please press and hold the main button for at least 10 seconds to power off the meter. Press and hold the main button for about 2 seconds to turn on the meter.

After turning on the Meter, you may perform a test again. If you do not see Er5, your meter is functioning properly.

CAUTION

- A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and meter shows "Apply Blood Sample."
- If the symbol is NOT showing on the screen, do not apply a sample to the test strip. Please re-insert the unused test strip correctly.
- It takes about 3 seconds for meter to check the strip after the test strip is inserted correctly. Please see the Owner's Manual and/or contact Customer Support for support on how to correctly insert a Test Strip.
- The meter should work normally after finishing the above steps. If the meter still does not work, contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.

Measurement Technology	Dehydrogenase Electrochemical Sensor
Measuring Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Test Time	5 seconds
Memory Capacity	1000 blood glucose test results with date and time
Power Saving	Turns off automatically after the default time 30 seconds or be set by the user. To turn off manually, press the main button for 2 seconds.
Operating Temperature	43 - 111°F (6 - 44°C)
Operating Relative Humidity	10 - 90%
Power Supply	Non-replaceable and Rechargeable lithium battery (3.7V)
Meter Dimension	60.0 mm x 110.0 mm x 14.0 mm

Meter Weight	95 ± 5g with batteries
Monitor	Color LCD
Display Area	2.8-inch touch panel
Meter Storage/Transportation Conditions	14 - 131°F (-10 - 55°C), Relative Humidity 10 - 90%
Sample	Refer to Test Strip insert
Minimum Sample Volume	
Hematocrit	
Test Strip Storage/ Transportation Conditions	
Battery Charging Time	3 hours (via AC adapter)

Specification

Charging Port	USB type C
Data Transmission	LTE network
Power Supply Specification	Input: 100-240V, 50/60Hz, 0.16-0.12A Output: 5V DC, 1A (5.0W) Class II
USB Type C cable 1 m	Shielding cable

FCC STATEMENT

FCC STATEMENT

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.

NOTE

- This equipment has been tested and found to comply with the limits for a Class B digitaldevice, pursuant to Part 15 of the FCC Rules and Regulations. 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 interference to radio frequency communications. There is no guarantee that interference will not occur in a particular installation.
- That the cellular meter may effect other medical electrical equipment. We recommend a safety distance no closer than 30 cm (12 inches) to any part of the and at least 1 meter for sensitive equipment.
- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided.

FCC STATEMENT

Turning the equipment on and off in proximity to a radio or television will determine whether the equipment is causing interference to signal reception. If interference is present, the user is encouraged to attempt to resolve it by one or more of the following methods:
• Reorient or reposition the receiving antenna.
• Increase the separation between the equipment and the receiving device.
• Connect the equipment to a different power outlet than the receiving device.
• Consult the dealer or an experienced radio or television technician.

FCC RF Radiation Exposure Statement:
1. This device must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For portable operation, this equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 5 centimeters between the radiator and your body.

CAUTION
Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Warranty

Smart Meter 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 a iGlucose Touch Blood Glucose Meter that has been altered, misused, tampered with or abused in any way.
This warranty applies only to the original purchaser of iGlucose Touch Blood Glucose Monitoring System.

Please complete and return the enclosed warranty card.

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

NOTE

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- During blood glucose test, the meter itself may come into contact with blood. All parts of the system are considered biohazardous and can potentially transmit infectious diseases. Please follow your local regulations to properly dispose of the system (please remember this meter contains a Li battery).
- Pollution degree of the intended environment: 2 Providing the RESPONSIBLE ORGANIZATION with maintenance instructions with regard to EM DISTURBANCES is a good and practical way for the MANUFACTURER to assure that the ME EQUIPMENT or ME SYSTEM remains safe with regard to EM DISTURBANCES throughout the EXPECTED SERVICE LIFE.
  For example, the technical description could include the following recommendations for actions that are known to affect the EMISSIONS and IMMUNITY of equipment throughout the EXPECTED SERVICE LIFE:
  • recommendations for maintenance or service intervals;
  • service procedures to maintain effectiveness of shields and grounds;
  • precautions to take if the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas.

We aim to provide great service to our customers. Please review these instructions to make sure you know how to use your product correctly. If you have any questions or encounter any issues with your product, please contact Smart Meter Customer Support Mon - Fri, 9am - 5pm EST at 844-445-8267 or email us at support@iglucose.com.
If abnormal behavior is observed due to EM disturbances, please contact the supplier or hospital for further information, and do not disassemble the device.

Description of used symbols

IVD	For *in vitro* diagnostic use		Use by Date		Biological risks
	Consult the instruction for use		Manufacturer		For single use only
	Temperature limitation	LOT	Lot number		Humidity limitation
FC	FCC Declaration of Conformity mark				Class II Equipment
	Caution (consult instructions for use and warnings)				
STERILE R	Method of sterilization using irradiation (only for lancet)				

Accuracy for Home Use by Lay-Users

Your iGlucose Touch 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 chart below shows the results of a study where 370 typical users used the iGlucose Touch to test their blood glucose level. For example, in this study, the iGlucose Touch gave fingertip results within 20% of their true blood glucose level 370 out of 370 times.

Difference range between the true blood glucose level and the iGlucose Touch result.		Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
The percent (and number) of meter results that match true blood glucose level within x%	Fingertip	62.4% (231/370)	90.0% (333/370)	98.6% (365/370)	100% (370/370)
	Palm	57.0% (211/370)	87.8% (323/370)	97.3% (360/370)	100% (370/370)
	Forearm	61.1% (226/370)	85.4% (316/370)	97.6% (361/370)	100% (370/370)

Precision for Home Use

The precision was evaluated including (i) 5 levels venous whole blood sample (ii) 5 levels glucose control solution in period of 10 days, by 10 meters and 3 batches of strips.

(i) Venous whole blood sample:

Glucose levels	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers (n)	300	300	300	300	300
(2) Mean mg/dL	41.9	91.3	129.1	225.5	339.7
(3) SD mg/dL	1.3	2.1	2.6	4.4	6.1
(4) CV (%)	3.1%	2.3%	2.0%	2.0%	1.8%

(ii) Control solution:

Glucose levels	CS-01	CS-02	CS-03	CS-04	CS-05
(1) Total test numbers (n)	300	300	300	300	300
(2) Mean mg/dL	37.2	103.9	136.4	205.3	263.5
(3) SD mg/dL	1.2	2.2	2.5	2.2	4.1
(4) CV (%)	3.2%	2.1%	1.8%	1.1%	1.6%

The expected blood glucose values for people without diabetes [1]

GLUCOSE LEVEL	Status
< 100 mg/dL (5.5 mmol/L)	Fasting
< 140 mg/dL (7.8 mmol/L)	2 hours after a meal

References

1) American Diabetes Association; Standards of Care in Diabetes—2023 Abridged for Primary Care Providers. Clin Diabetes 2 January 2023; 41 (1): 4–31.

1. Our product uses the telecommunications for data transmission, and encrypt with HTTPS SSL, the data which only contains the date and blood glucose record is not binding with your personal information.
2. The transmission speed and quality will be affected by the telecommunications signal, please contact with the telecommunications provider to solve the problem.
3. Please do not install any other software by yourself, our system does not support the firmware update.
4. The data will be transmitted by Smart Meter which will ensure the responsibility and safety for blood glucose record.
   Smart Meter will be the company that you agree the glucose data sharing service agreement with.
5. The SBOM of the Product.

SBOM	Supplier	Version	Relationship
Firmware	Bionime	GM777C002	Self
Firmware	Sonix Technology Co.	CMSIS-Core v1.3	Keil C Pack
Micro-controller	Sonix Technology Co.	SN32F298	Included in
LTE	Ublox	SARA-R500S 01B-00	Included in

6. The blood glucose record is stored in the blood glucose meter, the data transfer is not affected to the blood glucose record.
7. Please refer to “Error Messages and Troubleshooting” for the problem of transfer.
8. Individual results can not be deleted from the meter. All data can be deleted from the meter by resetting the meter. No data can be restored if the meter is reset.
9. The USB port of meter only supports charging and does not support data transmission.

Operating Bands	Cat M1 Band 2:1850-1910MHz Cat M1 Band 4:1710-1755MHz Cat M1 Band 12:699-716MHz
Modulation	QPSK、16QAM、BPSK
Bandwidth	1.4、3、5、10、15、20
Antenna Type	FPC
Max Power	23.5dBm

Manufacturer’s declaration-electromagnetic emissions		
The iGlucose Touch (GM777) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the product should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer’s declaration-electromagnetic immunity The iGlucose Touch (GM777) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the product should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s) + 0.5kV, +1kV,+ 2kV line(s) to earth	+ 0.5kV, +1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25/30 cycles Voltage interruptions: 0 % *UT*; 250/300 cycle	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 30 cycles Voltage interruptions: 0 % *UT*; 300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	The product power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer’s declaration-electromagnetic immunity			
The iGlucose Touch (GM777) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the product should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** product including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the iGlucose Touch (GM777)			
The iGlucose Touch (GM777) is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Manufacturer’s declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The iGlucose Touch (GM777) is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the product should assure that it is used in such an environment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Manufacturer’s declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The iGlucose Touch (GM777) is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the product should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Point / Window	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home healthcare)
30 kHz (a)	8	All points on photo below	CW	3	8
134,2 kHz	65	All points on photo below	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	All points on photo below	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.

Manufacturer's declaration-electromagnetic immunity The iGlucose Touch (GM777) is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the product should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s) + 0.5kV, +1kV,+ 2kV line(s) to earth	+ 0.5kV, +1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25/30 cycles Voltage interruptions: 0 % *UT*; 250/300 cycle	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25 cycles Voltage interruptions: 0 % *UT*; 250 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The product power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Name:

Address:

Home Phone: Work Phone:

Doctor: Doctor’s Phone:

Pharmacy: Pharmacy Phone:

Insulin/Pills: Log book date From: To:

In case of emergency contact:

Log book

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

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 Touch 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.