RIGHTEST™

Blood Glucose Monitoring System

Max Tel
User's Manual

RIGHTEST Blood Glucose Monitoring System Max Tel 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.

RIGHTEST Blood Glucose Monitoring System Max Tel is intended for self- testing outside the body (*in vitro* diagnostic use) by people with diabetes at home/indoor as an aid 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 RIGHTEST Blood Glucose Monitoring System Max Tel is comprised of the RIGHTEST Meter Max Tel and the RIGHTEST Blood Glucose Test Strip Max.

The RIGHTEST Blood Glucose Meter Max Tel is a LTE network device.

Thank you for choosing our product. This manual contains all the information you need to use your product to get accurate blood glucose test results. Please read this entire manual before you get started with any testing.

For people living with diabetes, it is important to regularly monitor blood glucose levels to reduce complications from diabetes. The easy-to-use RIGHTEST Blood Glucose Monitoring System Max Tel provides accurate, reliable test results to help you manage your diabetes better.

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. Please forward your warranty card to customer support to activate your warranty coverage.

The RIGHTEST Blood Glucose Monitoring System Max Tel is manufactured and supported by Bionime Corporation. If you have any questions or concerns, please contact your local Bionime Customer Service Representative or send an email to info@bionime.com for further assistance.

- Before using the RIGHTEST Blood Glucose Monitoring System Max Tel 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 RIGHTEST Blood Glucose Monitoring System Max Tel should be used with RIGHTEST Control Solution GC700.
- The Blood Glucose Meter Max Tel can only be used with extra spacing Blood Glucose Test Strips Max. 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 RIGHTEST Blood Glucose Meter Max Tel or Blood Glucose Test Strips Max 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.

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

Sample Size Example

0.75 µL	1.0 µL	1.5 µL	2.0 µL	3.0 µL
•	•	•	●	●

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 water before and after touching the meter, lancing device or test strips.
> - Equipment specified for use only in shielded location has appropriate marking/warning labels
> - This device should not be used adjacent to or stacked with other equipment.
> - Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.

- The RIGHTEST Blood Glucose Monitoring System Max Tel is not intended for serum or plasma testing.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Severe dehydration and excessive water loss may cause inaccurately low results.
- The blood glucose test result may be affected by a high blood concentration of interference ingredients. If you need more detailed information about interference ingredients, please see the RIGHTEST Blood Glucose Test Strip Max Insert.
- Not for screening or diagnosis of diabetes mellitus.
- These test strips should not be used with meters to test critically ill patients.
- 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.
- RIGHTEST Blood Glucose Monitoring System Max Tel is for over-the-counter use and single-patient use only.
- Alternative site testing (AST) should only be performed during steady-state times (when glucose is not changing rapidly). Please refer to the Alternative Site Testing (AST) chapter before you perform AST.
- DO NOT test on alternative sites (palm, forearm) if you are testing for insulin dose calculations, for Continuous Glucose Monitor (CGM) calibration or hypoglycemia (low blood glucose).

- To avoid potential electromagnetic interference, keep the meter away from electromagnetic radiation sources such as X-rays or MRI.
- LTE network is set on by default when the meter is on. Data transmission via LTE network is not suggested during flights at any time. This is because the meter, when turning on, will emit electronic signals, which should be restricted at all times aboard aircraft. Please turn on flight mode to avoid the auto-enabling of LTE network.

> **NOTE**
> To make the user's manual straightforward and easy to read, the product name will be abbreviated as follow in subsequently sections.
> - RIGHTEST Blood Glucose Monitoring System Max Tel as the system.
> - RIGHTEST Blood Glucose Monitoring Meter Max Tel as the meter.
> - RIGHTEST Blood Glucose Test Strips Max as the test strips.
> - RIGHTEST Control Solution GC700 as the control solution.
> - RIGHTEST Lancing Device as the lancing device.
> All products mentioned in this manual are under the RIGHTEST brand unless otherwise stated.

The following is a summary of safety information which must be observed before using the Max Tel. 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 Max Tel. All components of the Max Tel 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 Max Tel contains small components that may be dangerous if swallowed.

⚠ **PRECAUTION**
- **Use as Directed:** The AC power adapter, USB cable and USB charger provided with RIGHTEST Max Tel comply 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 user manual happens, please contact your healthcare professional or Customer Service.

Table of Contents

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

The items in RIGHTEST Blood Glucose Monitoring System Max Tel are:

1. RIGHTEST Blood Glucose Meter Max Tel (with Li-polymer battery, type C cable, 5V adapter)
2. User Documents (Getting Started Guide, User's Manual, Log Book, Warranty Card, Emergency Card)
3. RIGHTEST Blood Glucose Test Strips Max: 10 or 25 pcs (with Package Insert) *
4. RIGHTEST Control Solution GC700 (with Package Insert) *
5. RIGHTEST Lancing Device (with Package Insert) *
6. Clear Cap *
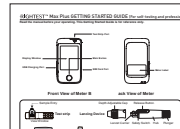7. Disposable Sterile Lancets (10 pcs) *
8. Carrying Case (not shown)

* Different packages have different bundled items. If you want to purchase the items not included in your kit, please contact distributor for more details.
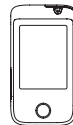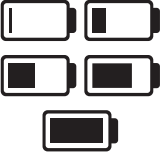
NOTE
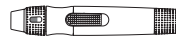- The RIGHTEST Blood Glucose Meter Max Tel is LTE network-compatible and can be connected to cloud data server.

Test Strip Port

Touch Panel

USB Charging Port

SIM Card Port

Main Button

SIM Card Port

USB Charging Port

Meter Label

Home Page

BG Measurement

Record   Messages

Support   Setting
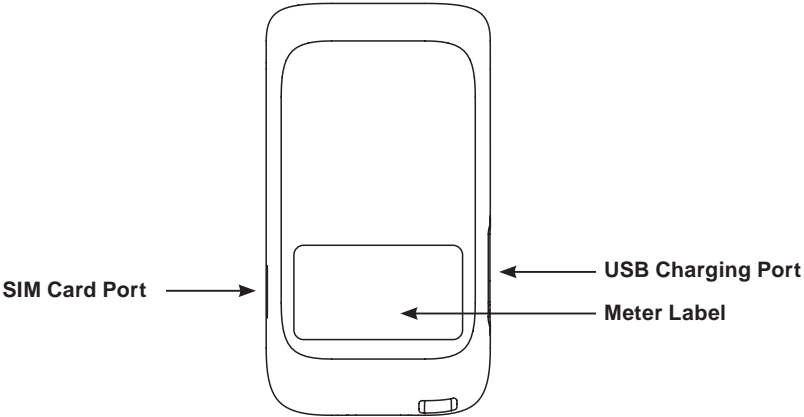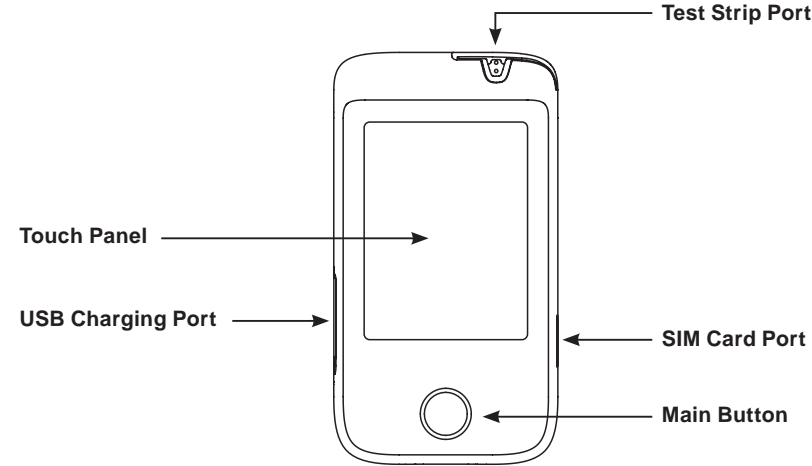
	Indicates that the current battery status. Larger black areas means the battery is more charged, and vice versa. When the black areas becomes smaller or empty, please charger your meter.
	Indicates that the battery is actively charging. When the black areas becomes full, your meter is fully charged.
	Indicates the signal of LTE network is available and ready for data uploading.
	Indicates the sound of meter is turned on.
	Indicates the sound of meter is turned off.
	Indicates the meter vibration is turned on.
	Indicates the flight mode is turned on (meter LTE network disabled).

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

Sample Entry
Apply a drop of blood or control solution here. The test requires only 0.75 μL of blood.

Noble Metal Electrodes
Electrochemical sensor.

Hand Bar
Grip here to insert the test strip into the test strip port with auto code key.

Indication Symbol
Insert strip with the symbol pointing towards the test strip port of the meter.

View Window
This window is yellow before applying a blood sample. It turns red when filled with blood.

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.
- For detailed strip information, please refer to RIGHTEST Blood Glucose Test Strip Max 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.
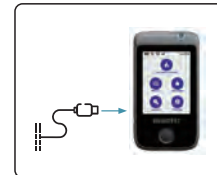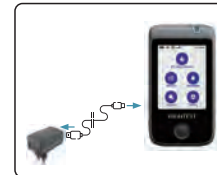
Charging the Meter

PRECAUTIONS :

- Cannot test during charging.
- Check the status of charging by the battery status icon (charging or discharging) is displayed in the top-right 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 should 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

From the meter display, battery level and the battery status icon (charging or discharging) is displayed in the top-right 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 should see battery status showed in the middle of the battery icon. The meter utilizes an intelligent battery charging technology that prevents overcharging.

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. Sleep mode

   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.

   You could also press the main button once, to manually turn the meter to sleep mode or wake it up from sleep mode.

Initial setting

When the meter is turned on for the first time, it will go into the setting process automatically. Follow the on-screen instructions to complete and save your own setting. After that, the meter will return to the home page. Now you can start using it.

Setting menu

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

Tap the item you want to set, and follow the on screen instruction to finish the setting according to your needs. 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.", you could find the Device S/N, IMEI number, and firmware version.

Note: The test unit of the meter is mg/dL by default and cannot be changed.

LTE connection

Before turn on the meter, please make sure that you have installed the sim card. The LTE connection will start automatically when the meter is turned on. If the LTE connection is successful, the date and time will be auto-set according to the LTE signal, and can't be change manually by user.

If the LTE connection is fail (or you did not install the sim card), you will need to set the date and time manually. Please note, that the correct time and date are necessary for the meter's analytic function.

If you install the sim after the meter was turned on, you could reboot the meter, or go into the "Setting" , find the "flight mode" in menu, turn on the mode then turn it off. Both ways could trigger the LTE connection.

Turn on/off flight mode

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

Setting	2/2
CS mode	▶
Flight mode	▶
Language	▶
System info.	▶
↑	Back	↓

Set Flight mode	
OFF	ON
Back	Save
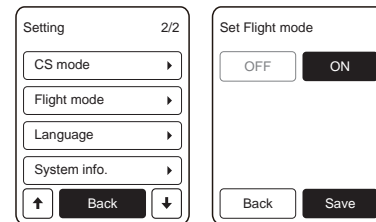
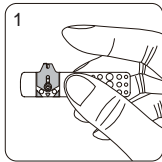📝 **NOTE**
- Please turn on flight mode in flight or electronic communications limited area.
  User can still perform blood glucose testing while flight mode is on.
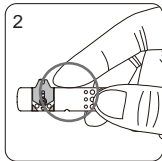 Please follow local electronic communications limited policy.

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.
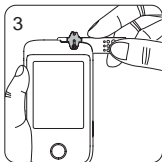
Removing a test strip:

1. Hold the test strip as shown.
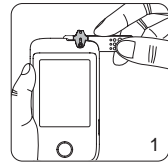
2. Rotate the test strip counterclockwise and pull up at the same time.

3. Take the strip out of the test strip port.
   Please follow your local regulations to discard used strips properly.

Depth Adjustable Cap — Release Button

Plunger

Lancet Carrier — Safety Switch — Hub
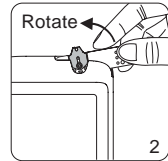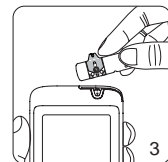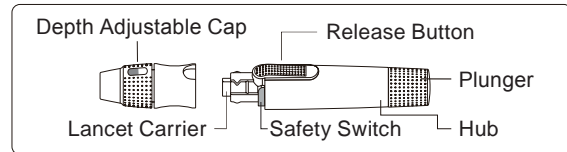
Prepare the Lancing Device:

1. Wash and dry your hands.

2. Hold the Depth Adjustable Cap in one hand and the hub in the other hand. Bend the cap downwards until a gap appears. The device will gently pop open.

3. Pull apart both ends to separate cap from the hub.

4. Insert a new disposable lancet firmly into the lancet carrier.

5. Twist off and set aside the protective cap of the lancet needle for later use.

6. Reconnect the Depth Adjustable Cap.
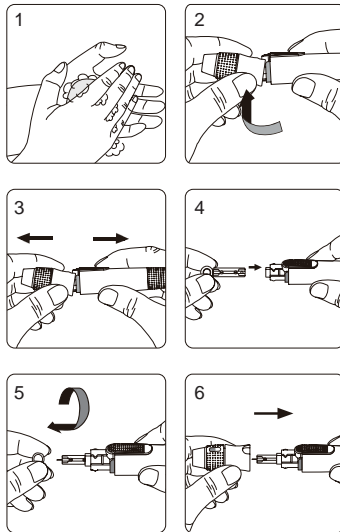
7. Rotate the clear top part of the cap to adjust the depth. Check the number of lines visible in the View Window. More lines correspond to a greater depth. Try:
" ▭ " for soft or thin skin; " ▭ " for ordinary skin;
" ▭ " for thick or calloused skin.

8. Pull back the plunger until you hear a click. The device is now primed. Let go of the plunger. It will return to its original position.

Performing a Test:

9. Take one test strip from the vial then immediately close the vial.

10. Insert the strip into the Test Strip Port of the meter with the View Window face up.
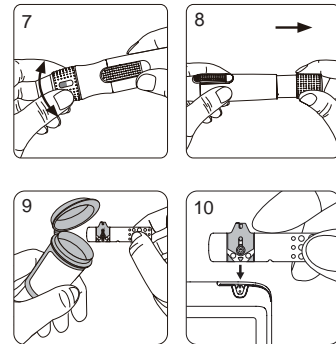
> **NOTE**
> - The meter will automatically detect the Code Number of the test strip. You do not need to check the Code Number on the meter display and strip vial.

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

12. "Apply Blood Sample" will display on the screen, please apply the sample within 2 minutes after you see it.

13. Place the lancing device against your fingertip and press the release button.

14. 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. In this case, discard the test strip and repeat the test procedure with a new test strip.

11
Check Strip

Checking...

12 Apply Blood Sample

13

14a

14b

14c
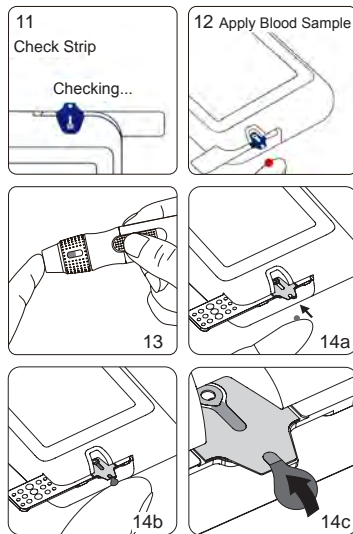
15. The screen will display a countdown timer. Your test result will be displayed after 5 seconds.

Lancet and Test Strip Disposal:

16. Separate the cap from the hub. Press the lancet needle into the side of its original protective cap.

17. (1) Hold down the release button and (2) pull back the plunger to eject the lancet.

18. Discard the lancet into a suitable biohazard container.

19. Replace the Depth Adjustable Cap after finishing the test.

5
15

16

17

18

19
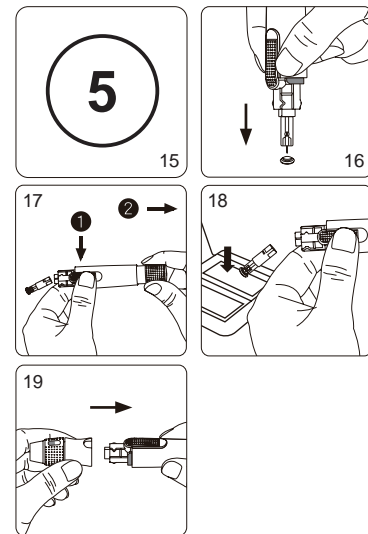
⚠ **CAUTION**
- Do not apply the blood sample before you see "Apply Blood Sample" appear. The meter is performing an internal check. Apply the blood sample too early will result in "Sampling Error". It will accompany by beeps if volume is turned on. If this happens, please repeat the test with a new 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.
- 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 biohazards and can potentially transmit infectious diseases, even after you have performed the cleaning and disinfecting procedure.
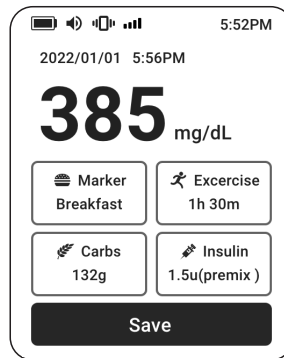- Users should wash their hands with soap and water after handling the meter, lancing device and test strips.
- Please refer to the section "Maintaining the Products" for surface cleaning.
- Do not reuse lancets. Discard used lancets properly.

| 10 Test Stri |
| Discard 4 months after open |
| Opening date: |
| Use by   YYYY-MM-DD |
| Lot No.   XXXXXXXXX |
| Control Solution Range mg/d |
| Level 1   XX- XX |
| Level 2   XX- XXX |
| Level 4   XXX - XXX |

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, and you could find the marked result in the "Record" (you could find it on the home page).

| 🔋 🔊 📳 📶 | 5:52PM |
| 2022/01/01 5:56PM | |

385 mg/dL

| 🍽 Marker Breakfast | 🏃 Excercise 1h 30m |
| 🌾 Carbs 132g | 💉 Insulin 1.5u(premix) |

Save

📎 **NOTE**
You can only set the markers after each time the test result shows. Once the result saved, the markers cannot be changed anymore.
If you leave the meter idle for more than 2 minutes after the test result shows, the meter will automatically save the results without any marker.
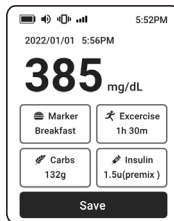
Uploading Data

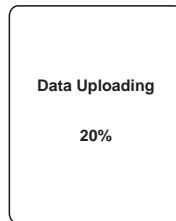The LTE network is set to on by default.
After saving the new test results, the meter will try to connect to the cloud and automatically upload the test results. After the upload is complete, the meter will automatically disconnect from the cloud.
If the LTE is not connected when the result is saved, the result will be stored in the meter.
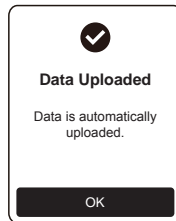The next time you perform a test with an LTE connection, stored results that may not have been uploaded will be uploaded together.

Save to trigger LTE connect with cloud.	Data uploading.	Data upload completed.

⚠ **CAUTION**
- Data transmission via LTE network is not suggested during flights at any time. This is because the meter, when turning on, will emit electronic signals, which should be restricted at all times aboard aircraft.
- Please turn on flight mode to avoid the auto-enabling of LTE network.

Alternative site testing: palm or forearm blood sampling
- Before performing alternative site testing, please replace the Depth adjustable cap with the clear cap for your lancing device. (For detailed information, refer to the RIGHTEST Lancing Device insert.)
- To increase blood flow, massage the intended puncture area of your palm or forearm for a few seconds.
- Immediately after massaging the area, press and hold the lancing device against palm or forearm.
- Press the release button.
- Continue pressing the lancing device against your palm or forearm and gradually increase the pressure for a few seconds until the blood sample is of sufficient size.
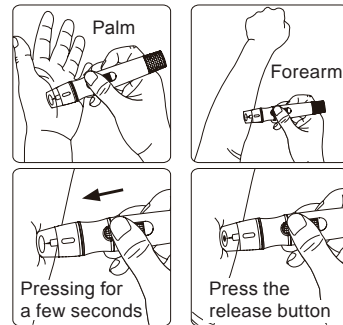
⚠ **CAUTION**

- Consult your healthcare professional before sampling from your palm or forearm.
- Alternate site testing should be done only during steady-state times (when glucose is not changing rapidly). Fingertip sampling can show rapid changes in glucose faster than palm or forearm samples.
- Only the fingertip should be used when glucose levels are rapidly fluctuating: after drinking, after a meal, after insulin injection or exercise, during illness, during periods of stress, if you think your blood sugar is low, or if your results are inconsistent with how you feel.
- 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.

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 happens, repeat the test with a new test strip.
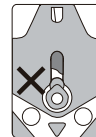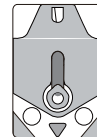
Insufficient blood sample   **Sufficient blood sample**

⚠ **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 rapidly after taking it out 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.

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 rapidly.

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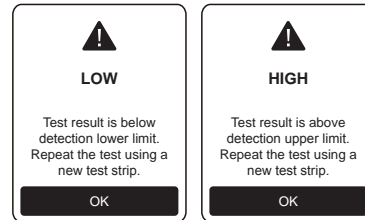
Consult your health care provider for advice on how to properly dispose of used test strips and lancets.

The meter displays results between 10 and 600 mg/dL (0.6 and 33.3 mmol/L).
If the test result is below 10 mg/dL (0.6 mmol/L), "LOW" will appear on the screen. Please repeat your test with a new test strip. If you still get a "LOW" result, contact your healthcare professional.

If the test result is above 600 mg/dL (33.3 mmol/L), "HIGH" will appear on the screen. Please repeat your test again with a new test strip. If you still get a "HIGH" result, contact your healthcare professional.

⚠	⚠
LOW	**HIGH**
Test result is below detection lower limit. Repeat the test using a new test strip.	Test result is above detection upper limit. Repeat the test using a new test strip.
OK	OK

✏ **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 ?

We recommend users perform a quality control test on a regular basis to ensure that the blood glucose system is working properly.

Use a bottle of control solution when testing your system in the control solution mode (CS mode).

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	mmol/L
	Level 1	28 - 48	1.6 - 2.7
	Level 2	106 - 146	5.9 - 9.1
	Level 4	315 - 427	17.5 - 23.7

10 Test Stri
Discard 4 months after open
Opening date
Use by   YYYY-MM-DD
Lot No   XXXXXXXXX
Control Solution Range   mg/d
Level 1   XX - XX
Level 2   XX- XXX
Level 4   XXX - XXX

> **NOTE**
> - The RIGHTEST Control Solution GC700 is compatible with the RIGHTEST Blood Glucose Monitoring Systems Max Tel. If you want to purchase additional supplies please contact Bionime customer service.

When could 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:

- RIGHTEST Blood Glucose Meter Max Tel
- RIGHTEST Blood Glucose Test Strip Max
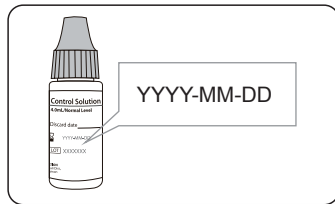- RIGHTEST Control Solution GC700

⚠ **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

Control Solution
4.0mL Normal Level

YYYY-MM-DD

- 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" together with a CS mode icon on the up left.
3. Take 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.
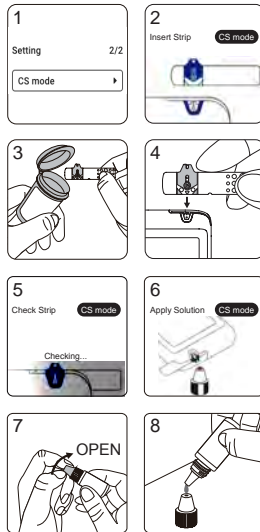
9. Touch the test strip sample port to the drop. Move the meter, not the cap.
10. The screen will display a 5-second countdown timer. You will hear a beep if the volume is on.
11. Recovery the cap and ensure it is screwed on securely.
12. The Quality Control Test Result will appear on the screen.

Compare the result with the Control Solution Range printed on the test strip vial label.
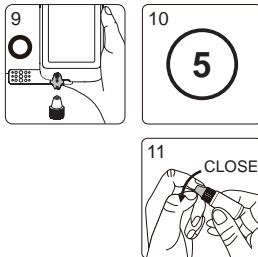

⚠ **CAUTION**

- 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". It will accompany by beeps if volume is turned on. If this happens, please repeat the CS test with a new test strip.
- Do not directly drip the control solution into the test strip's sample port. It is possible that doing so will 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.
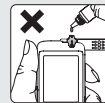
The control solution tests should fall within the control solution range printed on the test strips label, which means the system is functioning properly.

If the control solution test results was out of range, following are possible reasons:
- Your control solution is expired or was opened more than 3 months ago.
- Your test strips was 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 for the test. Please contact Bionime customer service.

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 and lancing device.
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
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.
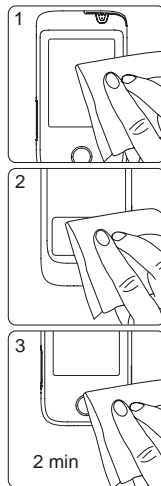
Cleaning and disinfection frequency: at least once a week.

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.
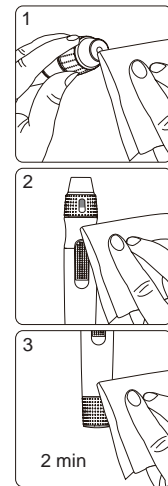

Cleaning and disinfection frequency: at least once a week.

To clean the lancing device:

1. Wipe down the whole surface of the lancing device using the disinfecting wipes described above to remove any dirt, dust, blood, or other bodily fluids.

To disinfect the lancing device:

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

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

If you have any queries or issues, please contact your local Bionime customer service or the authorized distributor.

The RIGHTEST Blood Glucose Meter Max Tel can automatically store up to 1000 test results along 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 the up and down icon to turn the page. Tap "back" could return to the home page.

Recalling Average Test Results

The RIGHTEST Blood Glucose Meter Max Tel 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.
Using "up" and "down" icon to change the interval of average you want to know.
Tap "back" could 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 "LOW" and "HIGH" 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 RIGHTEST 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.
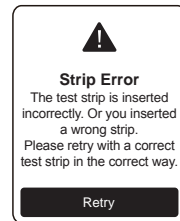
⚠️
Temperature Error

Please test between 6°C (43°F) and 44°C (111°F).

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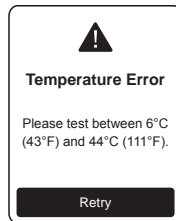
Battery Low
The battery power is too low and can't support the test. Please charge the meter immediately.

⚠️
**Battery Low**

Unable to measure. Charge your meter.

OK
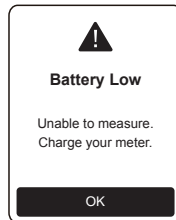
Strip Error
1. The meter will beep four times if the test strip is inserted incorrectly. Do not apply a sample when you see this error. Please re-insert the unused test strip correctly. Please follow the steps in "Handling RIGHTEST Blood Glucose Test Strip Max" to re-insert the unused test strip, or contact Customer Service for assistance.
2. This error notice could mean that you used incorrect test strips. Make sure you are using RIGHTEST Blood Glucose Test Strip Max by checking the test strip vial.

⚠️
Strip Error
The test strip is inserted incorrectly. Or you inserted a wrong strip. Please retry with a correct test strip in the correct way.
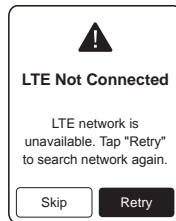
Retry

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 error message.

⚠️
Sampling Error

The blood is applied too early. Repeat the test using a new test strip.
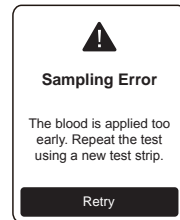
Retry

LTE Not Connected

Find a location covered with better LTE signal and tap "Retry".

⚠️

LTE Not Connected

LTE network is unavailable. Tap "Retry" to search network again.

Skip | Retry

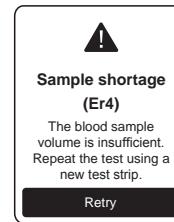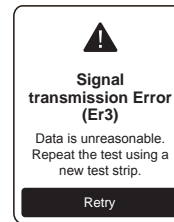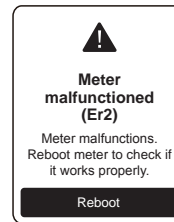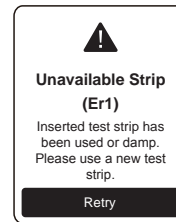## Data Not Uploaded

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 an LTE connection, stored results that may not have been uploaded will be uploaded together.

⚠️

Data Not Uploaded

Data is not uploaded. Tap "Retry" to search network again.

Cancel | Retry
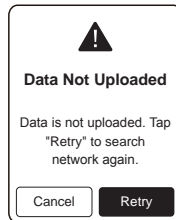
Testing Mode Error code

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

⚠️	⚠️	⚠️	⚠️	⚠️
Unavailable Strip (Er1)	**Meter malfunctioned (Er2)**	**Signal transmission Error (Er3)**	**Sample shortage (Er4)**	**Calibration Error (Er5)**
Inserted test strip has been used or damp. Please use a new test strip.	Meter malfunctions. Reboot meter to check if it works properly.	Data is unreasonable. Repeat the test using a new test strip.	The blood sample volume is insufficient. Repeat the test using a new test strip.	An issue calibrating the meter has occurred. Reboot meter to check if it works properly.
Retry	Reboot	Retry	Retry	Retoot

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

Er2 - The meter has malfunctioned. Reboot the meter as descripte in Er5 and perform a Quality Control Test to check whether the system is working properly. If not, please contact customer service.

Er3 - The transmission of the signal has been disrupted. Repeat the test with a new test strip.

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

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 tapping the "Reboot", or the screen does not pop out power off confirmation. Please press and hold the main button for at least 10 seconds to force power off the meter. Then 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.

Meter Malfunction

If the meter show the "System Error", please follow the steps below.

1. Press and hold the main button for about 2 seconds to turn the meter off. If the meter did not reboot after tapping the "Reboot", or the screen does not pop out power off confirmation. Please press and hold the main button for at least 10 seconds to force power off the meter.

⚠️

System Error

Roboot meter to check if it works properly.

Reboot
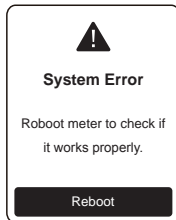
2. Press and hold the main button for about 2 seconds to turn the meter on. After turning on the Meter, if the "System Error" does not show, your meter should function normally. If you still see the "System Error" on the screen or the meter does not respond. Please contact your local RIGHTEST Customer Service or email us at info@bionime.com.

⚠️ **CAUTION**

A blood sample should ONLY be applied to the test strip after the test strip has been inserted correctly and meter show "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 checking the strip after the test strip inserting correctly. Please see the User's Manual and/or contact Customer Service for support on how to correctly insert a Test Strip.

Measurement Technology	Dehydrogenase Electrochemical Sensor
Measuring Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Test Time	5 seconds
Memory Capacity	1000 blood glucose test results with date and time
Power Saving	Turns off automatically 30 seconds after last user action. To turn off manually, press the main button for 3 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	
Minimum Sample Volume	
Hematocrit	Refer to RIGHTEST Test Strip Max insert
Test Strip Storage/ Transportation Conditions	
Battery Charging Time	3 hours (via AC adapter)

Specification

Charging Port	USB type C
Data Transmission	LTE network
Mean Service Time	2 years of typical use
Power Supply Specification	Input: 100-240V, 50/60Hz, 0.16-0.12A Output: 5V DC, 1A (5.0W) Class II

Certificate 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 digital device, 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 portable RF communications equipment can effect medical electrical equipment. We recommend a safety distance no closer than 30 cm (12 inches) to any part of the and at least 1 metre 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.

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.

NCC STATEMENT

- 減少電磁波影響，請妥適使用
- Support NCC CAT-M1 Band 3/8 and NB-IOT Band 8/28

Operating Bands	Operating Frequency(MHz)
	TX
NB IOT / Cat M1 Band 8	880 -915
NB IOT / Cat M1 Band 20	832 -862
LTE FDD Band 2	1850 -1910
LTE FDD Band 3	1710 -1785
LTE FDD Band 4	1710-1755
LTE FDD Band 8	885-915
LTE FDD Band 13	777-787
LTE FDD Band 28	703-748

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

This warranty does not apply to the performance of a RIGHTEST Blood Glucose Meter Max Tel that has been altered, misused, tampered with or abused in any way.
This warranty applies only to the original purchaser of RIGHTEST Blood Glucose Monitoring System Max Tel.

Please complete and return the enclosed warranty card.

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

NOTE
- During blood glucose test, The meter itself may come into contact with blood. All parts of the 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 contain 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.

Customer Service

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 Bionime Customer Service.

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	⧗	Expiry date	☣	Biological risks
📖	Consult the instruction for use	⏶	Manufacturer	②	For single use only
⌡	Temperature limitation	LOT	Lot number	%	humidity limitation
FC	FCC Declaration of Conformity mark			🌐	Importer
⚠	Caution (consult instructions foruse and warnings)	▢		Class II Equipment
STERILE R	Method of sterilization using irradiation (only for lancet)	⚠	Warning / Precaution

Accuracy for Home Use by Lay-Users

Your Meter Max Tel 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 350 typical users used the meter Max Tel to test their blood glucose level. For example, in this study, the meter Max Tel gave results within XX% of their true blood glucose level XXX out of XXX times.

Difference range between the true blood glucose level and the meter Max Tel 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	XX% (ooo/bbb)	XX% (ooo/bbb)	XX% (ooo/bbb)	XX% (ooo/bbb)
	Venous	XX% (ooo/bbb)	XX% (ooo/bbb)	XX% (ooo/bbb)	XX% (ooo/bbb)
	Forearm	XX% (ooo/bbb)	XX% (ooo/bbb)	XX% (ooo/bbb)	XX% (ooo/bbb)

Expected Glucose Values

Expected glucose values without diabetes [1]

Fasting Blood Glucose	
GLUCOSE LEVEL	**INDICATION**
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
From 100 to 125 mg/dL (5.6 to 6.9 mmol/L)	Pre-diabetes (Impaired fasting glucose)
126 mg/dL (7.0 mmol/L)and above on more than one testing occasion	Diabetes

References

1) Diabetes Information - American Association for Clinical Chemistry (AACC)[Electronic Version] Retrieved Jan. 26, 2021 form www.labtestsonline.org/understanding/analytes/glucose/test.html .
   -This device can be used in home healthcare and professional healthcare environment.

Manufacturer's declaration-electromagnetic emissions

Manufacturer's declaration-electromagnetic emissions		
The Max Tel, GM777 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Max Tel, GM777 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 Max Tel, GM777 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 Max Tel, GM777 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 emissions

Manufacturer's declaration-electromagnetic emissions		
The Max Tel, GM777 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Max Tel, GM777 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 Max Tel, GM777 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 Max Tel, GM777 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	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	