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EN(US)

RIGHTEST™

Blood Glucose Monitoring System

GM700 Pro 2

Rx Only

User's Manual

Preface

Thank you for choosing the RIGHTEST Blood Glucose Monitoring System GM700 Pro 2. This product is manufactured by Bionime Corporation and distributed by authorized dealers. Please read this manual carefully before use and follow the instructions. If you have any questions regarding this product, please call our customer service +1 888 481 8485 (Service hour: Mon. to Fri. 8:00 AM to 5:00 PM PST), or contact a local distributor.

The RIGHTEST Blood Glucose Monitoring System GM700 Pro 2 should be used with RIGHTEST Test Strip GS770 or GS700 and RIGHTEST Control Solution GC700.

CLIA Complexity

This test is WAIVED for capillary (draw from fingertip, palm and forearm) and venous whole blood under the Clinical Laboratory Improvements Amendments of 1988 (CLIA).

Laboratories with a Certificate of CLIA waiver can perform this test in a waived setting and must follow the manufacturer'sinstructions for performing the test. If a laboratory modifies the test instructions, the test will no longer be considered waived.
(Refer to the section of "CLIA Waiver Study Results/System Accuracy Result").

This manual provides all necessary instructions for the routine operation and maintenance of the RIGHTEST Blood Glucose Meter GM700 Pro 2. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Meter.

Indication for Use

The RIGHTEST Blood Glucose Monitoring System GM700 Pro 2 consists of the The RIGHTEST Blood Glucose Meter GM700 Pro 2 and The RIGHTEST Blood Glucose Test Strip GS770.

The RIGHTEST Blood Glucose Monitoring System GM700 Pro 2 is intended for Point-of-care, *in vitro* diagnosis, multiple-patients use for quantitative determination of glucose in capillary blood (draw from fingertip, palm and forearm) and venous whole blood. Whole blood glucose results are equivalent to plasma results with biochemical analyzer.

The system is intended for use at clinical environments (ie. genenral primary care centers, outpatient settings for endocrinology and metabolism).

When testing from the fingertip, only single-use, auto-disabling lanceing device should be used. For alternative site test, single person use lancing device should be used, and the testing could only perform during steady state time (when there is no rapid change in glucose).

The system is not intended for the screening or diagnosis of diabetes mellitus.

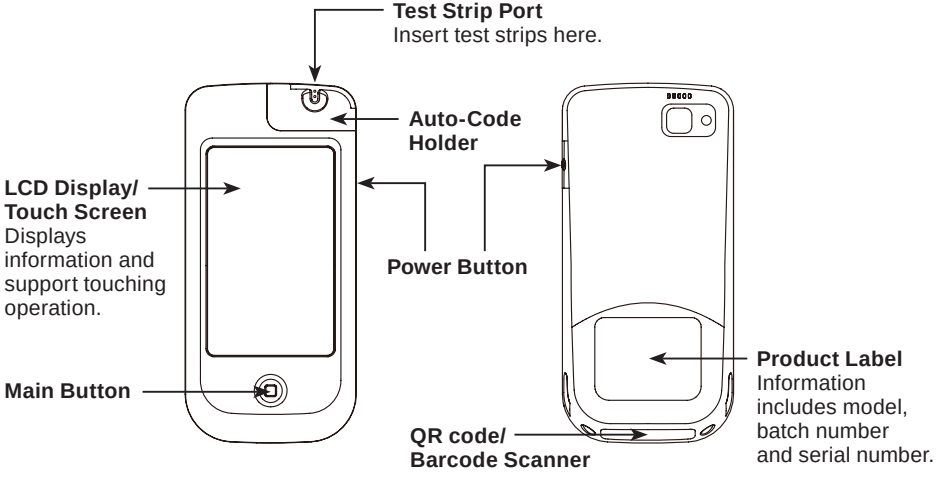
1.1 RIGHTEST Blood Glucose Monitoring System

Your RIGHTEST Blood Glucose Monitoring System GM700 Pro 2 contains the following:

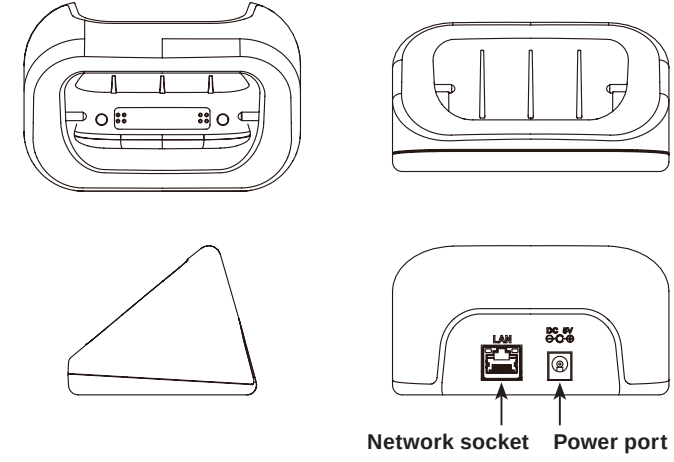
1. RIGHTEST Meter GM700 Pro 2 (with built-in rechargeable lithium battery)
2. Charging hub
3. Power cable*
4. Network cable*
5. User's manual
6. RIGHTEST Test Strip GS770 (with insert)*
7. RIGHTEST lancing device GD500 (with insert)*
8. Transparent cap for lancing device*
9. RIGHTEST lancet*
10. RIGHTEST Control Solution GC700 (Level 1, 2, 4) (with insert)*

(Contents may vary. Items marked with "*" may be supplied separately.)

1.2 RIGHTEST Blood Glucose Meter GM700 Pro 2

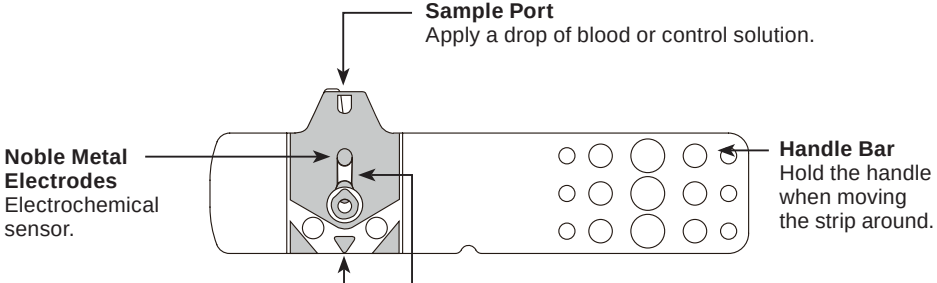


1.3 RIGHTEST Charging Hub

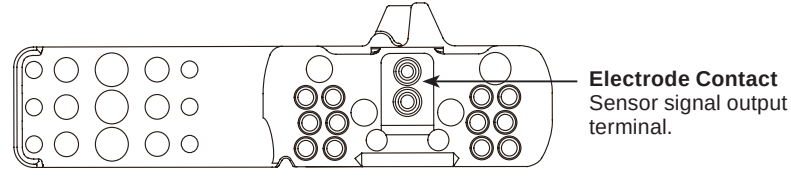


1.4 RIGHTEST Test Strips

The RIGHTEST Blood Glucose meter GM700 Pro 2 can only be used with RIGHTEST Blood Glucose Test Strip GS770 and the strip should be used with RIGHTEST Control Solution GC700.



RIGHTEST Blood Glucose Monitoring System



Important information

- Please refer to the Blood Glucose Test Strip GS770 insert for details.
- If the blood glucose meter or test strip are exposed to a sudden increase or drop in temperature or been placed outside the recommended operating temperature range (43 - 111°F or 6 - 44°C), please wait 60 minutes before using the meter and 30 minutes before using the test strip.

1.5 Auto-Code Holder

The auto-code holder automatically detects the code of a test strip. Our test strips deliver consistent performance without manual coding. The auto-code holder is reusable. When the auto-code holder is contaminated or damaged, please contact our customer service for replacement and installation.

⚠ **Important information**

- The auto-code holder automatically calibrates the strip when inserted into the device. The auto-code holder is reusable unless damaged of contaminated. However, strips are intented for single use only.
- If the auto-code holder is not functioning properly, please contact our customer service. Do not try to remove it on your own.

RIGHTEST Blood Glucose Monitoring System

1.6 Sample Size Example

The recommend sample volume is 0.75 to 3.0μL. Too large sample may contaminate the auto-code holder, too small sample may lead to the error message (error code 1004). If this occurs, repeat the test with a new test strip (For detail indication about sample size, please refer to Blood Glucose Test Strip GS770 Insert).

1.7 Interfering Substances

Before use, please refer to the RIGHTEST Blood Glucose Test Strip GS770 Insert for information on interfering substances.

1.8 Limitation

- This product is not intended for use at more than 10,745 feet (3,275m) above sea level.
- This product is not intended for plasma or serum testing. Please use a whole blood sample.
- Before use, please carefully read the RIGHTEST Blood Glucose Test Strip GS770 Insert. (which contains information on blood samples, hematocrit, and interfering substances).

Warning

- Keep the device away from strong electromagnetic radiation to prevent interference with proper operation of the meter.
- Keep your meter and test strip away from dust, water or any other liquid.
- Disposal of this product: This product contains lithium batteries. The entire system become infectious during the course of use. Please discard it in accordance with local regulations for biohazardous waste. If you don't know what to do, please contact our customer service.

RIGHTEST Blood Glucose Monitoring System

1.9 Product safety and important Information

1.9.1 General safety information

Please carefully read the following sections to ensure safe use of the device.

- To ensure your safety during operation, please read the entire user's manual, test strip insert, and other instructional materials thoroughly before starting usage.
- We recommend a performance comparison test between the device and and a laboratory reference device once per year. If any problems arise, please contact our customer service.

1.9.2 Battery

The device uses a rechargeable lithium battery. If the battery does not recharge or is damaged, please contact customer service for a replacement. Do not try to remove or replace the battery on your own.

1.9.3 RIGHTEST Charging Hub

- Do not use alcohol or any liquid to wipe the network socket or power port on the back of the charging hub.
- The charging status will be on when the device is on the charging hub. The charging status will display through the main button on device. Orange means the device is charging. Green means the device is fully charged. Do not use the device while charging.

1.9.4 Touch Screen

The touch screen is designed to be operated with a fingertip or stylus. Do not use any other kind of pen or sharp object as this may damage the touch screen.

1.9.5 Barcode Scanning

- Do not scratch the barcode scanning lens at the bottom of the device as this may cause issues with scanning. Do not look directly into the light or point it at another person's eyes when the scanner is on.
- Please hold the scanner approximately 7 cm above a barcode and allow the light to cover the entire barcode. Adjust the position of the scanner until the barcode can be read successfully.

1.9.6 Static Electricity Protection

- Keep the device away from strong electromagnetic radiation sources to prevent interference with proper operation of the meter.

1.9.7 Network Security

- Communication mode: WiFi, LAN (Ethernet hub), and Bluetooth (4.0).
- User management: Login requires an account number and password. Switch user as needed to manage login access.

RIGHTEST Blood Glucose Monitoring System

- Users are responsible for information security over the Internet and the setup of a secure IT environment. Use of the device is subject to the information security guidelines of the system to which the device is connected.

1.9.8 LAN Connection

- When the device is LAN-enabled. Test results can be uploaded to hospital systems via HTTPS.

1.9.9 WiFi Connection

- When device is WiFi-enabled. Test results can be uploaded to hospital systems via HTTPS.
- Please set up a WiFi connection according to the WiFi connection requirements of your individual hospital.
- WiFi signals are vulnerable to the surrounding environment. The actual transmission distance and performance will be affected by the user's surroundings.
- When connecting the device to the Internet, please check the security settings.
- The WiFi connection should be configured by your system administrator according to your local environment.

1.9.10 Biohazardous

The used strip, auto-disabling lancing devices, and lancet should be considered biohazards waste. Collect these wastes in suitable puncture-proof containers with biohazard labels and discard them in accordance with local regulations.

⚠ **Important information**

- Please read the user's manual before use. All pictures shown are for illustration purposes only.
- Healthcare professional users should complete appropriate training as required by their hospitals.
- Use single-use disposable lancing device for fingertip test only.
- Keep your meter free from dust, water or any other liquid. Do not immerse the device or place it underwater.
- While testing for multiple patients, ensure to clean and disinfect the device properly every time before you test for different patient.
- Wear/change new gloves every time prior to test for different patients.
- The device should be cleaning and disinfecting as described in the section 7.2 Cleaning and Disinfecting Procedures.

2.1 Installing RIGHTEST GM700 Pro 2

The device should be initialized by our service engineer before the it could be regular use.

2.2 Installing the Charging Hub

2.2.1 Cables and Connection

LAN transfer and charging power:

1. Connect LAN and Charging hub with the Ethernet cable.
2. Connect power supply and Charging hub with the power cable.

2.3 System Connection

Our service engineer will set the parameters and environment variables according to our system needs. During the initial setup of the system, our service engineers will set up this function according to the needs of the organization.

2.3.1 LAN/Wifi Configuration

Our service engineers will set up the Ethernet/Wifi connection according to the environment. LAN configuration can be found in the system settings and administration.

2.4 Recharging the Battery

The battery comes partially charged to enable initialization. Please charge the battery for 4 hours or more before first use.

NOTE
When the battery power is low, the main button will flash orange, please charge the device immediately when you see it.

The display will show the charging status when the device is inserted into the charging hub.
The charging status will also be indicated by the light of the main button. Orange means charging. Green means fully charged.
If the device does not recharge:
- Please make sure the device is fully connected to the RIGHTEST Charging Hub.
- Check if the metal point at the bottom of the device or the metal pins of the charging hub are dirty. Please refer to Section 7.3 Cleaning the metal contact point

3.1 Power on/off

3.1.1 Power on

Press and hold the power button for more than 2 seconds and the device will start the boot procedure.

3.1.2 Power off

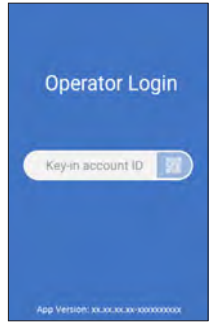
Press and hold the power button for 5 seconds and the device will ask for shutdown confirmation.

3.2 Power saving mode and waking up

When the screen is not touched for a certain length of time, it will turn off to save power. The length of time can adjusted in the management system.
When the screen is off, press the power/main button to wake the device.

3.3 User login

Login access of healthcare professionals (users) will be authorized by your system administrator. During the initial setup of the system, our service engineers will set up this function according to the needs of the organization.
- The system will display a user login screen on startup.
- The user will be asked to enter the password after their account ID if necessary.
- The user will be automatically logged out after a period of idle (default 5 mins). Users need to Log in again for use.



3.4 Device information

- Users can adjust the volume and brightness from the setup page.
- Device version information can also be found in the setup page.

Setup: To be adjusted by the user as needed.
Equipment: To allow quality control by the user.

3.5 Bluetooth connection

User can sync the device with other Bionime Bluetooth glucose meter blood glucose record while their Bluetooth connection (Optional function, default off, our service engineers will set up this function according to the needs of the organization).

This section is about the blood glucose test procedure and related important information.
Press the button on the home screen to start the procedure.

4.1 Patient search

Multiple patient search modes
- Patient list
- Manual patient search
- QR code/Barcode patient search

QR code/Barcode patient search

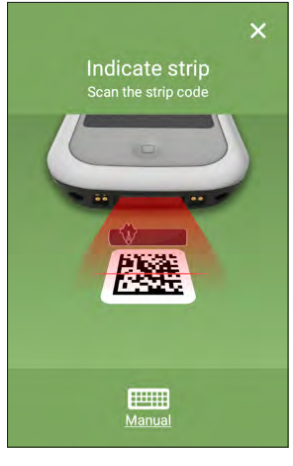
Warning
- Do not look directly into the light or point it at another person's eyes when using the QR code/barcode scanner.

4.2 How to enter test strip information

With the vial of strip you are going to use for test, there are 3 ways you could do:

1. Scan the barcode on the test strip label.
2. Manually enter the test strip information on strip label.
3. Select the test strip number from the list according to strip label.

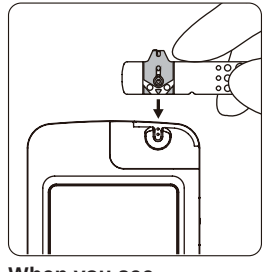
If the number is valid, the system will proceed to the next step. Otherwise an error message will be displayed. Please try again.



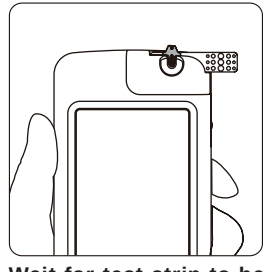
Blood Glucose Measurement

4.3 Wait for the test strip to be detected

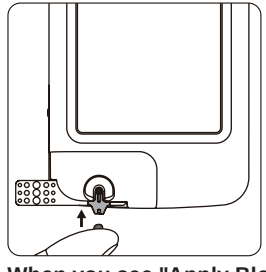
Follow the instruction on display, to make sure to test successfully.



When you see "Insert strip" on display, insert the test strip



Wait for test strip to be detected



When you see "Apply Blood Sample" on display, apply the blood sample

Warning

- Do not test the patient's blood before the test strip is detected and "Apply Blood Sample" instruction shown. Apply sample too early may result in error message (error code 1008).

4.4 Sample collection

4.4.1 Fingertip capillary sample

Please use single-use, auto-disabling lancing devices, to collect fingertip capillary blood samples for the patient.

The sample collection procedure brief described as follow:

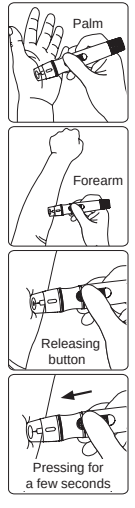
1. Clean the patient's fingertip with an alcohol swab/pads (or other proper cleaners applicable), ensure that the fingers are completely dry after cleaning.
2. Puncture the patient's fingertip, squeeze the finger to form a drop of blood.
3. Apply the blood sample to the Strip port for testing (make sure the "apply blood sample" show on display when you conduct this step).
4. The display will count down for 5 seconds and then show the test result.

4.4.2 Alternative site testing-palm or forearm blood sampling

For alternative sampling site (palm and forearm), we recommend using the RIGHTEST Lancing Device GD500 (with clear cap), this device is for single patient use only, and should be using with sterilized lancet (see 4.4.3 section for the instruction of how to use lancing device).

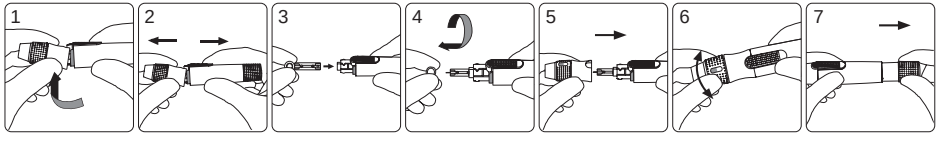
The sample collection procedure brief described as follow:

1. Clean and Massage the target area on the palm or forearm for a few seconds to increase blood flow.
2. Immediately after massaging, press and hold the lancing device against the target area.
3. Press the release button, continue holding the lancing device against the skin. Gradually push the device against your skin with increasing pressure until the blood droplet formed enough size for testing.
4. Apply the blood sample to the Strip port for testing (make sure the “apply blood sample” show on display when you conduct this step).
5. The display will count down for 5 seconds and then show the test result.



4.4.3 Preparing the Lancing Device

1. Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub.
2. Pull the cap and hub off in opposite directions, remove the cap.
3. Insert a new disposable lancet firmly into lancet carrier.
4. Twist off and set aside the protective cover of the disposable lancet.
5. Replace the depth adjustable cap.
6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type " " for soft or thin skin; " " for average skin; " " for thick or calloused skin.
7. Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, it will automatically move back to its original position near the hub.



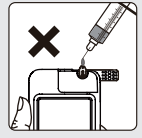
Blood Glucose Measurement

Important information

- Fingertip samples can show rapid changes in glucose faster than palm or forearm samples.
- Test results may vary if blood samples are taken from different sites.
- Do not test the blood sample from palm or forearm when glucose is changing rapidly (scenarios: after drinking, after meal, after exercise).
- Do not test on the palm or forearm if the testing aims for insulin dose calculations or hypoglycemia (low blood glucose) or calibrating continuous glucose monitoring systems (CGMS).

Warning

- Check the expiration date printed on the strip label and the opening date recorded on the label every time before using the test strip. Do not use any expired test strips.
- Use test strips immediately after taking it out from the vial.
- Do not reuse test strips.
- If the blood glucose meter or test strip is exposed to a sudden increasing or dropping temperature, please wait for at least 60 minutes before using the meter, at least 30 minutes before using the test strip.
- Do not use the syringe to inject blood into the sample port directly. Doing so may contaminate or damage the device.

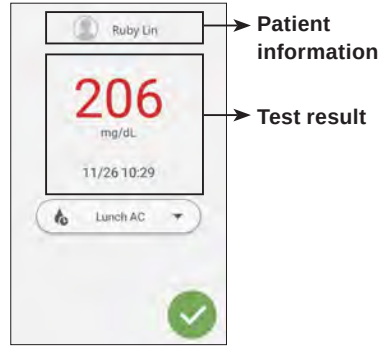


Warning

The used strip, auto-disabling lancing devices, and lancet should be considered biohazards waste which may potentially transmit infectious diseases. Collect these wastes in suitable puncture-proof containers with biohazard labels and discard them in accordance with local regulations.

4.5 Checking test results

- A successful test will show the test result and patient information.
- Select the patient information.
- The test results are classified into 3 conditions, please follow the instruction on screen for further operation. The condition level will be defined according to organization, our service engineers will set up this function according to customer needs).



- If the blood glucose level is outside the measuring range, the system will display a message as follows:

  HI: above the measuring range (600 mg/dL).

  LO: below the measuring range (10 mg/dL).

- To note the test period, press "Test Period" or "Glycemic Period" and a list of test periods will be displayed. Select your choice. Available choices can be set by your organization.

Important information

- If a blood test result is unusually high or low or if you suspect an error has occurred, please use a new strip and repeat the test. Alternatively, run a quality control test to check whether the meter and test strips are working correctly.

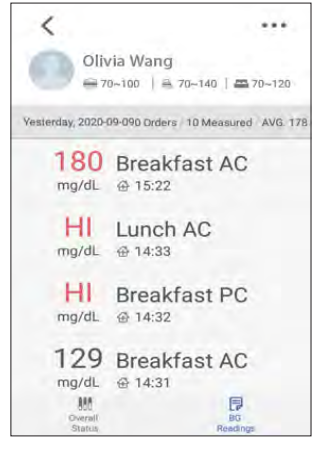
4.6 Making a test note

To make a test note, press the "Notes" button, and a list of preset notes will be displayed. Press to select a note. Press "OK" to finish making a test note.

4.7 Patient profile

4.7.1 Overall status

- Multiple time periods.
- HbA1c.
- Mean blood glucose.
- Blood glucose distribution.
- Blood glucose levels by period.



4.7.2 Blood glucose readings

Display patient test results by time and date.

This section is about the quality control procedure and important related information. Please perform a quality control test to ensure your blood glucose monitoring system works properly.

Recommended Quality Control Frequency

- If the system is for daily use, please perform quality control before starting the first testing every day.
- If the system is not for daily use, please perform quality control every time before starting a test.

Press "Quality Control" on the setup screen to enter the quality control screen. Press "QC now" and the system will start the quality control procedure.

QC lock function:

The test function will be locked if the last QC record is out of validated time, the system will demand user to perform the QC test then unlock the test function. (This function is default off, the validated time period could be customized, our service engineers will set up this function according to the needs of the organization).

QC Lock

Quality control

5.1 Select control solution concentration

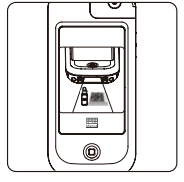
Select the control solution concentration to be tested. The applicable control solution for this device is RIGHTEST Control Solution GC700.

Warning

- Make sure to select the correct control solution level you are going to use.

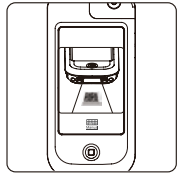
5.2 How to enter the control solution information

- Scan the barcode on the control solution label.
- Manually enter the control solution information according to the control solution label.
- According to the label, select the control solution number from the list.
- If the number is valid, the system will proceed to the next step. Otherwise an error message will display. Please try again.

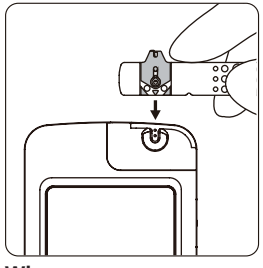


5.3 How to enter the test strip information

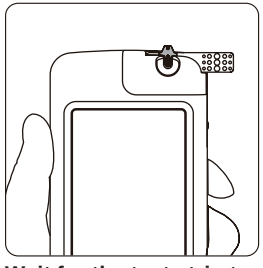
- Scan the barcode on the test strip label.
- Manually enter the test strip information according to the strip label.
- According to the label, select the strip number from the list.
- If the number is valid, the system will proceed to the next step. Otherwise an error message will display. Please try again.



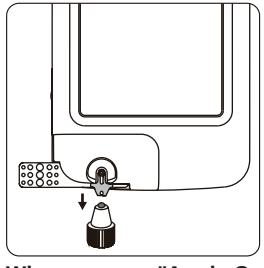
5.4 Wait for the test strip to be detected



When you see "Insert strip" on display, insert the test strip



Wait for the test strip to be detected



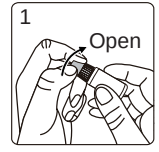
When you see "Apply Control Solution" on display, apply the blood sample

Follow the on-screen instructions and insert the test strip. Wait for the test strip to be detected before apply the control solution.

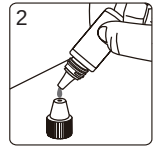
Warning

- Do not Apply the control solution before the test strip is detected This may result in an error message (error code 1008).

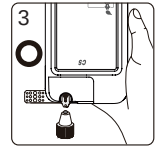
5.5 Prepare the control solution and take a measurement



1. Gently invert the bottle several times to ensure that the control solution is thoroughly mixed before use. There should not be any bubbles. Remove the cap and place it on a flat surface.



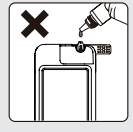
2. Place a drop of control solution on the top of the cap.



3. Touch the drop of solution with the sample port of test strip.

Important information

- Do not drop control solution onto the sample port of the test strip directly. Doing so may contaminate or damage the device.
- Do not touch the tip of the control solution bottle. If contact with the skin occurs, wash the tip with water and discard two droplets of solution.
- Please refer to the Control Solution Insert for detailed information of control solution.



5.6 Check the test result

A Pass/Fail message will be displayed in accordance with the acceptable concentration range for the selected control solution.

NOTE

If the QC Lock function is on, Fail QC result will trigger test function lockup. You have to perform the quality control test and obtain a pass result to unlock the test function.

Quality control result

5.7 Making a QC fail note

If "Fail" is displayed you can make a test note on the quality control result. Press "Notes" and a list of preset notes will be displayed. Select a note and press "OK".

6.1 Linear quality control

Your organization may choose whether to activate this feature based on your requirements. The linear quality control test comprises two steps: (1) a control solution test and (2) linear analysis. Please contact customer service for control solution if needed.

From the home screen, select “Functions” to perform a linear quality test. Otherwise select “Advanced Quality Control” to enter and initiate a linear quality control test.

6.1.1 Perform a control solution test

Please complete tests with all the required control solution levels. Follow the on-screen instructions and the quality control test procedure. If any test result is incorrect, please repeat the test. Make sure all results for all control solutions are within the accepted range before proceeding to linear analysis. The control solution level examples are shown in the table below:

Level 1	Low concentration
Level 2	Normal concentration
Level 3	Normal to high concentration
Level 4	High concentration
Level 5	Ultra high concentration

6.1.2 Perform linear analysis

The analysis can be performed after all the control solution tests are completed. Linear analysis will be displayed on the screen. A Pass/Fail message will be displayed according to the acceptable range for the correlation coefficient (R).

6.2 External quality control

The external quality control test allows your organization to purchase test solutions from a third party or use self-made artificial blood samples. Lab technicians will be permitted to enter the batch numbers for testing. Follow the screen instructions to perform **External quality control**.

7.1 Maintenance

Keep your meter free from dust, water or any other liquid. If your meter is dropped or damaged, perform a quality control test with the control solution before performing a blood glucose test.

Please follow these rules for cleaning:

- CAVIWIPES DISINFECTING TOWELETTES, manufacturer: Metrex, phone:(800) 841-1428. It is with Isopropanol as the active ingredient, have been shown to be safe for use with 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.

Warning

- Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals.
- The meter should be cleaned and disinfected following the manufacturer's instructions after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's cleaning and disinfection procedures are followed.

Maintenance and Care

Please see the following references for further information:

- FDA Public Health Notification: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication (2010). http://www.premiersafetyinstitute.org/wp-content/uploads/FDA-Fingerstick-Devices-Poses-Risk082610.pdf
- 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
- CDC Guidance: Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007) https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf

7.2 Cleaning and disinfecting procedure

Cleaning and Disinfecting frequency: Every time before perform test for patient and after finished all test.

To Cleaning Device/ Test Strip Port:

Throughly wipe the entire surface of the meter with disinfecting wipes listed above to clean any possible dirt, dust, blood and other body fluids.

To Disinfect Device/ Test Strip Port:

1. After cleaning, take another disinfecting wipe and wipe the meter wholly. (Note: All blood and body fluids should be cleaned from surface before performing the disinfecting procedure)
2. Allow the surface to remain wet for 2 minute.
3. Allow to air dry.

NOTE

The cleaning procedure can only remove contaminates from surfaces. The disinfecting procedure help to kill pathogens.

Maintenance and Care

NOTE

- Clean and disinfect the outside of the device only
- Do not drop liquid directly into the test strip port.
- The Meter has been tested to ensure that there is no change in the performance or external materials of the device after 6000 cleaning cycles and 6000 disinfecting cycles. The simulates test result reflected that the device could sustain at least 6000 glucose testing for patients.

7.3 Cleaning the metal contact point

If the metal contact point at the bottom of the device is stained, turn off the device first then use an alcohol wipe to clean it.

If the metal pin of the charging hub is stained, remove the power line first, then use an alcohol wipe to clean it.

Ensure to wait for the cleaned part to totally dry before turn on the device, reconnect the power line, or placing the device on the hub.

Error code	Descriptions	Troubleshooting
1001	Strip was used or damp	Please try again with a new test strip
1002	Device hardware error	Stop testing and contact customer service for support.
1003	Signal error	Please remove the strip and try again (if the sample was applied, please use a new strip).
1004	Sample shortage	Please use a new test strip and try again. The recommended minimum sample size is 0.75uL. Ensure sample fills entire strip viewing window.
1005	Wrong Strip inserted/ Strip detection error	A wrong strip was inserted into device. Please try again with an applicable one. If the error occurs repeatedly while using correct strip, the detection function might be damaged, please contact customer service.
1007	Temperature error	Current environment temperature too low (<6°C/42°F) or too high (>44°C/111°F). Please move to an environment within 6°C to 44°C (42°F to 111°F). Wait at least for 60 minutes before try again.

Error code	Descriptions	Troubleshooting
1008	Applied sample too early	Sample was applied before screen show the "Apply Blood Sample" direction. Please use a new test strip, make sure you follow the instruction on screen and try again testing.
1010	Sample application timeout	The system has been idle for more than 2 min after "Apply Blood Sample" instruction showed on screen. Please remove the strip then try again.
1011	Strip has been inserted	A strip has been inserted before "Insert strip" instruction showed on screen. Please remove the strip and try again. If this error occurs repeatedly, please contact customer service.
1012	Mismatch of Label and Strip information	The information entered does not match the device read from the test strip. Make sure that the test strip used for the test comes from the same test strip vial which you scanned/entered information, and then try again.

Temperature Limitation

The recommended operational ragne is 6°C to 44°C (42°F to 111°F). Recommended storage temperature is -10 to 60°C (14°F to 140°F), 10 to 90% relative humidity.

For other error messages, please follow the troubleshooting instructions on the screen.If the error message or abnormalities occurs repeatedly during operation, please contact customer service.

Measurement Technology	Electrochemical Sensor
Measurement Range	10 - 600 mg/dL
Measurement time	5 seconds
Memory Capacity	10,000 blood glucose test results with date, time and test note
Power Supply	3.7V rechargeable lithium battery
Battery Life	180 tests
Device Dimensions	152 mm x 72 mm x 22 mm
Device Weight	220 ± 30g
Interface	Capacitive touch screen
Screen Dimensions	4” Color TFT-LCD Screen
Device Storage/Shipping Conditions	-10 - 60°C(14°F to 140°F), 10 - 90% relative humidity
Operating Temperature	42°F - 111°F (6°C - 44°C).

Transmission	WiFi/Bluetooth/Ethernet (via charging hub)
Charging Hub	Input: 5V
Wireless	WiFi (802.11 a/b/g/n (5/2.4 GHz)
LAN	Support 10M/100M
Camera	800 Megapixels
Transformer Voltage/Frequency	100 - 240V / 50 - 60Hz; Input 35VA

Blood Sample	Please see the Blood Glucose Test Strip GS770 Insert
Minimum Sample Volume	
Hematocrit	
Test Strip Storage / Transportation Conditions	

*** The RIGHTEST Blood Glucose Monitoring System GM700 Pro 2 complies with 2020 FDA POC guidance.**

Customer Service/Warranty

Bionime wishes to provide complete, considerate service to our customers. Please review all the instructions to ensure you know how to operate the device correctly.
If you have any questions or have issues with the device, please contact customer service.

Bionime provides warranty and maintenance for your device starting at the time of purchase. We will perform free maintenance and replacements while the warranty is in effect.

The warranty applies only to the original purchaser of the Blood Glucose Meter. Any misuse, modification, alteration, damage or abuse will render the warranty void.

If you have any questions or concerns, please contact our customer service by calling: +1 888 481 8485 (Service hour: Mon. to Fri. 8:00 AM to 5:00 PM PST) or email info@bionime.com.

Symbols

Description of symbols used

IVD For *in vitro* diagnostic use	Humidity limitation	Biological risks
Consult the instructions for use	Direct current	Manufacturer
Temperature limitation	For single use only	Expiry date
STERILE R Method of sterilization using irradiation	FC FCC Declaration of Conformity mark	
Caution (consult instructions for use and warnings)	Importer	

Rx Only CAUTION: Federal law restricts this device to sale by or on the order of a physician.

The RIGHTEST Blood Glucose meter GM700 Pro 2 and RIGHTEST Blood Glucose Test Strip GS770 for the RIGHTEST Blood Glucose monitoring system GM700 Pro 2 were tested on capillary blood samples from xxx patients, and the results were compared to the comparator method (YSI 2300). The tables show differences in glucose values between the GM700 Pro 2 device and the comparator method. Table 1. represents samples for glucose results lower than 75 mg/dL (by the GM700 Pro 2). Table 2. represents samples for glucose results greater than or equal to 75 mg/dL.

Table 1. Capillary Whole Blood (from Fingertip, palm and forearm) with Glucose Concentrations < 75 mg/dL

Difference range between YSI 2300 laboratory comparator method and the GM700 Pro 2 device		Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL
The percent (and number) of samples for which the difference between the GM700 Pro 2 device and YSI 2300 laboratory comparator method were within the difference range shown in the top row.	Fingertip	xx% (ooo/aaa)	xx% (ooo/aaa)	xx% (ooo/aaa)	xx% (ooo/aaa)
	Palm	xx% (ooo/aaa)	xx% (ooo/aaa)	xx% (ooo/aaa)	xx% (ooo/aaa)
	Forearm	xx% (ooo/aaa)	xx% (ooo/aaa)	xx% (ooo/aaa)	xx% (ooo/aaa)

CLIA Waiver Study Results/System Accuracy Result

Table 2. Capillary Whole Blood (from Fingertip, palm and forearm) with Glucose Concentrations ≥ 75 mg/dL

Difference range between YSI 2300 laboratory comparator method and the GM700 Pro 2 device		Within ± 5%	Within ± 10%	Within ± 12%	Within ± 15%
The percent (and number) of samples for which the difference between the GM700 Pro 2 device and YSI 2300 laboratory comparator method were within the difference range shown in the top row.	Fingertip	xx% (ooo/bbb)	xx% (ooo/bbb)	xx% (ooo/bbb)	xx% (ooo/bbb)
	Palm	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)

The tables above show that xxx (aaa+bbb) of the xxx samples met the defined acceptance criteria.

Note: When glucose meter results are compared to the laboratory results, differences below 75 mg/dL are expressed in mg/dL, while those greater than or equal to 75 mg/dL are expressed in percent.

Federal Communications Commission (FCC) Statement

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

FEDERAL COMMUNICATIONS COMMISION (FCC) STATEMENT

15.21

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

FCC RF Radiation Exposure Statement:

This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

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.