

Bioland G-777G Blood Glucose Monitoring System

User Manual

bioland®

INTRODUCTION TO THE SYSTEM ABOUT YOUR SYSTEM

Intended Use

- The Blood Glucose Monitoring System is comprised of Blood Glucose Meter and Blood Glucose Test Strips.
- The Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The Blood Glucose Monitoring System is not for use in neonates.

Warnings

- The System is intended for use outside the body (in vitro diagnostic use). It is for single-patient use. It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples taken from the finger. The system is intended for use at home. It should not be used for the diagnosis of diabetes or for the testing of newborns.
- The System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).
- The G-777G blood glucose test strips are for use with the Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips.
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician's offices, or long-term care facilities because it has not been determined to be safe and effective for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- When the following phenomenon happens, the user should stop using meter and contact customer service:
 - The test result of control solution exceeds the range of vial labeled.
 - The meter fails to display relative information.
 - The meter does not respond when inserted test strips.
 - The meter damaged severely (e.g. Broken case, screen chalkboard)

Read this before using

DANGER - Misuse of this electrical device can cause electrocution, burns, fire and other HAZARDS. Basic safety precautions should always be taken, including all those listed below. Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.

The following basic safety notices should always be taken:

- Do not place the device in liquid, nor put it where it could fall into liquid.
- The following basic safety notices should always be taken.
- Use the device only for the intended use described in this manual.
- Do not use adjunct which are not supplied by the producer.
- Do not make the device come into contact with surfaces which are too hot to touch.
- Do not use the device where aerosol sprays are being used.
- Do not use the device if it is not working properly, or if it has been damaged.
- Read all the manuals, and practice the test, and then use the product to test your blood glucose. Do all quality control checks as directed and consult with a diabetes expert.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Limitations of use:

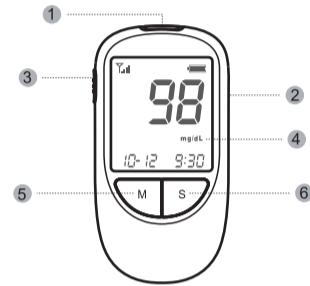
- The blood Monitoring System is not intended for use on neonates.
- The blood Monitoring System is not intended for use on artery blood, neonates' serum and plasma.
- The system can be used up to an altitude of 10744 feet.
- The following substances at levels greater than normal or therapeutic levels may cause significant interference (affect the result by greater than 10%) resulting in an inaccurate result: ascorbic acid, uric acid, hemoglobin, acetaminophen, Dopamine, L-dopa and Tolbutamide etc. These substances do not affect test results in normal concentration but may affect test results in high concentration. Do not use haemolysis sample, icterus sample or high lipemia samples.
- Patients undergoing oxygen therapy may yield falsely lower results.
- Not used for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
- Very low (less than 20%) or very high (more than 60%) red blood cell count (hematocrit) can lead to incorrect test results. If you do not know your hematocrit level, please consult your health care provider.
- High temperature (more than 104°F) and low temperature (less than 50°F) may lead to incorrect test results.
- High humidity (more than 85%) and low humidity (less than 10%) may lead to incorrect test results.

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Blood Glucose Meter



1. Strip port

Where you insert the test strip into strip port, the meter will turn on automatically.

2. USB port

Located at the side, is for cable connection with adaptor for power charging.

3. Strip ejector

Slide forward to eject the test strip after test.

4. LCD Display

It guides you through the test using symbols and simple messages.

5. "M" Button

It is used to turn on the meter enter the memory mode

6. "S" Button

It is used to set up the meter

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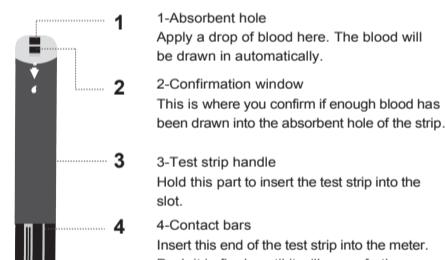
Meter Screen Display Message



- 1) Blood drop symbol
Flashes when it is ready to apply the blood sample.
- 2) Low battery symbol
Appears when the battery power is low.
- 3) Test strip symbol
Appears when the meter is turned on.
- 4) Antenna symbol
Displays glucose results
- 5) Test result area
Shows the test result in mg/dL.
- 6) Ketone display
- 7) Meal Symbol
- 8) Measurement unit
Shows the test result in mmol/L.
- 9) Transmission status
Shows the prompt data upload status.
- 10) Memory symbol
Appears when you review the memory
- 11) Time
- 12) Date

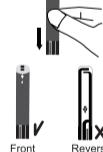
Test Strip

Each strip can be used only once. The test strip consists of the following parts:



Attention!

Test results might be wrong if the contact bar is not fully inserted into the test slot.



NOTE: The front side of the test strip should face up when inserting the test strip.

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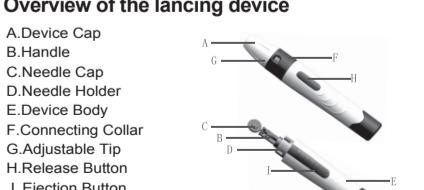
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Testing with blood sample

CAUTION:

- To reduce the chances of infection:
 - Choose a clean, dry work surface.
 - Never share a lancing device and lancet with another person.
 - Always use a new and sterile lancet. Lancets are for single use only.
 - Always use a new test strip. Test strips are for single use only.
 - Avoid getting lotion, oils, dirt or debris in or on the lancet and lancing device.
- Note: Before testing, please read the following steps thoroughly and carefully, please relax and do the test step by step. Simplifying or changing the test procedure may produce inaccurate results.

Overview of the lancing device

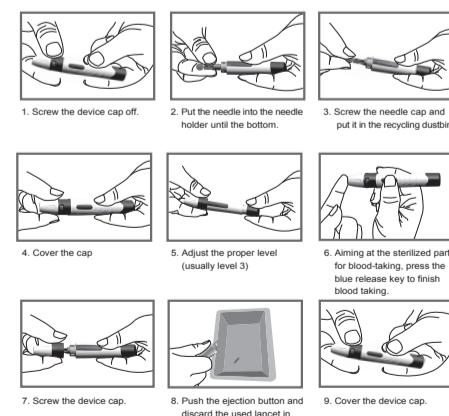


If your lancing device differs from the one shown here, please refer to the manufacturer's manual to ensure proper usage.

Note: To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris when handling the lancets.

Setting up the lancing device



NOTE:

The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip to the proper level:

- 1-2 level for soft or thin skin
- 3 level for average skin
- 4-5 level for thick or calloused skin

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Preparing the puncture site

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- Rub the puncture site for about 20 seconds before penetration.
- Select the puncture site at the fingertips.
- Clean the puncture site using cotton moistened with 75% alcohol and let it air dry.

Fingertip testing

Hold the lancing device firmly against the side of your finger. Press the release key. You will hear a click, indicating that the puncture is complete.

NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

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Performing a Blood Glucose Test

Step 1
Wash hands with soap and warm water.

Step 2
Remove a test strip from its vial. With clean and dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strip in any way. Remove the test strip from the vial and use it instantly.

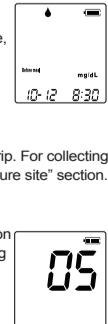
Step 3
Insert the test strip into the meter's test port and the meter is turned on. The screen will display a flashing blood drop, time and date.

NOTE: Be sure to use G-777G blood glucose test strips, other test strips may not produce an accurate result.

Step 4
When the blood drop symbol flashes on the screen, you may select the appropriate measurement mode, for selecting the measurement mode of Control (CTL) or General, please refer to the "The two measuring modes" section.

Step 5
Apply your blood to the absorbent hole of the test strip. For collecting blood sample, please refer to the "Preparing the puncture site" section.

Step 6
As soon as enough blood has filled the confirmation window of the test strip, you will hear a beep letting you know the test has begun. A countdown of 5 seconds starts.



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NOTE: You must wait for the end of 5-second count down to see the data display.

Note: Make sure the confirmation window of the Test Strip is completely filled with your blood sample.

Step 7
Your blood glucose level, along with date and time appears on the display. Blood glucose results are automatically stored in the memory.



NOTE:
The results obtained from this meter are plasma-calibrated. This helps you and your physician or other qualified healthcare provider to compare your meter results with laboratory tests. Refer to the instructions given by your physician or other qualified healthcare provider, do not deviate from these instructions on the basis of the result without first consulting your physician.

Step 8
After the measurement is completed, then through LTE upload the measured results, date, time and SN.



Step 9
Eject the used test strip and remove the lancet. To eject the test strip, point the strip at a disposal container for sharp objects. The meter will switch itself off automatically after the test strip is ejected. Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.



Reference value

Time of day	Normal plasma glucose range for people without diabetes
Before breakfast (fasting)	<100 mg/dL
Two hours after meals	<140 mg/dL

Source: American Diabetes Association. Standards of Medical Care in Diabetes-2012. Diabetes Care 2012;35 (Suppl.1) S11-S63.

Note: Please work with your doctor to determine a target range that works best for you.

Comparing Meter and Laboratory Results

The meter provides you with the measurement result equivalent to whole blood. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, please follow the guidelines below.

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If you continue to get control solution test results that fall outside the range printed on the vial, the system may not be working properly, do not use the meter. Please contact your customer support immediately.

NOTE:

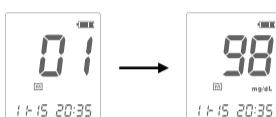
- Do not use the expired control solution. Only use the control solution, you can purchase this product through visits the website: www.taidoc.com.
- Users should periodically review their technique, and compare with the results that obtained from meter and obtained from laboratory method or a well-maintained and monitored system used by healthcare provider.

Recalling the Stored Test Results

1. Start with the meter off, press the "M" button to turn on the meter. The "M" symbol will flash with the time and date displayed on the screen.



2. Press "M" again, the most recent test results with date and time will display. Press "M" once more and the next most recent test results will appear. Each time you press and release "M", the meter will recall up to your last 500 test results in order. Press the "S" to turn off the meter. When the memory is full, the oldest result is dropped and the newest result is added.



Note: The control solution readings are not included in the average of your results.

When your glucose value is less than 20mg/dL, you will see the following message "Lo"; When your glucose value is higher than 600mg/dL, you will see the following message "Hi".

Care and storage for your system

- Handle the meter with care. Dropping or throwing the meter may cause damage to the device.
- Don't expose the Bioland G-777G Blood Glucose Monitoring System, Bioland Blood Glucose Test strips and Bioland Blood Glucose Control Solution to extreme conditions, such as high humidity, heat, freezing cold or dust. The storage conditions for the test strips are 39.2°F~104°F(4°C~40°C), 10%~85%RH. Storage conditions for the meter are -4°F~131°F(-20°C~55°C), ≤93±3%RH.
- Always wash your hands with soap and water and rinse and dry completely before handling the Blood Glucose Monitoring System and Test strip.
- Use CaviWipes (see below) to clean the Blood Glucose Monitoring System.
- Discard the used lancet into a container for sharp objects.

Cleaning and Disinfection

The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can insure the meter works well (for example, display will be clear to see after cleaning); and disinfection can avoid the infection and cross-infection to you or to the other people. We strongly warn that the device should be cleaned and disinfected following use on every patient. And we suggest you use the following product: CaviWipes (EPA registration number: 46781-8). You can purchase this product according to the following information: visit the web site: www.metrex.com or contact Metrex at 800-841-1428 for product or technical information. CaviWipes are also available at www.amazon.com or via a Google search. The G-777G meter can be cleaned and disinfected by the user twice per day over the 5-year use life of the device, up to 3,650 times. The meter should be cleaned and disinfected at least once per week.



Cleaning procedure:

The purpose of cleaning is to remove the dust or organic/inorganic contaminants from the glucose meters. About that we recommend use CLOROX Healthcare Bleach Germicidal Wipes. In addition, we recommend cleaning the meters every time after use. As for the cleaning procedure, please follow the steps below: With disinfectant towels, wiping(including test strips port, data port, strip ejector, LCD Display, M button, and S button) of the meter by using CLOROX Healthcare Bleach Germicidal Wipes. Air dried the meters and lancing devices carefully in room temperature.

Disinfection procedure:

A disinfection procedure is a procedure intended to remove the blood-borne pathogens on the meters. Disinfecting the entire outer crust of the meter with CLOROX Healthcare Bleach Germicidal Wipes carefully, including screen and button. In order to ensure the blood-borne pathogens were removed by the disinfectant infallibly, it is necessary to keep disinfectant (disinfectant is a chemical that is applied to kill microbes) on the meter for one minute. As for the disinfecting procedure, please follow the steps below: Wiping the entire outer crust of the meter with CLOROX Healthcare Bleach Germicidal Wipes and keeps the disinfectant on the meter for one minute. Carefully air dried the meters in room temperature.

- Before the test, the user should clean and wash hands. If you are a caregiver(not the patient), please use disposable gloves.
- After test, take one wipe to clean the meter's housing, buttons, lens, mark, USB cover and support block, including its front and back for 10 seconds cleaning until there is no soil on the surface. Then disinfect the meter's housing, buttons, lens, mark, USB cover and support block by using another wipe for 1 min, keep the surface wet for 1 min.
- Take off the glove; discard carefully according to your health-care provider's instruction.

Note:

- Each disinfection step requires a pre-cleaning step.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device shall be cleaned and disinfected first.
- The users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

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Specification

- Model: G-777G
- Machine size: 104mm (L)×54mm (W)×24mm(H)
- Weight: 63.0g (excluding batteries)
- Measuring method: Amperometric technology using glucose oxidase
- Measuring range: 20 mg/dL ~ 600 mg/dL
- Memory: 500 blood glucose tests
- Display: LCD display with backlight
- Power: Rechargeable Lithium Battery
- Battery life: Approx. 500 normal tests
- Storage condition (system: meter and test strips): 39.2°F~104°F (4°C~40°C), 10%~85%RH.
- Storage condition (meter): -4°F~131°F(-20°C~55°C), ≤93±3%RH
- Operating conditions: 50°F~104°F(10°C~40°C),
Humidity:10%~85%RH
- Blood source: Fresh capillary whole blood
- Blood volume: Minimum 0.7 micro liter.
- Use life: five years.
- LTE data transmission and Support 4G band.

DISPLAY MESSAGE

MESSAGE	WHAT IT MEANS	ACTION
Lo	Blood glucose level is lower than 20mg/dL	The message indicates very low blood sugar. You should consult with your healthcare professional.
Hi	Blood glucose level is higher than 600 mg/dL	This indicates severe hyperglycemia (high blood glucose). You should seek immediate medical assistance.
CTL	Meter is ready to test control solution under the CTL state.	Please place a drop of control solution onto the test well of test strip.
E-b	Battery power is low.	Please charge the battery.
E-U	Use a used test strip	Please use a new strip and re-test
E-F	Error message indicates that you may remove prematurely the strip after applying blood to the absorbent hole	Try again with a new test strip
E-E	Problem with the meter	Re-test with a new test strip. If the problem is still unsolved, please call the customer care line for help.
E-E	Environmental temperature is lower than 50°F~104°F	Please test at an environmental temperature within 50°F~104°F operation range

Problems

Problems	Causes	Solutions
Display remains blank after the test strip has been inserted into the Meter.	1. Battery power is too low to use. 2. Too much time has passed between inserting the Test Strip and performing the test. 3. Test Strip has not been fully inserted into the Meter.	1. Charge the battery 2. Reinsert the Test Strip into the Meter. 3. Reinsert the Test Strip into the Meter.
Test results are inconsistent or Control Solution test results are not fall within specified range.	1. Not enough sample in the Test Strip. 2. Test Strip or Control Solution has expired. 3. Test Strip has been damaged due to heat or humidity so that sample cannot be applied or the speed of applying sample is too slow. 4. System is not performing due to the environment being above or below room temperature.	1. Redo test with new test strip and make sure that enough sample has been added. 2. Redo test with new test strip. 3. Perform a Control Solution test using a new Test Strip. If results are still out of range, replace with new vial of Test Strips. 4. Bring system to a room temperature environment and wait approximately 30 minutes before performing a new test.
The Meter countdown did not start.	1. Test Strip has not been inserted correctly. 2. The blood sample volume is not enough.	Use a new Test Strip and redo the test.

Performance Characteristics

Precision

Within Run Precision (300 Venous Blood Tests per Glucose Level)

Glucose concentration interval (mg/dL)	30~50	51~110	111~150	151~250	251~400
	YSI Mean (mg/dL)	40.3	89.9	131.5	199.3
Lot 1	Mean (mg/dL)	40.0	89.7	130.8	200.0
	SD	2.7	3.1	4.6	7.2
	CV(%)	6.6%	3.5%	3.5%	3.4%
Lot 2	Mean (mg/dL)	40.2	90.2	130.0	199.9
	SD	2.7	3.1	4.7	10.9
	CV(%)	6.7%	3.5%	3.6%	3.4%
Lot 3	Mean (mg/dL)	40.0	89.9	130.7	201.3
	SD	2.5	3.1	4.6	10.1
	CV(%)	6.3%	3.4%	3.5%	3.1%
Pooled	Mean (mg/dL)	40.1	89.9	130.5	200.4
	SD	2.6	3.1	4.6	10.7
	CV(%)	6.5%	3.5%	3.6%	3.3%

Results show that the greatest variability observed between test strips when tested with blood is 2.9% or less.

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Between Run Precision

Glucose concentration interval (mg/dL)	30~50	51~110	111~150	151~250	251~400
YSI Mean (mg/dL)	41.9	94.0	131.1	199.2	325.3
Mean (mg/dL)	40.1	90.5	116.8	193.0	315.6
SD	2.0	2.5	3.2	4.8	6.3
CV(%)	5.1%	2.8%	2.8%	2.5%	2.0%
Mean (mg/dL)	40.1	90.3	116.9	192.4	314.2
SD	2.0	2.7	3.2	4.6	6.2
CV(%)	5.1%	3.0%	2.8%	2.4%	2.0%
Mean (mg/dL)	40.0	89.8	117.3	192.1	315.0
SD	1.9	2.5	2.9	4.0	6.0
CV(%)	4.9%	2.8%	2.5%	2.1%	1.9%
Mean (mg/dL)	40.1	90.2	117	192.5	314.9
SD	2.0</				