

# **Gluko Blood Glucose Monitoring System**

Dear Gluko System User,

Thank you for choosing the Gluko Blood Glucose Monitoring System! The Gluko Blood Glucose Monitoring System is designed for easy testing of blood glucose and helps you keep blood glucose under control.

Read this User's Manual carefully before you use your meter system. This manual will help you to get comfortable using the Gluko Blood Glucose Monitoring System and get reliable test results. Please keep your User's Manual in a safe place; you may want to refer to it in the future.

Thank you again for choosing the Gluko System.

## **Intended Use and Principle**

Gluko Blood Glucose Monitoring System is comprised of the Gluko Blood Glucose Meter (GC-BBGG-C1) and the Gluko Blood Glucose Test Strips (GC-BBGS-C1). The Gluko Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use) and should only be used by a single person and should not be shared.

This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

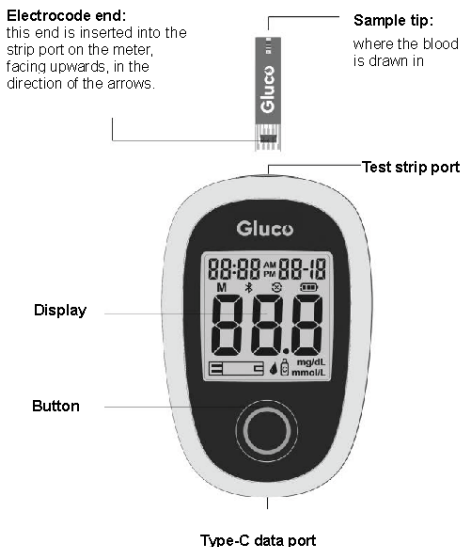
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## CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

### Your Meter System Overview

The **Gluco** Blood Glucose Meter and **Gluco** Strip



### Your Meter Display

The picture below shows all the symbols that appear on your meter display. Please make sure the display is working properly before testing. When the meter is off, press and hold  to see the complete display. All display segments will appear. If you need more time to check the display, repeat the above operation. All of the segments should be clear and exactly like the picture below. If not, contact Gluco Customer Support at 970-840-8297 (Monday-Friday 9 a.m.-8 p.m. Eastern Time) for help. Please contact your health care professional if you need help with your device.



Icon	What it Means
08-18	The top right area on the screen indicates the date.
08:08	The top left area on the screen indicates the time.
	Indicates empty battery or battery needs to be recharged
000	The center area on the display, this shows the test results or error codes.
	Indicates the system is ready to test.
	Control test result.
mg/dL	Test results are displayed as mg/dL
	Bluetooth
	The meter failed to sync with Bluetooth.
M	Memory

#### Notes:

Your Gluco meter is pre-set with beep sound function, the meter will beep when:

- The meter is turned on
- the test strip is inserted and ready to apply blood or control solution.
- sufficient blood or control solution is pulled into the test strip.
- the test is complete.
- it is time to perform a test if you set the test alarms.
- if any error occurs during operation.

#### Meter Use and Precautions

- The meter is preset to display blood glucose concentration in milligrams per

- deciliter (mg/dL) by default.
- Meter will shut off by itself after 2 minutes of inactivity.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry. Avoid exposing it to extreme temperatures or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do, check the meter by running a quality control test. Refer to **Quality Control Test** for instructions.
- Do not take the meter apart. This will void the warranty.
- Refer to the **Caring for Your Meter** section for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

**Note:** Follow proper precautions and all local regulations when disposing of the meter and used batteries.

### Important Safety Information

- The meter is single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- Always keep the test strips in the original vial. Tightly close the vial immediately after you have removed the test strip.
- Do not use the meter if it is dropping into water or splashing water on to it.
- Wash and dry your hands well before and after testing.
- Test strips and Safety lancets are for single use only.
- Do not drop blood directly on the flat surface of the test strip.
- Check the expiration dates and discard dates on your test strips vial label (or on the foil pouch) and control solution bottle label.
- Use only Gluco test strips with your Gluco meter.
- Use only Gluco control solution with your Gluco meter and Gluco strip.
- Please contact your physician or diabetes healthcare professional if you need to make a change on your current medical therapy or diet activity based on test results.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.



### Potential Biohazard

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

### Note:

1. The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
2. All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter and lancing device.
3. For more information, please refer to the FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>. You may also refer to the CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) at <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

## Limitations

- For single-patient use only.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit level.
- If you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) then your glucose results using this meter may not be reliable.
- Patients undergoing oxygen therapy may cause false result.
- Not for use on patients with critical illness.
- Not for use on patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis).
- The Gluco Blood Glucose Monitoring System should not be used following xylose absorption procedures.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use in hypotensive individuals.
- Do not use at altitudes above 13123ft (4000 meters) above sea level.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.



## Note:

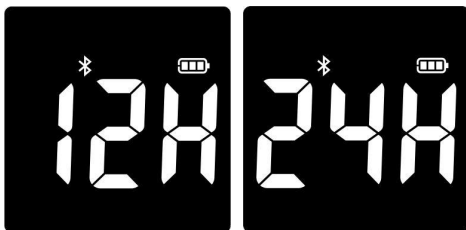
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 20 to 600 mg/dL.

## CHAPTER 2: SETTING UP YOUR SYSTEM



Before using your meter for the first time, or if you change your meter batteries, you should check and update your meter settings.

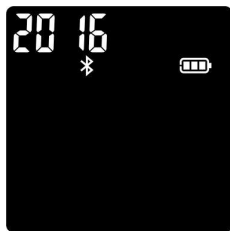
### 1. Set the Clock



Set the clock for either 12 or 24 hour mode Press  to adjust it then press and hold  to save your choice. Start setting the year, month and date.





### 2. Set the Date

The year will now flash. Press  to adjust it then press and hold  until the meter beeps to set, then it will shift to the next digit for setting. Repeat the above action until the year setting is completed.



The month will now flash. Press  to adjust the month, press and hold  until the meter beeps to set.





The date will now flash. Press  to adjust the date, press and hold  until the meter beeps to set, then it will shift to the next digit for setting. Repeat the above action until the year setting is completed.

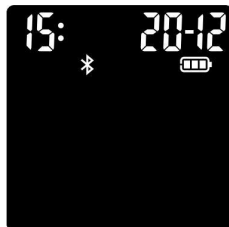




**Note:**

*Before your first test using the meter, please adjust the meter settings to set the date and time, ensuring that results stored in the memory are shown with the correct date and time.*

**3. Set the Time**

The hour will now flash. Press  to adjust the current hour, press and hold  until the meter beeps to set, then it will shift to the next digit for setting. Repeat the above action until the hour setting is completed.





The minute will now flash. Press  to adjust the minute, press and hold  to set.





### Set the Audio Feature

After you set the time, press  to select "On" or "OFF". Press and hold  to set.



Now you have completed your meter set up. A symbol of a test strip appears letting you know the meter is ready to test.



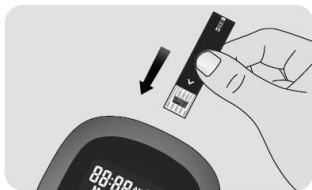
Your meter automatically stores up to 500 results with the time and date. Test results are stored from the newest to the oldest. If there are already 500 records in memory, the oldest record will be erased to make room for a new one.

## CHAPTER 3: TAKING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin testing. This includes your Gluco meter, the Gluco test strips and Gluco Safety Lancets.

### Preparing the Test Strip

1. Wash and dry your hands thoroughly before testing.
2. Remove a test strip from the test strip vial (or the foil pouch). Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the meter in the direction of the arrows. Meter turns on after a beep.
- 4.



5. A symbol with a test strip with a flashing blood will appear letting you know the meter is ready to test.



#### **Note:**

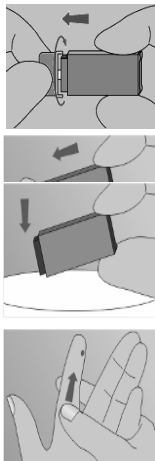
*Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month format. 2019/01 indicates January, 2019. Your Gluco test strips have 4 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water when washing hands to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.*

### Getting a Blood Drop and Testing

Here is an example of how to use a Gluco Safety Lancet for fingertip blood sampling. If you use a different single-use auto-disabling safety lancet or lancing device, please follow the manufacturer's instructions.

1. Carefully rotate and pull off the protective cap. Avoid placing your thumb or fingers over the uncapped end of the safety lancet.
2. Hold the safety lancet against the puncture site. **Note:** Before using a **single-use auto-disabling safety lancet** for blood sampling, wash both hands with soap and warm water and disinfect the puncture site with a topical skin antiseptic such as an alcohol swab.
3. Gently press the safety lancet against the puncture site to lance the skin. Listen for an audible click. This indicates that the safety feature of the device has been activated. Dispose of the lancet in an appropriate biohazard sharps container. Please see the **Caution Statement**.
4. Gently massage from the surrounding area toward the puncture site to collect the required blood volume.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make fingers sore and callused.



### Caution Statement

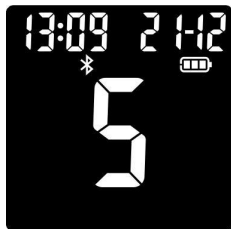
- Do not use the single-use auto-disabling safety lancet if the cap is missing or loose.
  - Always use a new, sterile single-use auto-disabling safety lancet. Do not reuse the single-use auto-disabling safety lancet.
  - Avoid getting the single-use auto-disabling safety lancet dirty with hand lotion, oil, dirt or debris.
  - Dispose of single-use auto-disabling safety lancets appropriate biohazard sharps container. If a biohazard sharps container is not available use a heavy duty plastic container such as a laundry detergent bottle. Ensure the container is leak-resistant and has a hard puncture proof lid. Do not place loose sharps into the trash and do not flush down the toilet. Do not place sharps into the recycle bin as they are not recyclable.
5. Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip. Make sure that the blood sample has fully filled the check window on the strip tip. Hold the tip of the test strip in the blood drop until the meter beeps.



**Note:**

*If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*

- The meter counts down 5 seconds and your result appears on the display after a beep. The test result will automatically be stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.



**Discard the Used Test Strip**

You can discard the used test strip by hand. The Meter turns off automatically after a beep.



**Potential Biohazard**

Dispose of the used test strips as medical waste.

**Note:**

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter and lancing device.

**Warning:**

- If your blood glucose reading is under 50 mg/dL or you see LO (less than 20 mg/dL) on the meter display, contact your health care professional as soon as possible.*
- If your test result is above 250 mg/dL or you see HI (greater than 600 mg/dL) on the meter display, contact your health care professional as soon as possible.*
- Please contact your physician if you plan to make a change on your current medical therapy based on Gluco test result.*

**Glucose Reference Ranges:**

Expected glucose values for people without diabetes:

Time of Day	Glucose Range
Fasting and before Meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Source: American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

### Questionable or Inconsistent Results:

If your blood glucose result does not match how you feel, please:

- Check the expiration date and the discard date of the test strip. Make sure that the test strip vial has not been opened for more than 4 months.
- Confirm the temperature in which you are testing is between 41-113°F.
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored at 36-86°F, 10-90% humidity..
- Make sure the test strip was used immediately after removing from the test strip vial (or the foil pouch).
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See **Performing a Control Test** for instructions).

After checking all of the conditions listed above, repeat the test with a new test strip. If you are still unsure of the problem, please contact Gluco Customer Support at 970-840-8297 (Monday-Friday 9 a.m.-8 p.m. Eastern Time). Please contact your health care professional if you need help outside of these hours.

## Testing with Control Solution

### Why Perform Control Tests

Performing a control test lets you know that your meter and test strips are working properly to give reliable test results. You should perform a control test when:

- Once a week
- You open a new box of test strips
- You want to check the meter and test strips
- Your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- You dropped the meter
- Your test result does not match with how you feel

### About the Control Solutions

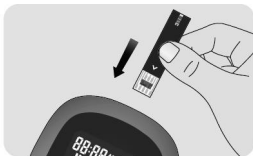
- Only use Gluco Control Solutions (1, 2 or 3) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not included in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity..
- All expiration dates are printed in Year-Month format. 2019/01 indicates January, 2019.
- Do not use control solution that is out of the expiration date or discard date (the control solution will expire 4 months after the bottle is opened for the first time).
- Shake the bottle well before use.
- Close the bottle tightly after use.

### Performing a Control Test

1. Remove test strip from the test strip vial (or the foil pouch). Tightly close the vial cap immediately after you have removed the test strip.

**Note:** Check the expiration and discard dates of the test strips. Do not use the expired test strip.

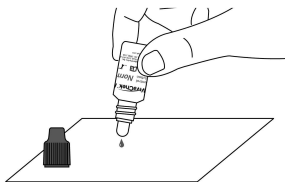
2. Insert a test strip into the meter in the direction of the arrows.



3. The meter turns on after a beep. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.



4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.



**Note:** Do not apply control solution to the test strip directly from the bottle.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.

**Note:**

*If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.*

6. Hold it in the drop until the meter beeps. You will then see the meter count down on the screen, followed by your control test result after a beep.

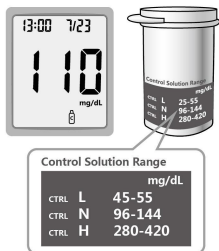


**Note:**

The meter will automatically recognize and mark the control result for you. Control results are not included in the 7, 14 and 30 day average calculation.

**Understand Your Control Test Result**

Compare your control test result with the ranges printed on the test strip vial label.



**Notes:**

If your control test result is out of range:

- Check the expiration dates and discard dates of the test strip and control solution. Make sure that the test strip vial and the control solution bottle have not been opened for more than 4 months. Discard any expired test strips or control solution.
- Confirm the temperature in which you are testing is between 50-104°F.
- Make sure that you stored strip and control solution at 36-86°F, 10-90% humidity.
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Make sure the test strip was used immediately after removing from the test strip vial (or the foil pouch).
- Make sure the control solution was mixed well.
- Confirm that you are using Gluco brand control solution.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. Contact Gluco Customer Support at 970-840-8297 (Monday-Friday 9 a.m.-8 p.m. Eastern Time) for help. Please contact your health care professional if you need help outside of these hours. To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will not be included in your blood glucose averages.

**Using the Meter Memory**



Your meter automatically stores up to 500 results with the time and date. Test

results are stored from the newest to the oldest.

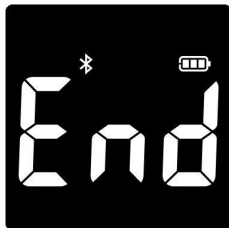
**Notes:**

- *If there are already 500 records in memory, the oldest record will be erased to make room for a new one.*

### Viewing Your Test Results

When your meter is off, press  to turn the meter on. After a beep, a symbol of a test strip flashes on the display. Continue to press  to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken.


When END appears on the display, you have viewed all of the results in the memory.




## CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

### Recharging the Battery

When the meter needs to be recharged, the Empty Battery symbol () will appear.

When the Empty Battery symbol () appears by itself on the screen, the meter cannot be used. You must recharge the battery before using your meter.

*The meter battery may be charged using one of the following options:*

- *USB Type C cable (computer charging)*
- *USB Type C cable with the AC adapter (wall charging)*



**Caution:**


- Do Not charge the meter outdoors or in a wet area.
- Do Not use the USB Type C cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odour. Contact your local distributor.
- Do Not plug the AC adapter into a wall socket and leave it unattended.
- Verify that the wall socket voltage matches the AC adapter voltage.
- Do Not allow unsupervised children to charge the meter battery.



**Caution:**

Do Not insert a test strip when the meter is connected to a computer or wall outlet.

**NOTE:**

- Using the USB Type C cable or AC adapter charges the battery in about 2 hours.
- When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.
- To optimise battery life, it is best to recharge the battery when the Low Battery symbol (  ) appears.

**Caution:**

- If you use the AC adapter which not provided by Gluco, make sure it meets the standard EN 60950-1;
- If you use the USB port on your computer to charge the battery, make sure it meets the standard IEC60950.

**Caring for Your Glucose Monitoring System**

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water and other contaminants.
- Gluco Blood Glucose Meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

**Cleaning and Disinfection**

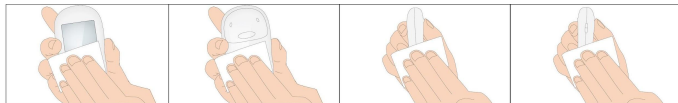
Your Gluco Blood Glucose Meter should be cleaned and disinfected a minimum of once per week. Use only Clorox™ Healthcare Bleach Germicidal Wipes, which has been proven to be safe to use with the Gluco Blood Glucose Meter. Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfecting reduces the risk of transmitting infectious diseases.

*Note: If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.*

**Cleaning Your Meter**

Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.

Step 2: Clean the entire meter surface including front side, back side, right side, left side and top.



Front side

Back side

Right Side

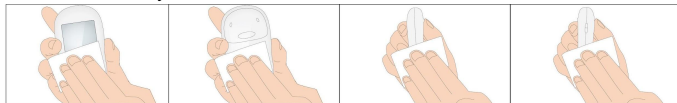
Left side

The meter should be cleaned whenever they are visibly dirty or a minimum of once per week. This pre-cleaning is to prepare the meter surface for a disinfection process.

### Disinfecting Your Meter

Step 1: After cleaning your meter, take out another new piece of Clorox™ Healthcare Bleach Germicidal Wipes.

Step 2: Wipe the entire surface including front side, back side, right side and left side of the meter, by a back and forth movement.



Front side

Back side

Right Side

Left side

Step 3: Keep the meter surface wet for at least one minute.

Step 4: Wait for the surface of meter to be dry.

Clorox™ Healthcare Bleach Germicidal Wipes containing Sodium hypochlorite 0.55%, which has been proven to be safe to use with the Gluco system. Clorox™ Healthcare Bleach Germicidal Wipes are available by contacting Krasity Medical Supply at 970-840-8297 directly or visiting and purchasing at <http://www.walmart.com> and <http://www.staples.com/>.

The meter should be disinfected a minimum of once per week. The meter disinfection process has been validated for 608 disinfection cycles, which is equivalent cleaning and disinfecting your meter every 3 days for 5 years. This is to ensure that your meter will operate properly over the 5-year life of the meter.

### Notes:


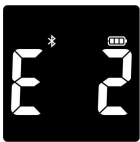

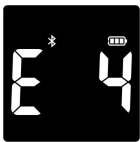
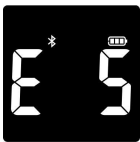
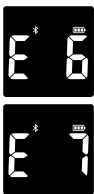
- Do not use alcohol or any other solvent.
- Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the data port.
- Do not squeeze the wipe or gauze into test strip port.
- Do not spray cleaning solution on the meter.
- Do not immerse the meter in any liquid.





### Notes:

Although it has not been observed, some alterations may appear on your meter due to the cleaning and disinfection procedure. Such as: cloudy display window, plastic housing cracking, meter buttons do not function, partial display on full screen, unable to execute the meter's initial set up, etc. If you notice any of these external changes to your meter or any changes to the performance of your meter stop using the meter and please contact Customer Support for help.

If you have questions about cleaning or disinfection, or if you see evidence of physical damage, contact Gluco Customer Support at 970-840-8297 (Monday-Friday 9 a.m.-8 p.m. Eastern Time). Please contact your health care professional if you need help outside of these hours.

## Troubleshooting Guide

What You See	What It Means	What You Should Do
	Blood or control solution was applied to the test strip before the flashing blood drop appeared on the display	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a Gluco test strip
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and Gluco control solution are used for the test.
	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
	Potential software or hardware issue.	Restart the meter. If the problem continues, contact Gluco Customer Support at 970-840-8297 (Monday-Friday 9 a.m.-8 p.m. Eastern Time). Please contact your health care professional if you need help.

	<p>A test strip was inserted while the meter was connected to a computer or wall outlet.</p>	<p>When the charge is completed (about 2 hours when charging an empty battery), remove the USB Type C cable from the meter, and then take a test.</p>
	<p>Insufficient sample.</p>	<p>Repeat the test and apply enough sample to fill the test strip check window.</p>
	<p>The test result is above 600 mg/dL.</p>	<p>Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.</p>
<div data-bbox="98 682 187 759" data-label="Image"> </div> <p><b>Caution:</b> Glucose levels above 250 mg/dL may indicate a potential serious medical condition.</p>		
	<p>The test result is below 20 mg/dL.</p>	<p>Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.</p>
<div data-bbox="98 1024 187 1101" data-label="Image"> </div> <p><b>Caution:</b> Glucose levels below 50 mg/dL may indicate a potential serious medical condition.</p>		

## Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

### Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

### Ketones (ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth

### High blood glucose (Hyperglycemia):


- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

### **Warning:**

*If you are experiencing any of these symptoms, test your blood glucose. If your test result is under 50 mg/dL or above 250 mg/dL, contact your health care professional immediately.*

## CHAPTER 5: TECHNICAL INFORMATION

### System Specifications :

Feature	Specification
Measurement Range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary whole blood
Sample	Fresh capillary whole blood
Sample Volume	0.8 µL
Test Time	5 seconds
Power Source	Rechargeable 3.7 Volt Lithium Ion battery
Charging Current	100mAh,  Direct current
Battery Type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Glucose Units of Measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 500 records with date and time
Automatic Shutoff	2 minutes after last action
Dimensions	82 mm x 54 mm x 23 mm
Display Size	32mm x 32 mm
Weight	Approximately 53g
Operating Temperature	41-113°F
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	20-70%
Data Port	USB Type-C
Bluetooth	Version 4.1

The Gluco Blood Glucose monitoring system was tested by 352 lay users using capillary blood samples and three Gluco test strip lots. The results were compared to the YSI Model 2300 STAT PLUS Glucose Analyzer, a laboratory instrument. The tables below show how well the two methods compared.

**Table 1-Linear Regression Results**

Slope	1.0137
Y- Intercept	-2.3501 mg/dL
Correlation coefficient(R)	0.9977
Number of sample	352
Range tested	52.3 ~ 516.0 mg/dL

**Table 2-Consumers Accuracy Results**

The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

Difference range between the true blood glucose level and the Gluco Blood Glucose meter result.	Within ±5%	Within ±10%	Within ±15%	Within ±20%
The percent (and number) of meter results that match true blood glucose level within x%	71.9% (253/352)	96.6% (340/352)	100% (352/352)	100% (352/352)

Accurate Results (Meter result is +/-15% of laboratory result)	352 out of 352 (100% of results)
More Accurate Results (Meter result is +/-10% of laboratory result)	340 out of 352 (96.6% of results)
Most Accurate Results (Meter result is +/-5% of laboratory result)	253 out of 352 (71.9% of results)

If the meter fails to work for any reason other than obvious abuse within the first two (2) years from purchase, Gluco will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.  
Date of purchase: \_\_\_\_\_

**Note:**

*This warranty applies only to the meter in the original purchase, and does not apply to the batteries supplied with the meter.*