

Dear BGM039 Link Owner

Thank you for choosing the BGM039 Link Blood Glucose Monitoring System to help you easily monitoring your blood glucose. We hope it will be of great help in the management of your diabetes. This manual explains how to use your new meter. Before testing, carefully read through this manual and the package inserts that come with: BGM039 blood glucose test strip, Contrex Plus 4 glucose control solution. Pay particular attention to listed warnings and cautions. Please keep this manual at hand for future reference.

Please call us at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday for questions and inquiries. If you have any questions or need assistance outside the operational days and times, please contact your health care provider.

Intended Use

The BGM039 Link Blood Glucose Monitoring System is comprised of the BGM039 Link Blood Glucose Meter and the BGM039 Blood Glucose Test Strips.

The BGM039 Link Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

IMPORTANT:

- Testing is done outside the body (In Vitro diagnostic use).
- Do not use test strips if expiration date has passed.
- Use BGM039 Blood Glucose Test Strips within 6 months of opening test strip vial.

Important Safety Instructions

- 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 and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

The link of public health notification and standard practice guideline are:

- “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
- “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

Warning

- 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.”

Limitations

- Inaccurate results may occur in
 - Severely hypotensive individuals
 - Patients in shock
 - In a hyperglycemic-hyperosmolar state with or without ketosis
- Do not use on critically ill patients.
- Do not use on neonates.
- Do not use the system above 10,335 feet (3,150 meters) in altitude.
- Do not use if hematocrit exceeds the acceptable range between 10% to 70% when testing blood glucose.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For In Vitro Diagnostic only.
- For Over the Counter use.
- Perform an Alternative Site Testing (AST) only if your glucose level is not changing rapidly.
- For single-patient use only.
- Do not use AST measurements to calibrate Continuous Glucose Monitors (CGMs).
- Do not use AST measurements for insulin dosing calculations.

The following drugs do not generally interfere with the BGM039 Link system at normal or therapeutic levels. However, higher concentrations (listed below) were found to interfere with glucose measurements.

- If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations > 10 mg/dL) you may get inaccurate results with this system. If you are unsure, then ask your doctor.
- If you are taking Paralidoxime Iodide (PAM) or Paralidoxime Iodide (PAM) containing drugs at blood concentrations > 50 mg/dL, you may get inaccurate results with this system. If you are unsure, then ask your doctor.
- If you have certain conditions that may cause your blood level of uric acid to rise (> 15 mg/dL in your blood), such as gout or kidney disease, then your blood glucose results may be inaccurate with this meter. If you are unsure, then ask your doctor.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask your doctor how long to wait before performing a glucose test.

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Understanding Your New Blood glucose Monitoring System

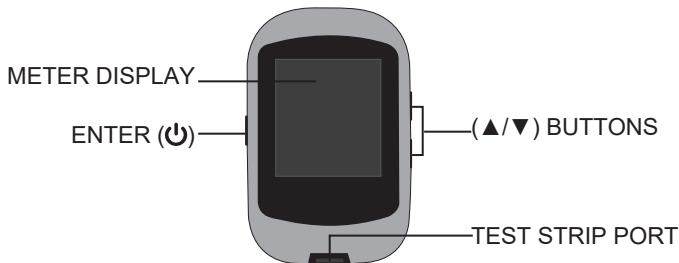
The BGM039 Link Blood Glucose Monitoring System comes in either as a Complete Kit or a Simple Kit. Each package may include the following items:

Contents	Package Configuration	
	Complete Kit	Simple Kit
BGM039 Link Blood Glucose Meter	V	V
Instruction Manual	V	V
Carrying Case	V	V
Log Book	V	V
BGM039 Blood Glucose Test Strips (vial or foil-wrapped)	V	

Note:

- Contrex Plus 4 Glucose Control solutions are required, but not provided and should be purchased separately.
 - The lancets and lancing device are not provided in the kit and will need to be purchased separately by the user
- Please contact us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST for purchasing information.

The BGM039 Link Blood Glucose Meter



TEST STRIP PORT

This is where you insert the test strip and the meter will turn on automatically.

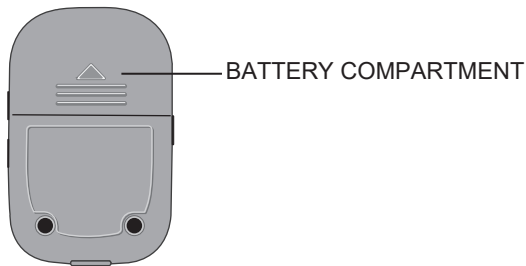
METER DISPLAY

Shows your blood glucose test results, memory values, averages, and other messages.

ENTER (power) and (▲/▼) BUTTONS

Press and hold Enter (power) for 2 seconds to turn on or off the meter, or press Enter (power) to go into setup mode when not testing.

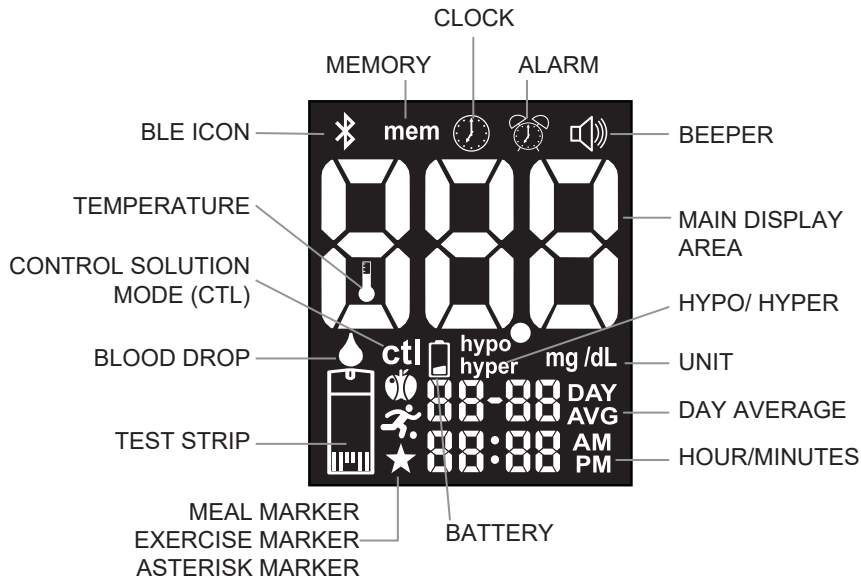
Press ▲ or ▼ to enter control mode with test strip inserted, during meter setup, or to navigate the stored test values and averages.



BATTERY HOLDER

Holds two CR 2032 3V Lithium coin cell batteries.


The BGM039 Link Blood Glucose Meter Display Screen





MEMORY	Indicates that you are using the memory
CLOCK	Appears when setting date and time (see page 18);
ALARM	Appears when setting the alarm function (see page 21)
HYPO	<ul style="list-style-type: none"> • Setting up your hypoglycemic threshold value (see page 25) • Indicates your test result maybe at or below your hypoglycemic threshold value • Indicates the memorized result maybe at or below your hypoglycemic threshold value
HYPER	<ul style="list-style-type: none"> • Setting up your hyperglycemic threshold value (see page 25) • Indicates your test result maybe at or above your hyperglycemic threshold value • Indicates the memorized result maybe at or above your hyperglycemic threshold value
BLOOD DROP.....	This icon will flash to indicate that the meter is ready for blood or control solution testing
MAIN DISPLAY AREA.....	Displays test results, stored test values, result averages and messages.
UNIT OF MEASUREMENT ...	Unit of measurement for your blood glucose is mg/dL.
TIME	Shows time (HH:MM, 12H AM/PM or 24H format).

DAY AVERAGE.....	Shows the period related to the displayed average (1, 7, 14, 30, 60 or 90 days –(see page 48).
DATE.....	Shows the date (MM-DD format)
WRONG TEMPERATURE ...	Appears when it is either too hot or too cold to test (outside the ranges of 50 °F~104 °F).
LOW BATTERY.....	Appears when batteries need to be replaced (see page 49).
MEAL MARKER	Display when marking a result as before or after meal, or viewing a marked result (see page 50).
EXERCISE MARKER.....	Display when marking a result as exercise, or viewing a marked result (see page 51).
ASTERISK MARKER	Display when marking a result as being unique or different in some way, or viewing a marked result (see page 51).
CTL.....	Indicates a control solution test (see page 30)
BEEPER.....	Appears when turning ON/OFF tone sound (see page 23)
TEST STRIP	This icon will flash to prompt you to insert a test strip for testing
HOUR/MINUTES.....	Displays time in 12-hour format or 24-hour format.

BLE ICON.....Indicates the Bluetooth connectivity is turned ON

 The icon is flashing rapidly. The meter is ready for a device pairing.

 The icon is flashing steadily. The meter has paired with a mobile device and is transmitting data.

 The icon is displayed without flashing. The meter has paired with a mobile device and is waiting for instructions.

The BGM039 Blood Glucose Test Strip

Contact Points

Insert this end to the test strip port on the meter



Sampling End

Apply blood or control solution here

The BGM039 Blood Glucose Test Strip is a glucose specific, biosensor-based test strip that can test glucose in capillary whole blood in as quickly as 5 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results. The test strip has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that every reading you get is an accurate and meaningful result.

IMPORTANT:

- The BGM039 Blood Glucose Test Strip is sensitive to moisture and light. For vial test strip, it is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use. For Foil-wrapped test strip, do not open the foil wrapping until performing tests.
- DO NOT reuse test strips. Test strips are for single use only.
- Carefully discard used test strips and lancets in proper waste containers.
- Be sure to use only the BGM039 Blood Glucose Test Strip with the BGM039 Link Blood Glucose Meter. Other brands of test strips will not work with the meter.

Contrex Plus 4 Glucose Control Solution




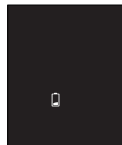
Call your local supplier or pharmacy to order control solution. If they do not stock it, please contact us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST.

The Contrex Plus 4 Glucose Control Solutions are required to perform a glucose control solution test. The solutions are available at 3 concentrations. Contrex Plus 4 L1 Glucose Control Solution helps you to validate the performance of your system at a low range blood glucose reading, while L2 solution helps you to validate your system performance at a middle range blood glucose reading, while L3 solution helps you to validate your system performance at a high range blood glucose reading. Please see Control Solution Testing section on page 31.

Setting Up Your New System

Inserting (or Changing) the Battery

Batteries need to be changed when the “” icon appears on the meter display.



Material you will need:

- Two CR 2032 3V Lithium coin cell batteries
- Your BGM039 Link Blood Glucose Meter

Step 1.

Turn meter off. Remove the battery cover on the back of the meter by pushing the tab and pulling the door up. Remove the old batteries.

Step 2.

Insert the new batteries with the + side up. They do not snap into place but rest on the metal contact. The door holds the batteries down.

Put the battery door back in the place and snap it closed.

NOTE:

- After changing the batteries, the meter automatically prompts you to check the time and date when it is turned on either by inserting a test strip or pressing “⏻”. If it is correct, press “⏻” to confirm setup and exit, or if the time and date are not correct, turn to page 18 for Setting the Clock.
- The stored results in memory will not be erased when the batteries are being changed.
- Discard used batteries according to your local regulation.
- The meter uses two 3-volt lithium batteries, coin cell CR2032. This type of battery can be found in many stores. Always keep a spare packaged battery on hand.
- Be sure the batteries go in + side up.
- Remove the batteries if unused for a long time.

Clock Setup

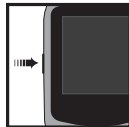
Material you will need:

- Your BGM039 Link Blood Glucose Meter

Begin Set Up

Step 1.

Press and hold “⏻” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen

**Step 3.**

Press “▲” twice and the meter display screen shows “🕒”.

**Set Year****Step 4.**

Press “⏻” and the current year will flash. Press “▲” or “▼” to select the correct year.

Press “⏻” to confirm your choice and advance to set the month

**Set Month****Step 5.**

The current month will flash. Press “▲” or “▼” to select the correct month.

Press “⏻” to confirm your choice and advance to set the day.



Set Day

Step 6.

The current day will flash. Press “▲” or “▼” to select the correct day. Press “⏻” to confirm your choice and advance to set the 12-hour or 24-hour time format.



Set 12-hour or 24-hour Time Format

Step 7.

The current time format will flash. Press ▲ or ▼ to select either 12-hour format or 24-hour format. Press “⏻” to confirm your choice and advance to set the hour.



Set Hour

Step 8.

The current hour will flash. Press ▲ or ▼ to select the correct hour. Press “⏻” to confirm your choice and advance to set minutes.



Set Minutes

Step 9.

The current minutes will flash. Press ▲ or ▼ to select the correct minutes. Press “⏻” to confirm your choice and finish setting the clock.



Begin testing by inserting a BGM039 Blood Glucose Test Strip (see Testing Your Blood Glucose on page 31), or press and hold “⏻” to turn off the meter, or continue to set up the alarm feature on your meter.

NOTE:

- If you do not set the date and time on the BGM039 Link Blood Glucose Meter, the test or control results will not be stored in the meter’s memory.
- Anytime during setup, you can insert a BGM039 Blood Glucose Test Strip to begin testing. Any changes made so far will be stored.
- You may need to reset time after changing batteries.

Alarm Setup

You can set up to three alarms on the BGM039 Link Blood Glucose Meter. The feature is to remind you when to perform a (blood glucose) test. You must set the clock before setting the alarms. When the alarm reaches the set time, the meter sounds for 30 second. Pressing “⏻” or inserting a test strip will silence the alarm.

Materials you need:

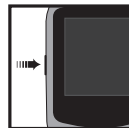
- Your BGM039 Link Blood Glucose Meter

CAUTION:

- Before setting the alarms please check that the time is properly set.

Step 1.

Press and hold "⏻" to turn on the meter.

**Step 2.**

The flashing test strip icon will appear on the meter display screen.

**Step 3.**

Press "▲" or "▼" until "🕒" starts to flash. Press "⏻" to enter alarm setting.



Step 4.

The display screen will indicate alarm 1 status (the default is OFF). You can turn it on by pressing ▲ or ▼. Press “⏻” to confirm your choice and advance to set hour.

**Step 5.**

The hour will flash. Press ▲ or ▼ to select the hour. Press “⏻” to confirm your choice and advance to set minutes.

**Step 6.**

The minutes will flash. Press ▲ or ▼ to select the correct minutes. Press “⏻” to confirm your choice and advance to set alarm 2.


**Step 7.**

Set alarm 2 and 3 by following steps 4 through 6. After you have finished setting up alarm 3, press “⏻” to exit alarm setup.



NOTE:

- Alarm will not ring during testing.
- Alarm will follow the time format (12-hour or 24-hour) you choose when setting up the clock.
- Alarm settings will not be erased when changing the batteries.

Begin testing by inserting a BGM039 Blood Glucose Test Strip (see Testing Your Blood Glucose on page 37 or Control Solution Testing on page 31), or press and hold “” to turn off the meter.


Beeper Setup

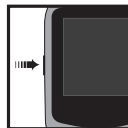
The beeper on your BGM039 Link Blood Glucose Meter is preset to ON. Turning off the beeper could mean you miss many important cues from your meter, such as confirmation or error messages. You can adjust the beeper feature as follows.

You will need:

- Your BGM039 Link Blood Glucose Meter

Step 1.

Press and hold “” to turn on the meter.



Step 2.

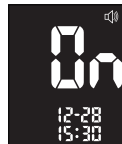
The flashing test strip icon will appear on the meter display screen.

**Step 3.**

Press “▲” or “▼” until meter display screen shows “”.

**Step 4.**

Press “” to enter beeper setup. Use “▲” or “▼” to turn on/off the tone.

**Step 5.**

Press “” to confirm and exit once you have made your selection.

NOTE:

- Anytime during setup, you can insert a Test Strip and begin testing. Any changes made so far will be stored.
- Your volume settings will not be erased when changing batteries.

Setting up hypo/hyper warning value

Your BGM039 Link Blood Glucose Meter has an alarm feature that allows you to set your high (hyperglycemia) and low (hypoglycemia) blood glucose thresholds. Based on the values set, the screen will show “hypo” or “hyper”, depending on whether your blood glucose test result is below your low glucose or above your high glucose threshold values. Please consult your physician or healthcare provider when setting up the Hypo and Hyper values



(example)

HYPO (hypoglycemia) warning



(example)

HYPER (hyperglycemia) warning

IMPORTANT:


- Do not alter or stop your medication based on this feature, always consult your physician or healthcare provider before altering or stopping medication.

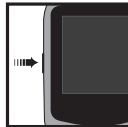
The BGM039 Link Blood Glucose Meter comes with Hypo/Hyper warning OFF as preset, and the preset threshold value is 200 mg/dL (11.1 mmol/L) for Hyper and 70 mg/dL (3.9 mmol/L) for Hypo. Follow the steps below to adjust the Hyper and Hypo threshold values.

Material you will need:

- Your BGM039 Link Blood Glucose Meter

Step 1.

Press and hold “” to turn on the meter.



Step 2.

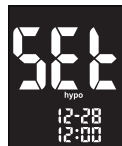
The flashing test strip icon will appear on the meter display screen.



Setting up hypo (hypoglycemia) warning value

Step 3.

Press “▲” or “▼” until the meter display screen shows “hypo”.



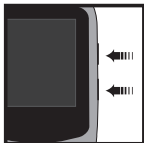
Step 4.

Press “⏻” to enter Hypo setup. Use “▲” or “▼” to turn on/off hypo warning.

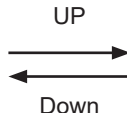


Step 5.

Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” will accelerate numbering. Press “⏻” to confirm and exit Hypo setup.



(example)



(example)

NOTE:

Default blood glucose threshold value setting and setting ranges are described below:

Hypoglycemia warning

Factory Default: 70mg/dL

Setting Range 20~179mg/dL

Setting up hyper (hyperglycemia) warning value

Step 3.

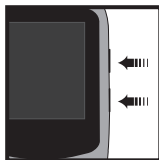
Press “▲” or “▼” until the main display screen shows “hyper”.

Step 4.

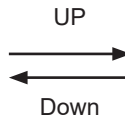
Press “⏻” to enter Hyper setup. Use “▲” or “▼” to turn on/off hyper warning.

Step 5.

Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” will accelerate numbering. Press “⏻” to confirm and exit Hyper setup.



(example)



(example)

After setting up the Hypo and Hyper values, you can either press and hold “symbol” to turn off the meter, or insert a test strip to begin testing (see Testing Your Blood Glucose on page 38, or Control Solution Testing on page 32).

NOTE:

- Default blood glucose threshold value setting and setting ranges are described below:

Hyperglycemia warning

Factory Default: 200mg/dL

Setting Range: 71~600mg/dL

Control Solution Testing

The purpose of the control solution testing is to make sure the BGM039 Link Blood Glucose Meter and the BGM039 Blood Glucose Test Strip is working properly.

You should perform control solution testing when:

- Using the meter for the first time
- Using a new bottle of BGM039 Blood Glucose Test Strips
- You drop the meter
- You suspect your meter and test strips are not working properly
- The blood glucose test results do not reflect how you feel
- You want to practice the testing procedure

NOTE:

- To test your meter and BGM039 Blood Glucose Test Strip only use the Contrex Plus 4 glucose control solutions (provided separately). Other brands of control solution will produce inaccurate result.

CAUTION:

- Always check the expiration date. DO NOT use control solutions if they are expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- For accurate test results, allow the control solution to adjust to its surroundings for at least 30 minutes before running the control test:
 - Temperature: 41 to 113 °F;
 - Relative Humidity: 20 to 90% RH.
- DO NOT FREEZE. Store the control solutions at 39°F - 86°F.
- Do not drink the control solution. It is not intended for human consumption.
- Avoid contact of the solution with the skin and the eyes as this could cause inflammation.
- Discard used control solution bottles according to your local regulation.

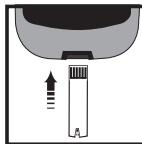
Performing a Control Solution Test

You will need:

- Contrex Plus 4 glucose control solution (L1, L2 and L3)
- Your BGM039 Link Blood Glucose Meter
- A new BGM039 Blood Glucose Test Strip

Step 1.

Insert a BGM039 Blood Glucose Test Strip into the meter with the blood sample reaction zone facing up. Make sure the test strip contact points are inserted all the way into the meter. The meter will turn on automatically.

**Step 2.**

The flashing blood drop and test strip icons appear on the lower left of the meter display screen

**Step 3.**

Press “▲” or “▼” to enter the control mode. You will see “ctl” on the lower left of the screen.

**Step 4.**

Gently shake the control solution vial before testing. Discard a drop before use.

Squeeze a drop of control solution (Level 1, Level 2 or Level 3) onto a clean, hard, dry nonabsorbent surface to avoid cross contamination. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.



NOTE:

- The test will not start if you apply your control solution not directly to the edge of the sampling end of the test strip. The test starts when the meter detects the control solution. During the test the meter counts down from 5 to 1.
- Tightly close the control solution vial.
- Do not touch the test strip once the meter has started the countdown.

Step 5.

Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip.

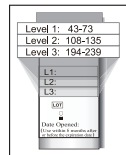
Step 6.

The screen will start to count down. After 5 seconds, the control test result will appear on the meter's display screen.

A “ctl” flag will also be attached when results are shown on the screen

Step 7.

Compare the reading on the screen to the control range printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). If the reading falls outside the control range, see Control Solution Trouble Shooting on page 36.



(Ranges are only for example)

NOTE:

- Control solution testing results will be stored into the meter's memory and indicated with "ctl" icon.
- If the user entered the control testing in the mode as described above, the control results will be marked with the "ctl" and they won't be included in the averages. But, if the control mode was not entered, then the result will be averaged in with the blood test results of the user.
- Replace the bottle cap on the control solution bottle immediately after use.

Step 8.

Remove the used test strip by pulling it out with your hand and throw it into a proper wastebasket, the meter will turn off automatically. The meter will also time-out after 1.5 minutes of inactivity.

Perform other levels of control solution testing by repeating the above steps.

IMPORTANT:

- Do not reuse test strips. Test strips are for single use only.

We suggest you should periodically review your technique. You can also compare the result obtained with your meter to a result obtained using a laboratory method or a well-maintained and monitored system used by your healthcare provider.

Control Solution Trouble Shooting

If your control solution testing is out of range (too high or too low), it may be caused by the following:

Possible Causes	What you can do ...
<ul style="list-style-type: none"> • Wrong brand of control solution being used 	<ul style="list-style-type: none"> • Make sure you are using Contrex Plus 4 Glucose Control Solution (Level 1, Level 2 and Level 3).
<ul style="list-style-type: none"> • Control solution not at right storage temperature 	<ul style="list-style-type: none"> • Make sure the testing environment is between 41°F~113°F.
<ul style="list-style-type: none"> • Expired or contaminated control solution or damaged test strip 	<ul style="list-style-type: none"> • Check the expiration and opened date on both the control solution and test strips. Repeat testing using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.
<ul style="list-style-type: none"> • Meter malfunction 	<ul style="list-style-type: none"> • If problem persists, please call us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST for questions and inquiries.

Testing Your Blood Glucose

Material you will need:

- Your BGM039 Link Blood Glucose Meter
- A new BGM039 Blood Glucose Test Strip
- Lancing device with a sterile, unused lancet
- Clear cap for Alternative Site Testing (AST) on palm and forearm

Before you begin, make sure:

- Set up your meter properly and run a control test. See Setting Up Your New System on page 17 and Control Solution Testing on page 31 for details.
- Wash your hands and the testing site thoroughly with soap and warm water, and dry well.
- You are testing in an area within the temperature ranges of 41°F~113°F and relative humidity ranges of 20~90%. Your meter will not test outside of this range and will display thermometer icon. Move the meter into an area that is within 41°F~113°F and 20~90% RH, and let it sit for 10 to 15 minutes before testing again.
- If the meter is being operated by a second person who is providing testing assistance to you, the meter and lancing device should be cleaned and disinfected (Page 58) appropriately when testing is conducted by the second person.

IMPORTANT:

- DO NOT use test strips after their expiry date. The expiry date is either written on the test strip vial or on the foil pouch.
- When you open a bottle of test strips for the first time, record the “open date” on the test strip bottle. Discard the bottle and any remaining test strips 6 months after the open date.
- After taking a test strip out of the bottle, close the cap of the bottle immediately.
- Use each test strip immediately after taking it out from the bottle.
- Do not use wet, bent, scratched, or visibly damaged test strips.
- For accurate test results, allow the test strips to adjust to the their surroundings for at least 30 minutes before testing your blood glucose levels:
Temperature: 41°F to 113°F;
Relative Humidity 20 to 90% RH.

Preparing Your Lancing Device**CAUTION:**

- The lancets are for single use only. Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.

- Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets.
- When performing a blood glucose test, use a new sterile lancet every time. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

Step 1.

Wash hands with soap and warm water and dry thoroughly. Warm water stimulates blood flow to the fingers making it easier to obtain a sample.

Step 2.

Hang the arm down at the side for 10 to 15 seconds massaging through the wrist, palm, and then finger. This can stimulate the blood flow to the finger more quickly.

Step 3.

Hold the lancing device or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device or lancet should be used.

TIP:

- To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

Important Information on Alternative site testing (AST)

The BGM039 Link Blood Glucose Monitoring System can test for blood glucose from areas other than your fingertip such as palm and forearm (alternative site testing, or AST). Alternative site testing can be less painful than fingertip testing, but because of the physiological differences between your fingertip and palm and forearm⁽¹⁾; alternative site test result maybe significantly different from fingertip testing result under certain conditions. You should consult your doctor or healthcare professional before using alternative site testing.



DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal)
- 2 hours or more after taking insulin
- 2 hours or more after exercise

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs). Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).

Alternative site measurements should never be used for insulin dosing calculations.

Do NOT perform an AST when:

- You have hypoglycemic unawareness (not able to tell if you have low blood sugar).
- You will be operating machinery or driving a car.
- You are not feeling well.
- Within 2 hours of a meal, exercise, or medication.
- When You think your blood glucose is low.
- Your AST results do not match how you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Consult with your healthcare professional to decide if AST is right for you.

NOTE:

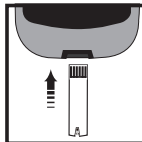
- Rubbing forearm until warm before lancing will help minimize the difference with fingertip test results. The palm (at the base of the thumb) does not require rubbing before testing.
- If results from alternative site testing do not agree with how you feel, use fingertip testing instead.

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. *Diabetes Care* 28(3):708–709, 2005
2. American Diabetes Association Position Statement: Standards of Medical Care in Diabetes—2020. *Diabetes Care* 2020; 43 (Suppl.1). https://care.diabetesjournals.org/content/43/Supplement_1/S1

Performing a Blood Glucose Test

Step 1.

Insert a BGM039 Blood Glucose Test Strip to turn on the meter.



Step 2.

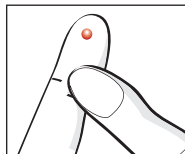
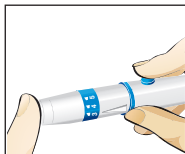
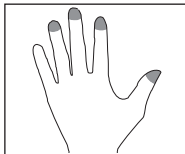
Wait for the flashing blood drop and test strip icons to appear on the left of the meter display screen.



Step 3- obtain blood sample

For Fingertip Testing:

Hold the lancing device against the side of your fingertip and press the release button to create a puncture.



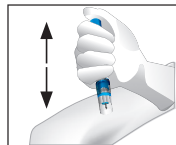
For Testing on Palm and Forearm:

Do only when it is more than two hours after a meal, diabetes medication, or exercise. Select a puncture site on forearm or palm. Avoid veins, hair, moles, bone and tendon.

For palm testing, it is not necessary to rub the skin or pump the device. Press the clear endcap firmly against the puncture site and then press the release button.

For forearm testing only, rub testing area vigorously until it feels warm to increase blood flow. Press the clear endcap firmly against the puncture site and then press the release button. Keep the device in constant contact with the skin and pump (apply and release pressure) up and down 2–3 times without lifting device away from skin.

When the blood is about the size of a pen tip (approximately:●) lift the lancing device straight up without smearing the blood.

**NOTE:**

- Rubbing forearm until warm before lancing will help minimize the difference with fingertip test results. The palm (at the base of the thumb) does not require rubbing before testing.
- If results from alternative site testing do not agree with how you feel, use fingertip testing instead.

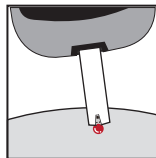
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).

TIP:

- Gently massage your hand and finger toward the puncture site to form a drop of blood (approximately:●). Do not “milk” or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

Step 4.

Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.



Step 5.

The screen will start to count down. After 5 seconds, your glucose testing result will appear on the meter display screen.



CAUTION:



If LO or HI appears on the screen:

- If you see “HI” or “LO” displayed, your blood glucose level may be above 600 mg/dL or below 20 mg/dL. Test again using fingertip testing, DO NOT test on palm or forearm. If you still receive the same result, call your physician or healthcare professional immediately

If test results do not match with how you feel:




- Make sure you have performed the test correctly as explained in Page 37. Then, conduct a glucose control test to check that the system is working properly (Page 30). Repeat the test using a blood sample taken from a fingertip (do not use an alternative site). If the test result still does not match how you feel, contact your doctor or healthcare professional.
- Do not ignore test results. Do not alter your blood glucose management or treatment without first consulting your doctor or healthcare professional.

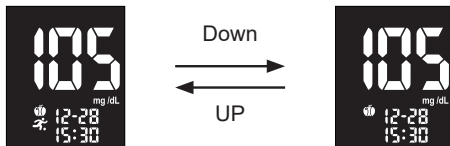
Step 6. -Select the before/after meal marker

With the test result on the display, and the test strip STILL IN THE METER. Press either “▲” or “▼” buttons to select  for before meal,  for after meal or blank if the test result does not apply. Press “⏻” to confirm your choice and advance to select exercise state.



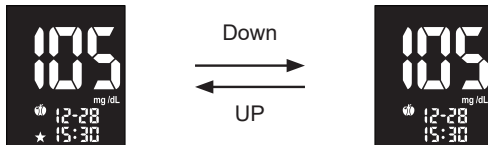
Step 7- Select the exercise marker

After selecting meal state, a flashing “” icon appears on the screen. Use either “▲” or “▼” to select “” for exercise or remain blank. Press “” to confirm your choice and advance to select the asterisk marker.



Step 8- Select the asterisk marker

After selecting exercise marker, a flashing “★” icon appears on the screen. You can mark your result with “★” for a special event. Use “▲” or “▼” to select “★” or remain blank. Press “⏻” to confirm your choice, and the result will be stored in memory.



Step 9.

Remove the used test strip by pulling it out with your hand and throw it into a proper wastebasket and the meter will turn off automatically.

The meter will also time-out after 1.5 minutes of inactivity.

Step 10

Remove the used lancet from your lancing device according to instructions and discard into a proper wastebasket according to your healthcare provider's instructions.

NOTE:

- For accurate test results, apply the drop of blood to the tip of the test strip within 20 seconds after puncturing.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood onto the test strip.
- Do not forcefully press the test strip into your puncture site.
- Do not touch the test strip once the meter has started the countdown.

CAUTION:

- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Clean and disinfect the meter after the test see page 58.
- Follow lancing device instruction for how to clean and disinfect the lancing device after the test.
- When ejecting the used test strip, point your meter downwards and away from others.
- Disposal of biohazard waste:
Used lancets and test strips are biohazard materials and can transmit blood-borne disease. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets and test strips.

Viewing Stored Readings from Memory

WARNING:


- Please make sure that time and date are correct before the first use, and adjust them if needed. If the time and date settings are not correct the meter will memorize the test results assigning them wrong time and date.

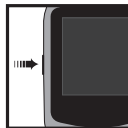
Your BGM039 Link Blood Glucose Meter automatically stores up to 500 test and control results with date and time. The meter also provides 1, 7, 14, 30, 60, and 90 days averaging to help track your blood glucose trend. You must set up the date and time on your meter before using the memory and day averaging function, see *Setting Up Your New System* on page 17. The meter will not memorize any test or control results if the date and time are not set.

You will need:

- Your BGM039 Link Blood Glucose Meter

Step 1.

Press and hold “” to turn on the meter.



Step 2.

The flashing test strip icon will appear on the meter display screen.



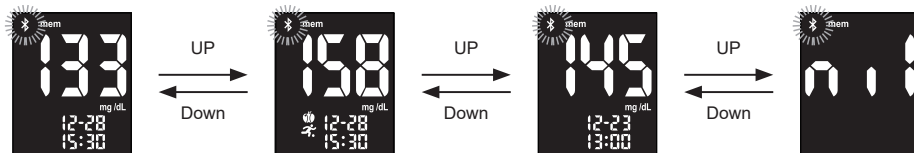
Step 3.

Use “▲” or “▼” until meter display screen shows “mem” press “⏻” to confirm your choice.



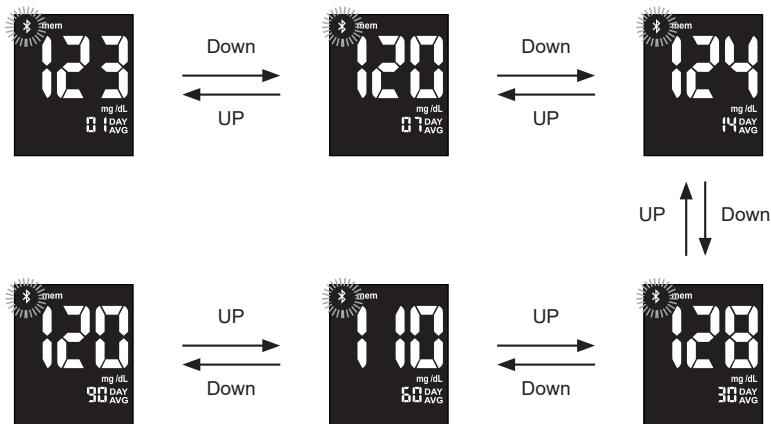
Step 4.

The most recent test result will appear on screen. Press “▲” to view your results from the most recent to the oldest. When scrolling to the end of results in the memory, the meter display screen will show “nil”.



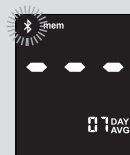
Step 5- Viewing day averages


When the most recent test result appears on screen, press “▼” to view the 1-, 7-, 14-, 30-, 60- and 90- day averages.



NOTE:

- Control testing results will be flagged by a “ctl” icon on lower left of the unit measurement.
- If the user entered the control testing in the mode as described above, the control results will be marked with the “ctl” and they won’t be included in the averages. But, if the control mode was not entered, then the result will be averaged in with the blood test results of the user.
- When the memory is full, performing a new test will delete the oldest test result.
- When there are no day average datas available, the display screen will show 3 dashes.
- Hypoglycemic readings and hyperglycemic readings will be accompanied by the corresponding icons.



After you finish viewing memory or daily average, either begin testing by inserting a test strip (see Testing Your Blood Glucose on page 37 or Control Solution Testing on page 31), or press and hold “” to turn off the meter.

Data transmission

Upload Data via Bluetooth

The process of connecting between the meter and the mobile device is called pairing. You will need an application on your mobile device that can accept the meter's data. You can use this application to wirelessly and selective synchronize your test information between the meter and the mobile device.

Material you will need:

- Your BGM039 Link Blood Glucose Meter
- A mobile device with Bluetooth
- Health2Syc APP (Both Android and Apple)

FOR UPLOADING A GLUCOSE/ CONTROL SOLUTION TEST


Step 1.

Follow the steps of performing Glucose or Control Solution test to get a test result

Pairing

Step 2

To make a Bluetooth transfer, open the app on your mobile device and follow the app instructions to pairing the meter.

The screen will show “**Ent**” and the Bluetooth icon “” will flash.



Step 3.

Press “” to pair with your mobile device

**Step 4.**

- When pairing is complete, the Bluetooth icon will stop flashing. Then the meter's screen will show the blood glucose testing result.
- If pairing fails, Er6 is displayed on the screen of the meter. See page 66 to solve problems.

**BLE transmission****Step 5.**

- Meter will start sending data to mobile device.



- If data transmission via Bluetooth fails, Er7 is displayed on the screen of the meter.
See page 66 to solve problems.



Step 6.

After the data transfer is completed, turn off the meter or it will automatically turn off after 1.5 min of inactivity.

UPLOADING READINGS FROM THE MEMORY


Step 1.

Follow the steps beginning on page 49 to view stored readings in the memory

Pairing

Step 2.

To make a Bluetooth transfer, open the app on your mobile device and follow the app instructions to pairing the meter.

The screen will show “Ent” and the Bluetooth icon “” shall be flashing on the meter.



Step 3.

Press “” to pair with your mobile device

**Step 4.**

- When pairing is complete, the Bluetooth icon will stop flashing. Then the screen of meter will show the blood glucose testing result of memory recall.
- If pairing fails, Er6 is displayed on the screen of the meter. See page 66 to solve problems.

**BLE transmission****Step 5.**

- Meter will start sending data to mobile device.
- If data transmission via Bluetooth fails, Er7 is displayed on the screen of the meter. See page 66 to solve problems



NOTE:

- You need to install an APP that accepts meter data on your mobile device. We recommend Health2Syc APP to be used with BGM039 Link meter. It is available for download from Apple's App Store and Google Play.
- You can only upload data to the mobile device from BGM039 Link meter. The data from the mobile device can't be downloaded into BGM039 Link meter.
- When the meter is in transfer mode, testing is not possible.
- Testing results stored in your meter memory will not be changed or deleted during data transmission
- Only pair your meter with the mobile device that you will be using.
- If the Bluetooth transmission function fails, the screen will display Er5, please contact Apex Biotechnology Corp. customer service.
- The distance between the meter and the mobile device can be transmitted within a range of 10 meters.

WARNING:

- Data transmission via Bluetooth may decrease battery life.
- DO NOT pair another person's meter with your mobile device. To pair the mobile device with your meter, following the steps of Upload data via Bluetooth.

Caring for the Meter

Caring for your BGM039 Link Blood Glucose Meter is easy. Follow these simple guidelines to keep your BGM039 Link Blood Glucose Meter working properly.

NOTE:

- DO NOT get water inside the BGM039 Link Blood Glucose Meter. Never immerse the meter or hold it under running water.
- DO NOT use glass cleaners or household cleaners on the meter.
- Do not contaminate the strip holder with blood or control solution.
- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.

Cleaning and Disinfecting Your Meter

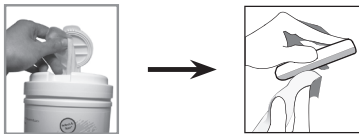
Cleaning and disinfecting your meter are very important in the prevention of infectious disease. Cleaning is the removal of dust and dirt from the meter surface so no dust or dirt gets inside. A cleaning step using a Clorox Healthcare Bleach Germicidal wipe must be performed before each disinfection step. Disinfection is the removal of blood borne pathogens that is the way to reduce your exposure to disease.

Your meter is validated to withstand cleaning and disinfection cycle of once per week for an average period of five years (260 cleaning cycles and 260 disinfection cycles

over the 5 year use life of the meter) using Clorox Healthcare Bleach Germicidal Wipes (EPA Registration Number: 67619-12). Clorox Healthcare Bleach Germicidal Wipes is available through major retailers online, please refer to page 62 for purchase information.

We recommend the frequency for cleaning and disinfection is once per week.

1. Wash hands with soap and water and dry thoroughly.
2. Inspect for blood, debris, dust, or lint anywhere on the meter.
3. To clean the meter, use Clorox Healthcare Bleach Germicidal Wipe.
Wipe all external areas of the meter including both front and back surfaces until visibly clean at a minimum wipe all surfaces with 3 vertical and 3 horizontal wipes.
Discard used towel in a sealed container where it will not be touched by others.



NOTE:

- If towelettes seem very dry, invert the canister once or twice to distribute the disinfectant on the towelettes. If the towelettes are excessively wet or dripping, squeeze the excess (dripping) liquid out before using them on the meter.
- Do not get water or other liquids inside the meter or immerse the meter in water or any other liquids.
- Do not use glass, household cleaners, or ammonia on the meter. Use only Clorox HealthCare Bleach Germicidal Wipes.
- The cleaning step should be performed prior to the disinfection step.

4. To disinfect your meter, wipe all external surface with a fresh Clorox Healthcare Bleach Germicidal Wipes. Allow the surface of meter to remain wet for at least 1 minute at room temperature. Wipe all external areas of the meter including both front and back surfaces until visibly clean.



5. Discard used towelettes in a sealed container where it will not be touched by others.
6. Allow to air dry.
7. Wash hands with soap and water and dry thoroughly.

NOTE:

- If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be cleaned and disinfected prior to use by the second person.
- Keep Clorox Healthcare Bleach Germicidal Wipes out of reach of children and stored according to its instruction.
- Do not flush towels down toilet.

IMPORTANT:

If you notice any of the below signs after cleaning and disinfecting your meter; stop using the device and call customer service immediately at 1-877-979-5454 Monday through Friday from 8am to 5pm EST:

- Control solution out of range.
- Clouding meter LCD display.
- Corrosion or erosion of plastic housing or buttons.
- Cracking of plastic housing.
- Malfunction of any meter button.

Purchase Information for Clorox Healthcare Bleach Germicidal Wipes

Clorox is the product of Clorox, the catalog number is 30577 (150 count) or 35309 (70 count).

Follow the website below to find your nearest Clorox Sales Representative.

<https://www.cloroxpro.com/products/clorox-healthcare/bleach-germicidal-disinfectants/>

To find a local distributor in your area, call Customer Service at 800.234.7700, Mon-Fri 8:30am - 5:00pm EST.

You can also purchase on <http://www.amazon.com> or in the retail store Walmart or Target.



If you need assistance or have question about cleaning and disinfection for the meter, please contact customer service at 1-877-979-5454 Monday through Friday from 8am to 5pm EST.




Storage and Precautions




- Handle the meter with care. Severe shock, such as dropping the meter, could damage the electronics.
- The meter and the test strips are designed to be used within a temperature range of 5°C ~45°C (41°F ~113°F) and the relative humidity ranges between 20~90%.
- Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car. The storage condition of meter is -4°F~122° F, <93% RH.
- Do not store or use the meter or test strips at high humidity levels, such as in the bathroom or kitchen.
- Do not take the meter apart. Doing so will void the warranty.
- This meter must not be co-located or operating in conjunction with any other antenna or transmitter.
- There are no risk or electromagnetic disturbance to operate the meter around the common RF emitters (e.g. electromagnetic anti-theft systems or metal detectors) in the home environment.
- Dispose of the meter according to your local regulations for correct disposal.
- Discard used lancet and test strip according to your health care provider.
- Always close the cap of the test strip bottle immediately after removing a test strip. Make sure the cap is tightly closed.
- If there are technical problems or questions, please call customer service at 1-877-979-5454 Monday through Friday from 8am to 5pm EST.

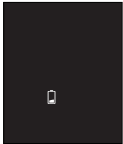


Solving Problems


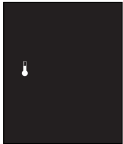
This section details the significant display screen messages and error codes you will encounter when using your BGM039 Link Blood Glucose Meter and BGM039 Blood Glucose Test Strips.

Message	What It Means	What You Should Do
	Damaged meter electronic or test strip	<ul style="list-style-type: none"> • Replace the batteries and turn on the meter again. • Remove the test strip and insert a new test strip again. • If problem persists, call us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST.
	Used or contaminated test strip	<ul style="list-style-type: none"> • Remove the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.

Message	What It Means	What You Should Do
	Not enough sample on the test strip to start	<ul style="list-style-type: none"> Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Glucose on page 37.
	Remove test strip during countdown	<ul style="list-style-type: none"> Turn off the meter and repeat the test with a new test strip.
	Meter fails in Bluetooth status check	<ul style="list-style-type: none"> Replace the batteries and turn on the meter again. If problem persists, call us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST.

Message	What It Means	What You Should Do
	Bluetooth pairing is fail	<ul style="list-style-type: none"> • Check Bluetooth device is working well and repeat confirm to pairing. • If problem persists, call us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST
	Data transmission via Bluetooth is fail	<ul style="list-style-type: none"> • Do Not insert a new strip to replace current strip during data transmission
	Bluetooth disconnection between meter and mobile device occurred during transmission procedure	<ul style="list-style-type: none"> • Check Bluetooth device is working well and repeat confirm to pairing and data transmission.

Message	What It Means	What You Should Do
	Low battery	<ul style="list-style-type: none"> Change the batteries according to instruction for Changing the Batteries on page 17.
	Test result higher than 600 mg/dL	<ul style="list-style-type: none"> Wash and dry your hands and repeat the test on your fingertip with a new test strip. If the result is still "HI", contact your physician or healthcare professional immediately.
	Test result lower than 20 mg/dL	<ul style="list-style-type: none"> Wash and dry your hands and repeat the test on your fingertip with a new test strip. If the result is still "LO", contact your physician or healthcare professional immediately.

Message	What It Means	What You Should Do
	No results in the memory in the meter	<ul style="list-style-type: none">• Check if the date and time on your meter is set up. See Setting Up Your New System on page 17.• Start testing your blood glucose, see Testing Your Blood Glucose on page 37.
	Temperature out of range	<ul style="list-style-type: none">• Move the meter into an area that is within 41°F~113°F, and allow 10 to 15 minutes for it to reach the new temperature.

Understanding Your Blood Glucose Test Results

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are⁽¹⁾

- less than 100 mg/dL (5.6 mmol/L) before meals.
- less than 140 mg/dL (7.8 mmol/L) two hours after meals.

It is important to consult with your physician or healthcare professional to determine an appropriate target range for you.

What to Do If You Get a High or Low Reading

If the meter displays results that are “HI” or “LO”, or you get a result that is more than your high or low blood glucose threshold value AND you feel ill:

- Treat your diabetes according to the instruction from your doctor and/or consult your healthcare provider.
- Test your meter with a control solution, refer to Control Solution Testing on page 31.
- Test again using fingertip with a new test strip.

If you still get a high or low reading, contact your healthcare professional immediately.

1.American Diabetes Association, Standards of Medical Care in Diabetes—2017. Diabetes Care, Vol.40, Supplement 1, p. S14, Table 2.4.

Product Warranty

Apex Biotechnology Corporation warrants the BGM039 Link Blood Glucose Meter to be free of defects in workmanship and materials under normal use for a period of five (5) years from the date of purchase to the consumer.

The liability of Apex Biotechnology Corporation is limited to repair or replacement and in no event shall Apex Biotechnology Corporation be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the Apex Biotechnology Corporation's authorized dealer responsible for the sale of the system. The warranty applies only to the original purchaser of the system.

Specifications

Product Name	BGM039 Link Blood Glucose Monitoring System
Test Range:	20 ~ 600 mg/dL (1.1~33.3 mmol/L)
Calibration:	Plasma
Test Time:	5 seconds
Sample Size:	≥ 0.5 µL
Hematocrit Range:	10~70%
Display Type:	LCD screen with back lighting
Memory:	500 test results with date and time
Result Averaging:	1, 7, 14, 30, 60, and 90 days averaging
Dimensions:	86L x 58W x 18H (mm)
Weight:	50g (without batteries)
Battery:	Two 3.0 V lithium batteries (CR2032)
Battery Life:	A minimum of 750 tests
Automatic Power-off:	After 1.5 minutes of inactivity
Operating Temperature:	5°C~45°C (41 to 113°F)
Operating Relative Humidity:	20-90%

Storage Condition: Meter at -4°F~122°F (-20°C~50°C), <93% RH
Test Strips at 39°F~86°F (4°C~30°C), 10~85% RH
For additional information, refer to the BGM039 Blood Glucose Test Strip insert.

Wireless Technology : Bluetooth 5, with the operating characteristics as following:

Radio Frequency Band: 2.4 GHz–2.483 GHz

Maximum Radio Transmitter Power: -4 dBm

Security Encryption: 128-bit AES (Advanced Encryption Standard) CCM, ECB, AAR

The transmitted distance between the meter and the mobile device : within a range of 10 meters.

Quality of service for the wireless connectivity for safe and effective data downloading

- Acceptable latency: 4 seconds
- Max throughput: low speed; 21 kbps
- Acceptable level of probability for loss of information within the network: probability is 0%
- Accessibility/ signal priorities of the network: only Bluetooth is available
- Data integrity: check sum function for transmitting and receiving packets.

Electromagnetic Compatibility (EMC):

The BGM039 Link meter complies with the electromagnetic requirements specified in IEC 60601-1-2 Edition 4.0 including selected electrostatic discharge immunity testing based on the basic standard IEC 61000-4-2. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the BGM039 Link meter.

Suppliers

S70463	BGM039 Link Blood Glucose Monitoring System (Complete Kit)
S70464	BGM039 Link Blood Glucose Monitoring System (Simple Kit)
S5641001	BGM039 Blood Glucose Test Strip 25s
S5641002	BGM039 Blood Glucose Test Strip 50s
S5641003	BGM039 Blood Glucose Test Strip 100s
S5641060	BGM039 Blood Glucose Test Strip 25s (Foil)
S5641061	BGM039 Blood Glucose Test Strip 50s (Foil)

Accuracy for Home Use by Lay-Users

The BGM039 Link Blood Glucose Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.

The chart below shows the results of a study where total of 143 fresh blood samples from fingertip, palm and forearm were collected by lay users. 16 samples were below 75mg/dL. 127 samples were above 75mg/dL. The following accuracy results were obtained.

Table 1: Accuracy for blood glucose level <75mg/dL			
Sample Source	Within \pm 5mg/dL	Within \pm 10mg/dL	Within \pm 15mg/dL
Lay users Fingertip vs. YSI	12/16 (75%)	16/16 (100%)	16/16 (100%)
Lay users Palm vs. YSI	15/16 (94%)	16/16 (100%)	16/16 (100%)
Lay users Forearm vs. YSI	13/16 (81%)	16/16 (100%)	16/16 (100%)

Table 2: Accuracy for blood glucose level $\geq 75\text{mg/dL}$

Sample Source	Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
Lay users Fingertip vs. YSI	65/127 (51.2%)	115/127 (90.6%)	127/127 (100%)	127/127 (100%)
Lay users Palm vs. YSI	69/127 (54.3%)	116/127 (91.3%)	127/127 (100%)	127/127 (100%)
Lay users Forearm vs. YSI	62/127 (48.8%)	110/127 (86.6%)	125/127 (98.4%)	127/127 (100%)

Table 3: Accuracy for Entire Glucose range

Sample Source	Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
Lay users Fingertip vs. YSI	76/143 (53.1%)	130/143 (90.9%)	143/143 (100%)	143/143 (100%)
Lay users Palm vs. YSI	79/143 (55.2%)	132/143 (92.3%)	143/143 (100%)	143/143 (100%)
Lay users Forearm vs. YSI	73/143 (51.0%)	125/143 (87.4%)	141/143 (98.6%)	143/143 (100%)

Federal Communications Commission Interference Statement

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.

CAUTION:

Any changes or modifications not expressly approved by the grantee of this device

could void the user's authority to operate the equipment.

RF exposure warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

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

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.