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.

<u>Intended Use</u>

The BGM039 Link Blood Glucose Monitoring System is intended to quantitatively measure blood 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:
- Dehydration – Severe dehydration may lead to inaccurate blood glucose test result. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- Hematocrit range – A hematocrit range that is higher than 70% or lower than 10% can cause inaccurate blood glucose test results.
- Not intended for use on neonates.
- 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

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.
- Never use AST measurements to calibrate Continuous Glucose Monitors (CGMs).
- Never use AST measurements for insulin dosing calculations.
- Do not use the system during a xylose absorption test. This may cause inaccurately high results
- There is no impact to the accurate test result when take Vitamin C (ascorbic acid)or Vitamin C (ascorbic acid) containing drugs at blood concentrations ≤ 6 mg/dL.

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.

- Acetaminophen levels above 10 mg/dL may give falsely high test results.
- Tolbutamide levels above 15 mg/dL may cause falsely low test results.
- Ibuprofen levels above 40 mg/dL may cause falsely low test results.
- Acetylsalicylic acid levels above 40 mg/dL may give falsely low test results.
- Tolazamide levels above 23 mg/dL may cause falsely high test results.
- Paralidoxime Iodide (PAM) levels above 50 mg/dL may cause falsely high test results.
- Uric acid levels above 15 mg/dL may give falsely low test results.
- Cholesterol levels above 500 mg/dL may give falsely low test results.
- Triglyceride levels above 1500 mg/dL may give falsely high test results.
- Glutathione levels above 46 mg/dL may give falsely high test results.

Warning

"This device 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 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."

Table of Contents

Understanding Your New Blood glucose Monitoring System

Each BGM039 Link Blood Glucose system may include the following items:

1. The BGM039 Link Meter
2. The BGM039 Blood Glucose Test Strip
3. User Guide
4. Lancing Device
5. Lancets
6. Contrex Plus 4 Level 1 Glucose Control Solution
7. Contrex Plus 4 Level 2 Glucose Control Solution
8. Contrex Plus 4 Level 3 Glucose Control Solution
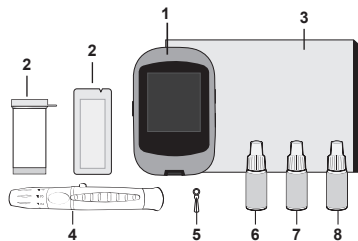
Note:
- Lancets and Lancing Device are optional components.
- BGM039 Blood Glucose Test Strip and Contrex Plus 4 Glucose Control Solution are necessary but sold separately.
  Please contact us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST for purchasing information.

The BGM039 Link Blood Glucose Meter

METER DISPLAY

ENTER (☉)

(▲/▼) BUTTONS
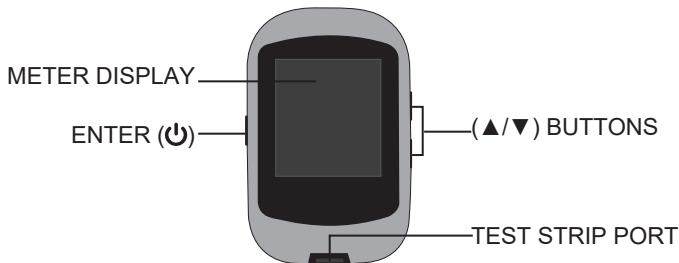
TEST STRIP PORT

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 (☉) and (▲/▼) BUTTONS
Press and hold Enter (☉) for 2 seconds to turn on or off the meter, or press Enter (☉) 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 COMPARTMENT
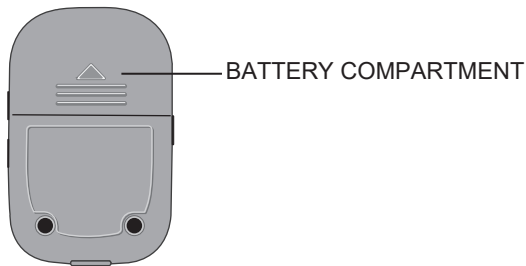
BATTERY HOLDER
Holds two CR 2032 3V Lithium coin cell batteries.

The BGM039 Link Meter Display Screen

CLOCK

MEMORY — ALARM

BLE ICON — BEEPER

TEMPERATURE

CONTROL SOLUTION MODE (CTL) — MAIN DISPLAY AREA

BLOOD DROP — HYPO/ HYPER

TEST STRIP — UNIT

DAY AVERAGE

HOUR/MINUTES

MEAL MARKER
EXERCISE MARKER
ASTERISK MARKER

BATTERY

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 ....• 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 ....• 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

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 assure 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.
- 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 Test Strip with the BGM039 Link 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. Run Level 1, Level 2 and Level 3 control solution tests to make sure the test strips and the meter are working together properly, to practice testing procedure, and when using a new lot of BGM039 Blood Glucose Test Strip.
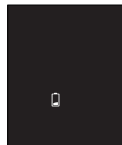
Setting Up Your New System

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 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 date and stored results 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.
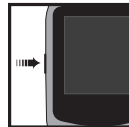- Remove the batteries if unused for a long time.

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 Meter, the test or control results will not be stored in the meter's memory.
- Anytime during setup, you can insert a BGM039 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 Meter. 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.
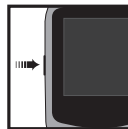
Materials you need:
•Your BGM039 Link Meter

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 31 or Control Solution Testing on page 25), or press and hold "⏻" to turn off the meter.
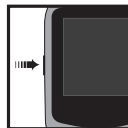
Beeper Setup

The beeper on your BGM039 Link Blood Glucose Meter is preset to ON. You can adjust the beeper feature as follows.

You will need:
• Your BGM039 Link 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

HYPO (hypoglycemia) warning

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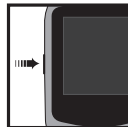
The BGM039 Link Meter comes with Hypo/Hyper warning OFF as preset, and the preset threshold value is 200 mg/dL (11.1 mmol/L) for Hyper and 70 mg/dL (3.9 mmol/L) for Hypo. Follow the steps below to adjust the Hyper and Hypo threshold values.

Material you will need:
• Your BGM039 Link Meter

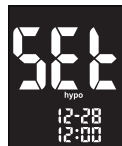Step 1.
Press and hold "⏻" to turn on the meter.

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.

UP

Down

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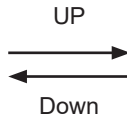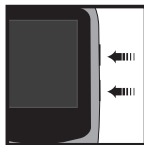Press "▲" or "▼" until the main display screen shows "hyper".

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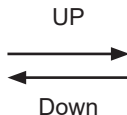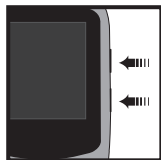
After setting up the Hypo and Hyper values, you can either press and hold "symbol" to turn off the meter, or insert a test strip to begin testing (see Testing Your Blood Glucose on page 38, or Control Solution Testing on page 32).

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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 Meter and the BGM039 Test Strip is working properly.

You should perform control solution testing when:
- you suspect the meter or BGM039 Blood Glucose Test Strip are not working properly;
- the meter has been dropped;
- the meter is damaged;
- You leave the test strip bottle cap open for a while;
- your blood glucose test results do not reflect how you feel;
- You want to check the performance of the meter and BGM039 Blood Glucose Test Strip when you first get them or any time you want to check their performance before a blood glucose test.

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 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.
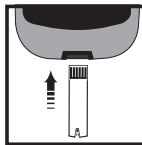
Step 2.
The flashing blood drop and test strip icons appear on the lower left of the meter display screen

Step 3.
Press "▲" or "▼" to enter the control mode. You will see "**ctl** " on the lower left of the screen.

Step 4.
Squeeze a drop of control solution (Level 1, Level 2 or Level 3) onto a clean, dry, nonabsorbent surface. 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.

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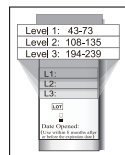
NOTE:
- Control solution testing results will be stored into the meter's memory and indicated with "ctl " icon.
- Control solution test results will not be used for calculating averages.
- Replace the bottle cap on the control solution bottle immediately after use.

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.

You should periodically compare the test system to another test system which is well maintained and monitored by a healthcare provider.

<u>Control Solution Trouble Shooting</u>

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 …
• Wrong brand of control solution being used	• Make sure you are using Contrex Plus 4 Glucose Control Solution (Level 1, Level 2 and Level 3).
• Control solution not at right storage temperature	• Make sure the testing environment is between 41˚F~113˚F.
• Expired or contaminated control solution or damaged test strip	• 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.
• Meter malfunction	• 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 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 appropriately when testing is conducted by the second person.

IMPORTANT:
- Check the expiration date printed on the test strip bottle. DO NOT use expired test strips.
- 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.
- Keep the test strips away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.

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.
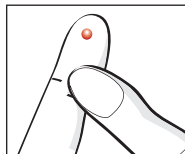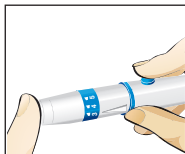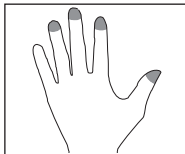Insert a BGM039 Blood Glucose Test Strip to turn on the meter.
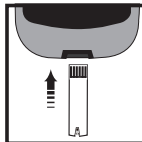
Step 2.
Wait for the flashing blood drop and test strip icons to appear on the left of the meter display screen.

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.
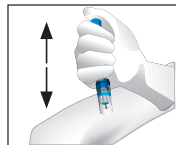
NOTE:

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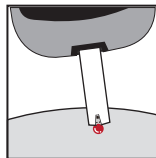
Step 5.
The screen will start to count down. After 5 seconds, your glucose testing result will appear on the meter display screen.

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.
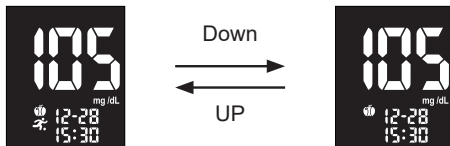
Step 8- Select the asterisk marker

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.
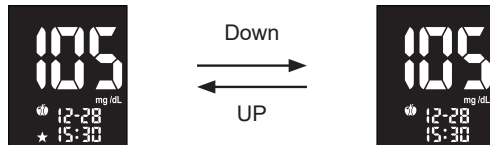
Step 9.

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 and 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 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 Meter

Step 1.
Press and hold "⏻" to turn on the meter.
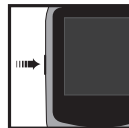
Step 2.
The flashing test strip icon will appear on the meter display screen.

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**".
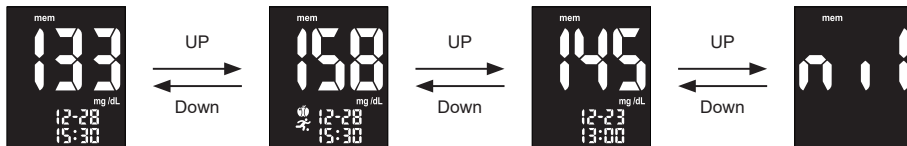
Step 5- Viewing day averages
When the most recent test result appears on screen, press "▼ " to view the 1-, 7-, 14-, 30-, 60- and 90- day averages.
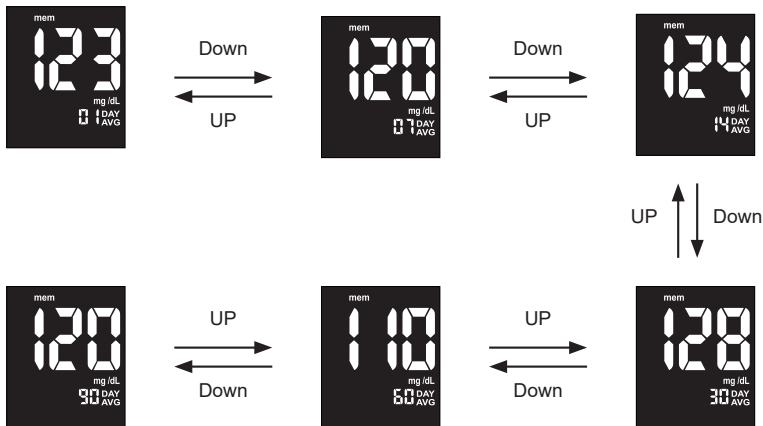
NOTE:
- Control testing results will be flagged by a "**ctl**" icon on lower left of the unit measurement.
- When the memory is full, performing a new test will delete the oldest test result.
- Control testing results will not be included in the day averages. When there are no day average datas available, the display screen will show 3 dashes.
- Hypoglycemic readings and hyperglycemic readings will be accompanied by the corresponding icons.
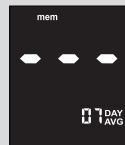
After you finish viewing memory or daily average, either begin testing by inserting a test strip (see Testing Your Blood Glucose on page 37 or Control Solution Testing on page 31), or press and hold "⏻" to turn off the meter.

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 Meter
• A mobile device with Bluetooth

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 62 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 62 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 "(BLE symbol)" 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 62 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 62 to solve problems

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NOTE:
- You need to install an app that accepts meter data on your mobile device.
- 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.

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 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 and Lancing Device

Cleaning and disinfecting your meter and lancing device are very important in the prevention of infectious disease. Cleaning is the removal of dust and dirt from the meter and lancing device 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 and lancing device is validated to withstand cleaning and disinfection cycle of once per day 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 or lancing device.
3. To clean the meter or lancing device, use Clorox Healthcare Bleach Germicidal Wipe.
   Wipe all external areas of the meter or lancing device 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.
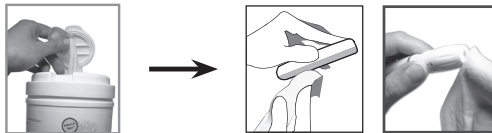
NOTE:

- 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 or lancing device in water or any other liquids.
- Do not use glass, household cleaners, or ammonia on the meter or lancing device. Use only Clorox HealthCare Bleach Germicidal Wipes.
- The cleaning step should be performed prior to the disinfection step.

4. To disinfect your meter or lancing device, wipe all external surface with a fresh Clorox Healthcare Bleach Germicidal Wipes. Allow the surface of meter or lancing device to remain wet for at least 1 minute at room temperature. Wipe all external areas of the meter or lancing device including both front and back surfaces until visibly clean.
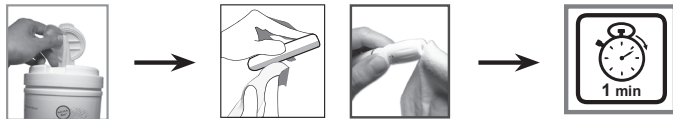
5. Discard used towelettes in a sealed container where it will not be touched by others.
6. Allow to air dry.
7. Wash hands with soap and water and dry thoroughly.

NOTE:
- If the meter or lancing device is being operated by a second person who is providing testing assistance to the user, the meter or lancing device 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 or lancing device; 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 purchase the Clorox on the web site below: http://www.amazon.com

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.
- 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.
- 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 local regulations.
- 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 Meter and BGM039 test strips.
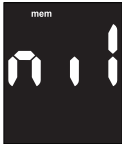
Message	What It Means	What You Should Do
Er 1	Damaged meter electronic or test strip	• Replace the batteries and turn on the meter again. • Remove the test strip and insert a new test strip again. • If problem persists, call us at 1-877-979-5454 Monday through Friday from 8am to 5pm EST.
Er 2	Used or contaminated test strip	• 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
Er3	Not enough sample on the test strip to start	• Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Glucose on page 37.
Er4	Remove test strip during countdown	• Turn off the meter and repeat the test with a new test strip.
Er5	Meter fails in Bluetooth status check	• 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
Er6	Bluetooth pairing is fail	• 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
Er7	Data transmission via Bluetooth is fail.	• Do Not insert a new strip to replace current strip during data transmission
Er8	Bluetooth disconnection between meter and mobile device occurred during transmission procedure	• Check Bluetooth device is working well and repeat confirm to pairing and data transmission.

Message	What It Means	What You Should Do
	Low battery	• Change the batteries according to instruction for Changing the Batteries on page 17.
	Test result higher than 600 mg/dL	• 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	• 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
mem	No memorized results in the meter	• 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	• 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.

NOTE:
- 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.

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 Blood Glucose Test Strip
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:	60g (without batteries)
Battery:	Two 3.0 V lithium batteries (CR2032)
Battery Life:	A minimum of 1000 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 Test Strip insert.

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 ± 5mg/dL	Within ± 10mg/dL	Within ± 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 ≥75mg/dL				
Sample Source	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lay users Fingertip vs. YSI	67/127 (53%)	115/127 (91%)	125/127 (98%)	127/127 (100%)
Lay users Palm vs. YSI	68/127 (54%)	119/127 (94%)	127/127 (100%)	127/127 (100%)
Lay users Forearm vs. YSI	64/127 (50%)	109/127 (86%)	125/127 (98%)	127/127 (100%)

The meter meets the electromagnetic compatibility requirements as Per IEC 60601-1-2:2014

Guidance and manufacturer's declaration - electromagnetic emissions		
Test	Compliance	Electromagnetic Environment - Guidance
Conducted and Radiated emission EN 55011	Group 1 Class B	The BGM039 Link Blood Glucose meter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Class A	The BGM039 Link Blood Glucose meter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The BGM039 Link Blood Glucose meter is internally powered by two CR2032 3V Lithium coin cell batteries.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	Electromagnetic environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15kV air	±8 kV contact ±2, ±4, ±8, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
RF Radiated susceptibility IEC 61000-4-3	10 V/m at frequencies up to 80~2700MHz, 80% AM	10 V/m at frequencies up to 80~2700MHz, 80% AM	The BGM039 Link complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2:2014, for residential, commercial and light industry environments. Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended 10 cm separation distance. The BGM039 Link has been designed to meet EMC standards. However, should you suspect that the machine performance (e.g. pressure or flow) is affected by other equipment, move the machine away from the possible cause of interference. The BGM039 Link complies with Part 15 of the FCC Rules.
RF Conducted susceptibility IEC61000-4-6	3 Vrms 6 Vrms for ISM bands 0.150 MHz to 80 MHz	3 Vrms 6 Vrms for ISM bands 0.150 MHz to 80 MHz	

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
			FCC ID: 2AV24BGM039.Operation is subject to the following two conditions: This machine may not cause harmful interference,and this machine must accept any interference received, including interference that may cause undesired operation. **Recommended separation distance:** $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
			a ⚠ Field strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BGM039 Link is used exceeds the applicable RF compliance level above, the geko™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the geko™ b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Guidance and manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for input/ output lines	±2 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.

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.