

Dear GlucoSure Link Owner

Thank you for choosing the GlucoSure 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 though this manual and the package inserts the come with: GlucoSure Link blood glucose test strip, Contrex Plus III 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 GlucoSure 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 for glucose test 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 mellitus 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 55% or lower than 30% 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 GlucoSure Link Blood Glucose Test Strip within 3 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 Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” <https://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
- “CDC website on “Infection Prevention during Blood Glucose Monitoring and Insulin Administration.” <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.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 6,562 feet (2,000 meters) in altitude.
- Do not use if hematocrit exceeds the acceptable range between 30% to 55% when testing blood glucose.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For In Vitro Diagnostic use only.
- For Over-the-Counter use only
- 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.

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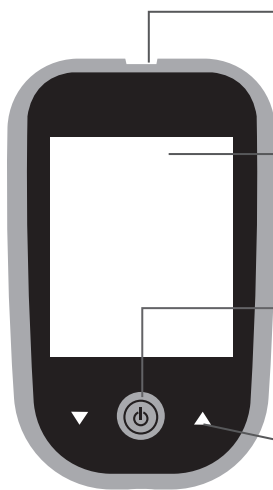
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Understanding Your New Blood Glucose Monitoring System Content

The GlucoSure Link Blood Glucose Monitoring System comes in either as a kit or simple package. Each package may include the following items:

Contents	Package Configuration	
	Kit	Simple
GlucoSure Link Blood Glucose Meter	★	★
Instruction Manual	★	★
Carrying Case	★	★
Log Book	★	★
Lancing Device with Clear Cap	★	
Test Strips	★	
Lancets	★	

The GlucoSure Link Blood Glucose Meter



Test Strip Port

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

Meter Display

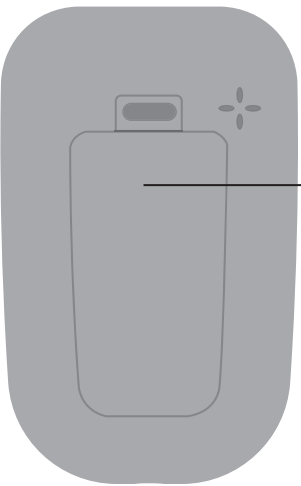
Shows your blood glucose test results, memory values, averages, and other messages.

Enter (power) 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 (see page 14)

UP/DOWN triangle buttons

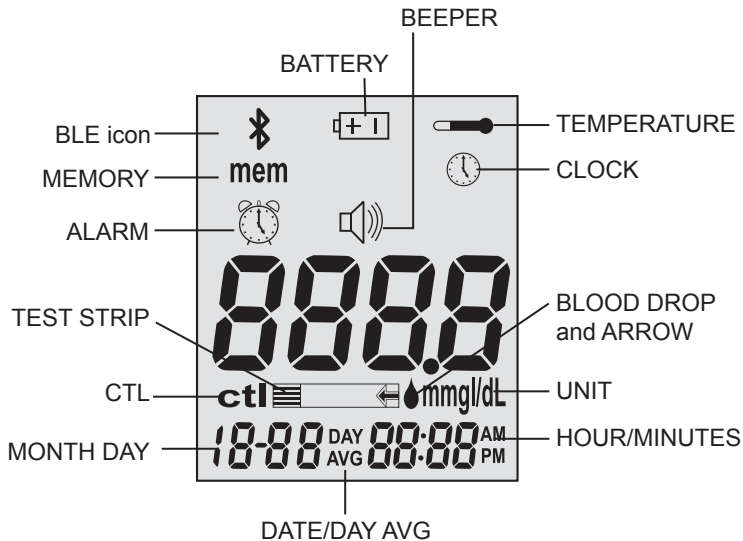
Press triangle up or triangle down to enter control mode with test strip inserted (see page 24), during meter setting (see page 14), or to navigate the stored test values and averages (see page 43)



Battery Holder

Holds two AAA batteries

The GlucoSure Link Meter Display Screen



BLE.....	Indicate Bluetooth is turn on
MEMORY	Indicates the number in the meter display is a stored test value (see page 43).
BATTERY	Appears when batteries need to be changed (see page 51).
UNIT	Unit of measurement for your blood glucose is mg/dL.
CTL.....	This icon indicates a control solution test (see page 24) or the stored value is a control solution result (see page 43).
ALARM	Indicates alarm has been set (see page 19).
BEEPER.....	Set beeper on and off (see page 22).
CLOCK	Indicates during setting time and date (see page 16).
HOUR/MINUTES.....	Displays time in 12-hour format or 24-hour format.
DATE/DAY AVERAGE	Display date or 7, 14, 30 day averages.
TEMPERATURE.....	Appears when it is either too hot or too cold to test (outside the ranges of 50 °F~104 °F).
BLOOD DROP and ARROW	Indicate the meter is ready for testing (see page 36).

The GlucoSure Link 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 GlucoSure Link Blood Glucose Test Strips are glucose specific, biosensor-based test strips that require very little blood sample to quickly test glucose in fresh capillary whole blood. The test results are plasma-calibrated for easy comparison to lab results, however, results may be 10% to 15% higher than results obtained from whole-blood referenced blood glucose assays. The test strip is also equipped with 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:

- Immediately close the vial cap of the test strip bottle tightly after each use. Keep the unused test strips in its original bottle. 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 GlucoSure Link Blood Glucose Test Strip with the GlucoSure Link Blood Glucose Meter. Other brands of test strips will not work with the meter.

Contrex Plus III Glucose Control Solution (Required)



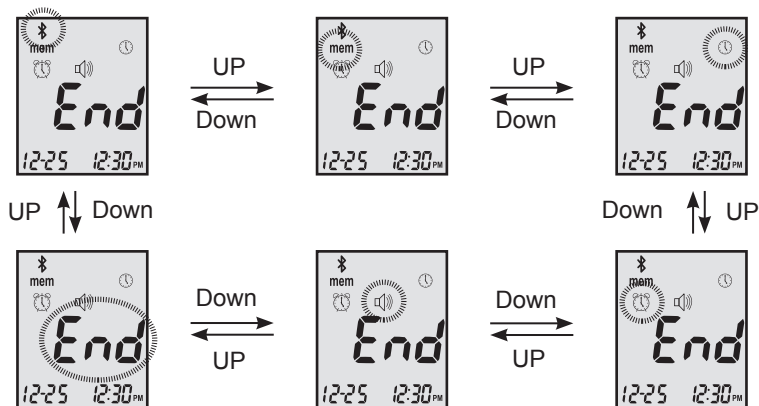
Call your local supplier or pharmacy to order control solution. If they do not stock it, please contact us at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday.

It is the standard glucose concentration solution required to perform a Glucose Control Solution Test (See Control Solution Testing). It is available at 3 levels. Contrex Plus III Low Glucose Control Solution helps you to validate the performance of your system at a low range blood glucose reading, while L1 solution helps you to validate your system performance at a middle range blood glucose reading, while L2 solution helps you to validate your system performance at a high range blood glucose reading. Run the control test to make sure the Test Strips and the Meter are working together properly, to practice testing procedure, and when using a new lot of Glucosure Link Blood Glucose Test Strip.

Setting Up Your New System

The Setup Screen

The Setup Screen of the GlucoSure Link Blood Glucose Meter lets you take advantage of the advance functions of this meter. Simply use ▲ ▼ buttons to navigate to the desired function icon, and press the Enter (⏻) button to enter the function when the icon is flashing. Navigate to End at the display screen to exit the Setup Screen.



BLE..... Press Enter (⏻) to turn on or off BLE function.

mem Press Enter (⏻) to enter Memory to retrieve stored results. Your meter can memorize up to 300 memories with date and time. (see page 43).



..... Press Enter (⏻) to enter Clock Setup (see page 16).



..... Press Enter (⏻) to enter Alarm Setup (see page 19). Your meter can set up to 3 alarms.



..... Press Enter (⏻) to enter Beeper Setup (see page 22).

End Exit Setup Screen and return to testing.

Setting the Clock

You will need:

- Your GlucoSure Link Blood Glucose Meter

NOTE:

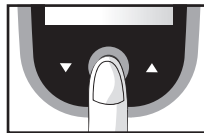
- If you do not set the date and time on GlucoSure Link Blood Glucose Meter, the test or control results will not be stored in the meter's memory.

Step 1.

Press and hold Enter (⏻) to turn on the meter.

Step 2.

Press Enter (⏻) to go into setup screen, then press ▲ or ▼ until ⌚ start to flash. Press Enter (⏻) to enter clock setup.



Step 3 - Set the Year

The current year will flash. Press ▲ or ▼ to select the correct year. Press Enter (⏻) to confirm your choice and proceed to set the month.



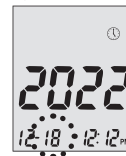
Step 4 - Set the Month

The current month will flash. Press ▲ or ▼ to select the correct month.
Press Enter (⏏) to confirm your choice and proceed to set the date.



Step 5 - Set the Date

The current date will flash. Press ▲ or ▼ to select the correct date.
Press Enter (⏏) to confirm your choice and proceed to set time format.



Step 6 - Set 12-hour or 24-hour Time Format

The current time format will flash. Press ▲ or ▼ to select for either 12-hours format or 24- hour format.
Press Enter (⏏) to confirm your choice and proceed to set hour.



Step 7 - Set the Hour

The current hour will flash. Press ▲ or ▼ to select correct hour.
Press Enter (⏏) to confirm your choice and proceed to set minutes.



Step 8 - Set Minute

The current minutes will flash. Press ▲ or ▼ to select the correct minutes.

Press Enter (⏏) to confirm your choice and finish setting the clock.



NOTE:

- Anytime during setup, you can insert a GlucoSure Link Test Strip to begin testing. Any changes made so far will be stored.
- You may need to reset time after changing batteries.

Begin testing by inserting a GlucoSure Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 32 or Control Solution Testing on page 24), or press and hold Enter (⏏) to turn off the meter, or see the next section on how to set up the alarm feature on your meter.

Setting the Alarms

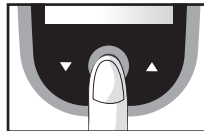
You can set up to three alarms on the GlucoSure Link Blood Glucose Meter. You must set the clock before you can set the alarms. When an alarm sounds, the meter will turn on, and a melody will sound for 30 seconds. Pressing Enter (⏻) or inserting a test strip will silence the alarm. You can set up one or all three alarms.

You will need:

- Your GlucoSure Link Blood Glucose Meter

Step 1.

Press and hold Enter (⏻) to turn on the meter.



Step 2.

Press Enter (⏻) to enter setup screen.

Step 3.

Press ▲ or ▼ until ⌚ start to flash. Press Enter (⏻) to enter alarm setting.

Step 4.

The display screen will indicate alarm 1 status (the default is OFF). You can turn it on or off by pressing ▲ or ▼.



Step 5.

Press Enter (⏻) and the hour will flash.

Press ▲ or ▼ to select the hour. Press Enter (⏻) to confirm your choice and proceed to set minutes.



Step 6.

The current minutes will flash. Press ▲ or ▼ to select the correct minutes.

Press Enter (⏻) to confirm your choice and proceed to set alarm 2.



Step 7.

Set alarm 2 and 3 following steps 4 through 6.

After you have finished setting up alarm 3, press Enter (⏻) to exit alarm setup.

NOTE:

- Alarm will not sound 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 batteries.

Begin testing by inserting a GlucoSure Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 32 or Control Solution Testing on page 24), or press and hold Enter (⏻) to turn off the meter, or see the next section on how to set up the beeper on your meter.

Setting Beeper Function

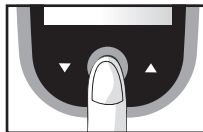
The default setting for the beeper function is on, and can be switched off to conserve battery power.

You will need:

- Your GlucoSure Link Blood Glucose Meter

Step 1.

Press and hold Enter (⏻) to turn on the meter.



Step 2.

Press Enter (⏻) to go into setup screen. Press ▲ or ▼ until 🔊 start to flash. Press Enter (⏻) to enter beeper setting.

Step 3.

Press ▲ or ▼ to turn on or off the beeper, and then press Enter (⏻) again to exit beeper setting.



NOTE:

- Anytime during set up, you can insert a GlucoSure Link Blood Glucose Test Strip and begin testing.
Any changes made so far will be stored.
- Beeper setting will not be erased when changing batteries.

Begin testing by inserting a GlucoSure Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 32 or Control Solution Testing on page 24) or press and hold Enter (⏻) to turn off the meter.

Control Solution Testing

Performing a Control Solution Test

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

You should perform control solution testing when:

- Using the meter for the first time
- Using a new bottle of GlucoSure Link Blood Glucose Test Strips
- You leave the test strip bottle cap open for a while
- 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

IMPORTANT:

- Use only the Contrex™ Plus III Glucose Control Solutions with the GlucoSure Link Blood Glucose Test Strips. Other brands of control solution will produce inaccurate result.
- 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 3 months after opening.

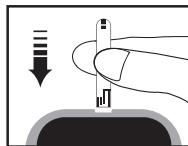
- DO NOT FREEZE. Store the control solutions at 59°F to 86°F.
- Do not drink the control solution. It is not intended for human consumption.
- Avoid contact of the solution with the skin and the eyes as this could cause inflammation.
- Discard used control solution bottles according to your local regulation.

You will need:

- Contrex™ Plus III Control Solution (Low, L1 and L2)
- Your GlucoSure Link Blood Glucose Meter
- A new GlucoSure Link Blood Glucose Test Strip

Step 1.

Take out a GlucoSure Link Blood Glucose Test Strip from the test strip bottle and close the bottle immediately. Insert the test strip to turn on the meter.



IMPORTANT:

- Check the expiration date on the test strip bottle and its package. Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle.
- Do not use wet or damaged test strips.

- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- Record the "date opened" on the bottle label. Discard the bottle and any remaining test strip after 3 months from date of opening.
- Test under the temperature range of 50°F to 104°F, relative humidity 20 to 85%RH. Your meter will not work outside these ranges.
- Must insert test strip into the test strip port. .
- Must see a flashing blood drop icon if the test strip has been inserted to the test strip port.

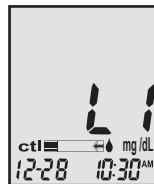
Step 2.

Wait until the flashing blood drop and arrow icons appear on the meter display screen. Press ▼ to enter Low or L1 control solution testing.

Step 3.

ctl icon will appear next to the test strip icon and L1 will appear on the meter display screen, please apply control solution onto the test strip.

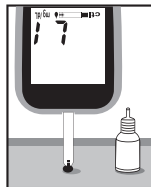
If you decide not to do a control solution test, Press ▲ until ctl disappeared from the meter display.



Step 4.

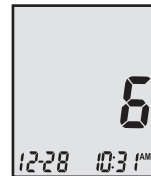
Squeeze a drop of control solution onto a clean, dry, nonabsorbent surface.

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.



Step 5.

Gently touch the drop of the control solution to the tip of the test strip. The meter will beep indicating it has received the control solution.



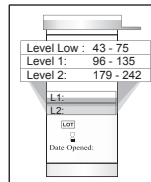
Step 6.

The screen will start to count down.

After 6 seconds, the control test result will appear on the meter's display screen.

Step 7.

Compare the reading on the screen to the Level 1 range printed on the test strip bottle or its package. If the reading falls outside the Level Low or Level 1 range printed on the test strip bottle or its package, see Control Solution Trouble Shooting, on page 29.



NOTE:

- Control solution testing results will be stored into the meter memory and indicated by cti icon.
- Control solution testing result will not be used for calculating averages.

Step 8.

Remove the used test strip. The meter will automatically turn off.

Discard the used test strip into proper wastebasket.

IMPORTANT:

- Do not reuse Test Strips.

Follow steps 3 through 8 to do a Level 2 control solution testing and compare the result with the Level 2 range printed on the test strip bottle.

We suggest you should periodically review your technique. Moreover, 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 ...
Wrong brand of Control Solution being used	Make sure you are using Contrex™ Plus III Control Solution.
Control solution is not at proper storage condition 59°F to 86°F	Make sure the testing environment is between 50°F to 104°F, 20~85% RH.
Expired or contaminated control solution or damaged test strip	Check the expiration and open bottle 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 between 8:00 am and 5:00 pm EST, Monday through Friday for questions and inquiries. If out of the central time, you can contact your healthcare providers.

Testing Your Blood Glucose

You will need:

- Your GlucoSure Link Blood Glucose Meter
- A new GlucoSure Link Blood Glucose Test Strip
- Lancing device with a clean, unused lancet (or safety lancets)
- Clear cap for Alternate Site Testing (AST) on palm and forearm

Before you begin, make sure:

- To set up your meter properly and run a control test. See Setting Up Your New System and Control Solution Testing for details.
- Wash your hands and the testing site thoroughly with soap and warm water, and dry well.
- You are testing in an area between the temperature ranges of 50°F~104°F. Your meter will not test outside of this range and will display thermometer icon. Move the meter into an area that is between 50°F~104°F, 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 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 3 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 and massage through the wrist, palm, and then finger. This can stimulate the blood flow to the finger more quickly.

Step 3.

Hold the lancing device (puncture) or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device (puncture) 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 GlucoSure 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 measurements should never be used for insulin dosing calculations.

Alternative Site Testing SHOULD NOT be used:

- You have Hypoglycemic unawareness (not able to tell if you have low blood sugar)
- Within 2 hours of a meal, exercise, or medication.
- You will be operating machinery or driving a car.
- You are sick.
- You think your blood glucose is low.
- Your AST results do not match the way 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:

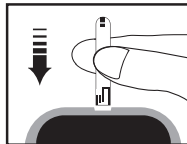
- Rubbing forearm until warm before lancing will help minimize the difference with fingertip test results. The palm (at the base of the thumb) does not require rubbing before testing.
- If results from alternate site testing do not agree with how you feel, use fingertip testing instead.

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

Performing a Blood Glucose Test

Step 1.

Take out a GlucoSure Link Blood Glucose Test Strip from the test strip bottle and close the bottle immediately. Insert the test strip into the test strip port to turn on the meter.

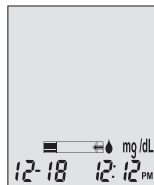


IMPORTANT:

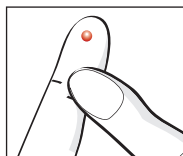
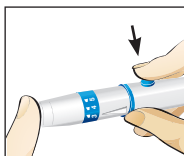
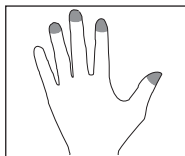
- Check the expiration date printed on the test strip bottle and its package. Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- Record the "date opened" on the bottle label. Discard the bottle and any remaining test strip after 3 months from date of opening.
- Must insert test strip into the test strip port.
- Must see a flashing blood drop icon when the test strip has been inserted into the test strip port.

Step 2.

Wait for a flashing blood drop and an arrow icon appears on the meter display screen.

**Step 3- obtain blood sample****For Fingertip Testing:**

Hold the lancing device (use the blue adjustable cap) against the side of your fingertip and press the release button to create a puncture.

**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.

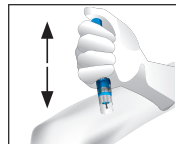
For Testing on Palm and Forearm:

Hold the lancing device (use the clear adjustable cap) against the test site (base of palm or forearm). Avoid a test site that has veins, moles, excessive hair, or bone.

Press the lancing device firmly against the test site and press the release button, do not lift up.

For forearm test sites, apply and release pressure (“pumping”) for a few seconds while keeping the lancing device in constant contact with the skin. Palm testing (at the base of the thumb) does not require pumping.

When the blood is approximately (●) size, lift the lancing device straight up without smearing the blood.

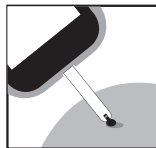


NOTE:

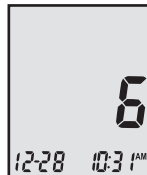
- Rubbing forearm until warm before lancing will help minimize the difference with fingertip test results. The palm (at the base of the thumb) does not require rubbing before testing.
- If results from alternate site testing do not agree with how you feel, use fingertip testing instead.

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 for testing.

**Step 5.**

The screen will start to count down. After 6 seconds, your glucose testing result will appear on the meter display screen. Your test result will be automatically stored into the meter memory.

**CAUTION:**

- If you see “HI” or “LO” displayed, your blood glucose level may be above 600 mg/dL (33.3 mmol/L) or below 20 mg/dL (1.1 mmol/L). Test again using fingertip testing, DO NOT test on forearm or palm. 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. Then, conduct a glucose control test to check that the system is working properly. 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.

Remove the used test strip into proper wastebasket. The meter will automatically shut off.

Step 7.

Remove the used lancet from your lancing device according to instructions and discard into proper wastebasket.

IMPORTANT:

- 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.
- 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.

Understanding Your Blood Glucose Test Results

Blood glucose value will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are⁽²⁾:

- less than 100 mg/dL before meals.
- less than 140 mg/dL 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 250 mg/dL or below 50 mg/dL AND you feel ill:

- Treat your diabetes according to the instruction from your doctor and/or consult with your healthcare provider.

If the Meter displays results that are “HI” or “LO,” or you get a result that is more than 250 mg/dL or below 50 mg/dL AND you DO NOT feel ill:

- Test your meter with a control solution, refer to page 24, Control Solution Testing.
- Test again using fingertip.

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

IMPORTANT:

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.

2. American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43 (Suppl. 1)

Viewing Your Meter's Memory

Your GlucoSure Link Blood Glucose Meter automatically stores up to 300 test and control results with date and time. The meter also provides 7, 14, and 30 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 14. The meter will not memorize test or control results if the date and time are not set.

Viewing Stored Readings and 7, 14, 30 Days Average from Memory

You will need:

- Your GlucoSure Link Blood Glucose Meter

Step 1.

Press and hold Enter (⏻) to turn on the meter.

Step 2.

Press Enter (⏻) to enter setup screen.

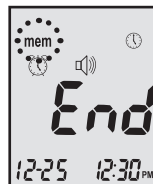
Step 3.

Press ▲ or ▼ until **mem** starts to flash. Press Enter (⏻) to enter.



mem will appear at the upper left corner of the display screen together with your most recent testing result. Press ▲ to see the next result, and the next, and so on. Holding ▲ will flash through the results.

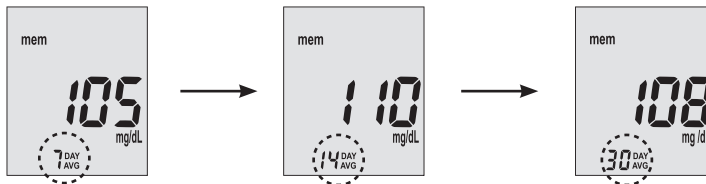
nil will appear on the display screen after the last recorded test result if less than 300 readings are stored. You can press ▼ to go back viewing from the oldest to the most recent readings.



Step 4.

When you reach the latest result, continue to press ▼ to start viewing day averages. The meter will display the 7 days average, press ▼ again to see 14 days average, and press ▼ again to see 30 days average.

The number of results included in the averages is shown right next to the ^{DAY}AVG icon. Control solution results are not included in the day average calculations.



NOTE:

- Control testing results is flagged by **ctl** on the bottom left corner of the display screen in addition to **mem**.
- When the meter memory is blank, the display screen will show **nil**.
- When there are no day average data available, the display screen will show 4 dashes.
- If the meter memory is full, adding a new test result will cause the oldest one to be deleted.
- Memorized test results and day averages will not be erased when changing batteries.
- You can begin testing anytime by inserting a test strip.

Data Transmission

Test results stored in the GlucoSure Link Blood Glucose Meter's memory can be transmitted to your personal computer or mobile devices.

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.

You will need:

- Your GlucoSure Link Blood Glucose Meter
- A mobile device with Bluetooth

For Performing a Glucose/ Control Solution Test Mode

Step 1

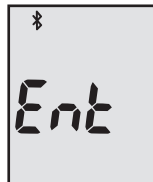
Follow the step of performing Glucose or Control Solution test to get a test result. Please remove strip during data transmission.

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 “BLE” icon (⌘) shall be flashing on the meter screen.



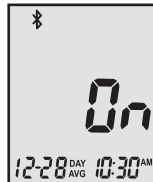
Step 3

Press Enter (⏏) to pair with your Mobile Device.

Step 4

The BLE icon stops flashing as pairing is completed. Then the screen of meter will show “On” and “BLE” icon (⌘).

As pairing fails, Err6 is displayed on the screen of the meter, please refer to “Solving Problem” for more details.



BLE Transmission

Step 5

Press Enter (⏏) to confirm Data transmission. Meter shall start sending data to mobile device.

When Err7 is displayed on the screen of the meter, refer to “Solving Problem” for more details.



NOTE:

- You need to install an app that accepts meter data on your mobile device.
- As long as the mobile device has an application that can accept meter data, the meter does not need to be paired.
- When the meter is in transfer mode, testing is not possible.
- If changing different mobile device, the pairing procedure must be performed.
- If BLE is switched to on from off, and pairing is performed again, the pairing operating flow shall quickly go to “On” display.
- The distance between the meter and the mobile device can be transmitted within a range 10 m/m.
- GlucoSure Link Blood Glucose Meter can only transfer memory data, but not accept or upload data.
- If the Bluetooth transmission function fails, the screen will display Er5, please contact customer service at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday for questions and inquiries.

CAUTION:

- 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.

Quality of service for the wireless connectivity for 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.

Caring for the Meter

Caring for your GlucoSure Link Meter is easy. Follow these simple guidelines to keep your meter working properly.

NOTE:

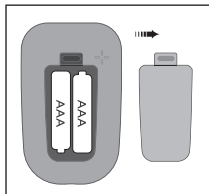
- DO NOT get water inside the GlucoSure Link Blood Glucose Meter. Never immerse the meter or hold it under running water.
- DO NOT use glass cleaners or household cleaners on the meter.
- DO NOT contaminate the strip holder with blood or control solution.
- DO NOT take the GlucoSure Link Blood Glucose Meter apart. Doing so will void the warranty. If there are technical problems or questions in use of the Meter, contact us at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday.
- Handle the Meter with care – severe shock, such as dropping the meter, could damage the electronics.

Changing the Batteries

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

Materials you will need:

- Two Alkaline AAA Batteries
- Your GlucoSure Link Blood Glucose Meter



Step 1.

Turn meter off. Press firmly on the battery cover and slide in the direction of the arrow. Remove the old batteries.

Step 2.

Insert new batteries . Slide the battery cover back into the meter firmly.

NOTE:

- If the batteries are inserted upside down, the meter will not operate.
- Meter will prompt you to reconfirm the date and time when turned on. See page 16 for Setting the Clock.
- The date, stored results and meter settings stay in memory when the batteries are changed.

- Dispose of old batteries according to local environmental regulations.
- To obtain accurate test results:
Improper use may cause explosion or leakage of flammable liquid.
Do not expose the batteries to extremely high temperatures or extremely low air pressure.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period.
- Keep batteries out of reach of small children. Should a child swallow a battery, consult a physician immediately.

Cleaning and disinfection procedures for GlucoSure Link Blood Glucose meter and Lancing Device

Cleaning and disinfection are different and both should be performed. Cleaning, such as removing dirt with a damp paper towel, is part of your normal care and maintenance, but cleaning does not kill germs effectively. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfection is the only way to reduce your exposure to disease. For cleaning and disinfecting information see pages 53–56 in this manual.

You should disinfect areas where there are both high concentrations of dangerous germs and a possibility that they will be spread to others. That is because disinfectants have ingredients that destroy bacteria and other germs. While surfaces may look clean, many infectious germs may be lurking around. Given the right conditions some germs can live on surfaces for hours and even for days.

The proper disinfection of GlucoSure Link blood glucose monitoring equipment is using DISPATCH Hospital Cleaner Disinfectant Towels With Bleach, it is pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Only Dispatch wipes have been validated for use in cleaning and disinfection of the meter. A cleaning step must be performed before each disinfection step.

Cleaning and disinfection frequency: The GlucoSure Link Blood Glucose meter and lancing device should be cleaned when it appears dirty or contaminated with blood. It should be disinfected every day according to the validated cycle of 1825 times. The validated cycle of $365 \times 5 = 1825$ times is equivalent to one cleaning plus one disinfection per day over 5 years.

Cleaning and disinfecting your meter and lancing device

Clean and disinfect your meter and lancing device at least 1 time per week using DISPATCH hospital cleaner disinfectant towels with bleach, with EPA registration number 56392-8. Other wipes with EPA Reg. No. 56392-8 may also be used.

1. Wash hands with soap and water.
2. Inspect for blood, debris, dust, or lint anywhere on the meter.
3. Clean or disinfect meter or lancing device.
4. To clean the GlucoSure Link Blood Glucose meter or lancing device, blood/body fluids must be thoroughly cleaned from surface and objects before disinfecting. Dispense the towel (DISPATCH) from its package. Wipe surface with towel (DISPATCH) until completely wet. You should wipe all external areas of the meter including both front and back surfaces. Allow to remain wet for one minute at room temperature (68-77°F). Discard used towel in a sealed container where it will not be touched by others.

5. To disinfect the GlucoSure Link Blood Glucose meter or lancing device, dispense a second towel (DISPATCH) from its package. Wipe surface with towel (DISPATCH) until completely wet. You must wipe all external areas of the meter including both front and back surfaces and allow 1 minute contact at room temperature. Wipe dry or allow to air dry. Oily substances must be removed prior to disinfection. Discard used towel in a sealed container where it will not be touched by others.



6. Wash hands with soap and water.

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. Avoid alcohol and ammonia. Even though these two ingredients are excellent disinfectants, they are not safe for your meter or lancet device. Alcohol damages the LED read out and ammonia corrodes the metal parts.
- The lancing device is for patient self-monitoring by a single person only. It must not be used to collect blood from more than one person as this poses an infection risk.

- User should wash hands thoroughly with soap and water after handling the meter, lancing device, and test strip.
- Keep DISPATCH out of reach of children.
- Do not flush towels down toilet.
- Do not get water inside the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Avoid wetting the test strip holder.
- Only DISPATCH hospital cleaner disinfectant towel should be used to do cleaning and disinfection with your meter or lancing device.

The list of things you should look for as signs of deterioration after disinfection

- Control solution out of range
- Clouding for LCD display
- Corroding for plastic housing or buttons
- Cracking of plastic housing
- Malfunction of any meter buttons

If these signs of deterioration are noted, you should stop using the device and call customer service at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday.

Purchase information for Dispatch Hospital Cleaner Disinfectant towers with Bleach

Dispatch is the product of Caltech, the catalog number is 69150 (150 count)
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 the Dispatch on the web site below:

<https://www.cloroxpro.com/products/dispatch/>

<http://www.amazon.com>

If you need assistance or have questions about cleaning and disinfection for the meter, please contact customer service at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday.

Storage and Precautions

- The Meter and the Test Strips are designed to be used within a temperature range of 50°F - 104°F and relative humidity between 20% - 85%.
- 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 where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Always close the cap of the test strip bottle immediately after removing a Test Strip. Make sure the cap is tightly closed.
- Do not take the meter apart. Doing so will void the warranty.
- Dispose of the meter according to your local regulations for correct disposal.
- Discard used lancet and test strip according to your local regulations.

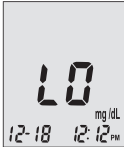
Solving Problems

This section details the significant display screen messages and error codes you will encounter when using your GlucoSure Link Blood Glucose meter and GlucoSure Link Blood Glucose test strips.

Message	What it means	What you should do
	The meter electronics or test strip is damaged	• Remove the battery 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 between 8:00 am and 5:00 pm EST, Monday through Friday
	Used or damaged test strip	• Remove the Test Strip and repeat the test with a new test strip. Remember add sample only until you see the flashing blood drop icon on the display screen.

Message	What it means	What you should do
	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 32.
	Meter fails in BLE 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.
	BLE pairing failure"	- Check Bluetooth device is working well and repeat pairing. - If problem persists, call us at 1-877-979-5454 between 8:00 am and 5:00 pm EST, Monday through Friday.

Message	What it means	What you should do
	Data transmission via BLE is fail.	Remove strip from the test strip port.
	BLE disconnection between meter and mobile device happens during transmission procedure.	Check Bluetooth device is working well and repeat pairing and data transmission.
	Batteries are low	Change the battery according to page 51, Changing the Battery.

Message	What it means	What you should do
	Temperature out of range	Move the meter into an area that is within 50°F~104°F, and allow 10 to 15 minutes for it to reach the new temperature.
	Test result is 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 is 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
	There are 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 16. • Start testing your blood glucose, see Testing Your Blood Glucose on page 32.

Product Warranty

Apex Biotechnology Corporation warrants the GlucoSure 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

Test Strips:	GlucoSure Link Blood Glucose Test Strip
Test Range:	20~600 mg/dL (1.1~33.3 mmol/L)
Calibration:	Plasma
Test Time:	6 Seconds
Sample Size:	≥ 0.8 µL
Hematocrit Range:	30~55%
Display Type:	Large LCD screen
Memory:	300 blood test results with date and time
Result Averaging:	7, 14, and 30 days averaging
Dimensions:	93L x 58W x 20.5H (mm)
Weight:	not more than 79 g with batteries
Battery:	Two 1.5 V AAA Alkaline Batteries
Battery Life:	1000
Automatic Power-off:	After 2 minutes of nonuse
Operating Temperature:	50 °F ~ 104 °F
Operating Relative Humidity:	20-85%RH
Storage Condition:	Meter at -4 °F ~ 122°F, <93% RH Test Strips at 41 °F ~ 86 °F, 10% ~ 85%RH

For additional information, refer to the GlucoSure Link Blood Glucose Test Strip insert.

Suggested Representation of Accuracy for Home Use by Lay-Users

The GlucoSure 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 350 typical users used the GlucoSure Link Blood Glucose Meter to test their blood glucose level. The following accuracy results were obtained.

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.
- 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.