Important Information for Users

Read carefully through this manual and the package inserts before testing. Pay additional attention to all listed warnings and cautions. Please keep this manual handy for future references.

If you have any questions, please call us at 1-877-979-5454 between 8:00 am and 5:00 pm Eastern Standard Time Monday through Friday or your healthcare provider.

Intended Use

The GlucoSure ADVANCE 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. Forearm and palm testing (also known as Alternative Site Testing, or AST) should be performed only when your feel your blood glucose level is not changing rapidly (steady-state). Testing is done outside the body (In Vitro Diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of your diabetes control. It should only be used by a single patient and not be shared. It is should not be used for the diagnosis or screening of diabetes or for use on neonates (infant under 4 weeks old).

The GlucoSure ADVANCE Link Blood Glucose Monitoring System is comprised of the GlucoSure ADVANCE Link Blood Glucose Meter and GlucoSure ADVANCE Link Blood Glucose Test Strip.

IMPORTANT:
- Do not use test strips beyond expiration date.
- Use GlucoSure ADVANCE Link Blood Glucose Test Strip within 6 months of first opening the test strip vial.

Important Safety Instructions

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

The link of public health notification and standard practice guideline are:
- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/ injectionsafety/Fingerstick-DevicesBGM.html

WARNING:
Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens."

Limitations

- Inaccurate results may occur in
  - Severely hypotensive individuals.
  - Patients in shock.
  - In a hyperglycemic-hyperosmolar state with or without ketosis.
- Do not use on critically ill patients.
- Do not use on neonates (infants under 4 weeks old).
- Altitude higher than 10,335 feet may cause inaccurate results.
- 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.
- For single-patient use only.
- Perform Alternative Site Testing (AST) only if your glucose level is not changing rapidly.
- Never use AST measurements to calibrate Continuous Glucose Monitors (CGMs).
- Never use AST measurements for insulin dosing calculations.
- If you have certain conditions that may cause your blood level of uric acid to rise (>10.25 mg/dL in your blood), such as gout or kidney disease, then your blood glucose results may be inaccurate with this meter. If you are unsure, then ask your doctor.
- Do not test blood glucose during or soon after a Xylose Absorption test (>7.5 mg/dL in your blood) since your blood glucose results may be inaccurate with this meter.
- If you are taking high doses of the pain medication acetaminophen (such as Tylenol, certain cold or flu remedies, and certain prescription drugs) (>7.5 mg/dL in your blood), then you

should know that this drug might affect the reliability of your blood glucose results. If you are unsure, please ask your healthcare professional.

- If you are taking high doses of the Tolazamide (>23 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, please ask your healthcare professional.
- If you are taking high doses of the Pralidoxime Iodide (PAM) (>125 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, then ask your doctor.

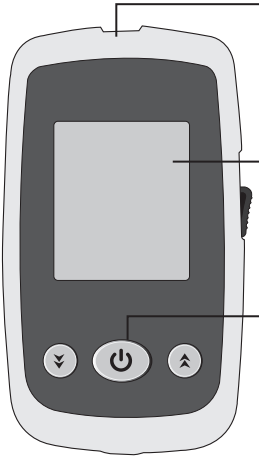
Table of Contents

Understanding Your New Blood Glucose Monitoring System

Each GlucoSure ADVANCE Link system may include the following items:
Lancing Device
The GlucoSure ADVANCE Link Meter
The GlucoSure ADVANCE Link Blood Glucose Test Strip (vial or foil-wrapped)
User Guide
Lancets
Contrex Plus 5 Level 1 Glucose Control Solution
Contrex Plus 5 Level 2 Glucose Control Solution
Contrex Plus 5 Level 3 Glucose Control Solution

NOTE:
- Lancets and Lancing Device are optional components.
- GlucoSure ADVANCE Link Blood Glucose Test Strip (vial or foil-wrapped) and Contrex Plus 5 Glucose Control Solution are necessary but sold separately. Please contact us at 1-877-979-5454 Monday through Friday from 8am to 7pm EST for purchasing information.

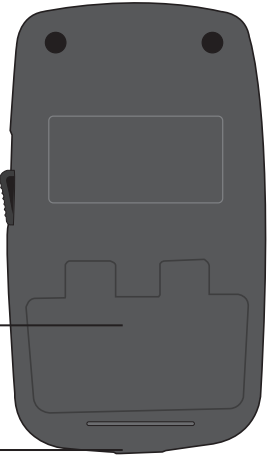
The GlucoSure ADVANCE Link Meter



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

Meter Display
Shows the blood glucose test results, memory values, and other messages.

Enter (⏻) and ▲▼buttons
Press and hold Enter (⏻) for 2 seconds to turn the meter on or off, 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.

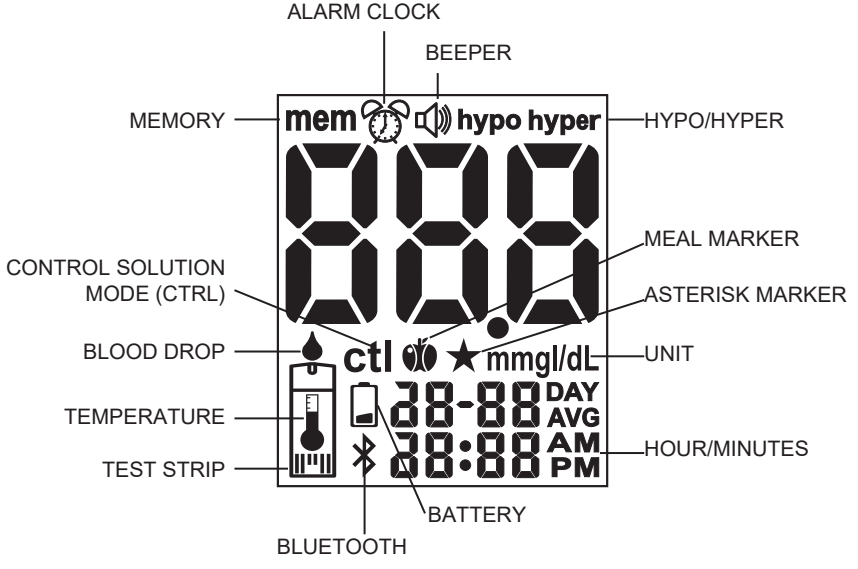


Ejection Switch
Push and eject an used test strip. Meter will turn off automatically when the test strip is ejected.

Battery Compartment
Holds two CR 2032 3V Lithium coin cell batteries.

Data Port
Transmits data to computer.

The GlucoSure ADVANCE Link Meter Display Screen



MEMORY	Indicates the results displayed are from meter memory (see page 52).
MAIN DISPLAY AREA	Displays test results, stored test values, and messages.
BATTERY	Appears when the battery is low and needs to be replaced.
TEMPERATURE	Appears when it is either too hot or too cold to test (outside the ranges of 41˚F~113˚F).
TEST STRIP	This icon will flash to prompt you to insert a test strip for testing.
UNIT	Unit of measurement for your blood glucose.
CTRL	This icon indicates a control solution test (see page 31).
BEEPER	Indicates the beeper is on (see page 23).
ALARM CLOCK	Indicates the alarm function is turned on.
BLOOD DROP	This icon will flash to indicate the meter is ready for testing.
HYPO	• Setting up your hypoglycemic threshold value (see page 27). • 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 28). • Indicates your test result maybe at or above your hyperglycemic threshold value. • Indicates the memorized result maybe at or above your hyperglycemic threshold value.

MEAL MARKER ..... Display when marking a result as before or after meal, or viewing a marked result.

ASTERISK MARKER ..... Marks any result as being unique or different in some way and for which you may want to make notes in your logbook. Seeing a result with this symbol next to it in the memory will help remind you that there is more information recorded about this test result.

BLE icon ..... Indicate Bluetooth is ON

 Used to indicate the icon is flashing rapidly and meter's BLE is on and waiting for pairing.

 Used to indicate the icon is flashing slowly and meter's BLE is transmitting data after pairing

 Again, used to indicate the icon is shown without flashing and meter's BLE is waiting instruction from cell-phone after pairing.

The GlucoSure ADVANCE Link Blood Glucose Test Strip

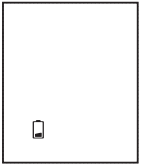
The GlucoSure ADVANCE Link Blood Glucose Test Strip is glucose specific, biosensor-based test strip that can test glucose in capillary whole blood in as quickly as 8 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that each reading you get is an accurate and meaningful result.

IMPORTANT:

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

Setting Up the New System

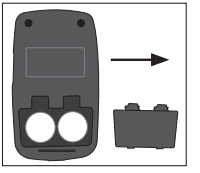
Inserting (or Changing) the Battery



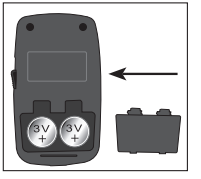
The battery needs to be inserted before using your GlucoSure ADVANCE Link Meter for the first time or when the " " icon appears on the meter display.

Material you will need:
- Two CR 2032 3V Lithium coin cell batteries
- Your GlucoSure ADVANCE Link Meter

Step 1.
Turn the 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:

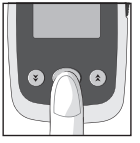
- After changing the batteries, the meter automatically prompts you to check the time and date when it is turned on either by inserting a test strip or pressing "⏻". If it is correct, press "⏻" o confirm setup and exit, or if the time and date are not correct, turn to page 17 for Setting the Clock.
- 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.

Setting the Clock

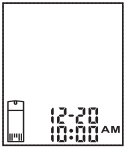
Material you will need:
• Your GlucoSure ADVANCE Link Meter

Begin Set Up

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

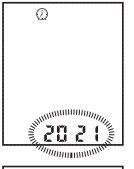


Step 2.
The flashing test strip icon will appear on the meter display screen.

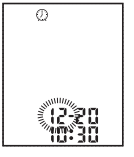


Step 3.
Press "▲" twice until meter display screen shows " ".

Set Year
Step 4.
Press "⏻" and the current year will flash. Use "▲" or "▼" to select the correct year.
Press "⏻" to confirm and advance to set the month.



Set Month
Step 5.
The current month will flash. Use "▲" or "▼" to select the correct month.
Press "⏻" to confirm and advance to set the day.



Set Day

Step 6.

The current day will flash. Use "▲" or "▼" to select the correct day.

Press "⏻" to confirm and advance to set the 12-hour or 24-hour time format.

Set 12-hour or 24-hour Time Format

Step 7.

The time format will flash. Use "▲" or "▼" to select the time format of your choice.

Press "⏻" to confirm and advance to set the hour.

Set Hour

Step 8.

The current hour will flash. Use "▲" or "▼" to select the correct hour.

Press "⏻" to confirm and advance to set the minutes.

Set Minutes

Step 9.

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

Press "⏻" to confirm and exit time setup.

NOTE:

- Anytime during setup, you may either press “Enter” to exit, or insert a GlucoSure ADVANCE Link Blood Glucose Test Strip to begin testing. The changes you have done so far will be memorized by the meter.
- You may need to reset time after changing batteries.

After setting up your clock, you can turn off the meter by holding and pressing “Enter”, continue to set your meter, or insert a test strip to begin testing (see Testing Your Setting the Alarm Blood Glucose on page 38 or Control Solution Testing on page 31).

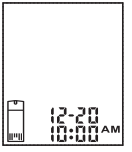
Setting the Alarm

You can set up to three alarms on the GlucoSure ADVANCE Link Meter. You must set the clock before setting the alarms. When an alarm rings, a melody will play for 30 seconds. Pressing “Enter” or inserting a test strip will silence the alarm.

Materials you need:

- The GlucoSure ADVANCE Link Meter

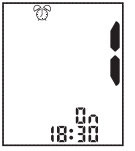
Step 1.
Press and hold “⏻” to turn on the meter.



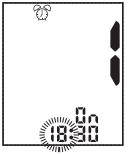
Step 2.
The flashing test strip icon will appear on the meter display screen.

Step 3.
Press "▲"or "▼" until “ ⏰ ” starts to flash. Press “⏻” to enter alarm setting.

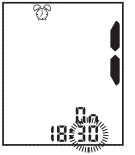
Step 4.
The display screen will indicate alarm 1 status (the default is OFF). You can turn it on by pressing "▲" or "▼". Press "⏻" to confirm your choice and advance to set hours.



Step 5.
The hours 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.



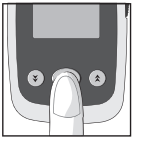
Step 7.
Set alarm 2 and 3 by following steps 4 through 6. After you have finished setting up alarm 3, press "⏻" to exit alarm setup.

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

Begin testing by inserting a GlucoSure ADVANCE Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 38 or Control Solution Testing on page 31), or press and hold "⏻" to turn off the meter.

Turning ON/OFF Tone Sound

The GlucoSure ADVANCE Link Meter comes with beeper sound ON as preset. The beeper will sound once to remind you when turning on/off the meter, applying samples, or ending countdown. You will get two beep sounds warning if the results show "hypo", "hyper", "HI" or "LO".



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 tone setting. Use "▲" or "▼" to turn on/off the tone.

Step 5.
Press "⏻" to exit once you have made the selection.

NOTE:
- Anytime during setup, you may either press "⏻" to exit, or insert a GlucoSure ADVANCE Link Blood Glucose Test Strip to begin testing. The changes you have done so far will be memorized by the meter.

Begin testing by inserting a GlucoSure ADVANCE Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 38 or Control Solution Testing on page 31), or press and hold "⏻" to turn off the meter.

Setting Warning Values

Your GlucoSure ADVANCE Link Meter has a feature to set your high and low blood glucose threshold (hyperglycemia and hypoglycemia values). Based on the values you have set up, the LCD screen will show “hypo” if your blood glucose test result is below your low glucose threshold value (hypoglycemia level), or the LCD screen will show “hyper” if your blood glucose test result is above your high glucose threshold level value (hyperglycemia level). Please consult your physician or healthcare provider when setting up the hypo and hyper values.

HYPO (hypoglycemia) warning

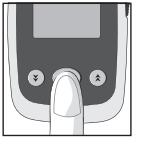
HYPER (hyperglycemia) warning

IMPORTANT:

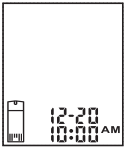
- Do not alter or stop your medication based on this feature, always consult your physician or healthcare provider before altering or stopping medication.
- Please consult your healthcare providers to decide the proper levels before setting up the hypo and hyper values.

The factory preset threshold value is 250 mg/dL for hyper and 70 mg/dL for hypo. The allowable range of the threshold setting is 100 to 600 mg/dL for hyper and 20 to 130 mg/dL for hypo, but the hyper value will never be lower than the hypo value. Follow the steps below to adjust the hyper and hypo threshold values.

Material you will need:
- The GlucoSure ADVANCE Link Meter



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



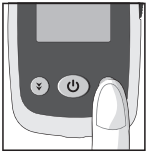
Step 2.
The flashing test strip icon will appear on the meter display screen.

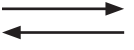
Setting up hypo (hypoglycemia) warning value

Step 3.
Press "▲" or "▼" until the meter display screen shows "hypo".

Step 4.
Press "⏻" to enter hypo setup.

Step 5.
Press"▲" or "▼" to select the desired value. Press and hold either "▲" or "▼" will accelerate numbering. Press "⏻" to confirm and exit hypo setup. You will return to the meter display screen.



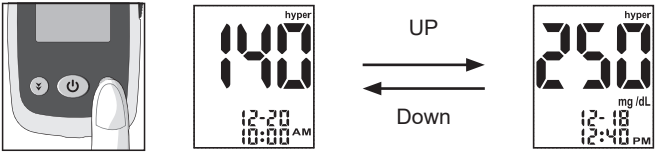


Setting up hyper (hyperglycemia) warning value

Step 6.
Press “▲” or “▼” until the main display screen shows “hypr”.

Step 7.
Press “⏻” to enter hyper setup.

Step 8.
Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” will accelerate numbering. Press “⏻” to confirm and exit hyper setup. You will return to meter display screen.



After setting up the hypo and hyper values, you can either press and hold “Enter” 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 31).

Enable/Disable QC Lock Mode

GlucoSure ADVANCE Link Meter offers you a choice to lock in the QC lock mode. When the QC lock mode is on and no control test has been performed in the past 24 hours, the message “qC” will flash on the screen and you will need to perform a control test before running a glucose

Materials you will need:
• The GlucoSure ADVANCE Link Meter

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

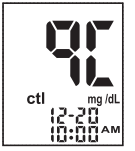
Step 2.
The flashing test strip icon will appear on the meter display screen.

Step 3.
Press“▲” or “▼” until the meter display screen shows “**ctl**”.

Step 4.
Press “⏻” to enter QC lock setting. Use “▲” or “▼” to turn on/off QC lock.

Step 5.
Press “⏻” to confirm and exit QC lock setup. You will return to meter display screen.

Begin testing by inserting a GlucoSure ADVANCE Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 38 or Control Solution Testing on page 31), or press and hold "⏻" to turn off the meter.



If the QC lock is on and no control test has been executed in the past 24 hours, the screen will show the flashing message "qC" when you insert a test strip. You will not be able to run glucose tests without running a control test first.

Press "▼" to select control level (L1, L2 or L3), see Control Solution Testing on page 31 for detail steps.

Control Solution Testing

Performing a Control Solution Test

The purpose of the control solution testing is to validate the performance of the GlucoSure ADVANCE Link Blood Glucose Monitoring System using the testing solution with a known range of glucose. Control solutions are necessary but sold separately, please contact us at 1-877-979-5454 Monday through Friday from 8am to 7pm EST for purchasing information.

You should perform control solution testing when:

- Using the meter for the first time
- You open a new package of GlucoSure ADVANCE Link Blood Glucose Test Strip
- You leave the cap of the test strip vial open for a while
- You drop the meter
- You suspect your GlucoSure ADVANCE Link Meter and GlucoSure ADVANCE Link Blood Glucose Test Strip are not working properly
- The blood glucose test results do not reflect how you feel
- You want to practice the testing procedure

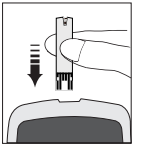
IMPORTANT:

- Use only the Contrex Plus 5 Glucose Control Solution (Level 1, Level 2 and Level 3) with the GlucoSure ADVANCE Link Blood Glucose Test Strip. Other brands of control solution will produce inaccurate results.
- Always check the expiration date. DO NOT use control solutions if expired.

- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
- NOT FREEZE or REFRIGERATE. Store the control solutions at 39˚F~86˚F.

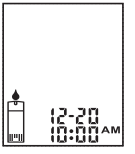
Materials you will need:
- Contrex Plus 5 Glucose Control Solution (Level 1, Level 2 and Level 3)
- Your GlucoSure ADVANCE Link Meter
- A new GlucoSure ADVANCE Link Blood Glucose Test Strip

Step 1.
Insert a GlucoSure ADVANCE Link 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.

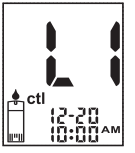


IMPORTANT:
- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip).
- Use each test strip immediately after removing it from the bottle or opening a foil wrapping.
- For vial test strip, replace the bottle cap immediately and close it tightly after removing a test strip from the bottle.
- Do not use wet, bended or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip in a dry, cool place.
- For vial test strip, record the “date opened” on the test strip bottle label when you first open it. Six months after first opened, discard the bottle and any remaining test strips..

- For foil-wrapped test strip, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Make sure you are testing in an environment between 41˚F~113˚F and 20~90% RH, and allow 10 to 15 minutes for it to reach the new temperature before use. Your meter will not begin testing if it detects an out-of-range temperature.
- This is an auto-coding meter. You do not need to insert a code card.
- Must see a flashing blood drop icon if the test strip has been inserted to the test strips port.



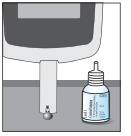
Step 2.
Wait until the flashing blood drop and test strip icons appear on the lower left of the meter display screen.



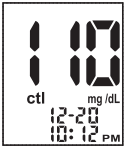
Step 3.
Press "▼" to enter the control mode. You will see "ctl" on the lower left of the screen. Use "▲" or "▼" to select control level (L1, L2 or L3).

Step 4.
Squeeze a drop of glucose control solution (Level 1, Level 2 or Level 3) onto a clean, dry, non-absorbent 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.

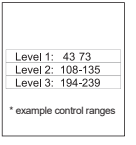
Step 5.
Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip.



Step 6.
The screen will begin to count down. After 8 seconds, the control solution testing result will appear on the meter 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 does not fall within the control range printed on the test strip bottle or box, see Control Solution Trouble Shooting on page 37.



NOTE:
- Control solution testing results will be stored into the meter’s memory and indicated by “**ctl**” icon.
- Different bottle or box of the test strip may have different control range.

Step 8.
Remove the used test strip either by pushing the ejection switch or by pulling it out with your hand and throw it into a proper wastebasket.

Insert a new test strip to perform the next test, or press and hold "⏻" to turn off the meter.

IMPORTANT:
• Do not reuse test strips.

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

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 5 Glucose Control Solution (Level 1, Level 2 and Level 3).
• Expired or contaminated control solution or damaged test strips	• Make sure the testing environment is between 41˚F~113˚F and 20~90% RH.
• Meter malfunction	• Check the expiration and opened date on bottles of both control solution and test strips. Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.
• Control solution not at room temperature	• Please contact at 1-877-979-5454 Monday through Friday from 8am to 7pm EST for questions and inquiries.

Testing Your Blood Glucose

Materials you will need:

- Your GlucoSure ADVANCE Link Meter
- A new GlucoSure ADVANCE Link 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 15 and Control Solution Testing on page 31 for more details.
- Wash your hands and testing site thoroughly with soap and warm water, and dry well.
- You are testing in an area between 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 "  ". Move the meter into an area that is between 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 the user, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

Preparing the Lancets

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.
- Dispose properly in biohazard waste.
- When performing a blood glucose test, use a new sterile lancet every time. If alcoholic 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 GlucoSure ADVANCE Link Blood Glucose Monitoring System can test for blood glucose from two sites other than your fingertip. These alternative sites are your palm and forearm (alternative site testing, or AST). Alternative site testing can be less painful than fingertip testing, but because of the physiological difference between your fingertip and palm and forearm[1], AST result may be significantly different than results from fingertip testing under certain conditions. You should consult with your doctor or healthcare professional before using AST.

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

AST SHOULD NOT be used when:

- 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.

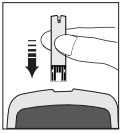
NOTE:

- If results from AST 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.
Insert a test strip to turn on the meter.



IMPORTANT:

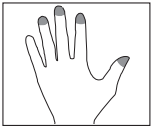
- Check the expiration date printed on the test strip bottle (for vial test strip) or box (for foil-wrapped test strip). Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle or opening a foil wrapping.
- Do not use wet, bended or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip in a dry, cool place.
- For vial test strip, record the “date opened” on the bottle label. Discard the bottle and any remaining test strip after six months from date of opening.
- For foil-wrapped test strip, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Insufficient blood specimen may cause incorrect results.
- Must see a flashing blood drop icon if the test strip has been inserted to the test strip port.

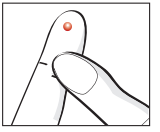
Step 2.
Wait until the flashing blood drop and test strip icons appear on the lower left of the meter display screen.

Step 3- obtain blood sample

For Fingertip Testing:

Hold the lancing device (use the blue 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 Palm and Forearm Testing:

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.

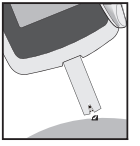
For palm testing.....it is not necessary to rub the skin or pump the device. Press the clear endcap firmly against the puncture site and then press the release button.

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 to 3 times without lifting device away from skin.

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

IMPORTANT:
- If results from AST do not agree with how you feel, use fingertip testing instead.

Step 4.
Must see the flashing blood drop icon before applying blood. 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 countdown, your glucose testing result will appear on the meter display screen.

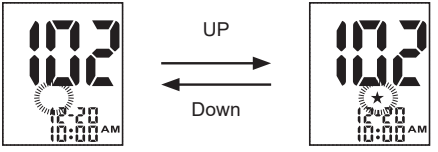
Step 6-Select the before/after meal marker

With the test result on the display, and the test strip still in the meter, press either "▲" or "▼" 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 asterisk marker.

Step 7-Select the asterisk marker

After selecting meal state, a flashing "★" icon appears in the middle of the screen. You can mark your result to remind you an event such as an AST result or exercise. Use "▲" or "▼" to turn the option on/off, and press "⏻" to confirm your choice. The result will be stored in memory.

The test result will be stored without markers if the strip is removed without selection.



The test result will be stored without markers if the strip is removed without selection.

CAUTION:

- If you see “HI” or “LO” is displayed, your blood glucose level may be beyond the meter measurement range (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. 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.

NOTE:

- “hypo” or “hyper” icons may appear on screen depending on the threshold limit you have set up. Refer to Setting Warning Values on page 25.
- Clean and disinfect the meter and lancing device after the test. Refer to Cleaning and Disinfection Your Meter and Lancing Device on page 56.

Step 8.
Remove the used test strip either by pushing the ejection switch or by pulling it out with your hand and throw it into a proper wastebasket.
Insert a new test strip to perform the next test, or press and hold “⏻” to turn off the meter.

Step 9.
Remove the used lancet from your lancing device according to instructions and discard it into a proper wastebasket.

IMPORTANT:

- 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.
- Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Understanding the 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[2]:

- less than 100 mg/dL before meals.
- less than 140 mg/dL 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 with your healthcare provider.
- Test your meter with a control solution, refer to Control Solution Testing on page 31.
- 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 this device.

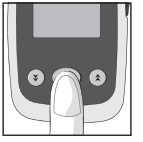
2. American Diabetes Association, Standards of Medical Care in Diabetes—2016. Diabetes Care, Vol.39, Supplement 1, p. S16, table 2.3.

Viewing Stored Readings from Memory

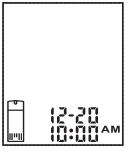
The GlucoSure ADVANCE Link Meter can store up to 1000 test and control results with date and time. You will need to set the meter date and time before using the memory, see Setting Up the New System on page 13. The meter will not memorize any test or control results if the date and time are not set.

Material you will need:
• The GlucoSure ADVANCE Link Meter

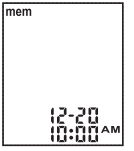
Step 1.
Press and hold "⏻" to turn on the meter.



Step 2.
The flashing test strip icon will appear on the meter display screen.

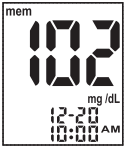


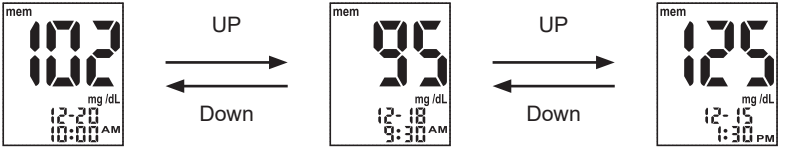
Step 3.
Use "▲" or "▼" until meter display screen shows "**mem**".



Step 4.
Press "⏻" to confirm.

Step 5.
The most recent test result will appear on screen. Press "▲" to view the results from the most recent to the oldest.
Press and hold either "▲" or "▼" will accelerate scrolling.





NOTE:
- Control testing results will be flagged by a "ctl" icon on lower left of the unit measurement.
- Hypoglycemic readings and hyperglycemic readings will be accompanied by the corresponding icons.

- If you get result of “HI” or “LO”, it will be stored automatically in memory as 600 mg/dL or 20 mg/dL without markers.
- If error messages appear, see Solving Problems on page 63.

After you finish viewing memory, either begin testing by inserting a GlucoSure ADVANCE Link Blood Glucose Test Strip (see Testing Your Blood Glucose on page 38 or Control Solution Testing on page 31), or press and hold “⏻” to turn off the meter.

FOR HEALTHCARE PROFESSIONAL USE:

- When using the meter on multiple patients, be aware that the results from different patients will be kept together in the meter memory chronologically.

Data transmission

Upload Data via USB

Material you will need:
- Your GlucoSure ADVANCE Link Meter
- A micro USB cable

Insert USB cable into the data port, the PC mode shows up as the right image.

Follow the Data Management System (DMS) instruction manual to upload data.
For purchase information of DMS, please call customer service at 1-877-979-5454 Monday through Friday from 8am to 7pm EST.

NOTE:
- The upload feature should be used only with DMS products that specifically identify the GlucoSure ADVANCE Link as a meter that is compatible with their DMS.

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 synchronies your test information between the meter and the mobile device.

Material you will need:
- Your GlucoSure ADVANCE Link 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.

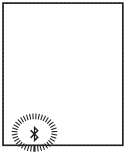
Pairing

Step 2

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

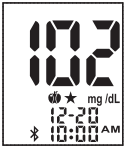
The screen will show "Ent" and the "BLE" icon" shall be flashing in the meter.

Step 3.
Press “symbol” to pair with your Mobile Device

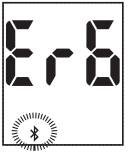


Step 4.

- As pairing is ok, the BLE icon stop flashing. Then the screen of meter will show “Ent” and “BLE“ icon.



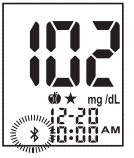
- As pairing fails, Er6 is displayed on the screen of the meter. To see page 47 to solve problems.



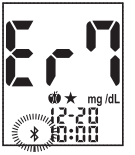
BLE transmission

Step 5.

- Meter shall start sending data to mobile device.



- When Er7 is displayed on the screen of the meter. To see page 47 to solve problems.

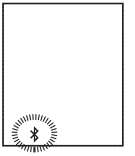


Step 6.
After the data transfer is completed, turn off the meter or the meter switches off automatically.

For Memory recall Mode
Step 1.
Follow the step of Viewing Stored Readings from Memory

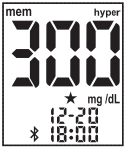
Pairing
Step 2.
To make a Bluetooth transfer, open the app on your mobile device and follow the app instructions to pairing the meter.
The screen will show “Ent” and the “BLE“ icon shall be flashing in the meter.

Step 3.
Press “symbol” to pair with your Mobile Device



Step 4.

- As pairing is ok, the BLE icon stop flashing. Then the screen of meter will show “Ent” and “BLE“ icon.
- As pairing fails, Er6 is displayed on the screen of the meter. To see page 47 to solve problems.



BLE transmission

Step 5.

- Meter shall start sending data to mobile device.
- When Er7 is displayed on the screen of the meter. To see page 47 to solve problems

NOTE:

- You need to install an app that accepts meter data on your mobile device or PC.
- 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 or PC 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 GlucoSure ADVANCE Link Meter is easy. Follow these simple guidelines to keep your GlucoSure ADVANCE Link Meter working properly.

NOTE:
- Do not get water inside the GlucoSure ADVANCE Link Meter. Never immerse the meter or hold it under running water.
- Do not use glass 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 are different, and both should be performed. Cleaning can remove visible soil, blood and oily substances prior to disinfecting, but does not kill germs effectively. Disinfecting can destroy most recognized pathogenic microorganisms to reduce your exposure to disease. For cleaning and disinfecting information, see Page 56 to 61 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 following products have been validated for cleaning and disinfecting the meter and lancing device:

- Dispatch® Hospital Cleaner Disinfectant Towels with Bleach
  (EPA Registration Number: 56392-8)
- Medline Micro-Kill+™ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol
  (EPA Registration Number: 59894-10)
- Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes
  (EPA Registration Number: 67619-12)
- Medline Micro-Kill™ Bleach Germicidal Bleach Wipes
  (EPA Registration Number: 69687-1-37549)
- Super Sani-Cloth® Germicidal Disposal Wipe
  (EPA Registration Number: 9480-4)

These wipes are pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Only the above wipes have been validated for use in cleaning and disinfecting the meter and lancing device. The wipe must be performed before each disinfection step.

Cleaning and disinfecting frequency: the meter and lancing device should be cleaned when it appears dirty or contaminated with blood. It should be cleaned using the validated wipe prior to each disinfection stop according to the validated cycle of 1825 times. Cleaning and disinfecting were validated for a cycle of 365x5=1825 times which is equivalent to one cleaning plus one disinfecting per day over 5 years.

WARNING:

- These disinfectants were validated separately. Only one disinfectant should be used on the device for the life of the device, as the effect of using more than one disinfectant interchangeably has not been evaluated.

Cleaning and Disinfecting Your Meter

Clean and disinfect your meter at least 1 time per week using the validated disinfectant towels with bleach or alcohol. The canister should be inverted for at least 2-3 minutes to ensure wetness of the towelettes at the beginning of the testing prior to the canister(s) of towelettes being used for testing.

1. Wash hands with soap and water and dry thoroughly.
2. Inspect for blood, debris, dust, or lint anywhere on the meter.
3. To clean the meter, blood/body fluids must be thoroughly cleaned from surface and objects before disinfecting. Wipe surface with one of the four validated disinfecting wipes until completely wet. You should wipe all external areas of the meter including both front and back surfaces using the same validated wipes for cleaning and for disinfection. Avoid wetting the test strip holder and data port. Discard used towel in a sealed container where it will not be touched by others.
4. To disinfect your meter, dispense a fresh towel from its package. Oily substances must be removed prior to disinfection. Wipe surface with towel until completely wet. You must wipe all external areas of the meter including both front and back surfaces. Avoid wetting the test strip holder and data port.

Allow the surface of the meter to remain wet at room temperature for:

- At least 30 seconds for Medline Micro-Kill™ Bleach
- At least 1 minute for Dispatch® and Clorox Healthcare®
- At least 2 minutes for Medline Micro-Kill+™ and Super Sani-Cloth®

5. Discard used towel 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.

Cleaning and Disinfecting Your Lancing Device

Clean and disinfect your lancing device at least 1 time per week with the validated cleaner disinfectant towels with bleach or alcohol. The canister should be inverted for at least 2-3 minutes to ensure wetness of the towelettes at the beginning of the testing prior to the canister(s) of towelettes being used for testing.

1. Wash hands with soap and water.
2. Inspect for blood, debris, dust, or lint anywhere on the lancing device.
3. To clean the lancing device and AST endcap, blood/body fluids must be thoroughly cleaned from surface and objects before disinfecting. Wipe surface with towel until completely wet. Discard used towel in a sealed container where it will not be touched by others.
4. To disinfect the lancing device and AST endcap, dispense a fresh towel from its package.

Oily substances must be removed prior to disinfection. Wipe surface with towel until completely wet. You must wipe surface with towel until completely wet. Wipe dry or allow to air dry.

Allow the surface of the lancing device to remain wet at room temperature for:

- At least 30 seconds for Medline Micro-Kill™ Bleach
- At least 1 minute for Dispatch® and Clorox Healthcare®
- At least 2 minutes for Medline Micro-Kill+™ and Super Sani-Cloth®

5. 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 assistance to the user, the meter and lancing device should be cleaned and disinfected prior to be used by the second person.
- Keep disinfecting wipes out of reach of children and stored according to its instruction.
- Do not flush towels down toilet.
- Do not get water inside the meter or immerse the meter or lancing device in water or any other liquids.
- Do not use glass or household cleaners on the meter or lancing device.
- Avoid using ammonia to clean the meter or lancing device.
- Avoid wetting the test strip holder and data port of the meter

The list of things you should look for as signs of deterioration after disinfection:
Meter
- Control solution out of range
- Clouding of the LCD display
- Corroding of the plastic housing
- Corroding of the buttons

Lancing Device
- Corroding of the plastic housing of Lancing Device and clear AST cap
- Corroding of the depth setting
- Corroding of the buttons

If these signs of deterioration are noted, stop using the meter and call customer service at 1-877-979-5454 Monday through Friday from 8am to 7pm EST.

Purchase Information for Validated Disinfecting Wipes

To find a local distributor in your area, call customer service at 1-877-979-5454 Monday through Friday from 8am to 7pm EST. You can also purchase the disinfecting wipes at the website:
- http://www.amazon.com
- http://www.staples.com

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 the temperature ranges between 41°F~113°F and the relative humidity ranges between 20~90%.
- Avoid leaving the meter in extremely hot or cold place, such as near a heat source or in an extremely hot or cold car.

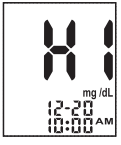
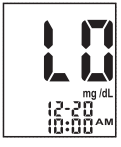
- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Always close bottle cap immediately after removing a test strip and make sure it is closed tightly.
- Do not take the meter apart. Doing so will void the warranty.
  - This meter must not be co-located or operating in conjunction with any other antenna or transmitter.
  - There are no risk or electromagnetic disturbance to operate the meter around the common RF emitters (e.g. electromagnetic anti-theft systems or metal detectors) in the home environment.
  - Dispose of the meter according to your local regulations for correct disposal.
  - Discard used lancet and test strip according to your local regulations.
- If there are technical problems or questions, please call customer service at 1-877-979-5454 Monday through Friday from 8am to 7pm EST.

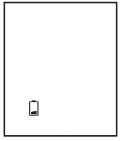
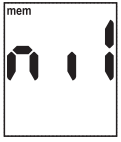
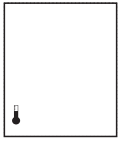
Solving Problems

This section details the significant display screen messages and error codes you may encounter when using your GlucoSure ADVANCE Link Meter and GlucoSure ADVANCE Link Blood Glucose Test Strip.

Message	What it Means	What You Should Do
	Damaged meter electronic or test strip	• Remove the batteries and turn the meter on 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 7pm EST
	Used or contaminated test strip	• Repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.

Message	What it Means	What You Should Do
	Not enough sample on the test strip to start	• Remove the test strip and repeat the test with a new test strip. See Testing Your Blood Glucose on page 38.
	Premature sample Application	• Remove the test strip and repeat the test with a new test strip, apply blood AFTER flashing blood drop icon appeared. See Testing Your Blood Glucose on page 38.
	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 7pm EST.
	BLE 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 7pm EST

Message	What it Means	What You Should Do
	Data transmission via BLE is fail.	• Remove USB cable from Data transmission port.
	BLE disconnection between meter and cell-phone happens during transmission procedure.	• Check Bluetooth device is working well and repeat confirm to pairing and data transmission.
	Test result higher than 600 mg/Dl	• Wash and dry your hands and repeat the test using 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 using 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
	Low battery	• Change the batteries according to instructions for Inserting (or Changing) the Battery on page 15.
	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 15. • Start testing your blood glucose, see Testing Your Blood Glucose on page 38.
	Temperature out of Range	• Move the meter into an area that is between 41˚F~113˚F, and allow 10 to 15 minutes for it to reach the new temperature.

Product Warranty

Apex Biotechnology Corporation warrants the GlucoSure ADVANCE Link 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 authorized dealer responsible for the sale of the system.
The warranty applies only to the original purchaser of the system.
If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Specifications

Test Strips:	GlucoSure ADVANCE Link Blood Glucose Test Strip
Test Range:	20~600 mg/dL
Calibration:	Plasma
Blood Sample Size:	Minimum 0.8 µL
Hematocrit Range:	10~70%
Event management:	Before/After meal marker and asterisk marker
Warnings:	User configurable hypoglycemia and hyperglycemia warnings, underfill warning
Display Type:	LCD screen with back lighting
Memory:	1000 test results with date and time
Data transfer:	Via micro USB cable or a Bluetooth device
Dimensions:	105L x 60W x 14.5H (mm)
Weight:	51g (without batteries)
Battery:	2 x CR 2032 3V Lithium coin cell batteries
Battery Life:	1000 tests of continuous use or one year
Automatic Power-Off:	After 2 minutes inactivity
Operating Temperature:	41˚F~113˚F
Operating RH%:	20~90%
Alarms:	3
Storage/Transport Condition:	Meter at -4˚F~122˚F, <93% RH Test Strips at 39˚F~86˚F, 10~85% RH
Radio Frequency Technology:	Bluetooth 5
Radio Frequency Band:	2.4 GHz–2.483 GHz

Maximum Radio Transmitter Power:	4 dBm
Security Encryption:	128-bit AES (Advanced Encryption Standard) CCM, ECB,AAR

Quality of service for the wireless connectivity for data downloading

Acceptable latency:	4 seconds
Max throughput: low speed;	21kbps

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

For additional information, refer to the GlucoSure ADVANCE Link blood Glucose Test Strip insert

Accuracy for Home Use by Lay-Users

A total of 137 fresh blood samples from fingertip, palm and forearm were collected by lay users. Eleven (11) samples were below 75 mg/dL. One hundred and twenty-six (126) samples were above 75 mg/dL. Fingertip and alternative site samples were tested by lay users. Blood was tested on the YSI 2300 Analyzer as a reference test.

Table 1: For glucose concentrations <75 mg/dL

Sampe Source	Within ± 5 mg/dL	Within ± 10mg/dL	Within ± 15 mg/dL
Lay users Fingertip vs. YSI	10/11 (91%)	11/11 (100%)	11/11 (100%)
Lay users Palm vs. YSI	8/11 (73%)	10/11 (91%)	11/11 (100%)
Lay users Forearm vs. YSI	9/11 (82%)	10/11 (91%)	11/11 (100%)

Table 2: For glucose concentrations ≥75 mg/dL

Sampe Source	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Lay users Fingertip vs. YSI	72/126 (57%)	115/126 (91%)	125/126 (99%)	126/126 (100%)
Lay users Palm vs. YSI	78/126 (62%)	114/126 (90%)	125/126 (99%)	126/126 (100%)
Lay users Forearm vs. YSI	72/126 (57%)	115/126 (91%)	125/126 (99%)	126/126 (100%)

The meter meets the electromagnetic compatibility requiremwnts 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 GlucoSure ADVANCE 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 GlucoSure ADVANCE 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 GlucoSure ADVANCE Link Blood Glucose meter is internally powered by two CR 2032 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 - Gudiance
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 GlucoSure ADVANCE 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 GlucoSure ADVANCE Link has been designed to meet EMC standards. However, should you suspect that the machine performance (eg, pressure or flow) is affected by other equipment, move the machine away from the possible cause of interference. The GlucoSure ADVANCE 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: 2AV24BGM036.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 √P d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √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: a 

Guidance and manufacturer's declaration - electromagnetic immunity			
Test	IEC 60601 Test Level	IEC 60601 Actual Level	electromagnetic environment - Gudiance
			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 GlucoSure 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.