



Advance Link Blood Glucose  
Monitoring System  
**Owner's Booklet**



Advanced Diabetes Management System

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\* Put the batteries into the battery compartment before first use.

**Thank you for choosing TRUE INTEGRAL Advance Link Blood Glucose Monitoring system. Before you start testing, carefully read this owner's Booklet.**

## **Intended Use**

The Advance Link Blood Glucose Monitoring System is composed of the Advance Link Blood Glucose Meter and Blood Glucose Test Strips, The Advance Link Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The Advance Link Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use) , by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control . This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

## **Test Principle**

The system uses amperometry, to check your blood glucose. It uses a reaction between glucose dehydrogenase and glucose to find out the amount of glucose in your blood . This helps you know your blood glucose levels and take care of your diabetes.

## 2 | Introduction

### Limitations

- 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.
- Not for use on critically ill patients, patients in shock or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Not for neonatal use.
- Not for Alternative Site Testing (AST).
- Not for screening or diagnosis of diabetes mellitus.
- Not for use with severe hypotension.
- Not for use with patients with severe dehydration.
- Not intended for diagnosis or screening of diabetes.
- Do not use at altitudes above 10000ft (3048 meters) above sea level.
- Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities.
- Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.

## Important safety Information

### **Warning**

- The device is not intended for use in hospitals or care facilities. When testing, the meter and lancing device may touch blood. cleaning them thoroughly after use can remove most but not all germs , some might still be there. This means all parts of the kit can spread diseases, even after cleaning.
- 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!
- If someone else is helping you with the meter, clean it before they use it.
- Remember to clean and disinfect the meter and lancing device regularly.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Wash your hands well before and after handling the meter, or test strips.
- Be careful as small parts can be a choking hazard. keep them away from children .
- Only use blood from your fingertips when testing with this Blood Glucose Monitoring system. other parts of the body should not be used.
- Do not use with neonates.
- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.

# 4 | Introduction

## Important Health-Related information

- If your test result doesn't match how you feel, first perform a control solution test to ensure the meter is working correctly then repeat the blood test. If the meter is working correctly and still get a similar result, ask your doctor for advice. Don't change your medication without approval from your healthcare provider.
- Not for use with severe dehydration.
- Not for use with critically ill patients.
- Test results may not be accurate at altitudes higher than 10,000 feet.
- 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 blood borne pathogens.

## INCLUDED IN YOUR KIT

- Advance Link Blood Glucose Meter.
- Blood Glucose Test Strips.
- Disposable safety lancets.
- Lancing device.



c



a



Vial test strips



b



d

Note: For more information on ordering, please contact your local distributor or contact customer service at 917 2953887.

**Note: the disposable safety lancet and lancing device included in this kit are manufactured by Beijing Ruicheng Medical Supplies Co. Ltd. They are 510k cleared(K222034 & K222408).**

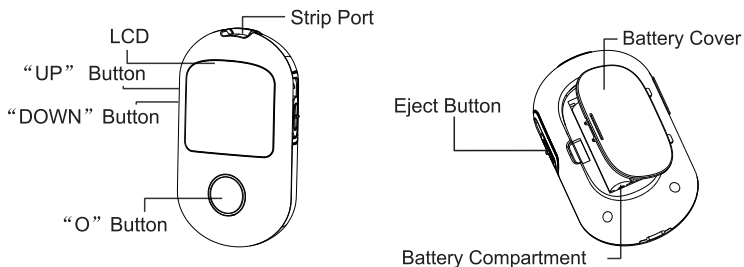
**WARNING:**

Keep the meter and testing supplies away from children. Small items such as the battery cover, batteries, test strips, disposable safety lancets, protective covers of the lancets, and control solution vial cap are choking hazards.

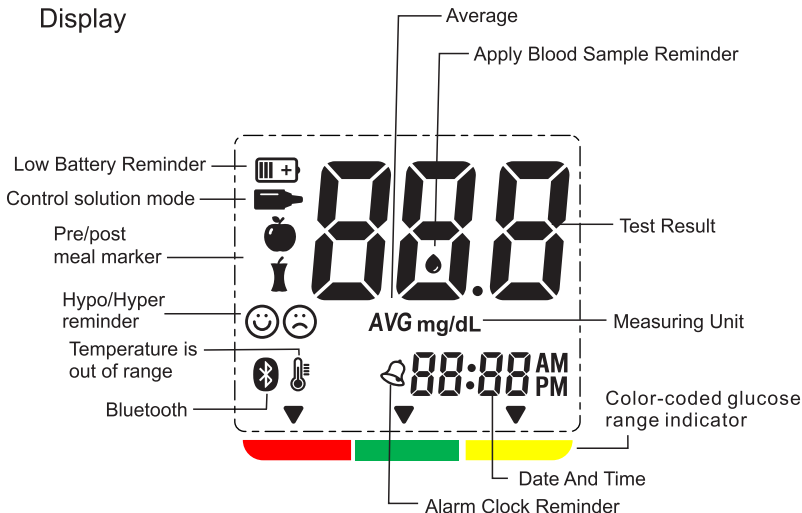
All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. Please use CaviWipes to clean and disinfect the meter after use. See the maintenance section for details.

# 6 | Getting to know your system

## a. Advance Link Blood Glucose Meter



### Display



## b. Blood Glucose Test strips



Contact Bar: Insert it into the meter's port until it can't go any further.

Blood sample slit: place where you put the blood sample.

Confirmation window: place where you check if the sample loading is complete.

**Important:**

- The Advance Link Blood Glucose Meter only works with Blood Glucose Test Strips. Using a different type of test strip will trigger an error code E-5, or the test strip will not fit into the test strip slot, or the test strip will not turn on.
- The system works at temperatures between 41°F to 113°F (5°C to 45°C) and 10~90% relative humidity.
- Keep the test strip package in the place between 33.8°F to 86°F (1°C to 30°C), 10~90% relative humidity, do not refrigerate or freeze the test strips.
- Only use test strips within the recommended temperature range.
- Always store your test strips in vials in their original vial and do not transfer them to another container.
- Individually wrapped bag test strips must be stored in original foil.
- For test strip in vials: Never store individual test strips outside the vial.
- Use the test strip immediately after removing it from vials or Individually wrapped bag test strips packages.
- Immediately recap the vial after removing a test strip and Individually wrapped bag test strips could not reuse.
- You can touch the test strip anywhere with clean and dry hands.
- Do not use test strips after their expiration date, as this may cause inaccurate results.
- Do not bend, cut, or alter test strips.
- Write the date on the vial label when you first open it. Dispose of the vial after 6 months from that date for vial test strips.
- The Individually wrapped bag test strips could not reuse.



**Warning:** The cap or vial contains drying agents that may be harmful if inhaled or swallowed and could cause skin or eye irritation.

## 8

## Setting up your meter

When using the meter for the first time, please set the parameters of the meter. With the meter off, press and hold the side DOWN button (on the left side) until the screen turns on to enter Settings mode.



### ① Set the year

Press and release the side UP or side DOWN button to move one year forward or backward. Keep pressing the buttons until the correct year appears on the screen. Press the "O" button to set the year and the Month' figure will start flashing.

A rectangular frame containing a digital display. The display shows the year "2021" in a seven-segment font. The last digit, "1", is surrounded by a dashed circle, indicating it is flashing.

### ② Set the month

Press and release the side UP or side DOWN button to move one month forward or backward. Keep pressing the buttons until the correct month appears on the screen. Press the "O" button to set the month and the date figure will start flashing.

A rectangular frame containing a digital display. The display shows "10-01" in a seven-segment font. The last digit, "1", is surrounded by a dashed circle, indicating it is flashing.

### ③ Set the date

Press and release the side UP button or side DOWN button to move one day forward or backward. Keep pressing the buttons until the correct date appears on the screen. Press the "O" button to set the date and the hour figure will start flashing.

A rectangular frame containing a digital display. The display shows "10-01" in a seven-segment font. The last digit, "1", is surrounded by a dashed circle, indicating it is flashing.



④ Set the hour

Press and release the side UP button or side DOWN button to move one hour forward or backward. Keep pressing the buttons until the correct hour appears on the screen. Press the "O" button to set the hour and the minute figure will start flashing.



⑤ Set the minute

Press and release the side UP button or side DOWN button to forward or backward one minute until the correct minute appears. After the minute is set, press button "O" to set the minute and the time format figure will appear.



OR

⑥ Set the time format

Use the side UP or side DOWN buttons to switch between the 12H and 24H format. Set your preferred format by pressing the "O" button. The meter will then proceed to the Hypoglycemia(Hypo)reminder setting.



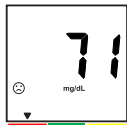
Note:

Please consult your healthcare professional to help you decide the low and high glucose level that suit for your situation for the following setting reminder function.

# 10 | Setting up your meter



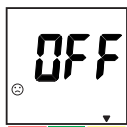
OR



⑦ Set the Hypoglycemia (Hypo) reminder function  
1. After setting the time format, you can set the hypo reminder, which indicates a possible hypoglycemic condition (blood glucose level is too low). When you set the hypo reminder, the ☹ flashes along with "OFF" (as default) on the display.

2. Press side UP or DOWN button to turn the Hypo reminder function on or off. Press "O" to save the set.  
3. If you select the hypo reminder "on", the display shows 50 mg/dL (as default).

4. Press the side UP/DOWN button to modify the hypo reminder value you want to set.  
5. The settable range is: 50-71 mg/dL.



OR



⑧ Set the hyperglycemia (Hyper) reminder function  
1. After setting the Hypoglycemia (Hypo) reminder function, you can set the hyper reminder function, which indicates a possible hyperglycemia condition (blood glucose level is too high). When you set the hyper reminder, the ☹ flashes along with "OFF" (as default) on the display.

2. Press side UP or DOWN button to turn the Hyper reminder function on or off. Press "O" to save the set.  
3. If you select the hyper reminder "on", the display shows 288 mg/dL (as default).  
4. Press the side UP/DOWN button to modify the hyper reminder value you want to set.  
5. The settable range is: 288-324 mg/dL.



OR



OR



OR

⑨ Set voice mode (ONLY Applicable to the meter with voice function)

After setting the Hypoglycemia (Hypo) reminder function, you enter into the voice setting mode. "SPH" and "On" are shown on the display (The voice is on as default), Press side UP/DOWN button to turn the voice on or off. If chose "On" the meter will issue a voice prompt during use, If chose "OFF" the meter will not issue a voice prompt during use. Press button "O" to save the setting.

**Voice function description** (ONLY Applicable to the meter with voice function)

When you turn on voice your meter will broadcast when:

- The test result appears on the display.
- The meter generates an error and display the error code.
- Test memory values appears on the display.
- Display "🔋" when meter battery is low.
- Display "🌡️" when the ambient temperature exceeds the normal operating temperature range of the the meter.

⑩ Set the alarm clock

The meter can set up to 6 alarms to remind you of the testing time.

1. Use the side up/down buttons to choose an alarm.
2. Press "O" to confirm.
3. Turning the alarm on/off using the side buttons.
4. If it's on, press "O" to adjust the alarm time. Refer to steps 4 and 5 for time setting.
5. If it's off, you can skip that alarm setting. Repeat these steps for all alarms. Press "O" to move to the next setting.
6. Last setp, press the "O" key to exit the setting mode. During any setting stage in the setting mode, you can shut down the meter directly by pressing and holding the "O" button for three seconds.

## 12 | Bluetooth connection

Your Advance Link Blood Glucose Meter has a Bluetooth function that enables you to transfer your test results to your mobile device using the GlucoJoy App.

The "Glucojoy" App is compatible with Android 6.0 or above, and iOS 10.0 or above operating system.

For cybersecurity, please follow these guidelines:

- Keep the login information secure and change the login password regularly.
- Please turn on the lock screen function of your smart device.
- The meter can only pair with 1 device at a time.
- If Bluetooth cannot connect to the App, please check whether the mobile device's Bluetooth is on. If yes, please restart the meter to reconnect Bluetooth. If it remains unconnected after 3 attempts, please call Customer Service at 917 2953887, Monday-Friday 8:00 AM-4:30 PM ET.
- To make sure that test results are secure, keep your bluetooth pairing code from other people, only let trusted people (doctor, family, etc.) connect your meter to a mobile App.
- The meter cannot be updated or patched by user, so DO NOT accept any change or update to the Meter.
- The meter has not been tested or certified for use with any software other than the Glucojoy App. The manufacturer is not responsible for any erroneous results from the use of other software.
- If any other suspected cybersecurity event occurs, please do not allow the Meter to automatically connect the Bluetooth, but the meter can test blood glucose still, and call Customer Care 917 2953887, Monday-Friday 8:00 AM-4:30 PM ET.

You can do the following things with your Glucojoy App:

- Add Notes (Medication, Insulin, Carbs, Activities) that help to explain your results.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Review your Notes and View All results on a daily graph.

The Glucojoy App does these things for you:

- Automatically displays your results.
- Saves your Notes.
- Displays your trends and test results.

## **Using Your Meter without the App**

The meter can be used without a Smart Phone or the App. You can still test your blood glucose and review your test results on the meter screen.

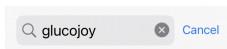
# 14 | Bluetooth connection

## Download the "GlucoJoy" App

Step 1: On your compatible smartphone, go to the App Store or the Google Play store.

Step 2: Search for the "GlucoJoy" APP

Step 3: Install the "GlucoJoy" APP.



## How to use the "GlucoJoy"APP

Step 1: Open the APP.

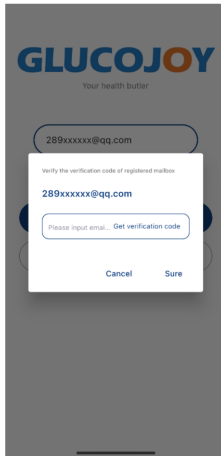
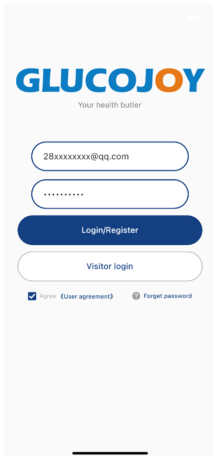
Step 2: Register or log in to the software with your email account (See below Login/Register section)

Step 3: Click the connection icon "  " to connect your meter with your smartphone (see below Pairing(Connecting) Meter with Mobile device via Bluetooth section).

Step 4: The test results will be uploaded automatically.

### Login/Register

- Enter your email address as your GlucoJoy account name.
- Set a strong password for GlucoJoy App.
- Accept the terms of use and privacy policy. Tap Login/Register.
- Get your verification code and enter the verification code you get in the email address you use as account.
- Finish your registration.



### GlucoJoy Verification Code

 GlucoJoy




Your verification code is: 544487

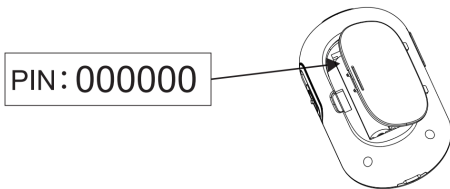
# 16 | Bluetooth connection

## Pairing(Connecting) Meter with Mobile device via Bluetooth

Pairing enables the meter to upload the test results from the meter's memory to the "Glucojoy" APP on the mobile device. To ensure successful pairing, the meter must be powered on and the Glucojoy APP software must be installed on the mobile device. The Bluetooth function can only be workable on the mobile device when the Bluetooth is not connected to other devices. The distance between the meter and the mobile device must be within 5 meters (16 feet) for the results to be uploaded.

Please follow the below steps to make the first pairing:

- Insert a test strip to enter testing mode when the meter is power off. The "  " will be flashing on the meter.
- Open the GlucoJoy app on your mobile device, make sure your Bluetooth is on. Login the GlucoJoy APP with your registered GlucoJoy account. Click the icon  on the homepage to start searching your meter. (Look for a device named Glu-710b).
- Enter the meter PIN (found inside the battery compartment) into the mobile device. (Please refer to the below picture or detail). This is the meter's PIN number. And wait for the mobile device to confirm the connection.
- Once the two devices are paired successfully, the "  " on the meter stops flashing, indicating that the meter has been successfully paired with your mobile device.



**If you have connected your meter with this app before, your meter will be automatically connected to your mobile device via Bluetooth.**

This device complies with Part 15 of the FCC Rules. It shall function under the following two conditions:

- (1) this device may not cause harmful interference to other devices.
- (2) this device must accept any interference received, including interference that may cause undesired operation.

**\*Note:**

- Performance evaluations have shown that this device meets the general RF (Radio Frequency) exposure requirements.
- This device can be used in portable conditions without any restrictions.
- Performance evaluations have confirmed that this device complies with the limits for a Class B digital device, as stated in Part 15 of the FCC Rules. This device generates and uses radiofrequency energy, which may cause harmful interference to radio or television reception. You can determine if the device is causing interference by observing the effects when you turn it on and off. If interference occurs, you can try the following methods to correct it:
  - Adjust or relocate the receiving antenna.
  - Increase the distance between the equipment and the receiver.

## **Warning**

- 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.
- If someone else helps you with testing, make sure to clean and disinfect the meter before letting them handle it.
- It is important to keep the meter clean and disinfected. For instructions on how to clean and disinfect the meter, see Maintenance chapter.
- Remember to wash your hands well before and after handling the meter and test strips.

## Blood Sampling

### IMPORTANT:

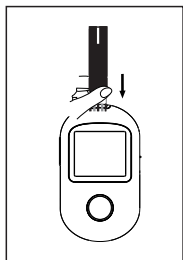
- Use only Blood Glucose Test Strips.
- Make sure that your meter and test strips are at the same temperature before doing the test.
- Accurate test results can be obtained within the temperature range of 41-113°F and 10~90% relative humidity.
- Tightly close the cap on the vial immediately after use to prevent contamination and damage to the remaining test strips.
- Store unused test strips only in their original container.
- Do not open the test strip vial until you are ready to perform a test. Use the test strip immediately after taking it out of the vial.
- Do not return the used test strip to the vial after a test.
- Do not reuse a test strip that has had blood or control solution applied to it. Test strips are for single use only.
- Write the date on the vial label when you first open it. Discard the vial 6 months after the first opening date.
- Users should clean hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

# 20 | Testing your blood glucose

## Meter Preparation



1. Wash hands with soap and water, rinse and dry thoroughly.
2. Take out the disposable safety lancet, lancing device, gauze or tissue paper ready prior to inserting the test strip.
3. Prepare the lancing device according to the manufacturer's instructions. The instruction is within lancing device package.



### ① Enter Testing mode



Insert a test strip's contact bars into the meter's port firmly. Keep pushing until the screen lights up and the meter goes into the testing mode.

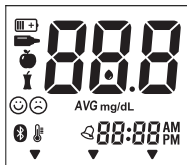
**Note:** If you do not start the test within three minutes, the meter will turn off. To restart your meter, take out the unused test strip and re-insert it back into the meter.

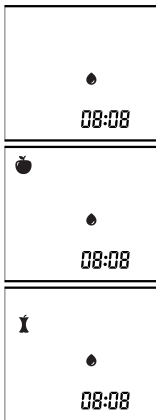
### ② System check screen


The screen will briefly display all content to confirm the meter is working.

Note:

- If  appears, it indicates that the current ambient temperature is beyond the normal operating temperature range of the instrument, please place the instrument at an ambient temperature of 41°F~113°F and keep it for half an hour, and then test it again. If the error persists, place the instrument at room temperature (68°F recommended) for half an hour and then test it again.
- If  appears, it indicates that the battery is almost empty. Replace the battery before testing.

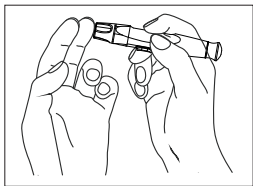




- ③ Pre/post meal marker settings
1. The pre/post-meal markers help you label your test results as before or after a meal. By default, no marker is activated.
  2. If you haven't eaten before testing, press the "O" button once to activate the "Before meal mode."
  3. If you have eaten before testing, press the "O" button twice to activate the "After meal mode."
  4. When you see a flashing blood drop symbol , it means the meter is ready for you to load your blood onto the test strip.

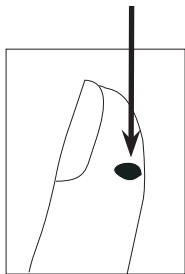
# 22 | Testing your blood glucose

## Blood Sampling



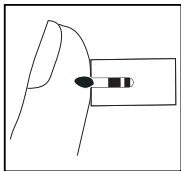
- ① Position the tip of the lancing device against the side of your chosen finger, press the trigger button, remove the lancing device , and set it aside.

Approximate size

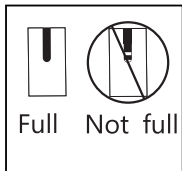


- ② Use gauze or tissue paper to wipe away the first drop of blood and apply the second blood sample to the tip of the test strip confirmation window.

## Testing



③ Apply the sample: Gently touch the blood drop with the “Blood sample slit” of the test strip to apply the sample to the strip.



④ Wait until the blood has filled the entire confirmation window. Once the test strip is full, the meter will start a countdown from 5, finishing with a beep. This indicates the end of the test and the result is ready for review.

**Note:**

- Do not try to load more blood to the test strip after you have already moved your test strip away from the blood drop. Repeated blood sampling may cause the testing to fail.



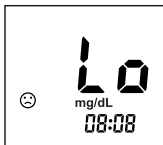
⑤ Read your result on the meter

After the beep, the meter will display your blood glucose level, along with the date and time of the test. It will also show a happy face if your glucose level is good or a sad face if it's not. The meter will store your results in its memory.

**Note:**

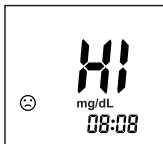
The colorful indicator bar displays a color representing your result value. Red/Green/yellow bars represent Low/Normal/High values.

## 24 | Testing your blood glucose



### ⑥ Low glucose results

If your test result is lower than 20 mg/dL, 'Lo' will appear on the meter display screen.



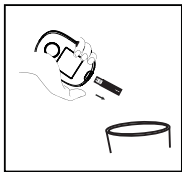
### ⑦ High glucose results

If your test is above 600mg/dL, 'Hi' will appear on the meter display screen .

If your blood glucose result does not match their symptoms, you should perform a control solution test to ensure our meter is working properly. If your meter is working properly, you should perform a new blood test with a new test strip. If the second test result remains the same, you should follow your treatment plan and contact your healthcare professional.

### CAUTION

- Do not make immediate changes to your treatment based on your test results. Always consult with your healthcare provider before making any changes to your treatment plan.



- ⑧ Turn off your meter  
Push the eject button gently to remove the test strip from the meter or remove it by hand. The meter will automatically shut down.

- ⑨ Wash your hands after completing the test and handling the meter.

## Waste Disposal

After testing, place the used test strip, disposable safety lancet, and any other waste that contacted with blood into an appropriate container.

Depending on local regulations this waste may be considered biohazardous. Follow the instructions from your healthcare professional to dispose of medical waste safely.

# 26 | Testing your blood glucose

## Interpreting Your Test Results

The meter can measure blood glucose levels accurately from 20 to 600 mg/dL.

Excepted Blood Glucose Level for persons without diabetes

Time	Blood glucose result for people without diabetes
Fasting and before meals	< 100 mg/dL
2 hour after meal	< 140 mg/dL

### References

- 1.American Diabetes Association; Standards of Care in Diabetes-2023

## Storing Blood Glucose Test Results

The meter remembers and saves up to 1000 blood glucose test results, including the date, time, and any special notes. You can look at your test results whenever you want. The newest results are at the top, and the oldest ones are at the bottom. To make sure the results make sense, remember to set the correct time and date on your meter.

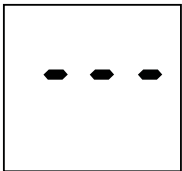
### ① Enter Memory Mode

To enter memory mode, start with the meter turned off and without any test strip inserted. Press the “O” button once to activate memory mode.



### ② View previous memory in order

Press the side UP button or DOWN button to scroll forward or backward to see all stored results. Your most recent result will display first.



Note: If there is no test result stored, the meter will display “ - - - ” for a few seconds, then automatically turns off.

## 28 | Memory and averages



### ③ View 7-, 14-, 28-day average

To access the average value display, press and hold the UP button on the side of the device for 3 seconds. The first memory display screen that appears shows your 7-day average, which includes all readings from the past seven days. From here, press the side UP button to see your 14-day average, press the side DOWN button to see your 28-day average.



### ④ Delete all memory

Press and hold the side DOWN button for about 3 seconds. After the memory is cleared, the meter will display “dEL” and then turn off automatically.

### ⑤ Exit

In memory mode, press and hold the “O” button for few seconds until the meter turns off.

## When to perform a control test

**Note:** The control solution test is only used to check that the meter is working properly. The meter will automatically identify the control solution test. When the control solution is identified, the result interface will display "➡" symbol and the meter will not store the test data of the control solution.

Control Solution contains a specific amount of glucose and is used to check whether the meter and the test strips are working properly.

### Do a control solution test:

- Whenever you open a new vial of test strips.
- Whenever you want to check if you are testing correctly.
- If you suspect the meter and test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- Your test result does not match how you feel.
- When you drop the meter.

### NOTE:

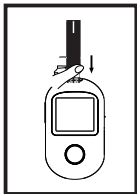
- Only use the Blood Glucose Control Solution.
- Close the control solution bottle tightly after each use.
- Write the date when you first open the control solution bottle on the bottle label. The control solution must be discarded 3 months after the first opening date or the expiration date on the vial label, whichever comes first.
- Do not use the control solution that exceeds the expiration date or discard date.
- Refer to the control solution label for control solution storage conditions.
- The control solution can stain fabric. Remove stains by washing it with soap and water.
- Keep away from direct sunlight, fluorescent light, and heat. Do not freeze.
- Shake the control solution well before using.
- Wipe the container tip clean after use and make sure to close it tightly.
- No reconstitution or dilution of the control solution is necessary.



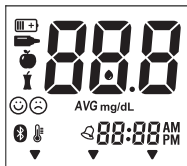
**CAUTION:** Do Not swallow control solution. It is not for human consumption. Do Not apply control solution to the skin or eyes as it may cause irritation.

# 30 | Control solution testing

## Performing a control test



- ① Insert a test strip to turn the meter on



- ② System check screen  
The screen will briefly display all content to confirm that the display is working properly.



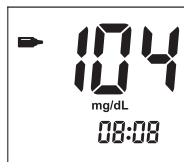
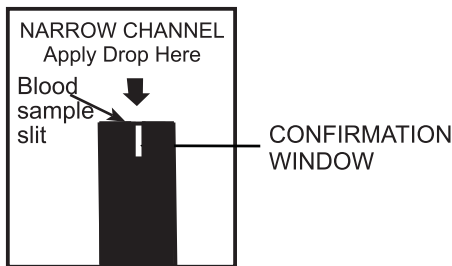
- ③ A blood drop symbol flashing on the screen indicates that the meter is ready for the test.

- ④ Shake the control solution vial before each test, then remove the cap and squeeze the vial to discard the first drop. After that, wipe the tip with a clean tissue. Hold the vial upside down and gently squeeze out a hanging drop.

## Performing a control test



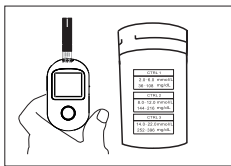
- ⑤ Touch the hanging drop of control solution with the narrow channel of the blood sample slit of the test strip to load the sample. Ensure that the confirmation window is filled. Do not apply control solution to the fat face of the test strip.



- ⑥ Once the confirmation window is full, the meter will start counting down from 5 and beep at the end. The blood glucose level will then appear, along with the testing date and time.

# 32 | Control solution testing

## Understanding out-of-range control test results



Each control solution has a specific glucose level range. Compare your test result with the range printed on the test strip vial or individually wrapped test strip to see if it falls within that range.

The following is an example set of data display on label:

CTRL 1: 36-108 mg/dL

CTRL 2: 144-216 mg/dL

CTRL 3: 252-396 mg/dL

Out-of-range results may be due to:

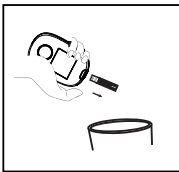
- not following the instructions correctly
- expired or contaminated control solution
- expired or damaged test strip
- meter malfunction



**CAUTION:** The control solution range printed on the test strip vial is for the Blood Glucose Control Solution only. It is not recommended range for your blood glucose level.



**CAUTION:** If you continue to get control solution test results that fall outside the range printed on the test strip vial, **Do Not** use the meter, the test strips, or the control solution. Contact the vendor.



⑦ Turn off your meter

To turn off the meter, press the eject button to release the test strip or remove it by hand. After that, the meter will automatically turn off.


Remember to handle the used test strip as mentioned before.

⑧ All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

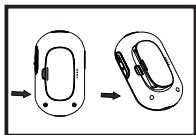
⑨ Wash their hands after completing the test and handling the meter.

## Replacing the battery

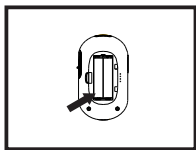
Your meter comes with two AAA alkaline batteries.

The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol “” appears on display screen until you change the battery.

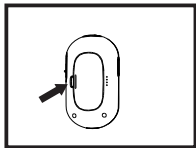
Important: When this symbol appears, you should replace the battery immediately as **following**.



- ① With the meter off, open the battery cover.



- ② Remove the old batteries and place the new batteries.



- ③ Put the battery cover back into position until it locks into place.

- ④ Check your meter settings  
Replacing the battery does not affect your stored results. However, you may need to re-set your meter settings. ‘See Setting Up Your Meter’ section.



Please dispose of the waste batteries according to the local regulations.

## **Meter maintenance**

Don't let dirt, dust, blood, control solution, water, or any other liquids get into the test strip port of the meter.

Important: Never soak the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.

## **Storing your system**

1. Store your meter, test strips, control solution and other items in your carrying case after each use.
2. Test strips and control solution should be stored between 33.8°F~86°F (1°C~30°C)/10%~90% relative humidity.
3. Meter and other items could be stored between -4°F~131°F (-20°C~55°C)/10%~95% relative humidity.
4. Do not refrigerate the test strips.
5. Keep everything away from direct sunlight and heat.
6. After use, make sure to tightly close the caps on the test strip vial and control solution vial to prevent contamination or damage.
7. Store test strips only in their original vial or individually wrapped test strip.

## **Checking for expiration and discard date of the test strips and control solutions**

When you get a new vial of test strips or control solution, look at the vial label for the expiration date. Write down the date you opened the vial and the discard date on the label. To find the discard date, read the instructions on the test strip or control solution vial.

## **Cleaning and Disinfection**

Cleaning is a normal part of maintenance of your meter and should be done before disinfection. Cleaning alone does not kill germs and the purpose is to remove debris and prepare for disinfection. Disinfection is an important step to reduce the risk of spreading disease.

# 36 | Maintenance

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

You should disinfect your meter once a week. The results of the cleaning and disinfection cycle's effect on the meter's performance have shown that the meter remains functional after 4000 cleaning and disinfection cycles.

Therefore, the cleaning and disinfection procedure would not damage the meter throughout its lifetime of 3 years. When assisting others with their blood glucose testing using their meter, you should disinfect the meter before testing.

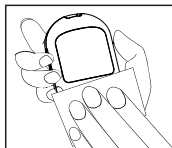
**Note:** The CaviWipes™ have been shown to be safe for use with our blood glucose monitoring system. It can be obtained from retail websites offering disinfection products, e.g., [www.officedepot.com](http://www.officedepot.com) or [www.staples.com](http://www.staples.com). For more information on purchase options, contact your local distributor.

## Cleaning your meter

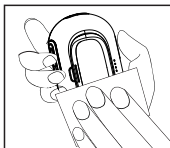
**Note:** The meter should be cleaned and disinfected whenever they are visibly dirty or a minimum of once per week.

Step 1: Take one piece of CaviWipes™ from the container.

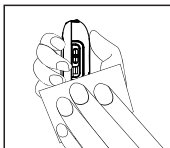
Step 2: Clean the entire meter surface for 2~3 minutes including frontside, back side, right side and left side.



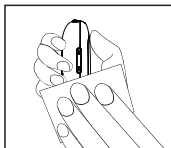
Front side



Back side



Right Side



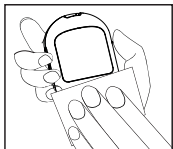
Left side

This cleaning is to prepare the meter surface for a disinfection process.

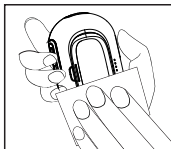
## Disinfecting Your Meter

Step 1: After cleaning your meter, take out another new piece of CaviWipes™ from the container.

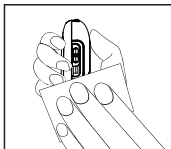
Step2: Wipe the entire surface including front side, back side, right side and left side of the meter, by a back and forth movement.



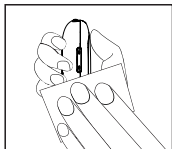
Front side



Back side



Right Side




Left side

Step 3: Keep the meter surface wet for at least 2~3 minutes.

Step 4: Let the meter air dry.

Step 5: Check the meter for any signs of damage, Examples of damage may include a fogged display, cracked case, illegible labels, a button not working, or meter malfunction (such as repeated error messages).

**CAUTION:** Do not use your meter if you notice any damages. If you have any questions about cleaning or disinfection, or if you notice any damage, please Contact Customer Service at 917 2953887. Phone support is available from 8:00 AM -4:30 PM ET. Monday- Friday.

Message	Possible Cause	What to do
E-1	The system check may be failed	Remove the battery and reinsert it after 30 seconds. If it still doesn't work, please contact the vendor.
E-2	The test strip may be used or damaged.	Make sure that the strip model is correct and retest with a new strip.
E-3	The sample was applied before the meter was ready.	Repeat with a new strip. Applying blood after the  symbol flashes on the screen.
E-4	The test strip may be moved during testing or sampling data is unstable.	Retest with a new strip. Make sure that the method of applying sample is correct, and test strip can not be moved during testing.
E-5	The meter encountered a problem and cannot read the test strip.	Make sure correct test strip was used. Retest with a new Blood Glucose test strip.



Battery power is low.

Replace the battery



The meter is out of operating temperature range.

Place the system in appropriate operating environment for 30 minutes before retesting.

## Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
Battery power is low.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly.
Test strip inserted upside down, or incompletely inserted into the meter.	Check that the test strip is inserted correctly.
Defective meter or test strips.	Contact the vendor.
Blood or foreign objects put into the test strip port.	Contact the vendor.

## Test does not start after applying the blood sample.

Probable Cause	What to Do
Defective test strip.	Repeat the test with a new test strip.
Sample applied after meter times out and turns off.	Remove the test strip, and repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Contact the vendor.

## Meter Specification

Product description	Advance Link Blood Glucose Monitoring System
Assay method	Glucose dehydrogenase biosensor
Measurement range	20~600 mg/dL
Sample	Fresh capillary whole blood from the fingertips
Sample size	Approximate 0.6 microlitre
Response time	5 seconds
Calibration	Plasma equivalent glucose values
Battery	2xAAA alkaline batteries
Battery life	Approximately 1,000 tests
Unit of measure	mg/dL only
Memory	1000 blood glucose results with date and time
Size	3.74*2.22*0.90in(94.9*56.5*22.8 mm)(L*W*H)

# 42 | Technical information

## Specifications

LCD size	1.39*1.22 in (35.4*30.9mm)(L*H)
Weight	Approximate 50g, battery not included
Operating environment	41°F~113°F(5°C~45°C)
	10~90% RH (non-condensing)
Meter storage environment	-4°F~131°F(-20°C~55°C)
	10~95% RH (non-condensing)
Strip storage environment	33.8°F~86°F(1°C~30°C);10~90% RH (non-condensing)
Altitude	Up to 10,000 feet (3,048 meters) above sea level
Hematocrit	15%~60%
Meter Shelf life	Three years
Ingress protecting rating	IP22

## Electromagnetic Compatibility

This meter complies with CISPR11: Class B (Radiated Only). The emissions of energy used are low and not likely to cause interference to other electronic equipment nearby. The meter has been tested for electrical, mechanical, and thermal safety according to the IEC 60601-1-2 standard. Additionally, it has been tested according to the IEC 60601-4-2 standard. This system meets all requirements.

Do not use the meter close to sources of electromagnetic radiation such as cell phone, transceiver, radio control products, antennas, or other portable radiofrequency (RF) communications equipment that might be found in the home environment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) from the meter when testing your glucose. If too close, degradation of the meter's function of measuring your blood glucose level may result due to electromagnetic interference from RF communications equipment. In the unlikely event that there is interference from RF communications equipment and the meter's function is degraded, it is recommended that you increase the separation distance between the meter and the source of interference. You can also turn off the interfering device. Electromagnetic interference cannot damage the meter, but only temporarily degrades its function, and when removed, the meter's full function is immediately restored.

## Disposing of the meter test strips and batteries

Contact your health care professionals for proper handling and disposal of used meters, used test strips, used disposable safety lancets, and used batteries. Please consider the following points when disposing of used testing materials:

- Consider recycling the meters and batteries at an appropriate facility. Be aware that the meter is a potentially hazardous electronics scrap(e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be disposed of accordingly.
- Disinfect the meter before disposal.

\*29 CFR 1910.1030-Blood-borne pathogen control

\*Directive 2002/96/EC-Directive on waste electrical and electronic equipment(WEEE)

## Limited 2-Year Warranty

The meter is guaranteed for 2 years from the date of purchase. If the meter does not function properly due to defective components or poor workmanship, we will repair or replace it free of charge. This warranty does not cover damage caused by improper handling. Please note that the battery is not included in the warranty.

**Range:** The display range of the meter is 20 mg/dL to 600 mg/dL. "Hi" and "Lo" messages indicate results outside of this range.

• **Accuracy for Home use by lay-users.**

The table below shows the results where typical users enrolled in a clinical study used the Blood Glucose Meter to measure their blood glucose levels. In this study, the Blood Glucose meter displayed results within 15% of their actual blood glucose level in 346 out of 352 measurements as compared to an approved lab instrument.

Different range between the actual blood glucose level and the Advance Link Blood Glucose Meter result.	Within 5%	Within 10%	Within 15%	Within 20%
Percent(and number) of samples within specified rang	56.8% (200/352)	90.3% (318/352)	98.3% (346/352)	100.0% (352/352)

Accurate Results (Meter result is +/-15% of laboratory result)	346 out of 352 (98 .3% of results)		
More Accurate Results (Meter result is +/-10% of laboratory result)	318 out of 352 (90 .3% of results)		
Most Accurate Results (Meter res ult is +/-5% of laboratory result)	200 out of 352(56 .8% of results)		

A linear regression analysis was performed to evaluate the correlation between the self-test results and the corresponding capillary blood YSI2300 comparator test results. The results of the correlation analysis are presented in table below.

Regression Statistics	Percentages listed are meter results as compared to laboratory result
Observations	352
R Square	0.9867
Y-Int	1.2035
Slope	1.0244

# 46 | Performance Characteristics

## • Precision

Within Run Precision (300 Venous Blood Tests per glucose level)

Mean,mg/dL	Standard Deviation,mg/dL	Coefcient of Variation,%
40.23	1.72	4.27%
90.08	2.70	2.99%
130.04	3.28	2.52%
204.89	4.80	2.34%
348.52	7.66	2.20%

## • Intermediate Precision

Within Run Precision (300 Control Solution Tests per Glucose Level)

Control level	Mean, mg/dL	Standard Deviation, mg/dL	Coefcient of Variation, %
1	40.18	1.93	4.80%
2	91.98	2.93	3.18%
3	134.74	3.21	2.38%
4	195.29	4.72	2.42%
5	325.35	7.68	2.36%












To maximize the accuracy of comparing your self-test results with laboratory test results, you may follow these guidelines:




Before going to the lab:

- Perform a control solution test to ensure the meter is functioning correctly.
- Avoid eating for at least eight hours before testing your blood.
- Remember to bring your meter with you to the lab.

While at the lab:

- Conduct your meter test within 15 minutes of the lab test.
- Follow all instructions in this Owners Booklet for performing a blood glucose test with your meter.
- Use only fresh, capillary blood obtained from your fingertip.

	Consult instructions for use
	In vitro diagnostic medical device
	Serial number
	Caution
	Batch code
	Manufacturer
	Contain sufficient for $\langle n \rangle$ tests
	Storage temperature limitation
	Do not reuse
	Use by
	Storage humidity limitation

	Keep dry
	Please dispose of the waste according to the local regulations
	Direct Current
<b>IP22</b>	The first num.2: Protected against solid foreign objects of 12.5mm Ø and greater The second num.2: Protection against vertically falling water drops when ENCLOSURE tilted up to 15°

For more information see:

--FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens:

Initial Communication.

--CDC website on “Infection Prevention during Blood Glucose Monitoring and Insulin Administration.”

Document No: DBG-1404-087  
Version: C  
Date of Issue: 2025-05-13

Contact Customer Service at 917 2953887. Phone support is available from 8:00 AM -4:30 PM ET, Monday-Friday. For questions at all other times, contact your healthcare professional.

Manufactured by Sejoy Biomedical Co., Ltd.  
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