wellion®

GALILEO audio

MANUAL



Dear Wellion GALILEO audio owner,

Thank you for choosing the GALILEO audio blood glucose monitoring system to help you monitoring your blood glucose sugar levels.

Your new GALILEO audio blood glucose monitoring system is designed with convenience and accuracy in mind to make your life a little easier. The added convenience of the bilingual voice feature can be used as a verbal aid for using the meter and hearing test results by visually impaired users. All of the information needed to use and maintain your new meter is included in this manual. Please read it carefully.

Your GALILEO audio blood glucose monitoring system provides an easy and precise way to measure blood glucose using fresh capillary whole blood taken from fingertips, palm, or forearm. Testing is done outside the body (in vitro diagnostic use). The test results are plasma-calibrated for easy comparison to lab results. The GALILEO audio blood glucose monitoring system is a portable battery operated meter intended for use as an aid by persons with diabetes and by health care professionals to monitor glucose concentration in whole blood.

INTENDED USE

The Wellion GALILEO audio 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. The meter includes voice functionality to assist visually impaired users. It is indicated for self-testing use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

IMPORTANT:

- Dehydration – Severe dehydration may lead to inaccurate blood glucose test result. If you suspect you are severely dehydrated, contact your healthcare professional immediately.
- Hematocrit range – A hematocrit range that is higher than 70% or lower than 10% can cause inaccurate blood glucose test results.
- Not intended for use on neonates.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use).

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.

UNDERSTANDING YOUR NEW BLOOD GLUCOSE KIT

The **Wellion GALILEO audio** blood glucose monitoring system kit includes the following items:

Wellion GALILEO audio blood glucose meter
Wellion Lancing Device
10 Wellion Lancets
Owners Guide
Easy Start Guide
Carrying Case

IMPORTANT:

- Contents may change without notice.
- Lancets, Lancing Device and Control Solutions are optional components. Please contact the local distributor for purchasing information.

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Wellion GALILEO audio meter

Test Strip Port:
Insert test strip to turn on the meter.

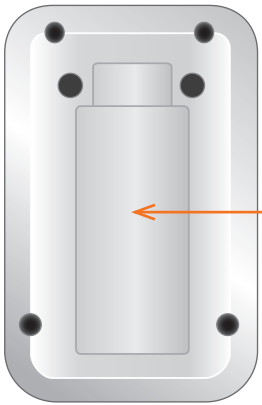


Meter Display:
Shows your blood glucose test results, memory values, averages, and other messages.

Enter ⏻ and ▲ ▼ buttons:

Press and hold Enter ⏻ for 2 seconds to turn on or off the meter, or press Enter ⏻ to go into setup mode when not testing. Press ▲ or ▼ to enter control mode with test strip inserted, during meter setting, or to navigate the stored test values and averages.

Wellion GALILEO audio meter



Battery Compartment:
Holds two AAA batteries.

Data port:
Transmits data to computer.

Meter display screen

Data port
Transmits data to computer.

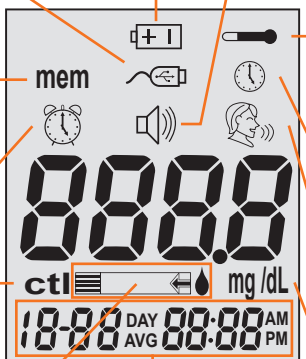
MEM
Indicates the number on the meter display is a stored test value.

Alarm
Indicates alarm has been set.

CTL
This icon indicates a control solution test or the stored value is a control solution result.

Blood drop and arrow
Indicate the meter is ready for testing.

Battery
Appears when batteries need to be changed.



Displays the date, time, am/pm (in 24-hours format, or type of day averages (7, 14 or 30).

Beeper
Set sound volume.

Temperature
Appears when it is either too hot or too cold to test. (outside the ranges of 5°C - 45°C).

Clock
Indicates the meter is ready to set up time and date.

Voice
Indicates the voice feature is on.

Units
Unit of measurement for your blood glucose is mg/dL or mmol/L.

The Wellion GALILEO blood glucose test strip

Sampling Area
The area where the blood sample or control solution is applied



Contact Points
Insert this end to the test strip port on the meter

The **Wellion GALILEO** blood glucose test strips are glucose specific, biosensor-based test strips that can test glucose in capillary whole blood in as quick as 5 seconds and requires a very little blood sample. The test result is plasma referenced for easy comparison to lab results and has underfill detection to alert you when there is not enough blood to perform a test, so you can be sure that each reading you get is an accurate and meaningful result.

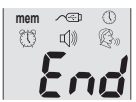
IMPORTANT:

- Be sure to use only the Wellion GALILEO Blood glucose test strip with the Wellion GALILEO audio meter. Other brands of test strips will not work with the meter.
- The Wellion GALILEO blood glucose test strips are sensitive to moisture and light, it is important to tightly close the vial cap of the test strip vial immediately after each use. DO NOT leave any test strips outside the vial while not in use.
- Carefully discard used test strips and lancets in accordance with local guidelines.
- DO NOT reuse. Test strip is for single use only.

SETTING UP YOUR NEW SYSTEM

The Setup Screen

The Setup Screen of the Wellion GALILEO audio meter lets you take advantage of the advance functions of this meter. Simply use ▲ ▼ buttons to navigate to the desired function icon, and press the Enter (⏻) button to enter the function when the icon is flashing. Navigate to End at the display screen to exit the Setup Screen. The Meter will also announce each function when the voice feature is on.



Mem	Press Enter (⏻) to enter Memory Recall to retrieve stored results. Your meter can memorize up to 300 memories with date and time.
Data port	Transmits data to computer.
Clock	Press Enter (⏻) to enter Time and Date Setup
Alarm	Press Enter (⏻) to enter Alarm Setup. Your meter can have as much as 3 alarm settings.
Beeper	Press Enter (⏻) to enter Volume Setup.
Voice	Press Enter (⏻) to enter Language Selection.
End	Exit Setup Screen and return to testing.

Setting the Clock

You will need:
Your Wellion GALILEO audio meter

NOTE:
If date and time on the Wellion GALILEO audio meter has not been set, test or control result will not be stored in memory.

Step 1: Press and hold Enter (⏻) to turn on the meter.

Step 2: Press Enter (⏻) to go into setup screen, then press ▲ or ▼ until 🕓 start to flash. If the voice function is on, the meter will say, *"Set date and time"*. Press Enter (⏻) to enter clock setup.

Step 3 - Set the Year: The current year will flash. If the voice function is on, the meter will say, *"Set Year"*. Press ▲ or ▼ to select the correct year. Press Enter (⏻) to confirm your choice and advance to set the month.

Step 4 - Set the Month: The current month will flash. If the voice function is on, the meter will say, *"Set Month"*. Press ▲ or ▼ to select the correct month. Press Enter (⏻) to confirm your choice and advance to set the date.



Step 5 - Set the Date: The current date will flash. Press ▲ or ▼ to select the correct day. If the voice function is on, the meter will say, *"Set Day"*. Press Enter (⏻) to confirm your choice and advance to set time format.



Step 6 - Set Time Format to 12-hour or 24-hour: The current time format will flash. If the voice funtion is on, the meter will say, "Set 24 hours." Press ▲ or ▼ to select for either 12-hour format or 24- hour format. Press Enter (⏻) to confirm your choice and advance to set hour.



Step 7 - Set the Hour: The current hour will flash. If the voice function is on, the meter will say, *"Set Hour"*. Press ▲ or ▼ to select the correct hour. Press Enter (⏻) to confirm your choice and advance to set minutes.



Step 8 - Set Minute: The current minutes will flash. If the voice function is on, the meter will say, *"Set Minutes"*. Press ▲ or ▼ to select the correct minutes. Press Enter (⏻) to confirm your choice and finish setting the clock.



NOTE:

- Anytime during set up, inserting a Wellion GALILEO blood glucose test strip will begin testing. Any changes made so far are stored.
- You may need to reset time after changing batteries.

After date and time has been set, the meter will announce the date and time if the voice feature is on. Begin testing by inserting an Wellion GALILEO blood glucose test strip, or press and hold Enter (⏻) to turn off the meter, or see the next section on how to set up the alarm feature on your meter.

Setting the Alarms

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

You will need:
Your Wellion GALILEO audio meter



Step 1: Press and hold Enter (⏻) to turn on the meter.

Step 2: Press Enter (⏻) to enter setup screen.

Step 3: Press ▲ or ▼ until start to flash. If the voice function is on, the meter will say, *"Set testing Alarm"*. Press Enter (⏻) to enter alarm setting.

Step 4: The display screen will indicate alarm 1 status (the default is OFF). You can turn it on or off by pressing ▲ or ▼.



Step 5: Press Enter (⏻) and the hour will flash. Press ▲ or ▼ to select the hour. Press Enter (⏻) to confirm your choice and advance to set minutes.

Step 6: The current minutes will flash. press ▲ or ▼to select the correct minutes. Press Enter (⏻) to confirm your choice and advance to set alarm 2.



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

NOTE:

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

Begin testing by inserting a Wellion GALILEO blood glucose test strip, or press and hold Enter (⏻) to turn off the meter, or see the next section on how to set up the voice feature on your meter.

Voice and Beeper Function

Your meter has a bilingual voice function that can be used as a verbal aid for using the meter and hearing test results. The default setting for the voice function is on, and can be switched off to conserve battery power. When the voice function is off, the meter will beep to alert you to important messages.

You will need:
Your Wellion GALILEO audio meter

Setting Volume:



Step 1: Press and hold Enter (⏻) to turn on the meter.

Step 2: Press Enter (⏻) to go into setup screen. Press ▲ or ▼ until 🔊 start to flash. Press Enter (⏻) to enter volume setting.



Step 3: The display screen will show the current sound volume (default is 2). Press ▲ or ▼ to adjust the sound volume from 1 (lowest) to 5 (highest). A melody will sound according to the sound volume you have selected. Setting to 0 will turn off the voice function. The meter will instead beep to alert you to important messages. Once you have determined the suitable volume, press Enter (⏻) again to exit volume setting.

Setting Language:



Step 1: Press and hold Enter (⏻) to turn on the meter.

Step 2: Press Enter (⏻) to enter setup screen.



Step 3: Press ▲ or ▼ until start to flash. The meter will announce *„Language Selection“*.

Step 4: The default language (1 on the display screen) is announced. Press Enter (⏻) to change the language. Press ▲ or ▼ to select another language. Press Enter (⏻) when you have finished selecting the language and exit language selection.

NOTE:

- Any time during set up you can insert a Wellion GALILEO blood glucose test strip and begin testing. Any changes made so far are stored.
- Your choice of language and volume settings will not be erased when changing batteries.

Begin testing by inserting an Wellion GALILEO blood glucose test strip or press and hold Enter (⏻) to turn off the meter.

VOICE FUNCTION TABLE

The voice function can be used as an aid for you to hear the test results and use the meter. The following table lists WHEN the meter will speak and WHAT the meter will say.

WHEN the meter will speak…	WHAT the meter will say…
Turned on.	Greeting Tone.
Prompt user to insert test strip.	*"Please insert test strip"*
Test strip is inserted and the meter is ready to test (with flashing arrow and blood drop).	*"Blood glucose test. Please apply blood to the test strip."*
Blood Glucose test is completed and the result is shown on screen.	*"Your blood glucose reading is (number) milligram per deciliter or millimol per liter."*
Blood Glucose test result is BELOW the measurement range of 20 mg/dL or 1.1 mmol/L.	*"Your blood glucose reading is below 20 mg/dL or 1.1 mmol/L."*
Blood Glucose test result is ABOVE the measurement range of 600 mg/dL or 33.3 mmol/L.	*"Your blood glucose reading is above 600 mg/dL or 33.3 mmol/L."*
Temperature is out the range of 5˚C - 45˚C.	*"Temperature is out of range"*
When the meter is turned off.	Melody

Test Strip is inserted and press ▲ or ▼ (CTL showing next to the test strip icon).

„Blood glucose test. Please apply blood onto the test strip.“



“L2 Control solution test. Please apply control solution onto the test strip.”

“L1 Control solution test. Please apply control solution onto the test strip.”

Setting meter funktions via the setup screen

Pressing Enter (⏻) to enter setup screen (after the meter has been turned on).



Memory recall



End up function mode



Language selection

PC Link





Set date and time



Set testing alarm



Set sound volume

WHEN the meter will speak…	WHAT the meter will say…
During date and time setup, setting up the year	*"Set Year"*
During date and time setup, setting up the month	*"Set Month"*
During date and time setup, setting up the day	*"Set Day"*
During date and time setup, setting up the hour	*"Set Hour"*
During date and time setup, setting up the Minutes	*"Set Minutes"*
After finish setting up date and time	*"The date and time is (year) (month) (day) (hour) (minutes)"*
Setting alarm 1, 2, or 3	*"Set Alarm (number)"*
When sending data to PC	*"Sending data to PC"*
Finish sending data to PC	*"Data transmission complete"*

Other warning messages

WHEN the meter will speak…	WHAT the meter will say…
Meter date and time has not been set	*"Please set date and time"*
Meter failure	*"Error 1 Meter Failure"*
Apply blood before blood drop icon appears	*"Error 2 Test Error"*
Used test strip	*"Error 3 used test strip"*
Not enough blood or control solution	*"Error 4 not enough sample"*

CONTROL SOLUTION TESTING

The purpose of the control solution testing is to make sure the Wellion GALILEO audio meter and the Wellion GALILEO blood glucose test strip are working properly. You can perform control solution testing when:

- Using the meter for the first time
- You leave the test strip vial cap open for a while
- You drop the meter
- You suspect your meter and test strips are not working properly
- The blood glucose test results do not reflect how you feel
- You want to practice the testing procedure

IMPORTANT:

- Use only the Wellion GALILEO blood glucose control solutions with the Wellion GALILEO blood glucose test strips. Other brands of control solution will produce inaccurate result.
- Always check the expiration date. DO NOT use control solutions if they are expired.
- After the first opening, a control solution bottle can be kept for up to three months.
- DO NOT FREEZE. Store the control solutions at 4 °C - 30 °C.

Control Solution Testing:

You will need:
Your Wellion GALILEO audio meter
Wellion GALILEO blood glucose test strip
Wellion GALILEO blood glucose control solution (Level 1 and Level 2)

Step 1: Take out an Wellion GALILEO blood glucose test strip from the test strip vial and close the vial immediately. Insert the test strip to turn on the meter.

IMPORTANT:

- Check the expiration date printed on the test strip vial. Do not use expired test strips.
- Use each test strip immediately after removing it from the vial.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat . Store the test strip vial in a dry, cool place.
- Record the „date opened" on the vial label. Discard the vial and any remaining test strip after 12 months from date of first opening.
- Test under the temperature range of 5 ˚C to 45 ˚C . Your meter will not work outside these ranges.
- Must insert test strip into the test strip port.
- Must see a flashing blood drop icon when the test strip has been inserted into the test strip port.
- Close the cap of the test strip vial immediately after you take the strip out.

Step 2: Wait until the flashing blood drop and arrow icons appear on the meter display screen. The meter will also announce, *"Please apply blood onto the test strip"* if you have the voice feature turned on. Press ▼ to enter Level 1 control solution testing.



Step 3: ctl icon will appear next to the test strip icon. The meter will also announce "control solution test, please apply control solution onto the test strip." If you decide not to do a control solution test, press ▲ until ctl disappear from the meter display.

NOTE:

- Shake the control solution bottle gently before use.

Step 4: Squeeze a drop of control solution onto a clean, dry, nonabsorbent surface. Do not apply control solution to the test strip directly from the vial. Replace the vial cap on the control solution vial immediately after use.



Step 5: Gently touch the drop of the control solution to the tip of the test strip. The meter will beep indicating it has received the control solution.

Step 6: The screen will start to count down. After 5 seconds, the control test result will appear on the meter's display screen.



Step 7: Compare the reading on the screen to the control range printed on the test strip vial or its package. If the reading falls outside the control range printed on the test strips vial or its package, repeat the test. If the reading still falls outside the control range contact your customer service for support.



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

Step 8: Remove the used test strip. The meter will automatically turn off. Discard the used test strip into a proper wastebasket.

IMPORTANT:
- DO NOT reuse. Test strip is for single use only.

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

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 • Control solution not stored at 4°C - 30°C (39°F - 86°F) • Expired or contaminated control solution or damaged test strip • Meter malfunction	• Make sure you are using Wellion GALILEO blood glucose control solution. • Make sure the testing environment is between 5 ˚C and 45 ˚C. • Check the expiration and open vial date on both the control solution and test strips. Repeat testing using a new test strip. If the result is still out of range, use a new vial of control solution and retest. • If problem persists, please call the local distributor for questions and inquiries.

TESTING YOUR BLOOD GLUCOSE

You will need:
Your Wellion GALILEO audio meter
Wellion GALILEO blood glucose test strip
Lancing device with a sterile, unused lancet

Before you begin, make sure:

- To set up your meter properly, please see "Setting Up Your New System" for details.
- Wash your hands and the testing site thoroughly with soap and warm water, and dry well.
- You are testing in an area between the temperature ranges of 5 ˚C - 45 ˚C . Your meter will not test outside of this range and will display thermometer icon with verbal indication if the voice feature is turned on. Move the meter into an area that is within 5 ˚C - 45 ˚C , and let it sit for 10 to 15 minutes before testing again.
- If the meter is being operated by a second person who is providing testing assistance to you, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

IMPORTANT:

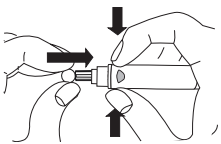
- Check the expiration date printed on the test strip vial. DO NOT use expired Test Strips.
- When you open a vial of Test Strips for the first time, record the "open date" on the test strip vial. Discard the vial and any remaining Test Strips 12 months after the open date.
- After taking a Test Strip out of the vial, close the cap of the vial immediately.
- Use each Test Strip immediately after taking it out from the vial.
- Do not use wet, bent, scratched, or visibly damaged Test Strips.
- Keep the Test Strips away from direct sunlight and heat. Store the test strip vial in a dry, cool place.

Preparing Your Lancing Device

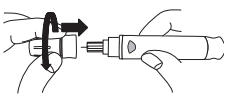
CAUTION:

- Lancets are for single use only. ② 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 of used lancets properly in biohazardous waste.
- If alcoholic wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

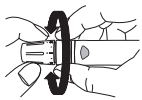
Step 1: Wash the puncture site with soap and warm water and dry thoroughly. Warm water stimulates blood flow making it easier to obtain a sample.



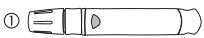
Step 2: Hang the arm down at the side for 10 to 15 seconds massaging through the wrist, palm, and then finger. This can stimulate the blood flow more quickly.



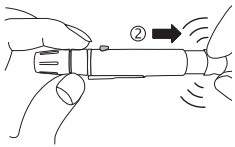
Step 3: Unscrew the adjustable cap of the lancing device and insert the lancet by pushing down firmly until it is fully seated.



Step 4: Twist the protective cover off from the lancet. Replace the adjustable cover back onto the lancing device.



Step 5: Adjust the puncture setting on the adjustable cap for the puncture depth level (1 is the lightest and 10 is the deepest).



Step 6: With one hand holding the lancing device, pull back the cocking handle with your other hand until you hear a click sound and the lancing device is ready.

The release button should now be coloured red to indicate the lancing device is ready for blood sampling.



If the release button is not red, pull the cocking handle again until the release button changes the colour to red.



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 Wellion GALILEO audio blood glucose monitoring system can test for blood glucose from areas other than your fingertip such as palm and forearm (alternative site testing, or AST). Alternative site testing can be less painful than fingertip testing, because of the physiological differences between your fingertip and palm and forearm [1]; alternative site test result may be significantly different than results from fingertip testing under certain conditions. You should consult with your doctor or healthcare professional before using alternative site testing.

DO AST ONLY in the following intervals:

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

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).

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

Alternative Site Testing SHOULD NOT be used when:

- You are Hypoglycemic unaware (not able to feel 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.

NOTE:

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

[1] Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708–709, 2005

Performing a Blood Glucose Test



Step 1: Take out an Wellion GALILEO blood glucose test strip from the test strip vial and close the vial immediately. Insert the test strip to turn on the meter.

IMPORTANT:

- Check the expiration date printed on the test strip vial. Do not use expired test strips.
- Use each test strip immediately after removing it from the vial.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip vial in a dry, cool place.
- Record the „date opened" on the vial label. Discard the vial and any remaining test strip after 12 months from date of first opening.
- Must insert test strip into the test strip port.
- Must see a flashing blood drop icon when the test strip has been inserted into the test strip port.

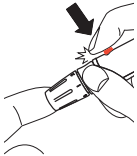


Step 2: Wait for a flashing blood drop and an arrow icon appears on the meter display screen. The meter will also announce, "Please apply blood onto the test strip" if you have the voice feature turned on.

Step 3 - obtain blood sample:

For Fingertip Testing:

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

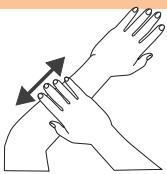


TIP:

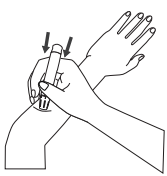
- Gently message your hand and finger toward the puncture site to form a drop of blood. Do not "milk," or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

For Testing on Palm and Forearm:

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 lancing device firmly against the puncture site and then press the release button.



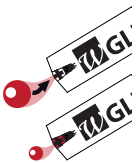
For forearm testing only, rub testing area vigorously until it feels warm to increase blood flow. Press the lancing device firmly against the puncture site

and then press the release button. Keep the device in constant contact with the skin and apply and release pressure up and down 2–3 times without lifting device away from skin.
When the blood is about the size of a pen tip 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: Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.



Step 5: The screen will start to count down. After 5 seconds, your glucose testing result will appear on the meter display screen and announced verbally if you have the voice feature turned on. Your test result will be automatically stored into the meter memory.



CAUTION:

- If you see "HI" or "LO" displayed, your blood glucose level may be above 600 mg/dL or 33.3 mmol/L or below 20 mg/dL or 1.1 mmol/L. Test again using fingertip testing, DO NOT test on forearm. If you still receive the same result, call your physician or healthcare professional immediately.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Clean the meter and lancing device after the test (see cleaning).

Step 6: Remove the used test strip into proper wastebasket. The meter will automatically shut off.

Step 7: Remove the used lancet from your lancing device according to instructions and discard into proper wastebasket.

CAUTION:

- Lancets are for single use only. ② 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 of used lancets properly in biohazardous waste.
- If alcoholic wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

UNDERSTANDING YOUR BLOOD GLUCOSE TEST RESULTS

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

- less than 100 mg/dL or 5.5 mmol/L before meals.
- less than 140 mg/dL or 7.8 mmol/L after meals.

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

What to do if you get a high or low reading

If the Meter displays results that are HI or LO, or you get a result that is more than 250 mg/dL (13.9 mmol/L) or below 50 mg/dL (2.8 mmo/L) AND you feel ill:

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

If the Meter displays results that are "HI" or "LO," or you get a result that is more than 250 mg/dL (13.9 mmol/L) or below 50 mg/dL (2.8 mmol/L) AND you DO NOT feel ill:

- Test your meter with a control solution.
- Test again using fingertip.

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

NOTE:

- 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, Clinical Practice Recommendations (2013) Diabetes Care, Vol. 36, Supplement 1, p S1–S100.

VIEWING YOUR METER'S MEMORY

Your Wellion GALILEO audio meter automatically stores up to 300 test and control results with date and time. The meter also provides 7, 14, and 30 days averaging to help track your blood glucose trend. You must set up the date and time on your meter to use the memory and day averaging function. The meter will not memorize test or control results if the date and time are not set.

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

You will need:
Your Wellion GALILEO audio meter



Step 1: Press and hold Enter (⏻) to turn on the meter.

Step 2: Press Enter (⏻) to enter setup screen.

Step 3: Press ▲ or ▼ until mem starts to flash. If the voice function is on, the meter will say "memory recall." Press Enter (⏻) to enter.



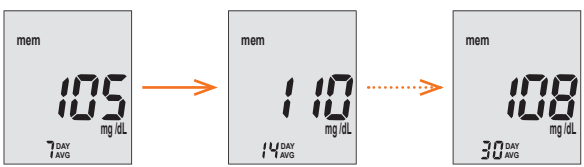
mem will appear at the upper left corner of the display screen together with your most recent testing result. Press ▲ to see the next result , and the next, and so on. Holding ▼ will flash through the results.

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



Step 4: When you reach the most recent result, continue to press ▼ to start viewing day averages. The meter will display the 7 days average, press ▼ again to see 14 days average, and press ▼ again to see 30 days average.

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



NOTE:

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

Upload Data

When "⌁" icon is flashing, press "⏻" button to enter PC mode. Then follow the Data Management System (DMS) instruction manual to upload data.



For purchase information of DMS, please contact the local distributor.

NOTE:

- The upload feature should be used only with DMS products that specifically identify the Wellion GALILEO audio as a meter that is compatible with their DMS.

CARING FOR THE METER

Caring for your Wellion GALILEO audio Meter is easy. Follow these simple guidelines to keep your meter working properly.

Changing the Battery

Batteries need to be changed when the [+ I] icon appears on the meter display.



You will need:
Your Wellion GALILEO audio meter
Two Alkaline AAA Batteries

Step 1: Press firmly on the battery cover and slide in the direction of the arrow.

Step 2: Insert new batteries [+ I]. Slide the battery cover back into the meter firmly.

NOTE:

- Meter will prompt you to reconfirm the date and time when turned on.
- The date, stored results, alarm settings, volume setting, and language choice stay in memory when the batteries are changed.
- Remove the batteries if not used for a long time.

Cleaning the Meter

- If the meter gets dirty, use a moist (NOT WET) lint-free cloth dampened with a mild detergent.
- Do not get water inside the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.

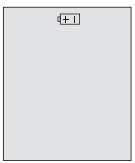
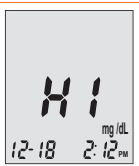
Storage and Precautions

- The Meter and the Test Strips are designed to be used within a temperature range of 5˚C to 45˚C . Do not leave in hot car.
- Avoid leaving the Meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the Meter or Test Strips at high humidity levels, such as in the bathroom or kitchen.
- Always close the cap of the test strip vial immediately after removing a Test Strip. Make sure the cap is tightly closed.

SOLVING PROBLEMS

This section details the significant display screen messages and error codes you will encounter when using your Wellion GALILEO audio meter and Wellion GALILEO blood glucose test strips.

What you see	What the meter says	What it means	What you should do
	*"Error 1 meter failure"*	The meter electronic or test strip is damaged.	• Remove the battery and turn on the Meter again. • Remove the test strip and insert a new test strip again. • If problem persists, call the local distributor.
	*"Error 2 test error"*	Error during the test	Retest using a new strip and carefully follow the instruction on testing. If the same error message shows up again, use another meter and new strip to test or call the local distributor.

	*"Error 3 used test strip"*	Used or damaged test strip	Repeat the test with a new test strip. Remember add sample only until you see the prompt on the display screen or the meter verbally prompts you to add sample.
	*"Error 4 not enough sample"*	Not enough blood for testing	Remove the Test Strip and repeat the test with a new test strip.
	*"Low battery"*	Batteries are low	Change the battery.
	*"Your blood glucose reading is above 600 mg/dL (33.3 mmol/L) "*	Test result is higher than 600 mg/dL (33.3 mmol/L)	Wash and dry your hands and repeat the test on your fingertip with a new test strip. If the result is still "HI," contact your physician or healthcare professional immediately.

	*"Your blood glucose reading is below 20 mg/dL (1.1 mmol/L) "*	Test result is lower than 20 mg/dL (1.1 mmol/L)	Wash and dry your hands and repeat the test on your fingertip with a new test strip. If the result is still "LO," contact your physician or healthcare professional immediately.
	NA	There are no memorized results in the meter	• Check if the date and time on your meter is set up. • Start testing your blood glucose.
	*"Temperature is out of range"*	Temperature out of range	Move the meter into an area that is within 5 ˚C to 45 ˚C, and allow 10 to 15 minutes for it to reach the new temperature.

SPECIFICATIONS

Test strips:	Wellion GALILEO blood glucose test strips
Test range:	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Calibration:	Plasma
Test time:	5 seconds
Sample size:	≥ 0.5 µL
Hematocrit range:	10 - 70%
Display type:	Large LCD screen
Memory:	300 blood test results with date and time
Result Averaging:	7, 14 and 30 days averaging
Dimension:	93 L x 58 W x 20.5 H (mm)
Weight:	79g
Battery:	2 Alkaline AAA batteries
Battery life:	1.000 tests of continous use or 1 year
Automatic Power-off:	After 2 minutes of nonuse
Operating Temperature:	5 °C to 45 °C
Relative Humidity:	20 to 90%
Storage/Transport Condition:	Meter at -20 °C to 50 °C Test strips at 4 °C to 30 °C

For additional information, refer to the Wellion GALILEO blood glucose Test Strip insert.

Classification according to IEC/EN 61326-1: IPXO, not evaluated as AP/APG equipment, continuous operation.

Electromagnetic Compatibility: This equipment complies with EMC requirement of EN IEC 61010-2-101:2022+A11:2022 und EN IEC 61326-2-6:2021

EU directive/classification: 98/79/EC Annex II, List B

SYMBOLS

	Use-by date
LOT	Batch code
	Temperature limit
	Consult instructions for use
IVD	In vitro diagnostic medical device
	Caution
REF	Catalogue number
	Keep away from sunlight
	Do not re-use
	Manufacturer
	Do not use if package is damaged and consult instructions for use
FOR SELF-TESTING	In vitro diagnostic, medical device for self-testing
	Separate collection for EEE (Electrical and Electronic Equipment)

MANUFACTURER'S WARRANTY

The manufacturer warrants the Wellion GALILEO audio blood glucose meter guarantee for material and manufacturing defects for a period of two years from date of purchase. This guarantee is lost when the device is not used as intended, has been poorly maintained or opened.

Warranty is limited to the repair of defective parts or - in accordance with the manufacturer - in replacement of the device. The right to cancel the purchase applies only if the replacement goods are also faulty. Other claims cannot be accepted. Warranty by MED TRUST is limited to the repair or replacement of the device and in no case can MED TRUST be held responsible for any collateral or consequential damages or losses.

The warranty is invalidated by damage from improper use, non-authorized repair or modification to the device.

Consumables are explicitly excluded from this warranty.

The warranty period cannot be extended.

wellion®

GALILEO audio

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CE 0197

IVD **In vitro diagnostic medical device**

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