wellion®

GALILEO GLU/KET



MANUAL

This manual can be used for the following devices:

- Wellion GALILEO GLU/KET
- Wellion GALILEO GLU/KET plus
- Wellion GALILEO GLU/KET BTE

Dear Wellion GALILEO Owner,

Thank you for choosing the Wellion GALILEO Blood Glucose and Ketone Monitoring System to help you easily monitor your blood sugar level and blood ketone level.

Your new Wellion GALILEO Blood Glucose and Ketone Monitoring System is designed to eliminate the need for manual coding, thereby greatly minimizing the potential for testing errors. This manual provides comprehensive information necessary for the proper use and maintenance of your Wellion GALILEO Monitoring System.

The Wellion GALILEO Blood Glucose and Ketone Monitoring System contains two test modes: glucose mode and ketone mode. It includes several convenient features to help you manage test results, such as warnings for hypogylcemia and hyperglycemia, markers for before and after meals, exercise and insulin application. Devices equipped with a color bar indicator display hypoglycemia and hyperglycemia results on the indicator. Moreover, the illuminated test strip port and the backlit display will help measuring in dim surroundings.

All the information needed to use and maintain your new meter is included in this manual. Please read it carefully before use.

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INTENDED USE

The Wellion GALILEO blood glucose and ketone measurement system is used for the quantitative measurement of blood glucose levels in fresh capillary blood from the fingertip, palm, or forearm, as well as blood ketone levels in venous whole blood or capillary blood from the fingertip. Alternative sites for the glucose test should only be done in steady-state (when glucose levels are not changing rapidly). The test is performed outside the body (in vitro diagnostics).

The system is intended for self-testing by people with diabetes or in clinical settings by healthcare professionals as an aid in monitoring blood glucose and blood ketone levels in diabetes mellitus. It is not intended for 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. A hematocrit range that is higher than 60% or lower than 20% can cause inaccurate blood ketone test results.
- Suitable for self-testing.
- Not intended for use on neonates.

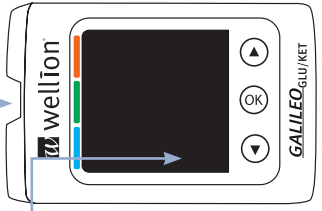
YOUR NEW MEASURING KIT

The Wellion GALILEO measuring kit includes the following items:

Wellion GALILEO meter incl. batteries
Wellion Lancing Device
Compact Pouch
Owner‘s Guide
Easy Start Picture Guide

Wellion GALILEO Blood Glucose and Ketone meter

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



"OK" and " ▲ " " ▼ "
Press and hold "OK" for 2 seconds to view memories or turn off the meter. Press and hold "OK" for 4 seconds to go into meter setup. Press " ▲ " or " ▼ " to enter control mode with test strip inserted, during meter setup, or to navigate the stored test values and averages.

Meter Display
Shows your test results, memory values, average, and other messages.

Color BAR*
Red bar: Indicates hyper test results, based on user-defined hyper values, with a left arrow displayed on the meter.

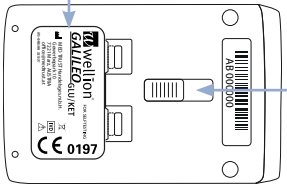
Blue bar: Indicates hypo test results, based on user-defined hypo values, with a left arrow displayed on the meter.

Green bar: Represents test results that fall outside the user-specified hypo or hyper ranges, under general test conditions, with a left arrow displayed on the meter

* Applicable for devices with a color bar indicator.

Battery Compartment
Holds 2 x CR2032 3V lithium coin cell batteries.

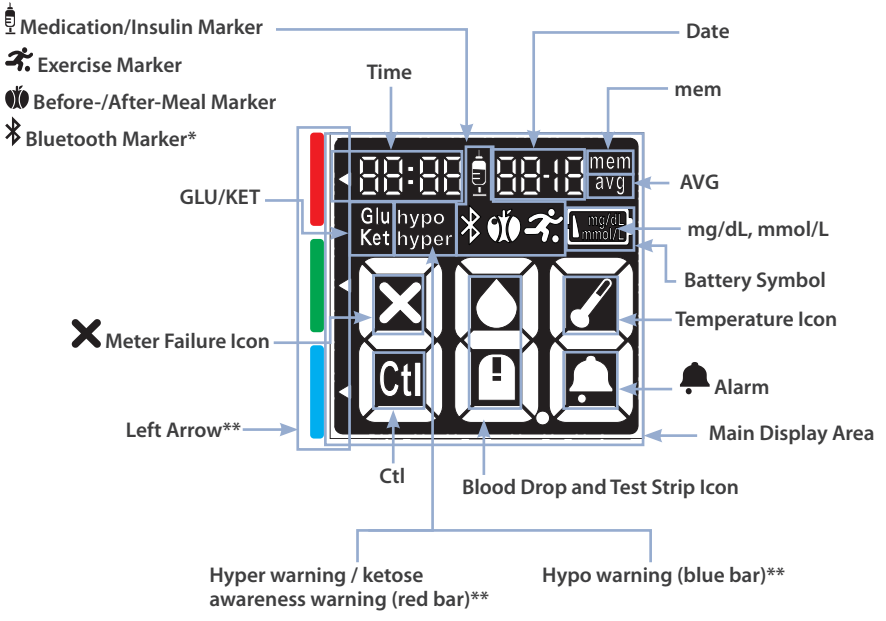
Data Port
Transmits data to a computer via the USB-cable, when connected with suitable software*



Eject Button (if available)
Push and eject a used test strip. Meter will turn off automatically when the test strip is ejected.

* The correct reading of your data can be ensured only with the original Wellion GALILEO USB cable.

Meter Display Screen



* Applicable for devices equipped with a Bluetooth function.
** Applicable for devices with a color bar indicator.

Left Arrow**	Used to indicate the color bar on the matching panel
Main Display Area	Displays test results, saved test results, errors and other messages
GLU/KET	Indicates whether the meter is in glucose or ketone test mode
Meter Failure Icon	Shown in the event of a device failure
mem	Indicates that the meter is in memory recall mode and the number on the main display area is a stored test result
Battery Symbol	Lights up to indicate that the battery needs to be replaced
Temperature Icon	Indicates the meter is outside of its operating temperature. The meter will not test if outside of this range. Move the meter to an environment within its operating temperature range (such as indoors) and wait 30 minutes before testing. Operating temperature: For glucose test: 5°C – 45°C; For ketone test: 10°C – 40°C
Blood Drop and Test Strip Icon	Indicates that the meter is ready for testing if both icons are lit
AVG	Displayed when viewing the 1, 7, 14, 30, 60 and 90 day averages. This only applies to glucose levels.
mg/dL, mmol/L	Specifies the unit of measurement for glucose or ketones. The unit of measurement is factory-set and cannot be changed.
Ctl	Indicates the meter is in control solution mode or shows a memorized control solution result

Time	Indicates the time: (Beep: Appears when the beep is turned on/off). The two digits on the left represent the hours and the two digits on the right represent the minutes.
Alarm	Indicates the alarm function is ON
hypo warning (blue bar)*	• Setting up your hypoglycemic threshold value • Indicates your test result is at or below your hypoglycemic threshold value • Indicates the memorized result is at or below your hypoglycemic threshold value
hyper warning / ketose awareness warning (red bar)*	• Setting up your hyperglycemic threshold value • Indicates your test result is at or above your hyperglycemic threshold value • Indicates the memorized result is marked at or above your hyperglycemic threshold value
Date	Indicates the date (dd/mm)
Medication/Insulin Marker	Displayed when a result is marked as "near to medication"/"insulin intake" or viewing a marked result
Exercise Marker	Displayed when a result is marked as "after exercise" or viewing a marked result
Before-/After-Meal Marker	Displayed when a result is marked as "before-meal" or "after-meal" or viewing a marked result
Bluetooth Marker**	Indicates Bluetooth is turned on

* Applicable for devices with a color bar indicator.
** Applicable for devices equipped with a Bluetooth function.

The Wellion GALILEO GLU 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 GLU Test Strip is a glucose specific, biosensor-based test strip that can measure glucose in capillary whole blood in just 5 seconds and requires a very small blood sample. The test result is plasma referenced for easy comparison to lab results and has an underfill detection feature that alerts 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 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 cap of the test strip vial immediately after each use. DO NOT leave any test strip outside when it is 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.

The Wellion GALILEO KET Blood Ketone 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 Ketone Test Strip is a ketone specific, biosensor-based test strip that can test blood ketone level in venous or capillary whole blood in just 8 seconds and requires a very small blood sample. The test result is plasma referenced for easy comparison to lab results and has an underfill detection feature that alerts 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 Ketone Test Strip with the Wellion GALILEO Meter. Other brands of test strips will not work with the meter.
- The Wellion GALILEO Blood Ketone Test Strips are sensitive to moisture and light. The test strip should be used within 10 minutes after removing from the aluminium foil package.
- 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

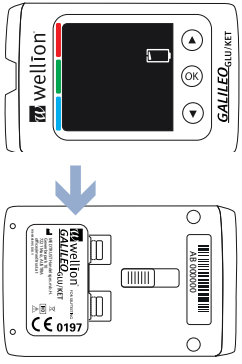
Inserting (or Changing) the Batteries

The batteries need to be inserted before using your Wellion GALILEO Meter for the first time or when the battery icon appears on the meter display screen.

Material you will need:
2 x CR 2032 3V Lithium coin cell batteries
Your Wellion GALILEO Meter

Step 1: Turn the meter off. Remove the battery cover on the back of the meter by pressing on the tabs and pulling them upwards. Remove the old batteries.

Step 2: Insert the new batteries with the "+" side up. They do not snap into place but rest on the metal contact. The cover must be replaced to secure the batteries.



NOTE

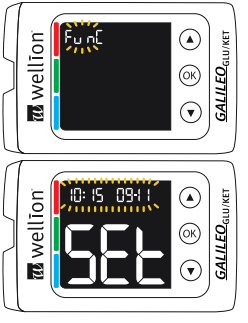
- All display illustrations in this manual depict a device equipped with a color bar indicator.

NOTE

- After a battery change, the meter automatically prompts you to set the time and date by inserting a test strip or pressing the OK button. The settings can be confirmed with OK or changed in the "Setting the clock" chapter.
- The date and stored results will not be erased when the batteries are being changed.
- Discard used batteries according to your local guidelines.
- The meter uses 2 x 3V lithium batteries, coin cell CR2032. This type of battery can be found in many stores. Always have a spare battery to hand.
- Be sure the batteries go in with the "+" side up.
- Remove the batteries if you are not going to use the meter for a long time.

Setting the Clock

Material you will need:
Your Wellion GALILEO Meter



Step 1: With the meter turned off, press and hold the "OK" - button until the screen displays "FunC".

Step 2: Release the "OK"-button and the meter will show the current date and time. If you are setting the date and time for the first time, the month will now start flashing to indicate you are in date and time set-up mode. If you are changing the date

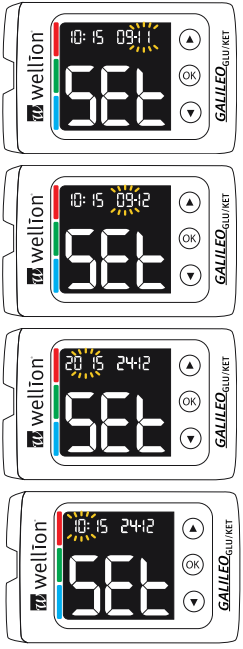
and time, “SEt” will show on the screen - press the “OK”-button to enter date and time set-up mode.

Step 3 - Set Month: The current month will flash. Use the arrow buttons to select the correct month. Press the “OK”-button to confirm your choice and advance to set the day.

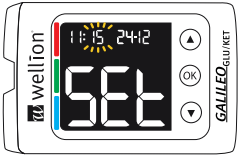
Step 4 - Set Day: The current day will flash. Use the arrow buttons to select the correct day. Press the “OK”-button to confirm your choice and advance to set the year.

Step 5 - Set Year: The current year will flash. Use the arrow buttons to select the correct year. Press the “OK”-button to confirm your choice and advance to set the hour.

Step 6 - Set Hour: The current hour will flash. Use the arrow buttons to select the correct hour. Press the “OK”-button to confirm your choice and advance to set the minute.



Step 7 - Set Minute: The current minute will flash. Use the arrow buttons to select the correct minute. Press the “OK”-button to confirm your choice and the result of your date and time correction will flash as a whole.



Press the arrow buttons to set the next function or insert a test strip to start a test. You can also turn off the meter by pressing and holding the “OK”-button until the display screens shows “OFF”.

Anytime during setup, you may insert a test strip to begin testing. The changes you have confirmed with “OK” so far will be memorized by the meter.

NOTE

- Your Wellion GALILEO Meter displays its time in 24-hour format. If error messages (E 1, E 2 etc.) appear, refer to “TROUBLESHOOTING“.

Setting Warning Values for Glucose / Ketose Awareness threshold

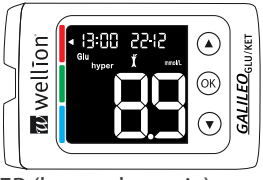
Your Wellion GALILEO blood glucose and ketone meter has a function that allows you to set your thresholds for high and low blood glucose levels (hyperglycaemia and hypoglycaemia levels). This helps to better understand your blood glucose levels and glycaemic status.

Based on the set values the LCD screen shows “hypo” if your blood glucose test result is below the threshold value for low glucose (hypoglycemia level) or shows “hyper” if your blood glucose test result is above the threshold value for high glucose (hyperglycemia level). Please consult your doctor or healthcare provider for your individual recommendation for the Hypo and Hyper alarm thresholds.

If you are using a device equipped with a colour bar the test results are assigned to the indicator:
A blue bar corresponds to hypo values.
A red bar corresponds to hyper values.
A green bar represents values outside the user-defined hypo and hyper ranges under general test conditions.



HYPO (hypoglycemia) warning



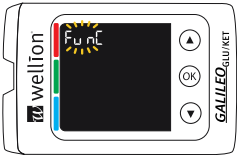
HYPER (hyperglycemia) warning

IMPORTANT:

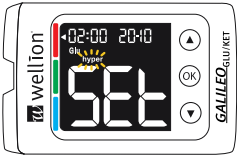
- In the default settings of the Wellion GALILEO meter the Hypo/Hyper warning is "ON", and the preset threshold value is 10 mmol/L (180 mg/dL) for Hyper and 3,9mmol/L (70 mg/dL) for Hypo. Follow the steps below to adjust the Hyper and Hypo threshold values.

Material you will need:
Your Wellion GALILEO Meter

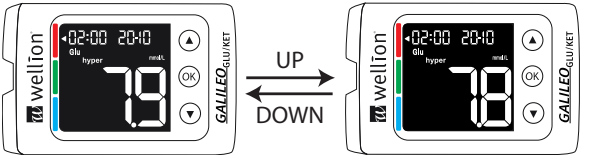
Step 1: With the meter turned off, press and hold the "OK"-button until the screen displays "FunC".



Step 2: Release the "OK"-button and the meter will show the current date and time will flash together with "SEt". Press the arrow buttons until the display shows "SEt" together with "GLU hyper" or "GLU hypo". Press the "OK"-button to enter the desired set up.

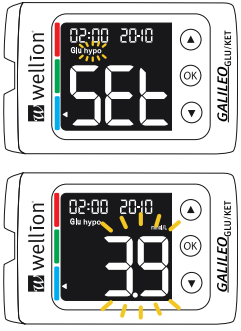


Step 3: **Hyper warning / Ketose awareness threshold:**
Press the "OK"-button to enter hyper setup. Use the arrow buttons to adjust the threshold for your individual hyper



warning/ketose aware-ness threshold. Confirm your choice with “OK“.
The hyper alarm threshold is the optimal tool to better assist you in recognizing the risk of a ketosis. When the meter shows a hyper warning with your glucose result, it is recommended to make a ketone measurement.

To make a ketone measurement you can use your Wellion GALILEO meter, together with the Wellion GALILEO ketone test strips (sold separately).



Step 4: **Hypo warning:** Press the “OK“-button to enter hypo setup. Use the arrow buttons to adjust the threshold for your individual hypo warning. Confirm your choice with “OK“.

Press the arrow buttons to set the next function to setup or insert a test strip to start a test. You can also turn off the meter by pressing and holding the “OK“-button until the display screens shows “OFF“.

Anytime during setup, you may insert a test strip to begin testing. The changes you have confirmed with “OK“ so far will be memorized by the meter.

SWITCH SOUND ON/OFF

Turning "OFF" the beep will cause you to miss many important cues from your meter – such as confirmation or error messages.

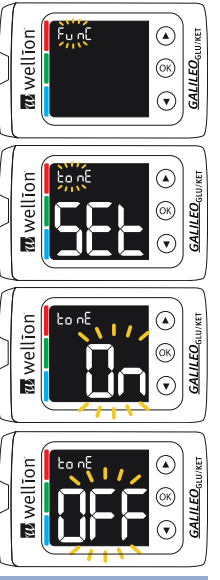
Material you will need:
Your Wellion GALILEO Meter

Step 1: With the meter turned off, press and hold the "OK"-button until the screen displays "FunC".

Step 2: Press the arrow buttons, go to tone set up and press the "OK"-button to enter tone setup.

Step 3: Use the arrow buttons to turn the tone "ON" or "OFF" and confirm by pressing "OK".

Press the arrow buttons to select the next function to setup or insert a test strip and begin testing. You can also turn off the meter by press and hold the "OK"-button until the display screens shows "OFF".



NOTE

- Anytime during setup, you may insert a test strip to begin testing. The changes you have confirmed with "OK" so far will be memorized by the meter.

Setting the Alarm

The Wellion GALILEO Meter allows you to set up 6 alarms - 3 for glucose and 3 for ketone. You must set the clock before you can set the alarms. The default setting for all alarms is "OFF".

When the GLU glucose alarm sounds, the meter will turn on and beep continuously. When the KET ketone alarm sounds, the meter will turn on and make 3 beeps, pause, 3 beeps, pause, ... in repetition. Pressing "OK"-button or inserting a test strip will silence the alarm.

Material you will need:
Your Wellion GALILEO Meter



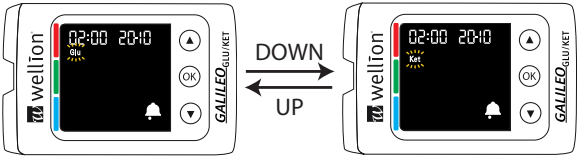
Step 1: With the meter turned off, press and hold the "OK"-button until the screen displays "FunC".



Step 2: Release the "OK"-button and the meter will show the current date and time will flash together with "SEt". Press the arrow buttons until to display shows the alarm symbol together with "SEt". Press the "OK"-button to enter alarms set up.

Step 3: The display screen will flash "Glu" or "Ket". For setting up alarms on glucose test-

ing, select “Glu” using the arrow buttons and press the “OK” button. For setting up alarms on ketone testing, select “Ket” using the arrow button and press the “OK”-button.



Step 4: The display screen will indicate the alarm 1 status (the default setting is “OFF”). You can turn it on by pressing “OK” and then choosing the desired setting with the arrow buttons.

Step 5: Press “OK” and the hour will flash. Select the hour using the arrow buttons. Confirm your choice by pressing “OK” and advance to set minutes.

Step 6: The current minutes will flash. Use the arrow buttons to select the correct minutes. Press “OK” to confirm your choice and advance to set alarm 2.

Step 7: Set alarm 2 and 3 following steps 4 to 6.
Set keton alarms by repeating steps 3 to 6.
Press the arrow buttons to set the next function or insert a

test strip to start a test. You can also turn off the meter by pressing and holding the "OK"-button until the display screens shows "OFF".

NOTE

- The alarm settings will not be erased when changing the batteries.
- Anytime during setup, you may insert a test strip to begin testing. The changes you have confirmed with "OK" so far will be memorized by the meter.

CONTROL SOLUTION TESTING

Performing a Glucose Control Solution Test

The purpose of glucose control solution testing is to validate the performance of the Wellion GALILEO Blood Glucose and Ketone Monitoring System using the testing solution with a known range of glucose. Control solutions are sold separately.
You can perform control solution testing when:

- Using the meter for the first time
- Opening a new vial of Wellion GALILEO Blood Glucose Test Strips
- The cap of the vial was open for a while.
- After dropping the meter.
- Suspecting your Wellion GALILEO Meter and Wellion GALILEO Blood Glucose Test Strips are not working properly

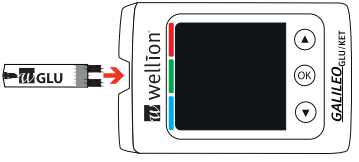
- The blood glucose test results do not correspond to the physical condition.
- Practising the testing procedure

IMPORTANT

- Only the Wellion GALILEO Glucose Control Solution (Level 0, Level 1 and Level 2) with the Wellion GALILEO Blood Glucose Test Strips are suitable. Other brands of control solution will produce inaccurate results.
- Always check the expiration date . DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution 3 months after opening (according to your local regulation).
- DO NOT FREEZE or REFRIGERATE. Store the control solutions at 4˚C-30˚C.

Materials needed:
Wellion GALILEO Glucose Control Solution (Level 0, Level 1 or Level 2)
Your Wellion GALILEO Meter
A new Wellion GALILEO GLU Blood Glucose Test Strip

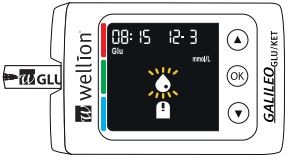
Step 1: Insert a Wellion GALILEO Blood Glucose Test Strip into the meter with the blood sample reaction zone facing up. Make sure that the test strip contact points are fully inserted into the meter. Close the test strip vial immediately.



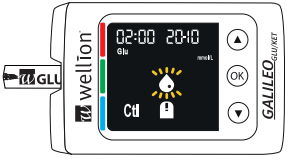
IMPORTANT

- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip vial.
- Use each test strip immediately after removing it from the vial.
- After removing a test strip from the vial, replace the vial cap immediately and close it tightly.
- 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 test strip vial label when you first open it. 12 months after first opened, discard the vial and any remaining test strips.
- Make sure that the ambient temperature is between 5 °C and 45 °C and wait 10 to 15 minutes until the device has reached the new temperature before using it. Your meter will not start the test if it detects a temperature outside the permissible range.
- You will see a flashing blood drop icon if the test strip has been inserted correctly into the test strip port.
- This is an auto-coding meter. You do not need to insert a code chip.

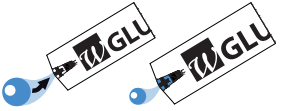
Step 2: The meter will turn on automatically. The "Glu" symbol, the flashing blood drop and test strip icons appear on the meter display screen.



Step 3: Press the arrow button to enter the control mode. You will see "Ctl" on the screen.

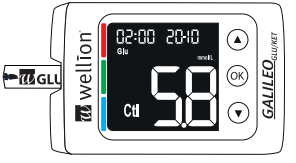


Step 4: Squeeze a drop of glucose control solution (Level 0, Level 1 or Level 2) onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the bottle. Close the control solution bottle immediately after use.



Step 5: Dip the test strip into the drop. The control solution is automatically drawn up.

Step 6: The countdown begins and after 5 seconds the test result of the control solution is shown together with the "Ctl" flag.



Step 7: Compare the reading with the control range printed on the test strip vial. If the reading does not fall within the control range printed on the test strip vial, see the chapter "Control Solution Trouble Shooting".

Step 8: Remove the used test strip either by pushing the ejection button (if available) or by pulling it out. Discard used test strips in accordance with local guidelines. The

meter will turn off automatically when the test strip is removed or after one minute of inactivity.

Step 9: In case you are using a Bluetooth-enabled device, the Bluetooth icon is switched on at the end of the test. If the meter is automatically paired with a portable device and the app is open, the test results can be uploaded to the device and the Bluetooth symbol flashes. Once the data transfer is complete, the Bluetooth symbol disappears.

Carry out further control solution tests by repeating the above steps.

NOTE

- Control solution testing results will be stored into the meter's memory and indicated by "Ctl" icon.
- Close the control solution bottle immediately after use.
- You can also transfer test results from the memory mode, please refer to "Viewing stored readings from memory."

IMPORTANT

- Do not reuse test strips.

Performing a Ketone Control Solution Test

The purpose of the ketone control solution testing is to validate the performance of the Wellion GALILEO Blood Glucose and Ketone Monitoring System using the testing solution with a known range of ketone. Control solutions are sold separately.

You can perform control solution testing when:

- Using the meter for the first time
- Opening a new package of Wellion GALILEO Blood Ketone Test Strips
- After dropping the meter
- You suspect your Wellion GALILEO Meter and Wellion GALILEO Blood Ketone Test Strips are not working properly
- Practising the testing procedure

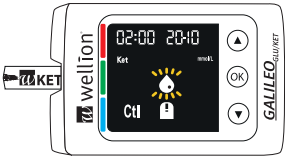
Materials you will need:
Wellion GALILEO Ketone Control Solution (Level 2)
Your Wellion GALILEO Meter
A new Wellion GALILEO Blood Ketone Test Strip

IMPORTANT

- Only the Wellion GALILEO Ketone Control Solution (Level 2) with the Wellion GALILEO Blood Ketone Test Strips are suitable. Other brands of control solution will produce inaccurate results.
- Always check the expiration date . DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution 3 months after opening (according to your local regulation).
- DO NOT FREEZE or REFRIGERATE. Store the control solutions at 4°C-30°C.
- Do not use a test strip that has expired. Check the expiration date  which is printed on the test strip foil and its package.
- Use each test strip immediately after removing it from the foil.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat . Store the test strips in a dry, cool place.
- Make sure that the ambient temperature is between 10 °C and 40 °C and wait 10 to 15 minutes until the device has reached the new temperature before using it. Your meter will not start the test if it detects a temperature outside the permissible range.
- You will see a flashing blood drop icon if the test strip has been inserted correctly into the test strip port.
- This is an auto-coding meter. You do not need to insert a code card.

Step 1: Insert a Wellion GALILEO Blood Ketone Test Strip into the meter with the blood sample reaction zone facing up. Make sure that the test strip contact points are fully inserted into the meter.

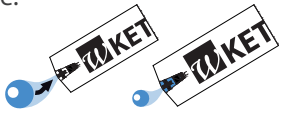
Step 2: The meter will turn on automatically. The "Ket" symbol, the flashing blood drop and test strip icons appear on the meter display screen.



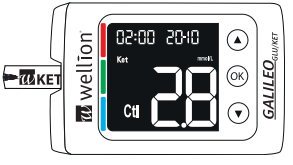
Step 3: Press the arrow button to enter the control mode. You will see "Ctl" on the screen.

Step 4: Squeeze a drop of ketone control solution (Level 2) onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the bottle. Close the control solution bottle immediately after use.

Step 5: Dip the test strip into the drop. The control solution is automatically drawn up.



Step 6: The countdown begins and after 8 seconds the test result of the control solution is shown together with the "Ctl" flag.



Step 7: Compare the reading with the control range printed on the test strip package. If the reading does not fall within the control range printed on the test strip package, see the chapter "Control Solution Trouble Shooting".

Step 8: Remove the used test strip either by pushing the ejection button (if available) or by pulling it out. Discard used test strips in accordance with local guidelines. The meter will turn off automatically when the test strip is removed or after one minute of inactivity. The meter can be turned off by pressing the "OK"-button for 2 seconds.

Step 9: In case you are using a Bluetooth-enabled device, the Bluetooth icon is switched on at the end of the test. If the meter is automatically paired with a portable device and the app is open, the test results can be uploaded to the device and the Bluetooth symbol flashes. Once the data transfer is complete, the Bluetooth symbol disappears.

NOTE

- Control solution testing results will be stored into the meter's memory and indicated by "Ctl" icon.
- Close the control solution bottle immediately after use.
- You can also transfer test results from the memory mode, please refer to "Viewing stored readings from memory."

IMPORTANT

- Do not reuse test strips. 

Control Solution Trouble Shooting

If your control solution result 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 • Expired or contaminated control solution or damaged test strips • Meter malfunction • Wrong control solution storage temperature	• Make sure you are using Wellion GALILEO Glucose Control Solution (Level 0, Level 1 and Level 2) or Wellion GALILEO Ketone Control Solution (Level 2). • Make sure the testing environment is between 5°C-45°C for glucose test or between 10°C-40°C for ketone test. • Check the expiration and opening date on bottles of the control solution and test strips. • Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest. • Please contact your local distributor if you require further help.

TESTING YOUR BLOOD GLUCOSE

Materials you will need:
Your Wellion GALILEO Meter
A new Wellion GALILEO Blood Glucose Test Strip
Lancing device with a sterile, unused lancet

Before you begin, make sure:

- You set up your meter properly and perform a control solution test. See the chapters "Setting Up Your New System" and "Performing a Glucose Control Solution Test" for more details.
- Wash your hands and the testing site thoroughly with soap and warm water and dry them 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 the temperature icon . Bring the meter to an area with a temperature between 5°C-45°C and allow it to rest for 10 to 15 minutes before testing again.

Preparing your Lancing device

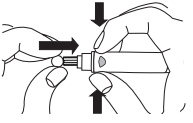
CAUTION

- Lancets are for single use only. Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Dispose them according to local government regulations to avoid injury or contamination.
- If alcoholic wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

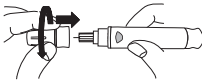
Step 1: Wash the puncture site with soap and warm water and dry thoroughly. Warm water stimulates blood circulation, which facilitates sample collection.

Step 2: Let the arm hang down at your side for 10 to 15 seconds while gently massaging from the wrist through the palm to the fingers. This can help stimulate blood flow more effectively.

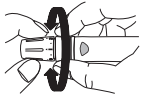
Step 3: Unscrew the adjustable cap of the lancing device and insert the lancet by pushing down firmly until it is fully seated.



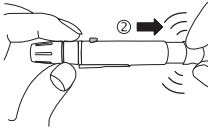
Step 4: Twist the protective cover off from the lancet. Replace the adjustable cover back onto the lancing device.



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: Hold the lancing device in one hand and use the other to pull back the cocking handle until you hear a click. The device is now ready for use.



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 it turns red.



TIP

- To avoid soreness, use the side of your fingertip for lancing. To prevent calluses, choose a different site each time you collect a blood sample.

Important Information on Alternative Site Testing (AST)

The Wellion GALILEO Blood Glucose and Ketone Monitoring System can test blood glucose from sites other than your fingertip such as palm and forearm (alternative site testing or AST). Alternative site testing can be less painful than fingertip testing, but because of the physiological difference between your fingertip and palm and forearm[1], AST result may be significantly different than results from fingertip testing under certain conditions. You should consult with your doctor or healthcare professional before using AST.



DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal)
- At least 2 hours after taking insulin
- At least 2 hours after exercising

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

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

AST SHOULD NOT be used when:

- You have hypoglycemic unawareness (you are not able to tell if you have low blood sugar).
- Within 2 hours of a meal, exercise or medication.
- You will be operating machinery or driving a car.
- You are sick.
- You think your blood glucose is low.
- Your AST levels do not correspond with your current symptoms.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Talk to your healthcare professional to determine whether AST is appropriate for you.

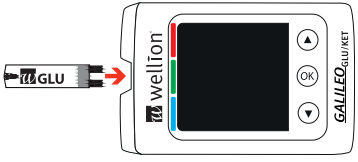
IMPORTANT

- If results from AST do not agree with your physical condition, use fingertip testing instead.

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differ s Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708–709, 20

Performing a Blood Glucose Test

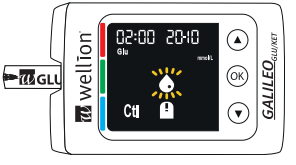
Step 1: Take out a Wellion GALILEO Blood Glucose Test Strip from the test strip vial and close the vial immediately. Insert the test strip to turn on the meter.



IMPORTANT

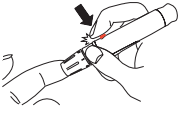
- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip vial.
- Use each test strip immediately after removing it from the vial.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat . Store the test strips in a dry, cool place.
- Record the "date opened" on the vial label. Discard the vial and any remaining test strip after 12 months from opening date.
- Insufficient blood volume may cause incorrect results.
- You will see a flashing blood drop icon if the test strip has been inserted to the test strip port correctly and the meter is ready for testing.

Step 2: Wait for the "Glu" symbol and the flashing blood drop and test strip icons to appear on the meter display screen.



Step 3: Obtaining a blood drop:

<u>For Fingertip Testing:</u>
Hold the primed lancing device firmly against the side of your fingertip and press the release button.



TIP

- Gently massage 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:
Avoid veins, hair, moles, bone and tendon.

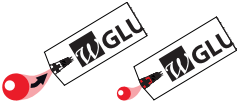
For palm testing, it is not necessary to rub the skin. Press the lancing device firmly against the puncture site and press the release button.

For forearm testing only, rub testing area vigorously until it feels warm to help to increase the 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 applying and releasing pressure up and down 2–3 times without lifting it away.
When the blood drop 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 your physical condition, use fingertip testing instead.

Step 4: Gently dip the test strip to the drop of blood at a slight angle. The blood is automatically absorbed. Keep the test strip in contact with the blood drop until the meter beeps, indicating there is enough blood to begin the test.

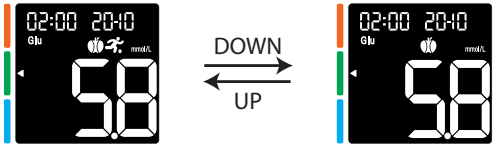


Step 5: The countdown starts automatically and after 5 seconds, the glucose test result will appear.

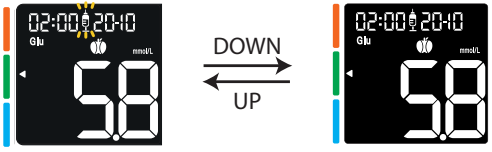
Step 6: Select the before/after meal marker:
With the test result on the display and the test strip STILL IN THE METER, you can now choose your desired markers.
Press the arrow buttons to select "before meal" marker, "after meal" marker or remain blank. Press "OK" to confirm your choice and advance to select exercise marker.



Step 7: Select the exercise marker:
After selecting meal marker, a flashing exercise icon appears on the screen. Use the arrow buttons to select the "exercise marker" or remain blank. Press "OK" to confirm your choice and advance to select the medication/insulin marker.



Step 8: Select the medication/insulin marker:
After selecting exercise marker, a flashing "medication/insulin" appears on the screen. Use the arrow buttons to select the marker or remain blank. Press "OK" to confirm your choice and the result will be stored in memory.



NOTE

- „hypo“(blue bar) or „hyper“(red bar) icons may appear on screen depending on the set threshold limit, accompanied by a left arrow pointing to the corresponding color bar. See Setting Warning Values on page 23 .
- The meter will turn off automatically when pulling out the test strip or after one minute of inactivity. If you do not select a marker before turning off the device the test result will be stored without any marker.
- If error messages (E 1, E 2, etc.) appear, see the chapter “TROUBLESHOOTING“.
- Please check that the glucose strip is removed before uploading the data.

CAUTION

- If “HI” or “LO” is displayed, your blood glucose level may be beyond the meter measurement range – above 33.3 mmol/L (600 mg/dL) or below 1.1mmol/L (20 mg/dL). Test again using fingertip testing. DO NOT test on palm or forearm. If you still receive the same result, call your physician or healthcare professional immediately.
- If you get a result of “HI” or “LO”, it will be stored as 33.3 mmol/L (600 mg/dL) or 1.1mmol/L (20 mg/dL) in the meter memory (but not counted for the average values).

Step 9: Remove the used test strip either by pushing the ejection button (if available) or by pulling it out. Discard used test strips in accordance with local guidelines. The meter will turn off automatically when the test strip is removed or after one minute of inactivity. The meter will also turn off by pressing the “OK”-button for two seconds.

Step 10: In case you are using a Bluetooth-enabled device, the Bluetooth icon is switched on at the end of the test. When the measuring device automatically pairs with a portable device and the app is open, the test results can be uploaded onto the device and the Bluetooth symbol is flashing. After the data transfer is finished, the Bluetooth icon disappears.

Step 11: Remove the used lancet from your lancing device. You can use the lancet ejector to prevent needlestick injuries. Push the lancet ejector forward with the thumb and discard the lancet in accordance with your local guidelines.

NOTE

- Please check that the glucose strip is removed before uploading the data.

IMPORTANT

- Used lancets and strips are biohazardous materials and can transmit blood-borne diseases. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets.

TESTING YOUR BLOOD KETONE

Materials you will need:
Your Wellion GALILEO Meter
A new Wellion GALILEO Blood Ketone Test Strip
Lancing device with a sterile, unused lancet

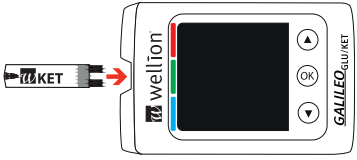
Before you begin, make sure:

- You set up your meter properly and carry out measurements with control solution. See the chapter "Setting Up Your New System" for more details.
- Wash your hands and the testing site thoroughly with soap and warm water, and dry them well.
- You are testing in an area between the temperature ranges of 10°C-40°C. Your meter will not test outside of this range and will display the temperature icon . Bring the meter to an area with a temperature between 10°C-40°C and allow it to rest for 10 to 15 minutes before testing again.

Preparing your Lancing device (see chapter "Preparing your Lancing device")

Performing a Blood Ketone Test

Step 1: Take out a Wellion GALILEO Blood Ketone Test Strip from the test strip foil. Insert the test strip to turn on the meter.

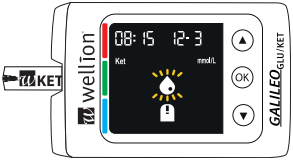


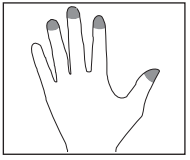
IMPORTANT

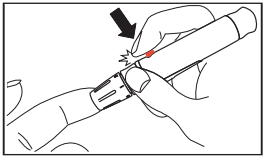
- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip foil.
- Use each test strip immediately after removing it from the foil.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat . Store the test strips in a dry, cool place.
- Insufficient blood volume may cause incorrect results.
- You will see a flashing blood drop icon if the test strip has been inserted correctly into the test strip port and the meter is ready for testing.

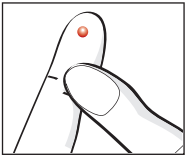
Step 2: Wait for the "Ket" symbol and the flashing blood drop and test strip icons to appear on the meter display screen.

Step 3: Obtaining a blood sample:
For Fingertip Testing: Hold the primed lancing device firmly against the side of your fingertip and press the release button.





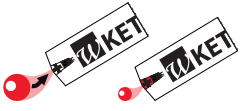




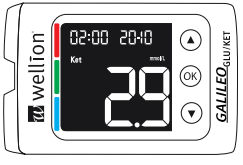
TIP

- Gently massage 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.

Step 4: Gently dip the test strip to the drop of blood at a slight angle. The blood is automatically absorbed. Keep the test strip in contact with the blood drop until the meter starts the countdown indicating there is enough blood to start a test.



Step 5: The countdown starts automatically and after 8 seconds, the ketone test result will appear.

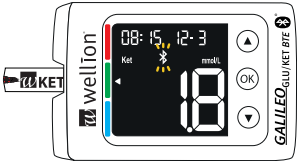


CAUTION

- If "HI" or "LO" is displayed, your blood ketone level may be beyond the meter measurement range (above 8.0 mmol/L or below 0.1 mmol/L). Test again using fingertip testing. If you receive a "HI" result again, call your physician or healthcare professional immediately. If you receive a "LO" result again, no further action is required as this represent normal blood ketone levels.
- If you get a result of "HI" or "LO", it will be stored as 8.0 mmol/L or 0.1 mmol/L in the meter's memory automatically.of used lancets.

Step 6: Remove the used test strip either by pushing the ejection button (if available) or by pulling it out. Discard used test strips in accordance with local guidelines. The meter will turn off automatically when the test strip is removed or after one minute of inactivity.
The meter will also turn off by pressing the "OK"-button for two seconds.

Step 7: In case you are using a Bluetooth-enabled device, the Bluetooth icon is switched on at the end of the test. When the measuring device automatically pairs with a mobile device and the app is open, the test results can be uploaded onto the device and the Bluetooth symbol is flashing. After the data transfer is finished, the Bluetooth icon disappears.



Step 8: Remove the used lancet from your lancing device. You can use the lancet ejector to prevent needlestick injuries. Push the lancet ejector forward with the thumb and discard the lancet according to local guidelines.

NOTE

- Please check that the Ketone strip is removed before uploading data.

IMPORTANT

- Used lancets and strips are biohazardous materials and can transmit blood-borne diseases. Please follow your local healthcare provider's recommendation regarding proper disposal of used lancets.

UNDERSTANDING YOUR TEST RESULTS

Understanding Your Blood Glucose Test Results

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are[2]:
- less than 5,6 mmol/L (100 mg/dL) before meals
- less than 7,8 mmol/L (140 mg/dL) after meals

It is important to consult with your doctor or healthcare professional to determine an your personal target range.

What to do when your blood glucose reading is high or low

If the meter displays "HI" or "LO" or if your result exceeds your established high or low blood glucose threshold and you feel unwell:
- Treat your diabetes according to the instruction from your doctor and/or consult with your healthcare provider.
- Test your meter and strips with the control solution - refer to the chapter "Control Solution Testing."
- Test again using fingertip blood with a new test strip. If you still get a high or low reading, contact your healthcare professional immediately.

2. American Diabetes Association Position Statement: Standards of Medical Care in Diabetes—2015. Diabetes Care 2015; 38 (Suppl.1).

IMPORTANT

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

Understanding Your Blood Ketone Test Results

Ketones are energy carriers produced by the body when it uses fats instead of carbohydrates for energy. This can occur, for example, during fasting, on a low-carbohydrate diet, or in cases of insufficient insulin supply (e.g., in diabetes mellitus). The concentration of ketones in the blood can provide insights into the current metabolic state and may indicate poorly controlled diabetes mellitus[3].

If your blood glucose is higher than 13,9 mmol/L (250 mg/dL) and your blood ketone result is[4]:

Below 0.6 mmol/L	Normal blood ketone level.
0.6 to 1.5 mmol/L	A moderate level of ketones which probably indicates fat metabolism and weight loss, but not a deficiency of insulin. Test again later and contact your healthcare professional for advice.

1.6 to 3.0 mmol/L	A high level of ketones which indicates a risk of diabetic ketoacidosis (DKA). Contact your healthcare professional immediately.
Above 3.0 mmol/L	Indicates a serious metabolic condition and emergency medical care is necessary.

What to do when your blood ketone reading is high or low:

If the meter displays results that are "HI":

- Treat your diabetes according to the instruction from your doctor and/or consult with your healthcare provider.
- Test your meter with the control solution - refer to the chapter "Control Solution Testing".
- Test again with a new test strip. If you still get a HI or above 0.6 mmol/L reading, contact your healthcare professional immediately.

If the meter displays results that are "LO":

- This is a normal blood ketone level. No further action is required.

3. DKA (Ketoacidosis) & Ketones, http://www.diabetes.org/living-with-diabetes/complications/ketoacidosis- dka.html, March 18, 2015
4. Richard M. Weil, Getting to Know Ketones, Diabetes Self –Management 2003 Nov-Dec; 20(6):100-1, 103-4.

IMPORTANT

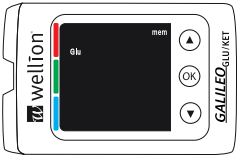
- Inaccurate results may occur for individuals whom are severely hypotensive, severely dehydrated in shock, or in a hyperglycemic-hyperosmolar state.

VIEWING STORED READINGS FROM MEMORY

Viewing Stored Readings and 1-, 7-, 14-, 30-, 60-, 90- Day Averages of Glucose Test Results from Memory

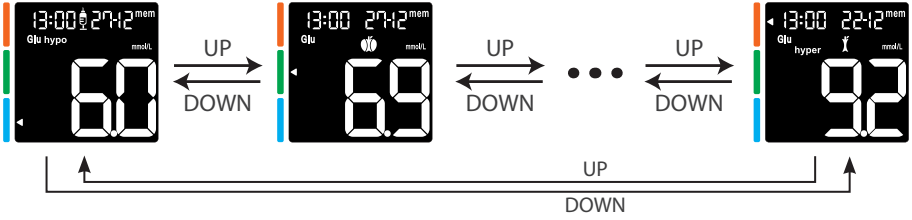
Your Wellion GALILEO Meter can store up to 400/500 glucose test and control results with date and time. In addition, the meter also provides 1-, 7-, 14-, 30-, 60-, 90-day averages to help you better track your efforts in controlling your blood glucose level. You will need to set your meter date and time before using the memory and day averaging function - see the chapter "Setting Up Your New System". The meter will not memorize any test or control results if the date and time are not set.

Material you will need:
Your Wellion GALILEO Meter

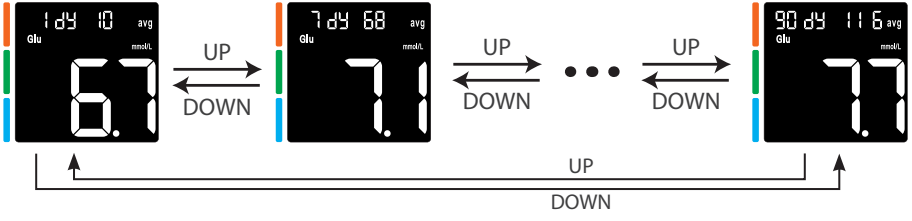


Step 1: Turn on the meter by pressing and holding the "OK"-button until the screen shows "mem". When "Glu" is flashing, press "OK" to confirm your choice.

Step 2: The most recent test result will appear on screen. Press the “arrow-up”-button to view your results from the most recent to the oldest. When scrolling to the end of results in the memory, the meter display screen will start again at the beginning.



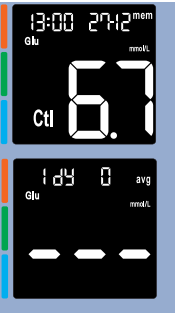
Step 3: Viewing day averages: Press the “OK”-button to view day averages. The first average will be the 1 day average. Press the arrow buttons to scroll through 7, 14, 30, 60, and 90 day averages.



Step 4: The meter is designed to upload memory records. If you are using a Bluetooth device, it automatically pairs with your mobile device when the app is open. The test results are then uploaded to the device, and the Bluetooth symbol flashes (refer to "UPLOAD DATA"). After the data transfer is finished, the Bluetooth icon disappears.

NOTE

- Control testing results will be flagged by a "Ctl" icon.
- When the memory is full, performing a new test will delete the oldest test result.
- Control testing results will not be included in the day averages. When there are no day average results available, the display screen will show 3 dashes (---).
- If you get a result of "HI" or "LO", it will be stored in the memory as 33,3 mmol/L (600 mg/dL) or 1,1mmol/L (20 mg/dL). These results will not be counted for the averages.



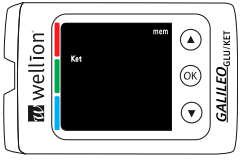
After you finish reviewing the memory, either start testing by inserting a test strip or press and hold "OK" to turn off the meter.

Viewing Stored Readings of Ketone Test Results from Memory

Your Wellion GALILEO Meter can store up to 100 ketone test and control results with date and time. You will need to set your meter date and time before using the memory - see the chapter "Setting Up Your New System". The meter will not memorize any test or control results if the date and time are not set.

Material you will need: Your Wellion GALILEO Meter

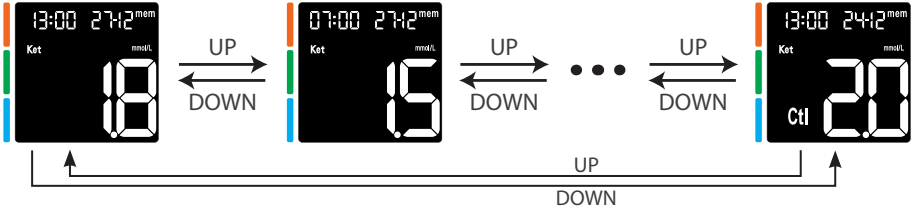
Step 1: Turn on the meter by pressing and holding the "OK"-button until the screen shows "mem". Then use the arrow buttons to see "Ket" and press "OK" to confirm your choice.



Step 2: The most recent test result will appear on screen. Press the "arrow-up"-button to view your results from the most recent to the oldest.

Step 3: The meter is designed to upload memory records (refer to "UPLOAD DATA"). If you are using a Bluetooth* device, it automatically pairs with your mobile device when the app is open. The test results are then uploaded to the device, and the Bluetooth symbol flashes. After the data transfer is finished, the Bluetooth icon disappears.

After you finish reviewing the memory, either start testing by inserting a test strip or press and hold "OK" to turn off the meter.



NOTE

- Control testing results will be flagged by a "Ctl" icon.
- When the memory is full, performing a new test will delete the oldest test result.
- If you get a result of "HI" or "LO", it will be stored in the memory as 8,0 mmol/L or 0,1 mmol/L.

* Applicable for devices equipped with a Bluetooth function.

UPLOAD DATA



Upload data via USB

Material you will need:
Your Wellion GALILEO Meter

Insert the Wellion GALILEO USB Cable into the data port. The “PC“ mode shows on the screen.
Follow the Data Management System (DMS) instruction manual to upload data. For purchase information of DMS, please contact your local distributor.

NOTE

- The upload feature should only be used with a DMS product that explicitly identifies the Wellion GALILEO as a compatible meter.

Upload data via Bluetooth

To make a Bluetooth transfer, open the app (e.g. Wellion App) on your mobile device and follow the app instructions to pair the meter and get started. At the end of the blood glucose/ketone measurement, the test results and the Bluetooth symbol are displayed.

The test results are uploaded to the device and the Bluetooth symbol flashes. After the transfer is complete, the Bluetooth symbol disappears.
You can also transfer test results from memory mode, please follow the app (e.g. Wellion App) instructions.

NOTE

- You need to install an app (e.g. Wellion App) on your mobile device that can process the meter data.
- As long as the mobile device has an application capable of processing meter data, pairing the meter is not necessary.
- When the meter is in transfer mode, testing is not possible.
- The distance between the meter and the mobile device must not be more than 10 meters during transmission.
- If the Bluetooth transmission function fails, the screen will display E 6, please contact an authorized representative.
- Wellion GALILEO Meter can only transfer memory data but not process or upload data.

METER CARE AND MAINTENANCE

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

Cleaning the Meter

- If the meter gets dirty, clean it with a damp (NOT WET) lint-free cloth lightly moistened with a mild detergent.
- Do not allow water to enter inside the Wellion GALILEO Meter. Never immerse the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Avoid cleaning the test strip holder.
- Do not contaminate the strip holder with blood or control solution.

Disinfecting the Meter

- Please clean the meter before disinfection.
- Disinfect the surface of the meter with recommended solutions (soapy water, 10% bleach or 75% alcohol).
- Please note that 75% alcohol is not effective against viral.

Storage and Precautions

- Handle the meter with care. Severe shock, such as dropping the meter, could damage the electronics.
- The meter and the test strips are designed to be used within the temperature ranges between 5°C and 45°C for glucose testing and between 10°C and 40°C for ketone testing.
- Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Always close the vial cap immediately after removing a test strip and make sure it is closed tightly.
- Do not take the meter apart. Doing so will void the warranty.
- Do not use this meter in dry environments, especially if synthetic materials are present. Items such as synthetic clothing or carpets can generate static electricity, which may damage the device.
- Do not use this meter near cellular or cordless telephones, walkie-talkies, garage door openers, radio transmitters or other electrical or electronical equipment that are sources of electromagnetic radiation, as these may interfere with the proper functioning of the meter.
- Follow local regulations for proper disposal of the meter.
- Keep the meter, test strips and other items out of the reach and sight of children. Small items may represent choking hazards.

TROUBLESHOOTING

This section details the significant display screen messages and error codes you may encounter when using your Wellion GALILEO Meter and Wellion GALILEO Test Strips.

Message	What It Means	What You Should Do
	Used or contaminated test strip	Remove the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample.
	Not enough blood sample on the test strip to start	Remove the test strip and repeat the test with a new test strip. See the chapters "Testing Your Blood Glucose" or "Testing Your Blood Ketone."
	Test strip removed during countdown	Repeat the test with a new test strip. See the chapters "Testing Your Blood Glucose" or "Testing Your Blood Ketone."
	Meter detects extreme condition	Bring the meter into an area with a temperature between 5°C to 45°C for glucose testing or 10°C to 40°C for ketone testing and allow it to set for 10 to 15 minutes. See the chapter "Storage and Precautions.

Message	What It Means	What You Should Do
	Meter failure	• Replace the batteries and turn the meter on again. • Remove the test strip and insert a new test strip. • If problem persists, contact your local distributor.
E 6	Bluetooth pairing failure	• Ensure that the Bluetooth device is functioning properly, then repeat the pairing confirmation process. • If a problem persists, contact your local distributor.
E 7	A USB cable or a test strip was inserted during data transmission. Do not interrupt the process — transmission will be completed shortly.	This is just a warning. Please wait until the data transmission is complete.
E 8	Data transmission fails	• Ensure that the Bluetooth device is functioning properly, then repeat the pairing confirmation process. • If problem persists, contact your authorized representative.

Message	What It Means	What You Should Do
	Glucose test result higher than 33.3 mmol/L (600 mg/dL)	Wash and dry your hands and repeat the test using a new test strip. If the result is still "HI", contact your doctor or healthcare professional immediately.
	Glucose test result lower than 1.1 mmol/L (20 mg/dL)	Wash and dry your hands and repeat the test using a new test strip. If the result is still "LO", contact your doctor or healthcare professional immediately.
	Ketone test result higher than 8.0 mmol/L	Wash and dry your hands and repeat the test using a new test strip. If the result is still "HI", contact your doctor or healthcare professional immediately.
	Ketone test result lower than 0.1 mmol/L	This is a normal blood ketone level. No further action is required.
	Low battery	Change the batteries according to instructions for Inserting (or Changing) the Batteries.

Message	What It Means	What You Should Do
	No memorized results in the meter	• Check if the date and time on your meter is set up. See "Setting Up Your New System." • Start testing your blood glucose or ketone - see "Testing Your Blood Glucose" and "Testing Your Blood Ketone."
	Temperature out of range	Bring the meter into an area with a temperature between 5˚C to 45˚C for glucose test or 10˚C to 40˚C for ketone test and allow it to set for 10 to 15 minutes.

SYMBOLS


(EXP) Expiration date (use by the last day of the month)



(LOT) Batch code


Temperature limitations


Consult instructions for use



In Vitro Diagnostic Medical Device


Caution! Consult accompanying documents



Catalogue number


Keep away from sunlight/direct light


Do not reuse


Do not use if package is damaged


Keep dry


Manufacturer



In vitro diagnostic, medical device for self-testing


Production date

SPECIFICATIONS

Test parameters:	Glucose and Ketone
Eject button:	Yes/only the plus version
Illuminated Test strip port:	Yes
Method of measurement:	Biosensor
Test Strips:	Wellion GALILEO Blood Glucose Test Strip Wellion GALILEO Blood Ketone Test Strip
Test Range:	1.1 - 33.3 mmol/L (20 - 600 mg/dL) for glucose test 0.1 - 8.0 mmol/L for ketone test
Test Time:	5 seconds for glucose test, 8 seconds for ketone test
Calibration:	Plasma
Blood Sample Size:	≥ 0.5 µL for glucose test, ≥ 0.8 µL for ketone test
Hematocrit Range:	10-70% for glucose, 20-60% for ketone test
Event marker:	Before/After meal marker, exercise marker, medication/ insulin marker
Warnings:	User-configurable hypoglycemia and hyperglycemia warnings. For devices with a color bar indicator, these warnings are shown on the indicator, under-fill warning
Display Type:	LCD screen with black lighting Color bars: red (hyper), green (normal) and blue (hypo)*

* Applicable for devices with a color bar indicator.

Memory (with date and time):	400/500 test results for glucose test, 100 test results for ketone test
Result Averaging:	1, 7, 14, 30, 60 and 90 days averaging for glucose test
Dimensions:	60 L x 90 W x 20 H (mm)
Weight:	59 g/67 g (incl. batteries)
Batteries:	2 x CR 2032 3V Lithium coin cell batteries
Battery Life:	700/1000 tests of continuous use or one year
Automatic Power-off:	After 90 seconds without activation (test strip already in the device, flashing blood drop symbol). After 60 seconds without activation after performing the test and setup.
Operating Temperature:	5°C to 45°C for glucose test, 10°C to 40°C for ketone test
Relative Humidity:	20-90% for glucose test, <85% for ketone test
Alarms:	3 for glucose test, 3 for ketone test
Storage/Transport Condition:	Meter at -20°C to +50°C Glucose test strip at 4°C to 30°C, Ketone test strip at 4°C to 30°C

For additional information, refer to the Wellion GALILEO Blood Glucose Test Strip insert or Wellion GALILEO Blood Ketone Test Strip insert.

Electromagnetic Compatibility:
This equipment complies with EMC requirement of EN 61326-1/ EN 61326-2-6.
EU directive/classification: Directive 98/79/EC Annex II, List B; Self-testing

The meter complies with the requirements of Directive 98/79/EC on in vitro diagnostic medical devices and with the requirements of Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment. The meter is in compliance with Directive 2014/53/EU on radio equipment. The full text of the EU Declaration of Conformity is available at the following internet address:
https://www.medtrust.at

MANUFACTURER'S WARRANTY

The manufacturer provides a two-year warranty from the date of purchase for the Wellion GALILEO blood glucose and ketone meter, covering material and manufacturing defects. This warranty is void if the device is used improperly, 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 device is also defective. Other claims cannot be accepted. MED TRUST's warranty liability is restricted to the repair or replacement of the device and under no circumstances shall MED TRUST be held liable for any incidental or consequential damages or loss.

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 GLU/KET

MED TRUST
THE MEDICAL SERVICES COMPANY

AUSTRIA

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IVD In Vitro Diagnostic Medical Device

W10-32KBTEENMGIMM 20250508

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