

wellion® *GALILEO* *GLU/KET*

OWNER'S GUIDE



Dear Wellion GALILEO GLU/KET (plus) Owner,

Thank you for choosing the Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone Monitoring System to help you easily monitor your blood sugar level and blood ketone level.

Your new Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone Monitoring System is a system that does not require you to code the meter manually so testing errors can be greatly reduced. All of the information you need to use and maintain your new Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone Monitoring System is included in this manual.

The Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone Monitoring System contains two test modes: glucose mode and ketone mode. It has many convenient new features to help you manage test results, such as hypoglycemia and hyperglycemia warnings, before & after meal marker, exercise marker and medication/insulin marker. Moreover, the illuminated test strip port and the backlit display will help measuring in dim surroundings.

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

INTENDED USE

The Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone Monitoring System is intended to quantitatively measure blood glucose in fresh capillary whole blood drawn from fingertips, palm, or forearm, and blood ketone in venous whole blood or capillary whole blood from fingertips. Alternative site testing for glucose test should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use).

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 level and blood ketone level in diabetes mellitus. It is not indicated 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.
- Haematocrit range - A haematocrit range that is higher than 70% or lower than 20% can cause inaccurate blood glucose test results. A haematocrit 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 GLU/KET (plus) measuring kit includes the following items:

Wellion GALILEO GLU/KET (plus) meter incl. batteries

Wellion GALILEO Glucose Strips (optional)

Wellion GALILEO Ketone Strips (optional)

Wellion Lancing device

10 Wellion Lancets

Compact Pouch

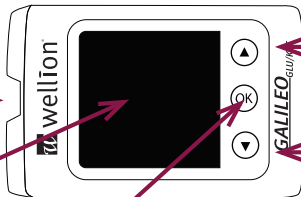
Owner's guide

Easy Start Picture Guide

Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone meter

Illuminated Test Strip Port

This is where you insert the test strip. The illumination facilitates measurements in a dark environment.



Arrow buttons

- Scroll between selections when setting up the meter
- Scroll between different memorized values when in the memory recall mode

Meter Display

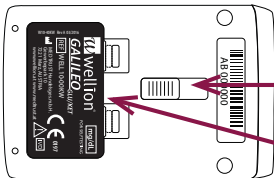
Shows your test results, memory values, average, and other messages

OK button

Press and hold the OK button for two seconds to access the memory recall mode or hold the button for 4 seconds to access the set up mode; view day average results when in memory recall mode, press and enter to set up a specific function in setup, hold and press to turn off the meter.

Data Port

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



Eject Button (if available)

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

Battery Compartment

Holds 2 CR2032 3V lithium coin cell batteries

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

Meter Display Screen

Time - indicates the time

hypo warning -

displayed when

- Setting up your hypoglycemic threshold value
- Indicates your test result when at or below your hypoglycemic threshold value
- Indicates the memorized result when at or below your hypoglycemic threshold value.

GLU/KET - indicates whether the meter is in glucose or ketone test mode

hyper warning / ketose awareness warning

- displayed when

- Setting up your hyperglycemic threshold value
- Indicates your test result when at or above your hyperglycemic threshold value
- Indicates the memorized result when at or above your hyperglycemic threshold value

Medication/Insulin Marker

- displayed when marking a result as being near to medication/insulin intake, or viewing a marked result

Date - indicates the date (dd/mm)

Exercise Marker - displayed when marking a result as after exercise, or viewing a marked result

Before-/After-Meal Marker - displayed when marking a result as before-meal or after-meal, or viewing a marked result



mem - indicates the meter is in memory recall mode and the number on the main display area is a memorized testing result

AVG - displayed when viewing the 1, 7, 14, 30, 60 and 90 days averaging. This is for glucose values only

Main Display Area - Displays test results, memorized testing results, errors and other messages

Meter failure icon

Ctl - indicates the meter is in control solution mode, or shows a memorized control solution result

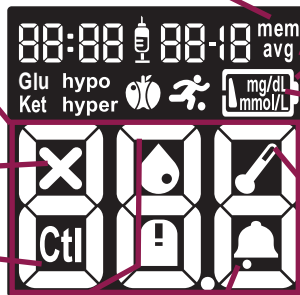
Blood drop and test strip icon - indicates the meter is ready for testing if both icons are lit up.

Alarm - indicates the alarm function is ON

Battery Symbol - Lights up to indicate a change of the battery is necessary

mg/dL, mmol/L - indicates the unit of measurement for glucose or ketone. The unit of measurement is set in the factory and cannot be changed.

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



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 Test Strip is a glucose specific, biosensor-based test strip that can test glucose in capillary whole blood in as little as 5 seconds and requires a very small blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be 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 GLU/KET (plus) 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 bottle immediately after each use. DO NOT leave any test strips outside the bottle 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. (2)

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 as little as 8 seconds and requires a very small blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be 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 GLU/KET (plus) 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 aluminum 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

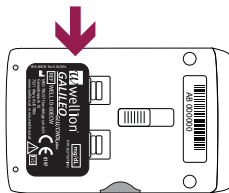
The batteries need to be inserted before using your Wellion GALILEO GLU/KET (plus) Meter for the first time or when the battery icon  appears on the meter display screen.

Material you will need:

2 x CR 2032 3V Lithium coin cell batteries

Your Wellion GALILEO GLU/KET (plus) Meter

Step 1: Turn the meter off. Remove the battery cover on the back of the meter by pushing the tab and pulling the door up. Remove the old batteries.



Step 2: Insert the new batteries with the "+" side up. They do not snap into place but rest on the metal contact. The door holds the batteries down. Put the battery door back in the place and snap it closed.

NOTE

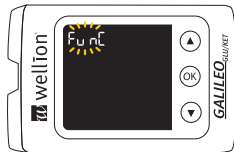
- After changing the batteries, the meter automatically prompts you to check the time and date when it is turned on either by inserting a test strip or pressing OK. If it is correct, press OK to confirm setup and exit, or if the time and date are not correct, refer to the chapter “Setting the Clock”.
- The date and stored results will not be erased when the batteries are being changed.
- Discard used batteries according to your local guidelines.
- The meter uses 2 x 3-volt lithium batteries, coin cell CR2032. This type of battery can be found in many stores. Always keep a spare packaged battery on hand.
- Be sure the batteries go in with the “+” side up.
- Remove the batteries if you are not going to use the meter for a long time.

Setting the Clock

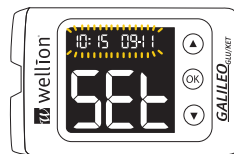
Material you will need:

Your Wellion GALILEO GLU/KET (plus) Meter

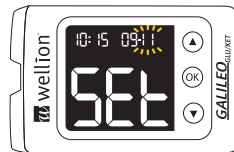
Step 1: With the meter turned off, press and hold the OK button until the screen displays “FunC”.



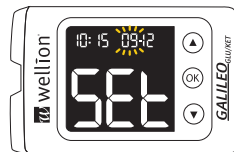
Step 2: Release the OK button and the meter will show the current date and time. If you are setting the date and time for the first time, the month will now start flashing to indicate you are in date and time set-up mode. If you are changing the date and time, "SEt" will show on the screen - press the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



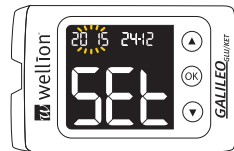
Step 3 - Set Month: The current month will flash. Use the arrow buttons to select the correct month. Press the OK button to confirm your choice and advance to set the day.



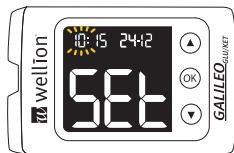
Step 4: Set Day: The current day will flash. Use the arrow buttons to select the correct day. Press the OK button to confirm your choice and advance to set the year.



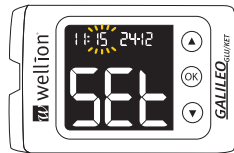
Step 5: Set Year: The current year will flash. Use the arrow buttons to select the correct year. Press the OK button to confirm your choice and advance to set the hour.



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 select the next function to setup, or insert a test strip and begin testing. 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.

Setting Warning Values for Glucose / Ketose Awareness threshold

Your Wellion GALILEO GLU/KET (plus) Blood Glucose and Ketone Meter has a feature to set your high and low blood glucose threshold (hyperglycemia and hypoglycemia values) to better assist you in understanding your blood sugar levels and glycemic state.

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

IMPORTANT

- Do not alter or stop your medication based on this feature, always consult your physician or healthcare provider before altering or stopping medication.
- The Wellion GALILEO GLU/KET (plus) Meter comes with Hypo/Hyper warning ON as preset, 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 GLU/KET (plus) Meter

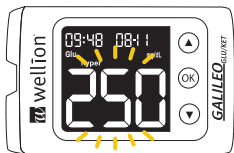
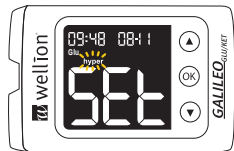
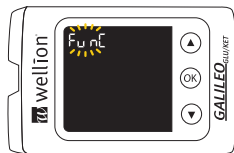
Step 1: With the meter turned off, press and hold the OK button until the screen displays "FunC".

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 awareness 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 GLU/KET (plus) 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 select the next function to setup or insert a test strip and begin testing. You can also turn off the meter by pressing and holding the OK button until the display screens shows OFF.

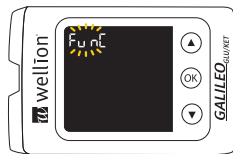
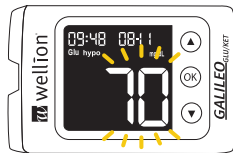
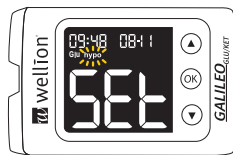
Anytime during setup, you may insert a test strip to begin testing. The changes you have confirmed with OK so far will be memorized by the meter.

Turning ON/OFF Tone Sound

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

Material you will need:

Your Wellion GALILEO GLU/KET (plus) 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.

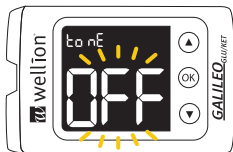
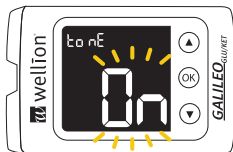
Step 3: Use the arrow buttons to turn the tone ON or OFF and confirm by pressing OK.

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.

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

You can set up a total of 6 alarms - 3 for glucose and 3 for ketone - on your Wellion GALILEO GLU/KET (plus) Meter. The default setting for all alarms is off. You must set the clock before you can set the alarms.

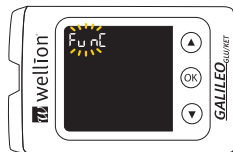



When the GLU glucose alarm sounds, the meter will turn on and beep continuously. When the KET ketone alarm sounds, the meter will turn on and make 3 beeps, pause, 3 beeps, pause, ... in repetition. Pressing **OK** button or inserting a test strip will silence the alarm.

Material you will need:

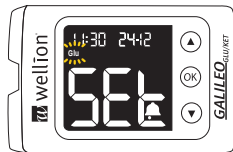
Your Wellion GALILEO GLU/KET (plus) Meter

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 testing, 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 is OFF). You can turn it on by pressing OK and then choosing the desired setting with the arrow buttons.

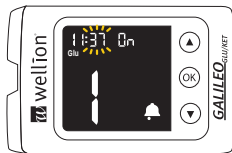
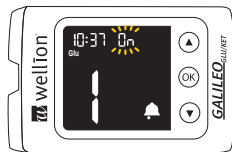
Step 5: Press OK and the hour will flash. Select the hour using the arrow buttons. Confirm your choice by pressing OK and advance to set minutes.

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.

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.

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 GLU/KET (plus) Blood Glucose and Ketone Monitoring System using the testing solution with a known range of glucose. Control solutions are sold separately.

You should perform control solution testing when:

- Using the meter for the first time
- You open a new bottle of Wellion GALILEO Blood Glucose Test Strips
- You leave the cap of the test strip vial open for a while
- You drop the meter
- You suspect your Wellion GALILEO GLU/KET (plus) Meter and Wellion GALILEO Blood Glucose Test Strips are not working properly
- The blood glucose test results do not reflect how you feel
- You want to practise the testing procedure


Materials you will need:

Wellion GALILEO Glucose Control Solution (Level 0, Level 1 or Level 2)

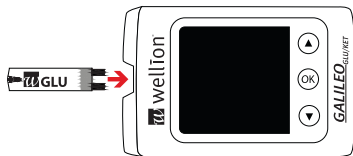
Your Wellion GALILEO GLU/KET (plus) Meter

A new Wellion GALILEO GLU Blood Glucose Test Strip

IMPORTANT

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

Step 1: Insert a Wellion GALILEO Blood Glucose Test Strip into the meter with the blood sample reaction zone facing up. Make sure the test strip contact points are inserted all the way into the meter. Close the test strip bottle immediately after you take out a test strip.





Step 2: 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.

IMPORTANT

- Do not use a test strip that has expired. Check the expiration date  which is printed on the test strip bottle.
- Use each test strip immediately after removing it from the bottle.
- After removing a test strip from the bottle, replace the bottle 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 bottle in a dry, cool place.
- Record the “date opened” on the test strip bottle label when you first open it. 6 months after first opened, discard the bottle and any remaining test strips.
- Make sure you are testing in an environment between 5°C-45°C, and allow 10 to 15 minutes for it to reach the new temperature before use. Your meter will not begin testing if it detects an out-of-range temperature.
- You will see a flashing blood drop icon if the test strip has been inserted correctly into the test strip port.

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. Replace the bottle cap on the control solution bottle immediately

after use.

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



Step 6: The screen will begin to count down. After 5 seconds, the control solution testing result will appear on the meter display screen. A "Ctl" flag will also be displayed when results are shown on the screen.



Step 7: Compare the reading on the screen to the control range printed on the test strip bottle. If the reading does not fall within the control range printed on the test strip bottle, 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 with your hand. The meter will turn off automatically. The meter will also time-out after 2 minutes of inactivity.

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

NOTE

- Control solution testing results will be stored into the meter's memory and indicated by "ctl" icon.
- Replace the bottle cap on the control solution bottle immediately after use.

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 GLU/KET (plus) Blood Glucose and Ketone Monitoring System using the testing solution with a known range of ketone. Control solutions are sold separately.

You should perform control solution testing when:

- Using the meter for the first time
- You open a new package of Wellion GALILEO Blood Ketone Test Strips
- You drop the meter
- You suspect your Wellion GALILEO GLU/KET (plus) Meter and Wellion GALILEO Blood Ketone Test Strips are not working properly
- You want to practise the testing procedure


Materials you will need:

Wellion GALILEO Ketone Control Solution (Level 2)

Your Wellion GALILEO GLU/KET (plus) Meter

A new Wellion GALILEO Blood Ketone Test Strip

IMPORTANT

- Use only the Wellion GALILEO Ketone Control Solution (Level 2) with the Wellion GALILEO Blood Ketone Test Strip. Other brands of control solution will produce inaccurate results.
- Always check the expiration date  . DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution 3 months after opening.
- DO NOT FREEZE or REFRIGERATE. Store the control solutions at 4°C-30°C

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

Step 2: The “Ket” symbol, the flashing blood drop and test strip icons appear on the meter display screen.

IMPORTANT

- 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 you are testing in an environment between 10°C-40°C, and allow 10 to 15 minutes for it to reach the new temperature before use. Your meter will not begin testing if it detects an out-of-range temperature.
- You will see a flashing blood drop icon if the test strip has been inserted correctly into the test strip port.

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. Replace the bottle cap on the control solution bottle immediately after use.



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



Step 6: The screen will begin to count down. After 8 seconds, the control solution testing result will appear on the meter display screen. A "Ctl" flag will also be displayed when results are shown on the screen.




Step 7: Compare the reading on the screen to 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 with your hand. The meter will turn off automatically. The meter will also time-out after 2 minutes of inactivity.

NOTE

- Control solution testing results will be stored into the meter's memory and indicated by "ctl" icon.
- Replace the bottle cap on the control solution bottle immediately after use.

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 ...
<ul style="list-style-type: none">• Wrong brand of control solution being used• Expired or contaminated control solution or damaged test strips• Meter malfunction• Control solution not at right storage temperature	<ul style="list-style-type: none">• 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 opened date on bottles of both control solution and test strip.• 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 GLU/KET (plus) 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. See the chapter “Setting Up Your New System” for more details.
- You 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 the temperature icon. Move the meter into an area that is between 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 the user, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

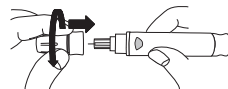
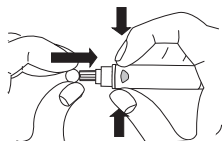
Preparing your Lancing device

CAUTION

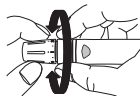
- Lancets are for single use only. ② Always use a new, sterile lancet each time you perform the test.
- DO NOT share your lancing device or lancets with other people. Sharing or reusing lancets can lead to disease transmission.
- Dispose of used lancets properly in biohazardous waste.
- If alcoholic 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.



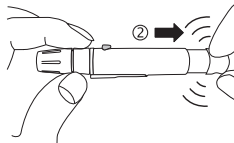
Step 3: Unscrew the adjustable cap of the lancing device and insert the lancet by pushing down firmly until it is fully seated.



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 to indicate if 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 GLU/KET (plus) 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 forearm¹, AST result may be significantly different than results from fingertip testing under certain conditions. You should consult with your doctor or healthcare professional before using AST.

DO AST ONLY in the following intervals:

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

Alternative site 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 results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Consult with your healthcare professional to decide if AST is right for you.

IMPORTANT

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

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differ s Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708–709, 200

Performing a Blood Glucose Test

Step 1: Take out a Wellion GALILEO Blood Glucose Test Strip from the test strip bottle and close the bottle 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 bottle.
- Use each test strip immediately after removing it from the bottle.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat ☀️. Store the test strips in a dry, cool place.
- Record the “date opened” on the bottle label. Discard the bottle and any remaining test strip after 6 months from date of opening.
- Insufficient blood specimen 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.

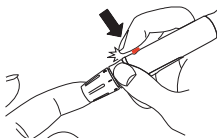
Step 2: Wait for the “Glu” symbol and the flashing blood drop and test strip icons to appear on the meter display screen.



Step 3 - Obtaining a blood drop:

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 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:

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 touch the test strip to 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 contact with 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.




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 if you want the result to be stored without any marker, or with one or more markers.

Press the arrow buttons to select  before meal marker,  after meal marker, or blank (= no meal marker). 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 icon  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.

Step 9: Remove the used test strip either by pushing the ejection button (if available) or by pulling it out with your hand. The meter will turn off automatically. The meter will also time-out after 2 minutes of inactivity.

Step 10: 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

- “hypo” or “hyper” icons may appear on screen depending on the threshold limit you have set up - see the chapter “Setting Warning Values”.
- The meter will turn off automatically when you pull the test strip out, or after 2 minutes of inactivity. If you do not select any marker before turning off, the test result will be stored without any marker.
- If error messages (E 1, E 2, etc.) appear, see the chapter “Solving Problems”.

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 1,1 mmol/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 1,1 mmol/L (20 mg/dL) in the meter memory (but not counted for the average values).

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 GLU/KET (plus) 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. See the chapter “Setting Up Your New System” for more details.
- You 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 10°C-40°C . Your meter will not test outside of this range and will display the temperature icon. Move the meter into an area that is between 10°C-40°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 the user, the meter and lancing device should be cleaned and disinfected appropriately when testing is conducted by the second person.

Preparing your Lancing device (please refer to pages 31 and 32)

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

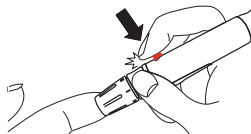
- Do not use a test strip that has expired. Check the expiration date  which is printed on the test strip foil.
- Use each test strip immediately after removing it from the foil.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat . Store the test strips in a dry, cool place.
- Insufficient blood specimen 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 icon 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 to create a puncture.



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 touch the test strip to 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 contact with the blood drop until the meter starts the countdown to indicate the test strip has enough blood to test.



Step 5: The screen will start to count down. After 8 seconds, your ketone testing result will appear on the meter display screen.

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 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 8,0 mmol/L or 0,1 mmol/L in the meter’s memory automatically.

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.

Step 6: Remove the used test strip either by pushing the ejection button (if available) or by pulling it out with your hand. The meter will turn off automatically. The meter will also time-out after 2 minutes of inactivity.

Step 7: 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.

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 are²:

- 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 physician or healthcare professional to determine an appropriate target range for you.

What to do if you get a high or low blood glucose reading

If the meter displays results that are “HI” or “LO”, or you get a result that is more than your high or low blood glucose threshold value and you feel ill:

- Treat your diabetes according to the instruction from your doctor and/or consult with your healthcare provider.
- Test your meter 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 made when the body is using fat for energy instead of using glucose because not enough insulin is available to use glucose for energy. It is a warning sign that your diabetes is out of control or that you are getting sick³.

If your blood glucose is higher than 13,9 mmol/L (250 mg/dL) and your blood ketone result is⁴:

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 if you get a high or low blood ketone reading:

If the meter displays results that are "HI" or "LO":

- 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 high or low reading, contact your healthcare professional immediately.

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 GLU/KET (plus) Meter can store up to 500 glucose test and control results with date and time. In addition, the meter also provides 1-, 7-, 14-, 30-, 60-, 90-day average 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 GLU/KET (plus) 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 days averages.

After you finish viewing the memory, either begin 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.
- 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.

Viewing Stored Readings of Ketone Test Results from Memory

Your Wellion GALILEO GLU/KET (plus) 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 GLU/KET (plus) 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.

After you finish viewing the memory, either begin 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.

Upload Data

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 specifically identifies the Wellion GALILEO GLU/KET (plus) as a meter that is compatible with their DMS.

CARING FOR THE METER

Caring for your Wellion GALILEO GLU/KET (plus) Meter is easy. Follow these simple guidelines to keep your Wellion GALILEO GLU/KET (plus) Meter working properly.

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 Wellion GALILEO GLU/KET (plus) Meter. Never immerse 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.
- Do not contaminate the strip holder with blood or control solution.

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 bottle cap immediately after removing a test strip and make sure it is closed tightly.
- Do not take the meter apart. Doing so will void the warranty.
- Do not use this meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.

- 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 operation of the meter.
- Dispose of the meter according to your local regulations for correct disposal.



SOLVING PROBLEMS

This section details the significant display screen messages and error codes you may encounter when using your Wellion GALILEO GLU/KET (plus) Meter and Wellion GALILEO Test Strips.

Message	What It Means	What You Should Do
E 1	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.

Message	What It Means	What You Should Do
E 2	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"
E 3	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"
E 4	Meter detects extreme condition	Move the meter into an area that is between 5°C to 45°C for glucose testing or 10°C to 40°C for ketone testing and allow 10 to 15 minutes for it to reach the new temperature. See the chapter "Storage and Precautions"
E 5	Meter failure	<ul style="list-style-type: none"> • 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.

Message	What It Means	What You Should Do
HI (with Glu symbol)	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 physician or healthcare professional immediately.
LO (with Glu symbol)	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 physician or healthcare professional immediately.
HI (with Ket symbol)	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 physician or healthcare professional immediately.
LO (with Ket symbol)	Ketone test result lower than 0,1 mmol/L	Wash and dry your hands and repeat the test using a new test strip. If the result is still "LO", contact your physician or healthcare professional immediately.

Message	What It Means	What You Should Do
	Low battery	Change the batteries according to instructions for Inserting (or Changing) the Battery
End	No memorized results in the meter	<ul style="list-style-type: none"> • 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	Move the meter into an area that is between 5°C to 45°C for glucose test or 10°C to 40°C for ketone test, and allow 10 to 15 minutes for it to reach the new temperature.

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



Manufacturer



In vitro diagnostic, medical device for self-testing

Software Version RDM0079-005-01 Rev 1.01

SPECIFICATIONS

Test parameters:	Glucose and Ketone
Eject button:	only on 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:	20-70% for glucose, 20-60% for ketone test
Event marker:	Before/After meal marker, exercise marker, medication/ insulin marker
Warnings:	hypoglycemia and hyperglycemia warning, underfill warning
Display Type:	VA screen with back lighting
Memory (with date and time):	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:	67 g (incl batteries)
Batteries:	2 x CR 2032 3V Lithium coin cell batteries
Battery Life:	1000 tests of continuous use or one year
Automatic Power-off:	After 2 minutes of inactivity
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.

Classification according to IEC/EN 61010-2-101

Electromagnetic Compatibility: This equipment complies with EMC requirement of EN 61326.

EU directive/classification: 98/79/EC Annex II, List B; Self-testing

MANUFACTURER'S WARRANTY

The manufacturer warrants the Wellion GALILEO GLU/KET (plus) blood sugar and ketone 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 MED TRUST can 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 *GLU/KET*



MEDTRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
AUSTRIA
www.medtrust.at

CE 0197



In Vitro Diagnostic
Medical Device

W10-32KEN RevA 09-2016

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