wellion®

CALLA mini

OWNERS GUIDE



Dear Wellion CALLA Mini Owner,

Thank you for choosing the Wellion CALLA Mini Blood Glucose Monitoring System to help you monitoring your blood sugar levels. We designed the Wellion CALLA Mini Blood Glucose Monitoring System to be accurate and easy to use.

Your new Wellion CALLA Mini Blood Glucose Monitoring System is designed with convenience and accuracy in mind to make your life easier. The No Code feature eliminates coding errors and ensures your test results are accurate on every test. All of the information needed to use and maintain your new meter is included in this manual. Please read it carefully.

The Wellion CALLA Mini Blood Glucose Monitoring System is a portable battery operated meter intended for use as an aid by persons with diabetes and by health care professionals to monitor glucose concentration in whole blood.

Intended Use: The Wellion CALLA Mini Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (in vitro diagnostic use). The Wellion CALLA Mini blood glucose meter is intended for both self-testing use by people with diabetes and professional use by healthcare professionals in a clinical setting, as an aid to monitoring glucose levels in Diabetes Mellitus. It is not intended for diagnosis 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 55% or lower than 30% can cause inaccurate blood glucose test results.
- Not intended for use on neonates.
- Patients undergoing oxygen therapy may receive inaccurate results.

If you have questions or simply need more information, please call our authorized representative or visit our website at www.medtrust.at

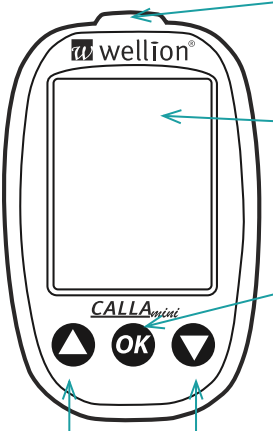
Thank you again for choosing the Wellion CALLA Mini Blood Glucose Monitoring System.

YOUR NEW BLOOD GLUCOSE KIT

The Wellion CALLA Mini Blood Glucose Monitoring System kit includes the following items:

Wellion CALLA Mini blood glucose meter
Wellion Lancing device
10 Wellion Lancets
Compact Pouch
User Guide

The Wellion CALLA Mini meter



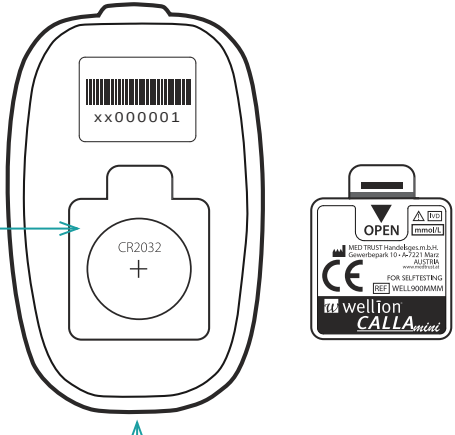
Test Strip Port
Insert test strip to turn on the meter.

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

OK Button
Press and hold to turn meter on and off.

Scroll Buttons
Press the scroll buttons to go into setup mode during meter setting, to navigate through stored test values and averages or when setting up the meter.

Das Wellion CALLA Mini Messgerät



Battery Compartment
Holds a 3V lithium battery (CR2032).

PC Connection Port
Plug in the data cable to transmit results onto a PC (Data cable and software sold separately*).

* The correct reading of your data can be ensured only with the original Wellion CALLA USB cable with Micro-USB connector.-

The Wellion CALLA Blood Glucose Test Strip

Sampling End
Apply blood or
control solution here



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

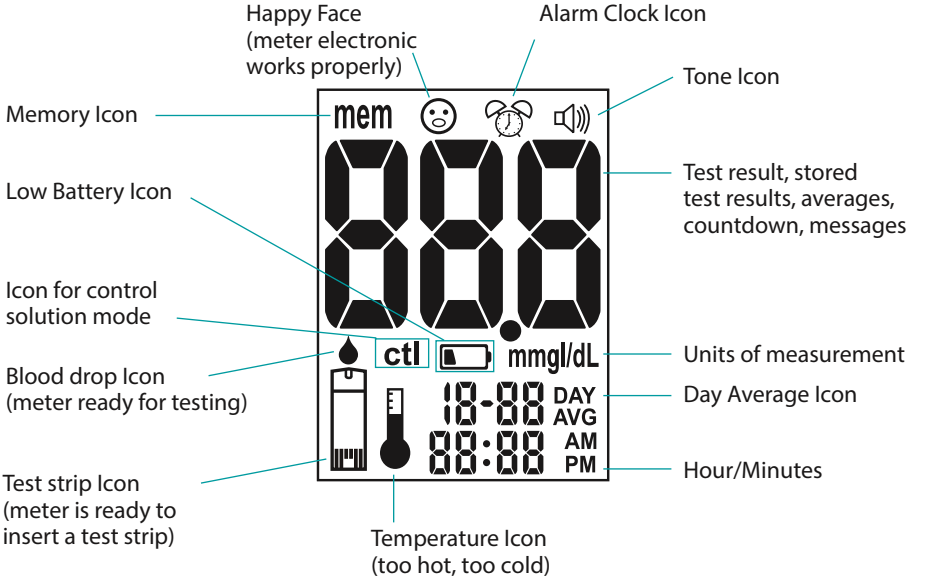
The Wellion CALLA Test Strips are glucose specific, biosensor-based test strips that can test glucose in capillary whole blood in as quickly as 6 seconds and require very little blood sample.

The No Code feature eliminates error in testing caused by incorrect coding or calibration procedure. The test result is plasma referenced for easy comparison to lab results. The meter has an under-fill detection to alert you when there is not enough blood to perform a test, so you can be assure that each reading you get is an accurate and meaningful result.

⚠ IMPORTANT:

- Be sure to use only the Wellion CALLA Blood Glucose Test Strip with the Wellion CALLA Mini Blood Glucose Meter. Other brands of test strips will not work with the Meter.
- The Wellion CALLA Blood Glucose Test Strips are sensitive to moisture and light, it is important to close the vial cap of the test strip bottle immediately tightly after each use. Keep the un-used test strips in the original bottle. DO NOT leave any test strips outside the bottle while not in use.
- DO NOT reuse test strips. Test strips are for single use only.
- Carefully discard used test strips and lancets in proper waste containers.

Meter Display Screen

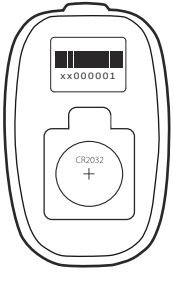


SETTING UP YOUR NEW SYSTEM

Inserting (or changing) batteries

Batteries need to be inserted before using your Wellion CALLA Mini Meter for the first time or when the battery icon appears on the meter display.

Materials you will need:
Your Wellion CALLA Mini Meter
One CR2032 3V Lithium coin cell battery (Supplied in Kit)



Step 1:
Unhook the hinge on the battery cover.

Step 2:
Insert a new battery to the battery socket with the "+" side facing up. Place the battery cover back into the meter firmly.

⚠ NOTE:

- The date and the stored results will not be erased when the batteries are being changed.
- When you change the battery, the meter automatically prompts you to check the time and date, when you turn on the meter or insert a test strip. If time and date are correct, press OK. If time and date are not correct, set them to the correct values.
- Discard used batteries according to your local regulation.

Setting the clock

Material you will need:
Your Wellion CALLA Mini Meter

⚠ NOTE:
- If date and time on the Wellion CALLA Mini Meter has not been set, test or control results will not be stored in the meter memory.

Step 1: Press and hold the OK button to turn on the meter.

Step 2: Release the OK button and the meter will run a system check automatically. "☺" will appear on the display before entering the main mode.

If an error message appears, please refer to chapter "solving problems"

After a flashing test strip icon appears on the screen, press the arrow-button ▲ twice until you can see the clock-symbol  .

Step 3 - Set Year:
Press the OK button to enter date and time set up. The current year will flash. Use ▼ or ▲ buttons to select the correct year. Press the OK button to confirm your choice and advance to set the month.

Step 4 - Set Month:
The current month will flash. Use ▲ or ▼ buttons to select the correct month. Press the OK button to confirm your choice and to advance to set the day.

Step 5 - Set Day:
The current day will flash. Use ▲ or ▼ buttons to select the correct day. Press the OK button to confirm your choice and to advance to set the time format.

Step 6 - Set Time format (12h/24h): The time format will flash. Use ▲ or ▼ buttons to select the time format. Press the OK button to confirm your choice and to advance to set the hour.

Step 7 - Set Hour:
The current hour will flash. Use ▲ or ▼ buttons to select the correct hour. Press the OK button to confirm your choice and to advance to set the minutes.

Step 8 - Set Minute:
The current minute will flash. Use ▲ or ▼ buttons to select the correct minutes. Press the OK button to confirm your choice and exit time setup.

Insert a test strip and begin testing, or turn off the meter by press and hold the OK button until the display screens shows OFF.

⚠ NOTE:

- Anytime during set up, inserting a CALLA Test Strip will begin testing. The changes you have done so far will be memorized by the meter.

Turning ON/OFF tone sound

The Wellion CALLA Mini Meter comes with tone ON as preset. Turning off the tone will cause you to miss many important cues from your meter - such as confirmation or error messages.

Material you will need: Your Wellion CALLA Mini Meter

Step 1: Scroll through the settings for the tone setting, press OK button to enter tone set up. The tone icon  will be visible and the current tone status will appear on the LCD screen.

Step 2: Use ▲ or ▼ buttons to turn the tone on or off. Press the OK button to confirm your choice.

Insert a test strip and begin testing, or turn off the meter by press and hold the OK button until the display screens shows OFF.

⚠ NOTE:

- Anytime during set up, inserting a CALLA Test Strip will begin testing. The changes you have made so far will be memorized by the meter.

Setting alarms

Your Wellion CALLA Mini Meter has 3 alarms that can be setup. The factory preset is off for all alarms. Follow the steps below to setup up your alarms.

Material you will need
Your Wellion CALLA Mini Meter

Step 1: Press ▲ or ▼ buttons in the settings menu until the alarm clock flashes.

Step 2: Press the OK button and enter alarm setup for alarm number 1.

Step 3: The actual status (OFF/ON) will flash.
Press ▲ or ▼ buttons to change the setting and turn ON/OFF alarm 1.

Step 4: If ON is selected and you press the OK button, you will proceed with setting the hour. Press the ▲ or ▼ to change the hour. Press OK to confirm your choice.

Step 5: Press the ▲ or ▼ to change the minute. Press OK to confirm your choice.

⚠ NOTE:
- If OFF is selected and the OK button is pressed, you will proceed to set the next alarm.
- After leaving the settings, the alarm clock icon will appear permanently to indicate that an alarm was set.

CONTROL SOLUTION TESTING

The purpose of the control solution testing is to validate the performance of the Wellion CALLA Mini Blood Glucose Monitoring System using the testing solution with a known range of glucose.

You can perform control solution testing when:
- Using the meter for the first time
- You open a new bottle of test strips
- You left the cap on the test strip vial open for a while

- You dropped the meter
- You suspect your meter and test strips are not working properly
- The blood glucose test results do not reflect how you feel
- Practice the testing procedure

Materials you will need:
Your Wellion CALLA Mini Meter
Wellion CALLA Control Solution Level 0/1/2
A new Wellion CALLA Blood Glucose Test Strip

⚠ IMPORTANT:

- Use only the Wellion CALLA Glucose Control Solutions with the Wellion CALLA Test Strips. Other brands of control solution will produce inaccurate results.
- Always check the expiration date ⌛. DO NOT use control solutions if expired.
- Mark the newly opened bottle of control solution with the date opened; discard any unused control solution three months after opening.
- DO NOT FREEZE. Store the control solutions at room temperature.
- Do not use test strip that has expired. Check the expiration date that is printed on the test strip bottle and its package
- 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, bent, scratched 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 date, discard the bottle and any remaining Test Strip
- Make sure you are testing between 10°C - 40°C. If the Meter displays , move the meter into an area that is 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’s outside this temperature range.

Step 1: Insert a Wellion CALLA Blood Glucose Test Strip into the meter. 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 strip.

Step 2: "☺" will appear, on the screen before entering the main mode. Wait for the test strip and flashing blood drop icons to appear on the meter display screen.

Step 3: Squeeze a drop of Wellion CALLA Control Solution onto a clean, dry, nonabsorbent 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 4: While holding the meter, touch the control solution to the edge of the test strip, and the control solution would be automatically sipped into the reaction area of the test strip. Hold the meter until it beeps.



Step 5: The screen will count down. After 6 seconds, the control solution testing result will appear on the meter display screen.

Step 6: Compare the reading on the screen to the corresponding control range printed on the test strip bottle or its package. If the reading does not fall within the ranges printed on the test strip bottle or its package, see chapter “Control Solution Trouble Shooting”.



Step 7: Remove and discard the used test strip into proper waste basket. The meter will automatically shut off after the test strip has been removed, or will shut off after 1,5 minutes of nonuse.

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

⚠ NOTE:

- Control solution testing results will be stored into the meter memory and indicated by ctl icon.
- Control solution testing result will not be used for calculating averages.
- DO NOT reuse test strips.

Control Solution Trouble Shooting

If your control solution testing is out of range (too high or too low), it maybe caused by the following:

Possible Causes	What you can do ...
• Wrong brand of Control Solution being used • Control solution not at room temperature • Expired or contaminated control solution • Damaged test strip • Meter malfunction	• Make sure you are using Wellion CALLA Control Solution. • Make sure the testing environment is between 10°C to 40°C. • Check the expiration and open bottle date on all control solution and test strips. Repeat testing using a new test strip. If the result is still out of range, use a new bottle of control solution and retest. • If problem persists, call our authorized dealer.

TESTING YOUR BLOOD GLUCOSE

After every turning on of the meter it will perform a system check automatically.

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

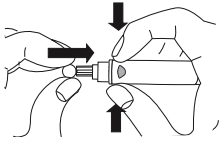
Before you begin, make sure:

- Set up your meter properly and run a control test. See chapters "Setting Up Your New System", and "Control Solution Testing" for details.
- Wash your hands and testing site thoroughly with soap plus warm water, and dry well.

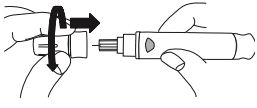
- You are testing in an area between the temperature ranges of 10°C to 40°C. Your meter will not test outside of this range and will display . Move the meter into an area that is between 10°C to 40°C and let it sit for 10 to 15 minutes before testing again.

Preparing your Lancing device

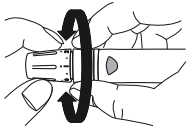
Step 1: Unscrew the adjustable cap of the lancing device and insert the lancet by push down firmly until it is fully seated.



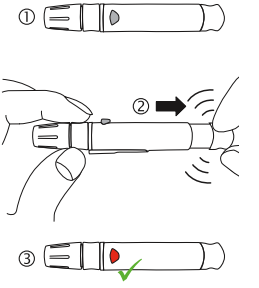
Step 2: Twist the protective cover off from the lancet. Twist clockwise the adjustable cover back onto the lancing device.



Step 3: Adjust the puncture setting on the adjustable cap for the puncture depth level (1 is the lightest and 10 is the deepest).



Step 4: 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 is now colored red, so you can easily verify if the lancing device is ready for blood sampling.

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

⚠ IMPORTANT:

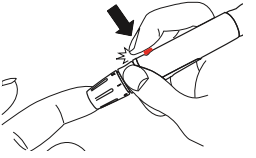
- Use a new sterile lancet every time you test to avoid cross contamination. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

⚠ IMPORTANT:

- Check the expiration date printed on the test strip bottle and its package. Do not use expired test strips.
- 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 strip bottle 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.

Step 1: Take out a Wellion CALLA Test Strip from the test strip bottle and close the bottle immediately. Insert the test strip to turn on the meter. Wait for the test strip and flashing blood drop icons to appear on the meter display screen.

Step 2: Hold the lancing device 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 3: Gently bring the test strip and touch the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in. Keep the test strip in the blood drop until the meter beeps to indicate the test strip has enough blood to test.



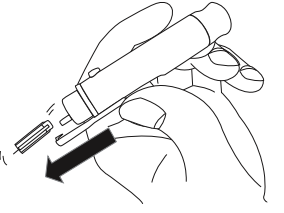
Step 4: The screen count down and after 6 seconds, your glucose testing result will appear on the meter display screen.

Step 5: Remove and discard the used test strip into proper wastebasket. The meter will automatically shut off.



⚠ CAUTION:
If you see "HI" or "LO" displayed, your blood glucose level may be above 600 mg/dL (33,3 mmol/L) or below 20 mg/dL (1,1 mmol/L). Test again using fingertip testing. If you still receive the same result, call your physician or healthcare professional immediately.

Step 6: 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 simultaneously pull out the sliding barrel to dispose of the used lancet. Discard the lancet into proper wastebasket.



⚠ IMPORTANT:
Discard used test strips and lancets according to your local disposal regulations where applicable.

UNDERSTANDING YOUR BLOOD GLUCOSE TEST RESULT

Blood glucose value will vary depending on food intake, medication, health, stress, and exercise. The ideal range for adult without diabetes should be:

- Less than 100 mg/dl (5,6 mmol/l) before meals
- Less than 140 mg/dL (7,8 mmol/L) two hours after meal[1].

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

Reference:
(1) American Diabetes Association Position Statement: Standarts of Medical Care in Diabetes - 2010. Diabetes Care 2010; 33 (Suppl.1): S11-S61.

What to do if you get a high or low reading?

If the Meter displays results that are marked with „HI“ or „LO“, OR you get a result that is more than 250 mg/dL (13,9mmol/L) or below 50 mg/dL (2,8mmol/L) AND you feel ill:

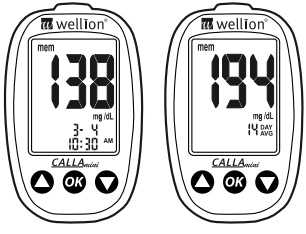
- Treat your diabetes according to the instruction from your doctor and/or consult your healthcare provider.

If the Meter displays results that are marked with „HI“ or „LO“, OR you get a result that is more than 250 mg/dL (13,9 mmol/L) or below 50 mg/dL (2,8 mmol/L) AND you DO NOT feel ill:

- Test your meter with a control solution, refer to chapter “Control Solution Testing”.
- Test again using fingertip.
- If you still get a high or low reading, contact your health care professional.

VIEWING STORED READINGS AND 7, 14, 21 UND 30 DAYS AVERAGE FROM MEMORY

The CALLA Mini Meter automatically stores up to 300 test and control results with date and time. In addition, the meter also provides 7, 14, 21 and 30 days averaging to help you better track your effort in controlling your blood glucose level. You will need to set your meter date and time to use the memory and day averaging function, see chapter "Setting Up Your New System". The meter will not memorize any test or control results if the date and time are not set.



Materials you will need:
Your Wellion CALLA Mini Meter

Step 1: Turn on the meter by press and hold the OK button. "☺" will appear, on the screen before entering the main mode. After the

flashing test strip icon appears, press the ▲ button once, and the "mem" will appear at the upper left corner of the display screen. Press "OK" to select the "mem" mode.

Step 2: The meter shows the latest memorized result. Press ▲ button to scroll through the results.

„nil" will appear if there are no recorded test results in the memory

Step 3: Press the ▼ button to scroll to the day averages. The first average will be the 7 days average. Continue to press ▼ button to scroll through 14, 21 and 30 days averages.

Step 4: Press and hold the OK button to turn the meter off when finished or insert a test strip to begin testing.

⚠ NOTE:

- Control testing results is flagged by "ctl" on the bottom left corner of the display screen in addition to "mem".
- Control testing results will not be included in the day averages.
- „nil" will appear if there are no recorded test results in the memory.
- When there are no day average data available, the display screen will show 3 dashes.
- If the memory already has 300 test results, adding a new test result will cause the oldest one to be deleted.
- Memorized test results and day averages will not be erased when changing batteries.

CARING FOR THE METER

Caring your CALLA Mini Meter is easy. Follow these simple guidelines to keep your 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 CALLA Mini 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 test strips are designed to be used within the temperature ranges between 10°C to 40°C.
- Avoid leaving the meter in extremely hot or cold place, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips in high humidity levels, such as bathroom or kitchen.
- Always close bottle cap immediately after removing a test strip and make sure it's closed tightly.
- Do not take the meter apart. Doing so will void the warranty. If there are technical problems or questions, call our authorized dealer for assistance.
- 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.

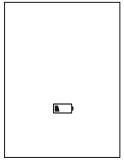
- Do not use this meter near cellular or cordless telephones, walkie-talkies, garage door openers, radio transmitters, or other electrical or electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

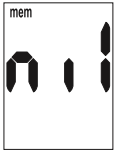
SOLVING PROBLEMS

This section details the significant display screen messages and error codes you will encounter when using your Wellion CALLA Mini meter and test strips.

What you see	What it meanst	What should you do
	Memory Error	• Remove the battery and turn on the meter again • Remove the test strip and insert a new test strip into the meter. • If the problem persists, contact the local distributor.

	Strip error	• Remove the test strip and insert a new test strip into the meter. • 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. • If the problem persists, contact the local distributor.
	Blood is not enough	• Remove the test strip and repeat the test with a new test strip. See chapter “Performing a blood glucose test”

	Test result is higher than 600 mg/dL (33,3 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.
	Test result is lower than 20 mg/dL (1,1 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.
	Battery is low	• Change the battery according to chapter "Inserting (or changing) the Battery"

	There are no memorized results in the meter	• Start testing your blood glucose, see chapter “Performing a blood glucose test”
	Testing has been performed outside of operating temperature.	• Move the meter into an area that is between 10°C to 40°C, and allow 10 to 15 minutes for it to reach the new temperature

MANUFACTURER´S WARRANTY

The producer warrants Wellion CALLA Mini blood glucose meter against defects in materials and workmanship for a period of two years from the date of purchase. The warranty is lost if the instrument is misused, poorly maintained or is tampered with.

Liability under this warranty is limited to the repair of defective parts or - at the discretion of the producer - to the replacement of the instrument. The right to rescind the purchase agreement exists only if the replacement is also found to be defective. Claims other than these will not be dealt with.

The liability of the producer is limited to repair or replacement and in no event shall the producer be liable for any collateral or consequential damages or loss.

The warranty is not valid if the damage results from misuse, neglect, unauthorized reapair or modification, maltreatment, tampering, human error and the use under extreme conditions. This guarantee specifically excludes expendables and consumables. The warranty period is not to be extended by any claim made under this warranty.

SPECIFICATIONS

Test Strips:	Wellion CALLA Blood Glucose Test Strips
Test Range:	20-600 mg/dl (1,1 - 33,3 mmol/L)
Calibration:	Plasma
Test Time:	6 Seconds
Sample Size:	0,65 µl
Hematocrit Range:	35 – 50 %
Display Type:	Large LCD screen
Memory:	300 blood test results with date and time
Dimension:	48 x 78 x 17 mm
Weight:	34g (incl. batteries)
Battery:	1 x CR 2032 3V Lithium coin cell battery
Battery Life:	1000 tests of continuous use or 1 year
Automatic Power-off:	After 1,5 minutes of nonuse
Operating Temperature:	10°C to 40°C
Relative Humidity:	Less than 85%
Storage Condition:	Meter at -20°C - +60°C Test Strips at 4°C - 30°C

For additional information, refer to the Wellion CALLA Test Strip insert. Alternate Site Testing (AST) on palm or forearm possible.

SYMBOLS

	Expiration date (use by last day of 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

FOR SELF-TESTING

In vitro diagnostic, medical device for self-testing

wellion®

CALLA mini

MED TRUST
THE MEDICAL SERVICES COMPANY

AUSTRIA

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In Vitro diagnostisches, medizintechnisches Gerät

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