wellion®

LEONARDO GLU/CHOL

OWNER'S GUIDE

Dear Wellion LEONARDO GLU/CHOL (plus) Owner,

Thank you for choosing the Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol Monitoring System to help you easily monitor your blood sugar level and cholesterol level.

The Glucose mode is auto-coding that does not require you to code the meter before use. The Cholesterol mode needs to be coded for each lot of test strips. All of the information you need to use and maintain your new Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol Monitoring System is included in this manual.

The Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol Monitoring System contains two test modes: glucose mode and cholesterol 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 the information needed to use and maintain your new meter is included in this manual. Please read it carefully.

INTENDED USE

The Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol Monitoring System is intended to quantitatively measure blood glucose in fresh capillary whole blood drawn from fingertips, palm, or forearm, and cholesterol in 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 cholesterol 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 results. 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 10% can cause inaccurate blood glucose test results. A haematocrit range that is higher than 55% or lower than 30% can cause inaccurate cholesterol test results.
- Suitable for self-testing.
- Not intended for use on neonates.

YOUR NEW MEASURING KIT

The Wellion LEONARDO GLU/CHOL (plus) measuring kit includes the following items:

Wellion LEONARDO GLU/CHOL (plus) meter incl. batteries
Wellion LEONARDO Glucose Strips (optional)
Wellion LEONARDO Cholesterol Strips (optional)
Wellion Lancing device
Wellion Lancets
Compact Pouch
Owner's guide
Easy Start Picture Guide

Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol meter

Illuminated Test Strip Port
This is where you insert the test strip. The illumination facilitates measurements in a dark environment.
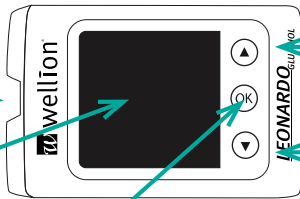
Meter Display
Shows your test results, memory values, average, and other messages

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

OK button
Use to turn the meter on/off, to access the meter memory mode and the set-up mode. Also used to select specific functions when in memory recall mode and set-up mode.

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

Code Card Port
Insertion site for the cholesterol code card.
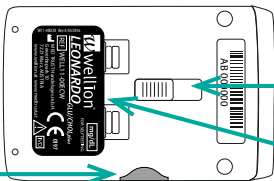
Eject Button (if available)
Push and eject a used test strip. Meter will turn off automatically when the test strip is ejected.

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

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

Meter Display Screen

Time - indicates the time.

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

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

Date - indicates the date (dd/mm).

GLU/CHOL – indicates whether the meter is in glucose or cholesterol test mode.

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

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
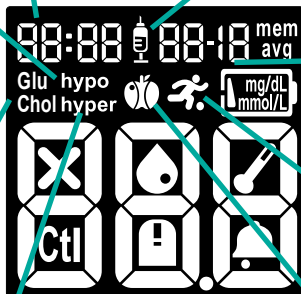• Indicates the memorized result when at or above your hyperglycemic threshold value

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 day averages. This is for glucose values only

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

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

Meter failure icon

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

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

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 cholesterol test 18°C - 38°C

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
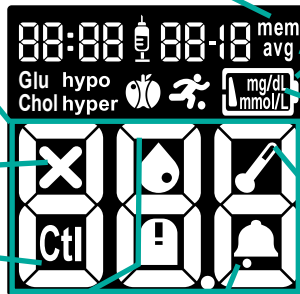
The Wellion LEONARDO Blood Glucose Test Strip

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 LEONARDO 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 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 LEONARDO Blood Glucose Test Strip with the Wellion LEONARDO GLU/CHOL (plus) Meter. Other brands of test strips will not work with the meter.
> - The Wellion LEONARDO 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 LEONARDO Cholesterol 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 LEONARDO Cholesterol Test Strip is a cholesterol specific, biosensor-based test strip that can test cholesterol in capillary whole blood in 90 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 LEONARDO Cholesterol Test Strip with the Wellion LEONARDO GLU/CHOL (plus) Meter. Other brands of test strips will not work with the meter.
- The Wellion LEONARDO Cholesterol Test Strips are sensitive to moisture and light. 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

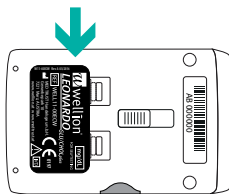### Inserting (or Changing) the Batteries

The batteries need to be inserted before using your Wellion LEONARDO GLU/CHOL (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 LEONARDO GLU/CHOL (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 into 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 LEONARDO GLU/CHOL (plus) Meter

Step 1: With the meter turned off, press and hold the OK button until the screen displays "FunC".
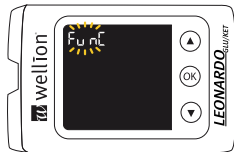
Step 2: Release the OK button and the meter will show the current date and time. If you are setting the date and time for the first time, the month will now start flashing to indicate you are in date and time set-up mode. If you are changing the date and time, "SEt" will show on the screen - press the OK button to enter date and time set-up mode.
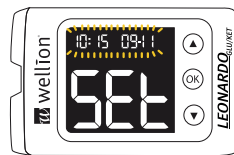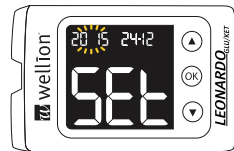
Step 3 - Set Month: The current month will flash. Use the arrow buttons to select the correct month. Press the OK button to confirm your choice and advance to set the day.
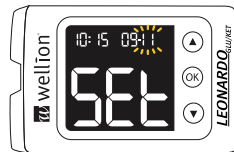
Step 4 - Set Day: The current day will flash. Use the arrow buttons to select the correct day. Press the OK button to confirm your choice and advance to set the year.
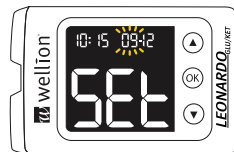
Step 5 - Set Year: The current year will flash. Use the arrow

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.
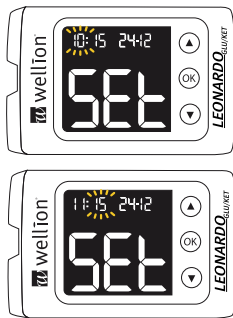
Setting Warning Values for Glucose threshold

Your Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol 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 LEONARDO GLU/CHOL (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:
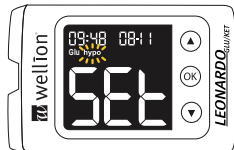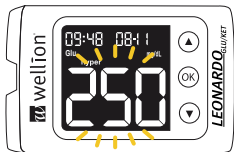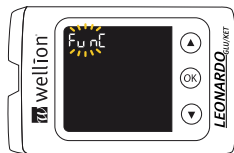Your Wellion LEONARDO GLU/CHOL (plus) Meter
Step 1: With the meter turned off, press and hold the OK button until the screen displays "FunC".

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 awareness threshold:** Press the OK button to enter hyper setup. Use the arrow buttons to adjust the threshold for your individual hyper warning awareness threshold. Confirm your choice with OK.

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.
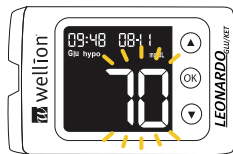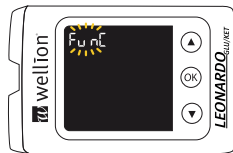
TURNING ON/OFF TONE SOUND

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 LEONARDO GLU/CHOL (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 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.
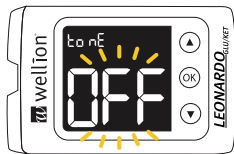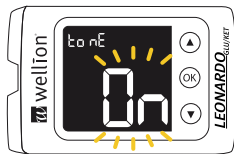
Setting the Alarm

You can set up a total of 6 alarms - 3 for glucose and 3 for cholesterol - on your Wellion LEONARDO GLU/CHOL (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 CHOL cholesterol alarm sounds, the meter will turn on and make 3 beeps, pause, 3 beeps, pause, ... in repetition. Pressing the OK button or inserting a test strip will silence the alarm.

Material you will need:
Your Wellion LEONARDO GLU/CHOL (plus) Meter

Step 1: With the meter turned off, press and hold the OK button until the screen displays "FunC".
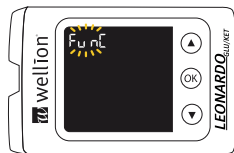
Step 2: Release the OK button and the meter will show the current date and time will flash together with "SEt". Press the arrow buttons until to display shows the alarm symbol 🔔 together with "SEt". Press the OK button to enter alarms set up.

Step 3: The display screen will flash "Glu" or "Chol". For setting up alarms on glucose testing, select "Glu" using the arrow buttons and press the OK button. For setting up alarms on cholesterol testing, select "Chol" using the arrow button and press the OK button.
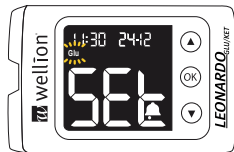
Step 4: The display screen will indicate the alarm 1 status (the default is OFF). You can turn it on by pressing OK and then choosing the desired setting with the arrow buttons.

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 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.
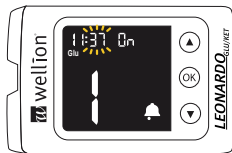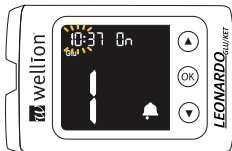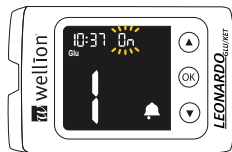
CODING THE METER

You must code the meter before you begin cholesterol testing on your Wellion LEONARDO GLU/CHOL (Plus) Meter. Coding is a process of programming the meter to the new package of cholesterol test strips and to ensure accurate test results. A new code card is packaged along with each box of Wellion LEONARDO Cholesterol Test Strips.

Materials your will need:
• A code card for the Wellion LEONARDO Cholesterol Test Strip
• A Wellion LEONARDO Cholesterol Test Strip
• Your Wellion LEONARDO GLU/CHOL (Plus) Meter

NOTE
• Make sure the Wellion LEONARDO Cholesterol Test Strip is not expired. Check the test strip expiration date ⧗ on the test strip foil.
• Make sure the code card is securely lodged into the code card port on the backside of the meter.

Step 1: Locate the code card in the package of Wellion LEONARDO Cholesterol Test Strips.

Step 2: Verify that the code number on the code card matches the code number on the test strip package.

Step 3: With the back of the meter facing you, insert the code card firmly and completely into the code card port.

Step 4: Turn the meter on either by pressing and holding "OK" or by inserting a test strip, the code number will then be memorized by the meter.

Step 5 – Confirming the code number: Insert a cholesterol test strip into the meter with the blood sample reaction zone facing up and ensure the test strip contact points are inserted all the way

Code

123

AB 000000

123

*ω*wellion®
LEONARDO
REF WELL11-00ECW GLU/CHOL*plus*
mg/dL
FOR SELFTESTING
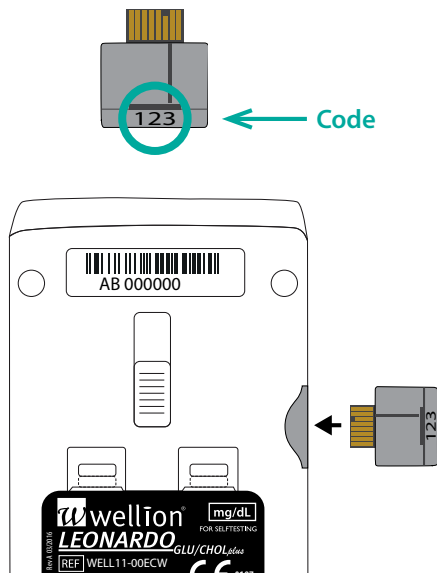
into the meter. The meter will turn on automatically.

Step 6: A 3-digit code number will be displayed on the meter display screen. Verify the code number on the screen with the number on the code card and the test strip foil pouch. All three sets of numbers should be the same.

IMPORTANT
- The code card found in the Wellion LEONARDO Cholesterol Test Strip package is for use with that particular package only. Different packages of Wellion LEONARDO Cholesterol Test Strips and other brands of test strips will produce inaccurate results.
- Re-coding needs to be done when a new package of test strips is opened for use.
- The code number will be memorized by the meter even if the code card is removed.

NOTE
- If the code number displayed on the screen does not match the code number printed on the test strip foil pouch or package, it will create inaccurate test results.
- If error messages (E 1, E 2, etc.) appear, see "Solving Problems".

Begin testing by inserting a test strip, or turn off the meter by pressing and holding "OK" until the meter display screen shows "OFF".

CONTROL SOLUTION TESTING

Performing a Glucose Control Solution Test

The purpose of glucose control solution testing is to validate the performance of the Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol 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 LEONARDO 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 LEONARDO GLU/CHOL (plus) Meter and Wellion LEONARDO 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 LEONARDO Glucose Control Solution (Level 0, Level 1 or Level 2)
Your Wellion LEONARDO GLU/CHOL (plus) Meter
A new Wellion LEONARDO Blood Glucose Test Strip

Step 1: Insert a Wellion LEONARDO 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.

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.

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 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 eject 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.

Performing a Cholesterol Control Solution Test

The purpose of the cholesterol control solution testing is to validate the performance of the Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol Monitoring System using the testing solution with a known range of cholesterol. 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 LEONARDO Cholesterol Test Strips
- You drop the meter
- You suspect your Wellion LEONARDO GLU/CHOL (plus) Meter and Wellion LEONARDO Cholesterol Test Strips are not working properly
- You want to practise the testing procedure

Materials you will need:
Wellion LEONARDO Cholesterol Control Solution (Level 1 or Level 2)
Your Wellion LEONARDO GLU/CHOL (plus) Meter
A new Wellion LEONARDO Cholesterol Test Strip

IMPORTANT
- Use only the Wellion LEONARDO Cholesterol Control Solution (Level 1 or Level 2) with the Wellion LEONARDO Cholesterol 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: You must code the meter before performing a cholesterol control solution test - see the section "Coding the Meter".

Step 2: Insert a Wellion LEONARDO Cholesterol 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.

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.
- Make sure you are testing in an environment between 18°C-38°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: The current code number will be displayed with a "Chol" icon. Verify the displayed code number with the code number printed on the code card and the test strip package. The flashing blood drop and test strip icons will then appear on the middle of the meter display screen.
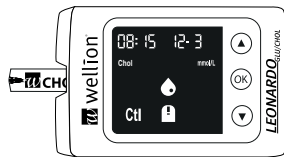
Step 4: Press the arrow button to enter the control mode. You will see "Ctl" on the screen.

Step 5: Squeeze a drop of cholesterol control solution (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 6: 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 7: 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 8: 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 9: Remove the used test strip either by pushing the eject 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. ②

Control Solution Trouble Shooting

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

Possible Causes:	What you can do …
• Wrong brand of control solution being used • Expired or contaminated control solution or damaged test strips • Meter malfunction • Control solution not at right storage temperature	• Make sure you are using Wellion LEONARDO Glucose Control Solution (Level 0, Level 1 and Level 2) or Wellion LEONARDO Cholesterol Control Solution (Level 1, Level 2). • Make sure the testing environment is between 5°C-45°C for glucose test, or between 18°C-38°C for cholesterol 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 LEONARDO GLU/CHOL (plus) Meter
A new Wellion LEONARDO 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

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

Step 2: Hang the arm down at the side for 10 to 15 seconds massaging through the wrist, palm, and then finger. This can stimulate the blood flow more quickly.
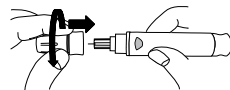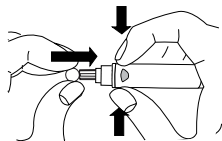
Step 3: Unscrew the adjustable cap of the lancing device and insert the lancet by pushing down firmly until it is fully seated.
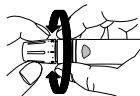
Step 4: Twist the protective cover off from the lancet. Replace the adjustable cover back onto the lancing device.

Step 5: Adjust the puncture setting on the adjustable cap for the puncture depth level (1 is the lightest and 10 is the deepest).
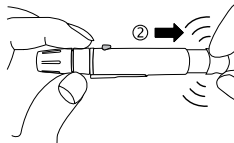
Step 6: With one hand holding the lancing device, pull back the cocking handle with your other hand until you hear a click sound and the lancing device is ready.
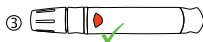
The release button should now be coloured red to indicate the lancing device is ready for blood sampling.

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

TIP
• To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

Important Information on Alternative Site Testing (AST)

The Wellion LEONARDO GLU/CHOL (plus) Blood Glucose and Cholesterol 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)
• 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 LEONARDO 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 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.
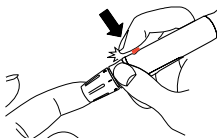
> **TIP**
> - Gently massage your hand and finger toward the puncture site to form a drop of blood. Do not "milk" or squeeze around the puncture site.
> - Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

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 eject 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 1.1mmol/L (20 mg/dL). Test again using fingertip blood. 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).

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 CHOLESTEROL

Materials you will need:
Your Wellion LEONARDO GLU/CHOL (plus) Meter
A new Wellion LEONARDO Cholesterol 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 18°C-38°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 18°C-38°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

Performing a Cholesterol Test

Step 1: You must code the meter before performing a blood cholesterol test - see the chapter "Setting Up Your New System".

Step 2: Take out a Wellion LEONARDO Cholesterol Test Strip from the test strip foil. Insert the test strip to turn on the meter.

Step 3: The current code number will be displayed with a "Chol" icon. Verify the displayed code number with the code number printed on the code card and the test strip package. The flashing blood drop and test strip icons will then appear on the middle of 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.
- 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 4 – Obtaining a blood sample
<u>For fingertip testing:</u> Hold the primed lancing device firmly against the side of your fingertip and press the release button to create a puncture.
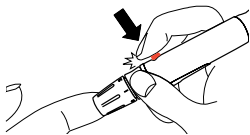
TIP
- The cholesterol test requires more blood than the glucose test so you may want to increase the puncture depth of the lancing device.
- Gently massage your hand and finger toward the puncture site to form a drop of blood. Do not "milk" or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

Step 5: 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 6: The screen will start to count down. After 90 seconds, your cholesterol testing result will appear on the meter display screen.

CAUTION
- If "HI" or "LO" is displayed, your cholesterol level may be beyond the meter measurement range - above 10,3 mmol/l (400 mg/dL) or below 2,6 mmol/l (100 mg/dL). Test again using fingertip blood. 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 10,3 mmol/l (400 mg/dL) or 2,6 mmol/l (100 mg/dL) 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 7: Remove the used test strip either by pushing the eject 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 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.

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

<u>What to do if you get a high or low blood glucose reading</u>
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 Cholesterol Test Results

High blood cholesterol is one of the major risk factors for cardiovascular disease. But high level of blood cholesterol does not cause symptoms - people do not feel ill just by having high blood cholesterol. Many people are totally unaware that their cholesterol level is too high, therefore it is very important to keep a constant monitor of your cholesterol level. Consult your physician about your blood cholesterol level.

Total cholesterol levels[3]:

<5,2 mmol/L (200 mg/dL)	Desirable
5,2 – 6,2 mmol/L (200-239 mg/dL)	Borderline High
≥ 6,2 mmol/L (240 mg/dL)	High

Contact your physician or healthcare professional for advice if you keep getting high results.

3. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: High Blood Cholesterol- What You Need to Know. NHLBI publication No.05-3290, June 2005.

IMPORTANT
- A haematocrit range that is higher than 55% or lower than 30% can cause inaccurate blood cholesterol test results.
- To ensure accurate test results, you should fast for at least eight hours before you perform your blood cholesterol test.

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 LEONARDO GLU/CHOL (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 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 LEONARDO GLU/CHOL (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 day 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 1.1 mmol/L (20 mg/dL). These results will not be counted for the averages.

Viewing Stored Readings of Cholesterol Test Results from Memory

Your Wellion LEONARDO GLU/CHOL (plus) Meter can store up to 100 cholesterol 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 LEONARDO GLU/CHOL (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 "Chol" 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 10,3 mmol/l (400 mg/dl) or 2,6 mmol/l (100 mg/dl) for cholesterol.

Upload Data

Insert the Wellion LEONARDO 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 LEONARDO GLU/CHOL (plus) as a meter that is compatible with their DMS.

CARING FOR THE METER

Caring for your Wellion LEONARDO GLU/CHOL (plus) Meter is easy. Follow these simple guidelines to keep your Wellion LEONARDO GLU/CHOL (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 LEONARDO GLU/CHOL (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 18°C and 38°C for cholesterol 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 LEONARDO GLU/CHOL (plus) Meter and Wellion LEONARDO 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.
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 Cholesterol"

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 Cholesterol"
E 4	Meter detects extreme condition	Move the meter into an area that is between 5°C to 45°C for glucose testing or 18°C to 38°C for cholesterol testing and allow 10 to 15 minutes for it to reach the new temperature. See the chapter "Storage and Precautions"
E 5	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	Expired cholesterol test strip	• Check if the date and time on your meter is set up. See "Setting the Clock" • Verify the expiration date of the cholesterol test strips • Verify that the code number on the code card matches the code number on the test strip package.

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 1,1mmol/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 Chol symbol)	Cholesterol test result higher than 10,3 mmol/l (400 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 Chol symbol)	Cholesterol test result lower than 2,6 mmol/l (100 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.

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	• Check if the date and time on your meter is set up. See "Setting Up Your New System" • Start testing your blood glucose or cholesterol - see "Testing Your Blood Glucose" and "Testing Your Cholesterol"
🌡	Temperature out of range	Move the meter into an area that is between 5°C to 45°C for glucose test or 18°C to 38°C for cholesterol 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	(LOT) Batch Code
4°C 39°F – 30°C 86°F	Temperature Limitations
📖i	Consult Instructions for Use
IVD	In Vitro Diagnostic Medical Device
⚠	Caution! Consult accompanying documents
REF	Catalogue number
☀	Keep away from sunlight/direct light
②	Do not reuse
⊘	Do not use if package is damaged
⬛	Manufacturer
FOR SELF-TESTING	In vitro diagnostic, medical device for self-testing

Software Version RDM0079-005-01 Rev 1.01

SPECIFICATIONS

Test parameters:	Glucose and Cholesterol
Eject button:	Only on the Plus Version
Illuminated Test strip port:	Yes
Method of measurement:	Biosensor
Test Strips:	Wellion LEONARDO Blood Glucose Test Strip Wellion LEONARDO Cholesterol Test Strip
Test Range:	1,1-33,3 mmol/l (20 - 600 mg/dL) for glucose test, 2,6-10,3 mmol/l (100 - 400 mg/dL) for cholesterol test
Test Time:	5 seconds for glucose test, 90 seconds for cholesterol test
Calibration:	Plasma
Blood Sample Size:	≥ 0,5 μL for glucose test, ≥ 3,6 μL for cholesterol test
Hematocrit Range:	10-70% for glucose, 30-55% for cholesterol 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 cholesterol test
Result Averaging:	1, 7, 14, 30, 60 and 90 days averaging for glucose test

Dimensions:	60 L x 90 B 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, 18°C to 38°C for cholesterol test
Relative Humidity:	20-90% for glucose test, <85% for cholesterol test
Alarms:	3 for glucose test, 3 for cholesterol test
Storage/Transport Condition:	Meter at -20°C to +50°C Glucose test strip at 4°C to 30°C, Cholesterol test strip at 4°C to 30°C

For additional information, refer to the Wellion LEONARDO Blood Glucose Test Strip insert or Wellion LEONARDO Cholesterol 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 LEONARDO GLU/CHOL (plus) blood sugar and cholesterol meter guarantee for material and manufacturing defects for a period of two years from date of purchase. This guarantee is lost when the device is not used as intended, has been poorly maintained or opened.

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

The warranty is invalidated by damage from improper use, non-authorized repair or modification to the device.
Consumables are explicitly excluded from this warranty.
The warranty period cannot be extended.

wellion®

LEONARDO GLU/CHOL

MED TRUST
THE MEDICAL SERVICES COMPANY

AUSTRIA

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IVD **In Vitro Diagnostic Medical Device**