GlucoMen® Lx 2

CODE NO Calibration

Markers

β-Ketone TESTING

COLOR DISPLAY

User Manual

Read this user manual carefully before you start testing

A.MENARINI diagnostics

MENARINI HELPLINE

Menarini Helpline: (UK) 0800 243667
(Republic of Ireland) 1800 709903
(Northern Ireland) 0800 7837286

This number is not for emergency or medical information.

Email: myglucomen@menarinidiag.co.uk

The GlucoMen® LX 2 is an *in vitro* diagnostic medical device intended for blood glucose and β-ketone self-testing.

The product conforms to the requirements of the Directive 98/79/EC on *in vitro* diagnostic medical devices.

Date of issue: July 2015

THANK YOU

A. Menarini Diagnostics thank you for choosing GlucoMen® LX 2. This User Manual contains important information on the system and how it works. Please read it carefully before using your new system for blood glucose and β-ketone self-testing.
The GlucoMen® LX 2 is designed to be convenient and easy to use. It gives accurate results in just 4 seconds (for glucose) or 10 seconds (for β-ketone) using a very small blood sample. This small sample allows you to use a thinner lancet because not as much blood is needed to do a blood sugar or β-ketone test. The meter also has a memory that stores your blood test results to help you and your healthcare professional manage your diabetes, including diabetic ketoacidosis (DKA).

PLEASE REGISTER YOUR METER

Before you get started, it is important to register your new meter to activate your lifetime product warranty, for free of charge replacement batteries, logbooks, control solutions, and full support from a UK based helpline. To register your meter please either:
visit www.glucomen.co.uk/register, or
call us on 0800 243667 (01189 444218), or
send us your details by email to myglucomen@menarinidiag.co.uk

Northern Ireland or Republic of Ireland Residents, please call:
Northern Ireland 0800 7837286
Republic of Ireland 1800 709903
Or visit www.mediconire.com

IMPORTANT INFORMATION!

• Before you begin using your new GlucoMen® LX 2, please read all of the instructions provided in this User Manual
• Your meter uses two CR2450 3-volt coin cell batteries. In case you need to install new batteries see Paragraph 10.2 on page 47
• Perform all quality control checks recommended in this User Manual
• Consult with your diabetes healthcare professional and follow his/her guidance for your blood glucose or β-ketone monitoring routine
• The GlucoMen® LX 2 system (meter, sensors and control solutions) does not contain latex

Notes, Cautions and Warnings:

Notes: *provide helpful operating information.*

Cautions: *provide information that is important for meter protection.*

Warnings: *provide information that is important for user protection or about risk of inaccurate results.*

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1. INTENDED USE

• The GlucoMen® LX 2 is intended to be used for the quantitative measurement of glucose and β-ketone in capillary whole blood. It is intended for use by people with diabetes mellitus at home as an aid to evaluate the effectiveness of diabetes and DKA control. It can also be used in clinical settings by healthcare professionals. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on newborns
• The GlucoMen® LX 2 is specifically indicated for the quantitative measurement of glucose in whole blood capillary samples obtained from the fingertip, palm and forearm or β-ketone in whole blood capillary samples obtained from the fingertip only
• The GlucoMen® LX 2 is intended for use outside the body (*in vitro* diagnostic use)
• It should only be used with GlucoMen® LX sensor and GlucoMen® LX β-Ketone sensor and GlucoMen® LX Glu/Ket control solutions
• It should be used for testing glucose (sugar) and β-ketone only with fresh capillary whole blood samples
• It should NOT be used to diagnose diabetes and DKA or to test newborns
• It should NOT be stored in the refrigerator or in the car

Warning:
• *The GlucoMen® LX 2 contains small parts. Keep the system out of reach of small children and pets*
• *Since any meter may fail, break, or be misplaced, you should always have a backup meter*

This product may become infectious in the course of use. Discard the product in accordance with local regulations for biohazardous waste.

Warning: *blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products with care. Items that are used to measure glucose and β-ketone, e.g., sensors, lancets, and alcohol swabs, must be disposed of in accordance to local regulations to avoid risk to anyone.*

2. SYMBOLS

	Manufacturer
	Attention, read user manual before use
SN	Serial number
	Direct current (voltage)
REF	Catalogue number
LOT	Batch code
	Temperature limitation
	Use by
	Consult instructions for use

CONT	Contents of Set
CE 0123	This product fulfils the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices
IVD	*In Vitro* Diagnostic Medical Device
SELF-TESTING	*In vitro* device for self-testing
Blood Glucose and ß-ketone Meter	Blood glucose and β-ketone meter
	Biohazard - This meter could be potentially contaminated due to the blood samples used
	Significant additions or changes from previous user manual revision
	Contents sufficient for <n> tests
	Dispose of used batteries in compliance with local regulations

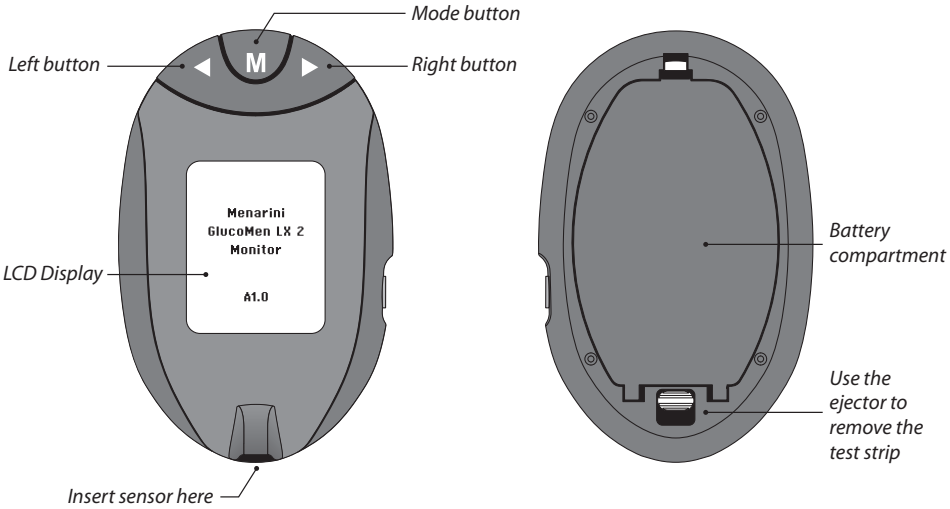
3.1 The GlucoMen® LX 2

The GlucoMen® LX 2 meter is a hand-held testing device that measures glucose and β-ketone in capillary blood. The meter activates after a GlucoMen® LX sensor (green colour) or GlucoMen® LX β-Ketone sensor (light purple colour) is inserted. The screen displays "Glu" or "Ket," depending on which type of sensor is inserted. The test process starts once the blood comes into contact with the sensor.

- A simple one-step process provides a result
- Test results are available in 4 (glucose) or 10 (β-ketone) seconds
- The memory is for one user only and it can hold up to 400 test results
- The meter is powered by two batteries (already installed) that can perform approximately 1000 tests
- Time and date are preset on the meter

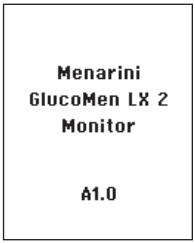
Caution: *the meter should be handled with care. Dropping, rough handling, etc. may damage the meter. If the meter is not to be used for an extended period of time, remove the batteries to eliminate the risk of battery leakage. Also, protect the meter from moisture, prolonged direct sunlight and extreme temperatures.*

3.2 Meter Description



GlucoMen® LX 2 meter

When you turn the GlucoMen® LX 2 meter on, a welcome screen is displayed.



GlucoMen® LX 2 meter screen

Note: *with no activity, time-out occurs after the following times:*
- *1 minute for all screens*
- *2 minutes during test mode*
- *3 minutes when the download cable is inserted*

3.3 Navigation Buttons

The meter responds to the pressing and the holding of the following keys:

Left/Right ◀ ▶ buttons

• Left/Right ◀ ▶ buttons move forward/backward through a series of stored test result screens or increments of value

• Press the Left/Right ◀ ▶ buttons to choose a new setting for time, date and beeper (see below how to enter the SETUP Mode)

• Hold down the Left/Right ◀ ▶ buttons to speed up screen change process

Mode M button

• When the Mode M button is pressed for less than 1.5 seconds to advance to the next function, the meter advances to the next screen immediately

• While the meter is in SLEEP Mode (OFF), pressing the Mode M button for less than 1.5 seconds turns on the meter and enters DATA REVIEW Mode

• While the meter is in SLEEP Mode (OFF), pressing the Mode M button for longer than 3 seconds turns on the meter and enters SETUP Mode

• While the meter is ON, pressing the Mode M button for longer than 1.5 seconds manually turns off the meter (SLEEP Mode)

3.4 Overview of GlucoMen® LX 2

To perform a test, the operator simply inserts a sensor; waits for the blood drop symbol to appear on the screen ("Glu" or "Ket" also appears - which indicates that the meter is ready); brings the sensor to the drop of blood; obtains a test result in 4 (Glu) or 10 (Ket) seconds. The test result is automatically stored into the meter's memory. The operator can recall and review test data stored in the meter.

3.5 Kit Contents

- GlucoMen® LX 2 meter
- Carry case
- Two batteries CR2450, 3V (already installed)
- User Manual
- Quick Start Guide, including prescription requirements and how to register
- Depending on the version, your set may include additional items
- Please refer to the box label for the list of contents of your set

3.6 Environmental Conditions

- The storage temperature range for the meter: -25 to 46 °C (-13 to 115 °F)
- The storage temperature range for the sensors: 4 to 30 °C (39.2 to 86 °F)
- The storage temperature range for the control solution: 2 to 30 °C (35.6 to 86 °F)
- The system operational temperature range: 5 to 45 °C (41 to 113 °F)
- The relative humidity range: 10% to 90% non-condensing

The meter complies with applicable EMC (electromagnetic) emission requirements. However, do not perform a glucose measurement with this meter near mobile devices or electrical or electronical equipments that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

3.7 Before Testing

Before testing and to ensure accurate glucose or β-ketone results, wash your hands and the testing site then thoroughly dry these areas. The GlucoMen® LX 2 meter can test your blood glucose on the fingers, forearm, or palm. β-ketone can be assayed using capillary blood from the fingers only. The blood sample size is just 0.3 µL (Glu) or 0.8 µL (Ket).

3.8 Reasons to Check for Low Blood Glucose

- You have symptoms such as weakness, sweating, nervousness, headache, or confusion
- You took insulin, but have delayed eating
- Your doctor or healthcare professional advises you to do so

3.9 Reasons to Check for β-ketone

- Your blood glucose levels are persistently higher than 13.9 mmol/L
- Your breath has a fruity odour
- Your stomach is upset and/or painful; loss of appetite
- You are ill (with nausea and/or vomit)
- You feel increasingly thirsty and urinate more frequently than usual
- You have symptoms such as weakness, deep gasping breathing, headache or confusion
- Your doctor or healthcare professional advises you to do so

3.10 Important Health Related Information

Diabetic ketoacidosis (DKA) is a potentially life-threatening complication in patients with diabetes mellitus. DKA arises because of an absolute lack or ineffectiveness of insulin in the body and therefore predominantly occurs in Type I diabetic patients. The association of insulin deficiency and increased counterregulatory hormones leads to altered production and disposal of glucose, in response to which the body switches to burning lipids. The free fatty acids that are released are subsequently oxidised to acidic ketone bodies (mainly β -hydroxybutyrate but also acetone and acetoacetate) into the liver.
DKA may be the first symptom of previously undiagnosed diabetes (mainly in paediatric patients), but it may also occur in known diabetics due to a variety of causes, such as intercurrent illness, emotional stresses or poor compliance with insulin therapy. Repeated high blood glucose levels (i.e., persistently higher than 13.9 mmol/L for several hours), fruity odour to the breath, vomiting, nausea, stomach pain, dehydration, frequent urination, deep gasping breathing, confusion and occasionally coma are typical symptoms.

If you are experiencing symptoms that are not consistent with your blood glucose or β-ketone test results and you have followed all instructions described in the User Manual, call your doctor or healthcare professional.

3.11 GlucoMen® LX sensor

The GlucoMen® LX sensor is designed for use with the GlucoMen® LX 2 and GlucoMen® LX PLUS meters only. Use each sensor only once, then discard. **DO NOT** reapply blood to the sensor.

- Requires a very small blood volume: 0.3 µL
- Automatically draws blood into the test area of the sensor
- Can be handled with clean, dry hands without affecting glucose readings

3.12 Important GlucoMen® LX sensor Information

- Only use GlucoMen® LX sensor when testing for glucose
- Remove the sensor from the vial only when ready to test
- Store the sensor package in a cool, dry place below 30 °C (86 °F). Do not refrigerate or freeze
- Do not store near heat or moisture
- Store the sensors in their original vial only
- **After removing a sensor from the vial, immediately put the vial cap back on and close tightly**.
- Do not use sensors beyond the expiry date printed on the package as this may cause inaccurate results
- Sensors should only be stored for 9 months after opening the vial. When first opening a new vial of sensors, count forward 9 months and write that date on the vial. Discard any remaining sensor after the date you have written on the vial
- Do not tamper with the sensor

***Warning**: the sensor vial contains small parts. Keep the sensor vial away from children and pets.*

3.13 GlucoMen® LX β-Ketone sensor

The GlucoMen® LX β-Ketone sensor is designed for use with the GlucoMen® LX 2 and GlucoMen® LX PLUS meters only. Use each sensor only once, then discard. **DO NOT** reapply blood to the sensor.

- Requires a very small blood volume: 0.8 µL
- Automatically draws blood into the test area of the sensor
- Can be handled with clean, dry hands without affecting β-ketone readings

3.14 Important GlucoMen® LX β-Ketone sensor Information

- Only use GlucoMen® LX β-Ketone sensor when testing for β-ketone
- Remove the sensor from the vial only when ready to test
- Store the sensor package in a cool, dry place below 30 °C (86 °F). Do not refrigerate or freeze
- Do not store near heat or moisture
- Store the sensors in their original packaging only
- Do not use the sensors beyond the expiry date printed on the package as this may cause inaccurate results
- Do not tamper with the sensor

Warning: *the sensor packaging contains small parts. Keep the sensors and packaging away from children and pets.*

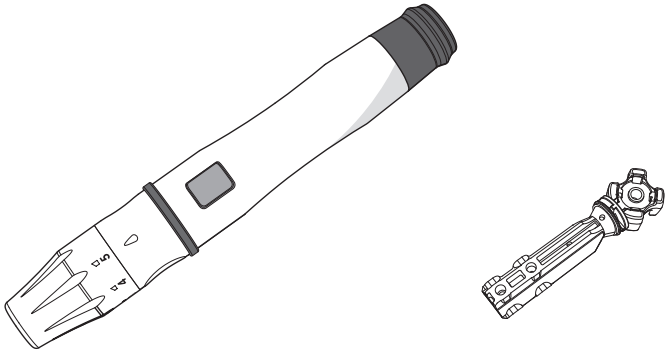
3.15 Limitations

The GlucoMen® LX sensor and GlucoMen® LX β-Ketone sensor give accurate results when the following limitations are observed:

- The sensors should not be used to diagnose diabetes, DKA or to test newborns
- Each sensor is for single use only. Do NOT reuse. Use a new sensor each time you test
- Your sensors are for personal use only. Do NOT share with others
- Use only fresh capillary whole blood
- There is no effect on blood glucose or β-ketone values for altitudes up to 3000 meters (10000 feet) above sea level
- The meter gives accurate results within the temperature range: 5 to 45 °C (41 to 113 °F)
- Extremes in humidity (higher than 90% and lower than 10%) may affect results
- Both GlucoMen® LX sensor and GlucoMen® LX β-Ketone sensor are calibrated against plasma
- Read carefully the instructions for use of GlucoMen® LX sensor and GlucoMen® LX β-Ketone sensor for information on specifications and limitations of use
- Glucose test results may be falsely low if the patient is severely dehydrated
- Critically ill patients should not be tested with home blood glucose and β-ketone meters

3.16 Lancing Device

The diagram below shows the components of the Lancing Device. Refer to the Instructions for Use of the Lancing Device for detailed instructions.



4. SETTING THE TIME, DATE, MARKERS AND BEEPER

Your GlucoMen® LX 2 meter is preset with time and date.
Having the correct time and date of each blood test result helps you and your healthcare professional track changes in your therapy. It is important to check the correct time and date so you have records of when you tested. In case time and date are not set, all blood monitoring results will be marked and will not be included in averages.

Your GlucoMen® LX 2 meter offers a beeper function that is preset "ON". This tells you when enough blood is applied to the sensor, when test is completed and prompts you through other steps in using your meter.

a. Press the Mode **M** button for longer than 3 seconds. The meter, if in SLEEP Mode, wakes up and enters the SETUP Mode.

This brings the meter display to the first setup screen: Time.

Modes

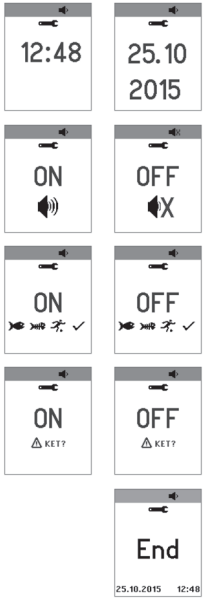
· Hour (Flashing) - Minutes (Flashing)
· Year (Flashing) - Month (Flashing) - Day (Flashing)
· Beep (ON or OFF)
· Sample Marking (ON or OFF)
· β-ketone test alert (ON or OFF)
· End (end of SETUP Mode)

b. Repeatedly press the Mode **M** button to find the Mode you want to change.

c. Press the Left/Right ◀ ▶ buttons to choose a new setting for that Mode.

d. Press the Mode **M** button to select the new settings or to skip to the next Mode.

Note: *remember to verify and adjust time and date settings as needed to match the local time after you replace the batteries. Once you have completed a blood glucose, blood β-ketone or control solution test, the last result will appear the next time your meter is turned on. The date and time displayed is the date and time of your previous blood or control solution test result, not the current date and time.*
Note: *if in SETUP Mode when the sensor is inserted, the meter saves all the values entered up to that point and immediately switches to TEST Mode. Upon exiting TEST Mode the meter screen goes blank and does not return to SETUP Mode.*



4.1 Glucose Result Marking

After a blood (not control) glucose analysis is performed with a valid result and the setup marking is enabled, you can mark the glucose result as pre-meal, post-meal, exercise, or check by scrolling the Left/ Right ◀ ▶ buttons.

a. The icon displays and flashes one at a time.

Pre-meal Post-meal Exercise Check

b. Select the desired marking by pressing the Mode **M** button while the icon is displaying and flashing.

Note: *the meter does NOT automatically save the marking status if the one minute time out occurs or the glucose sensor is removed.*

c. Once the pre-meal marker is selected, the pre-meal marker stops flashing, and the alarm icon is displayed: if the alarm is set, a test reminder alarm will alert the user 2 hours (120 + 1 minutes) later.
d. Toggle the alarm ON or OFF by pressing either the Left/Right ◀ ▶ buttons.
e. Then press the Mode **M** button to select the alarm ON or OFF.

f. The post-meal test reminder screen sounds 20 sets of alarm beeps (independent of setup beep ON/OFF), and displays the marked pre-meal result stored in the memory.
g. Press any button while the alarm is sounding to silence the alarm.
h. Inserting a sensor during the alarm, after the alarm has stopped, or after the alarm has been manually silenced enables a glucose test to be run. If no action is taken, the meter times out in one minute
• A currently set post-meal test reminder alarm is disabled if you perform another test and mark it as the post-meal result
• The currently set post-meal test reminder alarm is also disabled if you go into SETUP Mode and turn marking OFF
• The currently set post-meal test reminder alarm is also disabled if you go into SETUP Mode and change the date/time
• The currently set post-meal test reminder alarm is also disabled if you view stored results and disable the alarm at the 1 day average screen. You can disable or keep enabled the alarm by pressing either the Left/Right ◀ ▶ buttons, and then press the Mode **M** button

If the post-meal test reminder alarm expires during a glucose or a ketone analysis, the meter ignores and disables the alarm.
• Once a post-meal test reminder alarm has been disabled, you cannot re-enable the alarm again
• The meter can support only one post-meal test reminder alarm at a time
• The meter can NOT retain the currently set post-meal test reminder alarm after battery replacement (reset)

4.2 β-ketone Result Marking

After a blood (not control) ketone analysis is performed with a valid result and setup marking is enabled, mark (check) or unmark (blank) the ketone result by pressing the Left/Right ◀ ▶ buttons. The check icon displays and flashes.

Select the desired marking by pressing the Mode **M** button while the icon is displaying and flashing.

Note: *the meter cannot save the marking status if the one minute time out occurs or the ketone sensor is removed.*

5. GLUCOMEN® LX GLU/KET CONTROL

GlucoMen® LX Glu/Ket control solutions are standard solutions containing known amounts of both glucose and β-hydroxybutyrate (β-ketone).
Glucose or β-ketone control solution tests can be performed anytime you need to check if your meter and sensors are working correctly.

A glucose or β-ketone control solution test:
• Can be performed when you first get your meter and at least once a week thereafter
• Can be performed each time you open and begin using a new vial of GlucoMen® LX sensors or a new box of GlucoMen® LX β-Ketone sensors
• Must be performed if you leave the GlucoMen® LX sensor or GlucoMen® LX β-Ketone sensor vial cap open for an extended period of time (longer than 10 seconds per test)
• Must be performed if the meter is dropped, damaged or exposed to liquids
• Must be performed if you think your test results are not accurate or if your test results are not consistent with how you feel

A glucose or β-ketone control solution test is similar to a blood glucose test or a blood β-ketone test, except you use GlucoMen® LX Glu/Ket control and not a blood sample.
• Use this glucose and β-ketone control solution to check if your GlucoMen® LX 2 meter and GlucoMen® LX sensor or GlucoMen® LX β-Ketone sensor are working properly
• Use this solution to practice or to check that you are following the correct testing procedure without using your own blood
• If the meter reading is within the GlucoMen® LX Glu/Ket control's acceptable range, the GlucoMen® LX 2 system is working properly

5. GLUCOMEN® LX GLU/KET CONTROL

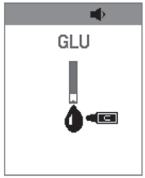
5.1 Important Information for GlucoMen® LX Glu/Ket control

• Only use the GlucoMen® LX Glu/Ket control for the test
• Check the expiry date on the GlucoMen® LX Glu/Ket control vial. Do not use GlucoMen® LX Glu/Ket control past the expiry date or you may get inaccurate results
• Only store for 3 months after first opening. When you open a new vial of GlucoMen® LX Glu/Ket control, count forward 3 months and write that date on the label of the GlucoMen® LX Glu/Ket control vial. Discard any remaining solution after the date you have written on the vial
• Store the GlucoMen® LX Glu/Ket control tightly closed at room temperature below 30 °C (86 °F). Do not freeze
• Shake the GlucoMen® LX Glu/Ket control vial vigorously before using

If your glucose control solution test results or β-ketone control solution test results repeatedly falls outside the range printed on the GlucoMen® LX sensor vial or GlucoMen® LX β-Ketone sensor vial:
• The GlucoMen® LX 2 meter may not be working properly; do not use the meter to test your blood
• The GlucoMen® LX sensor or GlucoMen® LX β-Ketone sensor may not be working properly; do not use the sensors to test your blood
• Call A. Menarini Diagnostics for assistance: Telephone numbers to use: (UK) 0800 243667 - (Republic of Ireland) 1800 709903 - (Northern Ireland) 0800 7837286 - Email: myglucomen@menarinidiag.co.uk

Warning: *the GlucoMen® LX Glu/Ket control range printed on the GlucoMen® LX sensor vial is for glucose control solution only. It is used to test the performance of both meter and sensors. It is not a recommended range for your blood glucose level. Similarly, the GlucoMen® LX Glu/Ket control range printed on the GlucoMen® LX β-Ketone sensor vial is for β-ketone control solution only. It is used to verify the performance of both meter and sensors. It does not represent a recommended range for your blood β-ketone concentration.*

6.1 Running a Glucose Control Solution Test



a. Insert a GlucoMen® LX sensor into the GlucoMen® LX 2 meter. If meter was off, the screen displays the welcome screen for 2 seconds then the blood drop symbol and "Glu" appear.
b. Press the Left/Right ◀ ▶ buttons to move between unmarked sample or marked control sample ( ); select control.
c. Shake the GlucoMen® LX Glu/Ket control vial. Discard a drop before use. Squeeze a drop of control solution onto a clean, hard, dry surface, e.g. control cap.
d. Pick up the meter with sensor inserted and touch the control solution drop with the sensor.
e. The display does a countdown from 4 to 1. A glucose control test result is available on-screen in 4 seconds.
f. Compare the result on the display with the range printed on the sensor vial. If the result falls within the range, your GlucoMen® LX 2 meter and GlucoMen® LX sensor are working correctly.
g. The result is automatically stored into memory. Marked ( ) glucose control solution results are not included in the average.

Out-of-range results may be caused by the following:
• An error in performing the control test. Retest and follow the instructions carefully
• The GlucoMen® LX Glu/Ket control may have expired or have been contaminated. Check the expiry date on the GlucoMen® LX Glu/Ket control vial. GlucoMen® LX Glu/Ket control is good for only 3 months after opening. Make sure the GlucoMen® LX Glu/Ket control vial is closed when not in use
• Expired GlucoMen® LX sensor. Check the expiry date on the sensor vial

• The GlucoMen® LX sensor may have been damaged. This can be caused by extreme temperatures or by leaving the sensor vial cap open. Retest using a new sensor
• Meter malfunction. The meter may not be working properly

Note: *if the sensor is removed before you start the test, the screen goes blank.*

Note: *it is important to select control solution test so the test result does not appear to be one of your blood glucose test results.*

Note: *if a test is not performed within 2 minutes from the insertion of the sensor, the screen goes blank. To perform the test, take out then replace the sensor starting from Step a.*

Note: *the GlucoMen® LX Glu/Ket control solution should be applied to a clean, hard and dry surface, i.e., control cap.*

Note: *the*  *symbol is displayed until sufficient control solution has been added to the sensor (Beeper sounds if enabled).*

Note: *if test result is above 33.3 mmol/L for glucose, the screen displays HI with Glu displayed. If test result is below 1.1 mmol/L for glucose, the screen displays LO.*

Note: *if the glucose control solution test result is outside the range (is either higher or lower), your meter or sensors may not be working properly. If available, repeat the process using a sensor from a new vial. Do not use the meter if test results repeatedly fall outside the appropriate range.*

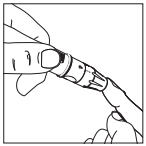
If the problem continues, call A. Menarini Diagnostics for assistance:
Telephone numbers to use:
(UK) 0800 243667
(Republic of Ireland) 1800 709903
(Northern Ireland) 0800 7837286

Email: myglucomen@menarinidiag.co.uk

6.2 Running a Blood Glucose Test

a. Wash hands with soap and warm water then dry thoroughly. As an alternative, use alcohol pads to clean area; dry thoroughly after cleaning.
b. Insert a GlucoMen® LX sensor into the GlucoMen® LX 2 meter. If the meter was switched off, the screen displays the welcome screen for 2 seconds. After 3 seconds, the blood drop symbol appears and "Glu" is displayed.

c. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
d. Use the lancing device, loaded with a new lancet, to puncture the finger (see lancing device instructions for use).
e. Gently squeeze your finger to help form a drop of blood.
f. Touch the end of the GlucoMen® LX sensor to the blood drop until the sensor is full and the on-screen countdown timer begins (beeper sounds if enabled).
g. A countdown on screen appears while test is in progress. Glucose result is available on-screen in 4 seconds.



6. GLUCOSE TESTING

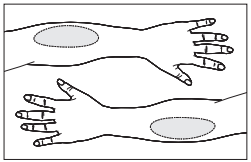
h. The result is automatically stored into memory.
i. Press the Left/Right ◀ ▶ buttons to move between marked (✓) or unmarked results.
l. Press the Mode **M** button to save the Marking Status: Marked (✓) or Unmarked.

Note: *if test result is above 33.3 mmol/L, the screen displays HI; if test result is below 1.1 mmol/L, the screen displays LO.*
Note: *Check marked glucose results (✓) are not included in the average.*
Warning: *excessive squeezing should be avoided, as hemolysis may lead to inaccurate results.*
Warning: *your lancing device is for your personal use only. DO NOT share with others. Sharing the lancing device or lancets can transmit very serious infections. To avoid accidental needle-stick injuries, do not store used lancets in the device after testing or arm the lancing device with a new sterile lancet unless ready to use.*
Warning: *lancets are for one-time use only. Use a new, sterile lancet each time you test. Test different areas on your fingertips to avoid developing calluses. Remove the used lancet from the lancing device.*
Warning: *discard the used lancets in accordance with local regulations for biohazardous waste.*
Warning: *cleaning of the puncture site is important.*
Note: *if the sensor is removed before you start the test, the screen goes blank.*
Note: *if a test is not performed within 2 minutes from the insertion of the sensor, the screen goes blank. To perform a test, take out then replace the sensor starting from Step a.*
Note: *the blood drop symbol is displayed until sufficient blood has been added to the sensor.*

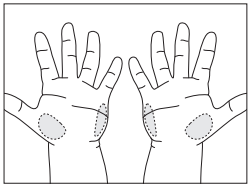
Note: *the meter will time out after 2 minutes of non-use or if the sensor is removed. The keys are disabled until a sensor is inserted. Results and marking status are saved if the meter times out, the sensor is removed, or the meter is turned off.*
Note: *you must apply the sample to the sensor while the blood drop symbol appears on the display. If the meter turns off before sample application, remove sensor and insert again.*
Note: *if blood is not applied within 2 minutes, the meter will go into "SLEEP Mode" to conserve the battery life.*
Note: *do not press the sensor directly against the skin. Touch the blood drop gently with the sensor.*

6.3 Obtaining and Applying a Blood Sample from Forearm or Palm (Glucose Testing Only)

The GlucoMen® LX 2 significantly reduces the pain of blood glucose monitoring by requiring blood samples as small as 0.3 µL only.
The GlucoMen® LX 2 additionally offers the possibility to test blood glucose at sites other than the finger (i.e., forearm and palm). These sites have fewer nerve endings than fingers, hence the pain associated to sampling is further reduced.

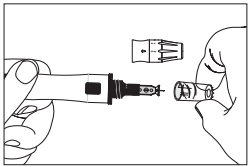


a. Select the forearm, palm heel or palm side test site in the highlighted areas as shown. The area should be free from visible veins, moles and hair and away from the bone.

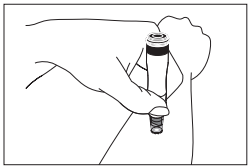


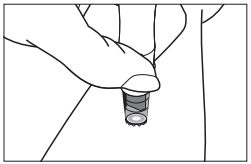
b. Wash area with warm, soapy water. Rinse and dry completely before lancing the site.

c. Attach the clear cap to the lancing device. Press and hold the lancing device FIRMLY against the forearm (or palm).



d. Continue to hold FIRMLY and press the release button to lance the area.
e. Continue to hold the device, pressing FIRMLY until a proper blood drop forms. The clear cap allows you to see the blood drop.
f. Apply blood drop to the edge of the sensor. The blood is drawn into the sensor. Hold the sensor to the blood drop until you hear a short beep or see the meter begin to count down.
g. The blood glucose test result is displayed and stored. The test is complete.





***Note*:** *thick hair at the sample site may cause the blood drop to smear.*
Warning: *the blood in the sensor should look similar to the red blood you are accustomed to seeing when you test your finger. If the sample looks clear, pink, or light in colour, retest with a fingertip sample.*
Note: *if you get an error message when testing on your forearm or palm or do not get a blood glucose reading after multiple attempts, test on your finger.*

6.4 Forearm and Palm Testing: Limitations and Considerations

Results from the forearm may be different from fingertip results when glucose levels are changing rapidly, e.g. after a meal, after taking insulin, or during or after exercise [(1)]. In contrast, the glucose results obtained testing blood samples from the palm were shown to be equivalent to those obtained using finger samples under all testing conditions [(2, 3)].
Only use finger or palm testing when the glycemic levels are expected to change rapidly.

Do not use forearm testing:
- **For a blood β-ketone test**
- For at least 2 hours after you have eaten or injected insulin

• You have a concern about hypoglycaemia (insulin reactions)
• You are doing risky activities (driving a car, working with machines…)
• If you have recently exercised
• If you think that your blood glucose may be changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise)
• If you routinely have widely fluctuating blood glucose values that are often low (hypoglycaemic)
• If you are using an insulin pump
• If you are feeling unwell or ill
• If you are under extra stress
• If you suffer from hypoglycaemic unawareness

If your forearm test results do not match the way you feel, retest using your finger or palm.

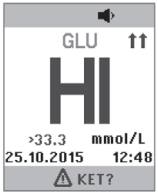
Warning: *always seek the advice of your doctor or healthcare professional before choosing to use forearm and palm sites. Bruising may occur with forearm and palm testing.*
Warning: *β-ketone testing must not use the forearm or palm site. Only use the fingertip for β-ketone testing.*

1. Jungheim K., Koshinsky T., 2002. "Glucose Monitoring at the Arm: Risky delays of hypoglycemia and hyperglycemia detection". Diabetes Care, 25 (6), 956-960.
2. Bina D.M., Anderson R.L., Johnson M.L., Bergenstal R.M., Kendall D.M., 2003. "Clinical Impact of Prandial State, Exercise, and Site Preparation on the Equivalence of Alternative-Site Blood Glucose Testing" Diabetes Care, 26 (4), 981-985.
3. Peled N., Wong D., Gwalani S.L., 2002. "Comparison of Glucose levels in capillary blood samples obtained from a variety of body sites. Diabetes Technol. Ther. 4, 35-44.

6.5 Your Blood Glucose Test Results

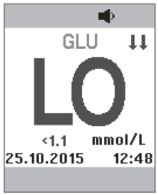
Your blood glucose test result is shown on the display.

If your test result is higher than 33.3 mmol/L, the meter displays "HI." You may have a high blood sugar concentration. Retest your blood glucose immediately using a new sensor. If your reading is still high, retest using the control solution. If the result of the control solution test falls within the expected range (confirming correct functioning of the system) you should treat yourself as advised by your healthcare professional and/or contact your healthcare professional immediately.



If your test result is lower than 1.1 mmol/L, the meter displays "LO." You may have a low blood sugar concentration. Retest your blood glucose immediately using a new sensor. If your reading is still low, you should treat yourself as advised by your healthcare professional and/or contact your healthcare professional immediately.

If you receive an Error Message, see Paragraph 11 at page 54 of this user manual.

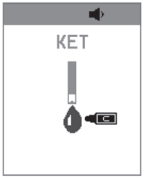


Warning: *test results greater than 13.3 mmol/L may mean high blood sugar concentrations (hyperglycaemia). Test results lower than 3.3 mmol/L may mean low blood sugar concentrations (hypoglycaemia). If you obtain results in these ranges, retest your blood glucose.*
If your reading is still in these ranges, you should treat yourself as advised by your healthcare professional and/or contact your healthcare professional immediately.

6.6 β-ketone Test Alert: Blood Glucose Value 13.9 mmol/L or Higher

If your own blood glucose value is 13.9 mmol/L or higher you will be alerted that a blood β-ketone test should also be performed. A special trill alarm beep will sound and the KET symbol will be displayed in red. You are being alerted to check your β-ketone. The alert will automatically stop after one minute or after the sensor is removed.

7.1 Running a β-ketone Control Solution Test



a. Insert a GlucoMen® LX β-Ketone sensor into the GlucoMen® LX 2 meter. If the meter was off, the screen displays the welcome screen for 2 seconds then the blood drop symbol and "Ket" appear.
b. Press the Left/Right ◀ ▶ buttons to indicate this sample is a control (is shown on the display).
c. Shake the GlucoMen® LX Glu/Ket control vial. Discard a drop before use. Squeeze a drop of control solution onto a clean, hard, dry surface, i.e., control cap.
d. Pick up the meter with sensor inserted and touch the sensor to the GlucoMen® LX Glu/Ket control solution drop.
e. The display does a countdown from 10 to 1. A flashing β-ketone quality control test result is available on-screen in 10 seconds.
f. Compare the result on the display with the range printed on the sensor vial. If the result falls within the range, your GlucoMen® LX 2 meter and GlucoMen® LX β-Ketone sensor are working correctly.
g. The result is automatically stored into the memory.

Out-of-range results may be caused by the following:
• An error in performing the control test, retest and follow the instructions carefully
• The GlucoMen® LX Glu/Ket control may have expired or been contaminated. Check the expiry date on the GlucoMen® LX Glu/Ket control vial. GlucoMen® LX Glu/Ket control is good for only 3 months after opening. Make sure the GlucoMen® LX Glu/Ket control vial is closed when not in use
• Expired GlucoMen® LX β-Ketone sensor - check the expiry date on the sensor vial

7. β-KETONE TESTING

• The GlucoMen® LX β-Ketone sensor may have been damaged. This can be caused by extreme temperature or accidental exposure to moisture (e.g. if the sensor vial has been left open). Retest using a new sensor
• Meter malfunction - the meter may not be working properly
Note: *if the sensor is removed before you start the test, the screen goes blank.*
Note: *it is important to select control solution test so the test result does not appear to be one of your blood test results.*
Note: *if a test is not performed within 2 minutes from the insertion of the sensor, the screen goes blank. To perform a test, take out then replace the sensor starting from Step a.*
Note: *the*  *symbol is displayed until sufficient control solution has been added to the sensor (beeper sounds if enabled).*
Note. *if test result is above 8.0 mmol/L for ketone, the screen displays HI with Ket displayed.*
Note: *if the β-ketone control solution test result is outside the range (is either higher or lower), your meter and sensors may not be working as a system. Repeat the process using a new sensor. Do not use the meter if test results repeatedly fall outside the appropriate range.*
Note: *if not firmly inserted into the meter, a β-Ketone sensor may be erroneously recognised as a glucose sensor (with blood drop symbol and "Glu" displayed). Remove and firmly re-insert the sensor.*

If the problem continues, call A. Menarini Diagnostics for assistance:
Telephone numbers to use:
(UK) 0800 243667 or 0118 9444128
(Republic of Ireland) 1800 709903
(Northern Ireland) 0800 7837286

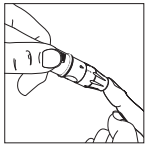
Email: myglucomen@menarinidiag.co.uk

7.2 Running a Blood β-ketone Test

Warning: *blood samples from forearm or palm are NOT suitable for β-ketone testing. Only use blood from the fingertip when testing for β-ketone.*

a. Wash your hands with soap and warm water then dry thoroughly. As an alternative, use alcohol pads to clean area; dry thoroughly after cleaning.
b. Insert a GlucoMen® LX β-Ketone sensor (light purple colour) into the GlucoMen® LX 2 meter. If meter was off, the screen displays the welcome screen for 2 seconds. After 3 seconds, the blood drop symbol appears and "Ket" is displayed.

c. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
d. Use the lancing device, loaded with a new lancet, to puncture the finger (see lancing device instructions for use).
e. Squeeze the finger to form a drop of blood.



7. β-KETONE TESTING

f. Touch the end of the GlucoMen® LX β-Ketone sensor to the blood drop until the sensor is full and the on-screen countdown timer begins (beeper sounds if enabled).
g. A countdown on screen appears while test is in progress. A flashing result is available on-screen in 10 seconds.
h. The result is automatically stored into memory.
i. Press the Left/Right ◀ ▶ buttons to move between marked (✓) or unmarked results.
l. Press the Mode **M** button to save the Marking Status: Marked (✓) or Unmarked.

Note: *if test result is above 8.0 mmol/L for β-ketone, HI appears on the screen and Ket is displayed. If test result is below 0.1 mmol/L for β-ketone, LO appears on the screen and Ket is displayed.*
Note: *if the sensor is removed before you start the test, the screen goes blank.*
Note: *if a test is not performed within 2 minutes from the insertion of the sensor, the screen goes blank. To perform a test, take out then replace the sensor starting from Step a.*
Note: *the blood drop symbol is displayed until sufficient blood has been added to the sensor.*
Note: *the meter will time out after 2 minutes of non-use or if the sensor is removed. The keys are disabled until a sensor is inserted. Results and marking status are saved if the meter times out, the sensor is removed, or the meter is turned off.*
Note: *do not press the sensor directly against the skin. Touch the sensor gently to the blood drop.*
Note: *if not firmly inserted into the meter, a β-ketone sensor may be erroneously recognised as a glucose sensor (with blood drop symbol and "Glu" displayed). Remove and firmly re-insert the sensor.*
Warning: *excessive squeezing should be avoided, as hemolysis may lead to inaccurate results.*

7. β-KETONE TESTING

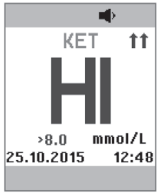
Warning: *your lancing device is for your personal use only. DO NOT share with others. Sharing the lancing device or lancets can transmit serious, even grave infections. To avoid accidental needle-stick injuries, do not store used lancets in the device after testing or arm the lancing device with a new sterile lancet unless ready to use.*
Warning: *lancets are for one-time use only. Use a new, sterile lancet each time you test. Test different areas on your fingertips to avoid developing calluses. Remove the used lancet from the lancing device.*
Warning: *discard the used lancets in accordance with local regulations for biohazardous waste.*
Warning: *cleaning of the puncture site is important.*

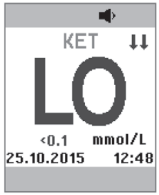
7.3 Your Blood β-ketone Test Result

Your blood β-ketone test result is shown on the display.

If test result is higher than 8.0 mmol/L (Ket), the monitor displays "HI". You may have high blood β-ketone level. Retest your blood β-ketone immediately using a new sensor. If your reading is still high, you should treat yourself as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
If test result is lower than 0.1 mmol/L (Ket), the screen displays "LO". No action is required.

Warning: *the normal adult blood β-ketone range for person without diabetes is less than 0.6 mmol/L. Consult with your healthcare professional for the blood β-ketone range that is appropriate for you. If the blood β-ketone result is between 0.6-1.5 mmol/L and blood glucose is more than 16.7 mmol/L, this may indicate development of a medical concern. You need to contact your healthcare professional for assistance. If the blood β-ketone result is more than 1.5 mmol/L and blood glucose is more than 16.7 mmol/L, contact with your healthcare professional immediately. This indicates a risk of developing DKA.*





8. DATA REVIEW IN MEMORY

To review test results that are stored in memory, start with the meter in the OFF position.
The meter is in the OFF position when the screen is completely blank. To turn off the meter, hold the Mode **M** button down until the screen goes blank then release the button.

a. With the meter OFF, press the Mode **M** button. The most recent test result should display. If there are NO results in memory, the screen displays 3 dashes.

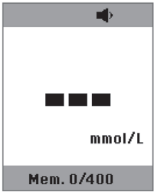
b. Press the Left/Right ◀ ▶ buttons to view all the data in memory. The Left ◀ button goes back in time and the Right ▶ button goes forward in time. All results including control results, marked results, and unmarked results can be viewed.

c. At the end of reviewing individual test results, the screen displays "End".

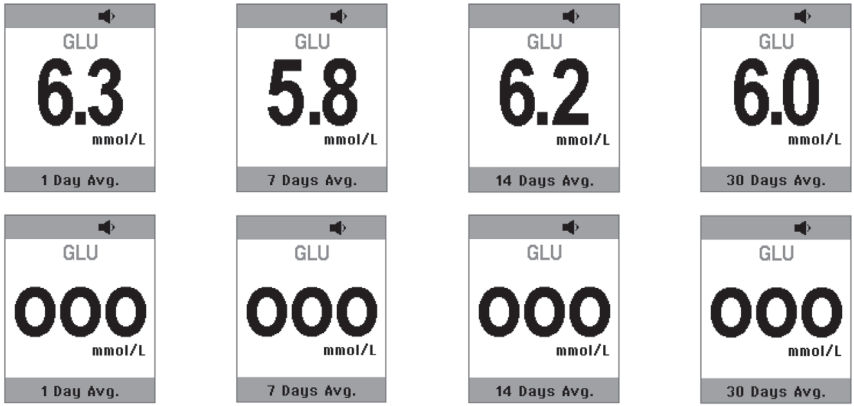
d. To review 1 day, 7 day, 14 day, and 30 day average results (**glucose only**), press the Mode **M** button.

e. If there are less than 2 test results in memory, the screen displays 000. If no results, the screen displays 3 dashes.

f. After reviewing the 30 day average, press the Mode **M** button to shut off the meter, or press no buttons and the meter will turn off automatically after 30 seconds.



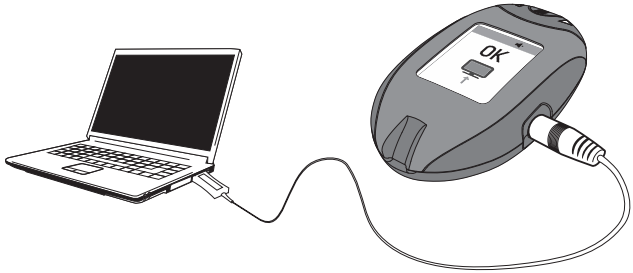
8. DATA REVIEW IN MEMORY



Note: *if a sensor is inserted while in the DATA REVIEW Mode, the meter immediately switches to TEST Mode. Upon exiting TEST Mode the meter goes blank and does not return to DATA REVIEW Mode.*
Note: *when the meter memory is full (400 test results), each new test result stored in memory will remove the oldest one.*
Note: *for data averaging,* ***only glucose results are averaged.*** *The averaging function equalises HI results to 33.3 mmol/L and LO results to 1.1 mmol/L. Check marked glucose results (✓) are not included in the average.*

9. DATA MANAGEMENT SOFTWARE

Glucose and β-ketone results stored in the GlucoMen® LX 2 meter's memory can be also downloaded from the audio jack port using a dedicated cable (as shown in the figure below) and filed by using dedicated software provided by A. Menarini Diagnostics. Both cable and software are supplied separately.

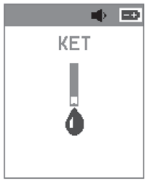


For further information on these products or ordering information call the GlucoMen® Helpline:
Telephone numbers to use:
(UK) 0800 243667 or 0118 9444128
(Republic of Ireland) 1800 709903
(Northern Ireland) 0800 7837286

Email: myglucomen@menarinidiag.co.uk

10.1 Battery Check

The meter is powered by two coin cell batteries, CR2450 (3V). The first time you see the battery icon in the upper right corner of the screen and the blood drop, the meter has sufficient charge for 20 more tests. Continue with testing as usual; the battery indicator will remain on-screen.

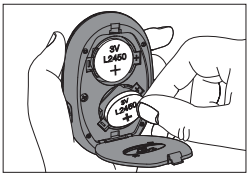


After 20 more tests have been performed, battery charge will be insufficient to continue testing, and the meter will no longer operate until the batteries are replaced. The battery icon will appear when a sensor is inserted and the icon will disappear when the sensor is removed. The battery icon is also displayed in DATA REVIEW Mode.

Battery low

Note: *battery low icon is displayed in every mode except SETUP Mode.*
Note: *once battery level goes below the threshold that triggers the "low battery" warning, it continues to give the warning until the meter becomes unusable due to low battery.*

10.2 Battery Replacement



Replace the batteries as follows:
a. Remove the battery cover at the back of the meter.
b. Remove the batteries and replace them with two new ones with the + side facing up.
c. Put the cover back on.

Note: *after the batteries are replaced, the meter displays the welcome screen. Then, the meter displays the time set up. Reset to the current time and date. If needed, go to Paragraph 4 at page 20 in this guide to review setting the time, date, markers, and beeper.*

Dispose of used batteries according to your local environmental regulations.

Note: *do not use rechargeable batteries.*
Warning: *keep all batteries out of reach of children.*

10.3 Cleaning and Care

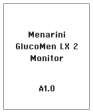
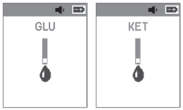
The exterior of the GlucoMen® LX 2 meter should only be cleaned with alcohol wipes/swabs. Keep liquids from entering the sensor port or the Left/Right ◀ ▶ buttons, and the Mode **M** button.

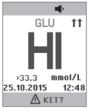
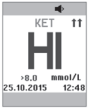
Caution: **DO NOT** *attempt to open the meter to make any repairs. Your warranty and all claims will be void!*

Call A. Menarini Diagnostics if the meter needs to be replaced.

11. DISPLAYS, MEANINGS, ACTIONS

This section addresses the messages that appear on your displays, what they mean and what action you need to take.

Display	What it Means	What to Do
	Welcome screen. Appears when: • Meter is turned on for SETUP Mode and DATA REVIEW Mode. • Sensor is inserted into the meter.	No action required.
	Blood drop symbol: meter is ready to accept blood. • **GLU** (green): blood glucose test • **KET** (purple): blood β-ketone test	Apply a blood sample to the sensor. Refer to how to run a blood sample.
	Countdown screen: 4 seconds for glucose and 10 seconds for β-ketone to perform the test and calculate the result.	No action required.
	A blood glucose test result in mmol/L.	No action required. Result is automatically stored into memory.

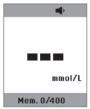
Display	What it Means	What to Do
	A blood β-ketone test result in mmol/L.	No action required. Result is automatically stored into memory.
	Your blood glucose reading is higher than 33.3 mmol/L. The reading is higher than the meter range.	Retest your blood glucose immediately using a new sensor. If your reading is still high, you should treat yourself as advised by your healthcare professional and/ or contact your healthcare professional immediately.
	Your blood β-ketone reading is higher than 8.0 mmol/L.	
	Your blood glucose reading is lower than 1.1 mmol/L. The reading is lower than the meter range.	Retest your blood glucose immediately. If your reading is still LO, treat yourself as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
	Your blood ketone reading is lower than 0.1 mmol/L.	No action required.

11. DISPLAYS, MEANINGS, ACTIONS

Display	What it Means	What to Do
	A blood glucose test result in mmol/L stored in the meter's memory with date/ time.	No action required.
	A blood β-ketone test result in mmol/L stored in the meter's memory with date/ time.	No action required.
	End of SETUP Mode or DATA REVIEW Mode.	No action required.
	The average of all blood glucose test results taken in the last 24 hours.	No action required. **Glucose only.**
	No test results in the last 24 hours.	No action required. **Glucose only.**

Display	What it Means	What to Do
	The average of all blood glucose test results taken in the last 7 days.	No action required. **Glucose only.**
	No test results in the last 7 days.	No action required. **Glucose only.**
	The average of all blood glucose test results taken in the last 14 days.	No action required. **Glucose only.**
	No test results in the last 14 days.	No action required. **Glucose only.**
	The average of all blood glucose test results taken in the last 30 days.	No action required. **Glucose only.**

11. DISPLAYS, MEANINGS, ACTIONS

Display	What it Means	What to Do
	No test results in the last 30 days.	No action required. **Glucose only.**
	There are NO results in memory.	No action required.
	Battery level is getting low, but you can still perform a test. Battery will appear on all screens.	We suggest that you replace the batteries immediately. There is only enough power to perform 20 tests. For free battery replacement call: (UK) 0800 243667 (Republic of Ireland) 1800 709903 (Northern Ireland) 0800 7837286
	A glucose control solution test result.	No action required.

Display	What it Means	What to Do
	When a blood glucose value is 13.9 mmol/L or higher, a β-ketone Test Alert will be displayed in the lower part of the screen (if ON is setup).	Perform a blood β-ketone test.
	A pre-meal glucose reading with alarm enabled.	The user has the option to set a post-meal test reminder after 2 hours to re-do a glucose test.
	A pre-meal marked glucose sample test result.	No action required.
	A post-meal marked glucose sample test result.	No action required.
	An after exercise marked glucose sample test result.	No action required.

11. DISPLAYS, MEANINGS, ACTIONS

Display	What it Means	What to Do
	A check marked glucose sample test result.	No action required.
	A check marked β-ketone sample test result.	No action required.
	Software Error.	Call A. Menarini Diagnostics for assistance: (UK) 0800 243667 (Republic of Ireland) 1800 709903 (Northern Ireland) 0800 7837286
	System Hardware Error.	Call A. Menarini Diagnostics for assistance: (UK) 0800 243667 (Republic of Ireland) 1800 709903 (Northern Ireland) 0800 7837286
	Operating Temperature Error.	Meter is outside the required testing temperature range of 5 to 45 °C (41 to 113 °F). Move meter and sensors to a warmer or cooler area and wait a few minutes.

Display	What it Means	What to Do
	Used Sensor Error: used or damaged sensor.	Retest with a new sensor.
	Blood Sample Error.	Incorrect application of blood sample or control solution onto the sensor, or the sensor may be damaged. Review your sampling technique. The blood sample quantity may be incorrect or haematocrit may be out of the allowed range for glucose measurement.
	Sensor recognition error/damaged or contaminated sensor port connector.	Remove and re-insert the sensor. After 3 attempts, try with a new one. If the problem persists, call A. Menarini Diagnostics for assistance. Telephone number (UK) 0800 243667 (Republic of Ireland) 1800 709903 (Northern Ireland) 0800 7837286.

11. DISPLAYS, MEANINGS, ACTIONS

Display	What it Means	What to Do
Meter does not turn on after inserting a sensor.	• Sensor is inserted upside down or not completely in.	Insert the sensor correctly with "LX" or "ket" facing up and out.
	• Batteries are dead.	Replace the batteries.
	• Batteries are installed incorrectly or there are no batteries in the meter.	Check that the batteries are correctly installed with the "+" sign facing you. Call A. Menarini Diagnostics for assistance: (UK) 0800 243667 (Republic of Ireland) 1800 709903 (Northern Ireland) 0800 7837286
Meter does not begin test countdown after applying a blood sample.	• Not enough blood sample.	Repeat the test with a new sensor.
	• Sample applied after meter automatically turned off.	Repeat the test with a new sensor.
	• Sensor may be damaged.	Repeat the test with a new sensor.
	• Meter may not be working properly.	After 3 attempts, call A. Menarini Diagnostics for assistance: (UK) 0800 243667 (Republic of Ireland) 1800 709903 (Northern Ireland) 0800 7837286

12.1 Specifications

Analyte	
• Glucose test	Blood β-D-glucose
• β-ketone test	Blood β-hydroxybutyrate (β-ketone)
Test Methodology	
• Glucose	Glucose oxidase (GOD) biosensor
• β-ketone	β-hydroxybutyrate dehydrogenase biosensor
Sensor Coding	
• Glucose	Not required
• β- ketone	Not required
Calibration	
• Glucose	Plasma values
• β- ketone	Plasma values
Sample Type	
• Glucose	Fresh Capillary Whole Blood
• β- ketone	Fresh Capillary Whole Blood
Test Results	
• Glucose	Plasma equivalent
• β- ketone	Plasma equivalent

Test Range	
• Glucose	1.1 to 33.3 mmol/L
• β- ketone	0.1 to 8.0 mmol/L
Acceptable Haematocrit Range	25 - 60%
Assay time	
• Glucose	4 seconds
• β- ketone	10 seconds
Sample Volumes	
• Glucose	0.3 µL
• β-Ketone	0.8 µL
Battery Life (nominal)	1000 Tests
Low Battery Life	About 20 Tests
Data Output Port	Audio Jack
Operating Ranges (for both glucose and β-ketone):	
• Temperature	5 to 45 °C (41 to 113 °F)
• Humidity	10% to 90% relative humidity, non condensing
Weight	75 g (2.65 oz)
Size	58 x 98 x 17 mm
Meter Data Storage	400 Results

12.2 Chemistry Measurement

Glucose test imprecision	Refer to GlucoMen® LX sensor instruction for use
β-ketone test imprecision	Refer to GlucoMen® LX β-Ketone sensor instruction for use

12.3 Comparing meter and laboratory results- glucose results

The GlucoMen® LX 2 system is calibrated versus capillary plasma values determined using a Yellow Springs 2300 analyser (YSI). The YSI analyser is calibrated (as secondary reference measurement procedure) using a series of YSI standards; the YSI standards (primary calibrators) are referenced directly to the NIST (National Institute of Standards and Technology, USA). If you want to compare your meter with a laboratory instrument, you have to use fresh capillary whole blood with the meter and the corresponding capillary plasma with the laboratory instrument (preferred option). Otherwise, you may use fresh capillary whole blood with the meter and venous plasma with the laboratory instrument, provided that the venous blood sample is withdrawn from the arm of the patient immediately after self-testing measurement. However, the result you get from your meter may slightly differ from the laboratory result.
This is because of the physiological difference existing between the capillary and venous compartment.

13. WARRANTY

Your GlucoMen® LX 2 meter is warranted to be free of material and workmanship defects for 2 years from the date of purchase (except as noted below). If at any time during the first 2 years after purchase, your GlucoMen® LX 2 meter does not work for any reason (other than as described below), it will be replaced with a new meter, or a substantial equivalent, free of charge. Should you wish to extend the warranty period for your meter, please refer to the warranty card.

This warranty is subject to the following exceptions and limitations:
• This warranty is applicable only to the original purchaser
• This warranty does not apply to units which malfunction or are damaged due to obvious abuse, misuse, alteration, neglect, unauthorized maintenance or failure to operate meter in accordance with instructions
• There is no other express warranty for this product. The option of replacement, described above, is the warrantor's only obligation under this warranty
The original purchaser must contact A. Menarini Diagnostics:
(UK) 0800 243667 - (Republic of Ireland) 1800 709903 - (Northern Ireland) 0800 7837286

A. Menarini Diagnostics is committed to using your personal information responsibly and in compliance with the law. You have our pledge that we will not share or sell your personal information with marketers or third-parties. The information you voluntarily share with us will be used to help us serve you better in the future.

UK

Distributed by:
A. MENARINI DIAGNOSTICS LTD
405 Wharfedale Road, Winnersh, Wokingham
Berkshire, RG41 5RA
Tel. +44-1189-444100
Fax +44-1189-444111

GlucoMen® Helpline:
(UK) 0800 243 667 or 01189 444128
(Republic of Ireland) 1800 709903
(Northern Ireland) 0800 7837286

E-mail: myglucomen@menarinidiag.co.uk

A. MENARINI DIAGNOSTICS S.r.l.
Via Sette Santi, 3
50131 Firenze - Italy

CE 0123

GlucoMen® LX 2
Made in U.S.A.

GlucoMen® LX sensor
GlucoMen® LX β-Ketone sensor
GlucoMen® LX Glu/Ket control
See relevant instructions for use

A.MENARINI diagnostics

47771 - 07/15

A. MENARINI DIAGNOSTICS S.r.l.
Via Sette Santi, 3
50131 Firenze - Italy

Description	GlucoMen LX 2 - U.Manual - UK
Code	47771
Rev	07/15
Size (mm)	150 x 102

Colours Used
C/M/Y/K
PANTONE 871
PANTONE 2635

Edition	1	2	3	4	5	6	7	8
Date p reparation								

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PLEASE REFER TO AGREED COLOUR STANDARDS / PANTONE REFERENCE FOR COLOUR MATCH

INDICAZIONI STAMPA - USER MANUAL - UK

composto da 60 pagine interne stampate ad 1 colore (k 100) in b/v + 4 di coperta stampata a 6 colori in bianca 1 colore in volta (k 100)