GlucoMen®
Day METER

Blood Glucose Monitoring System for Self-Test

Glucose Meter Set

A.MENARINI
diagnostics

Living your life.

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/ 1 General information

/ 1.1 Intended Use

GlucoMen® Day METER Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management effectively at home or in clinical settings. Fresh venous whole blood drawn by healthcare professionals can also be used. This Blood Glucose Monitoring System should be used only for self-testing outside the body (in vitro diagnostic use only). This Blood Glucose Monitoring System should not be used for the diagnosis of diabetes. Testing sites include the traditional fingertip testing along with alternate site testing on forearm and palm.

Glucose in blood samples reacts with the reagents in the test strip to produce a small electrical current. The GlucoMen® Day METER Glucose meter detects this electrical current and measures the amount of glucose in the blood sample.

• The GlucoMen® Day METER Glucose Meter should only be used with the GlucoMen® Day METER Test Strips.
• An abnormally high or low red blood cell count (haematocrit level over 65 % or below 15 %) may produce inaccurate results.
• Inaccurate blood glucose results may occur in severely hypotensive individuals or patients in shock. Inaccurate low blood glucose results may occur for individuals experiencing a hyperglycemic- hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

/ 1.2 The GlucoMen® Day METER Glucose Meter Set

GlucoMen® Day METER Glucose Meter Set includes the following items:

• GlucoMen® Day METER Glucose Meter
• User Guide
• Batteries
• Lancing Device Kit
• Accessories

Check all the components after opening the GlucoMen® Day METER Glucose Meter Set package. The exact contents are listed on the main box.

/ 1.3 The GlucoMen® Day METER Glucose Meter

Data Port
Used to transfer data from the meter to a computer with a cable

◀ ▶ Button
Turns the meter on, selects or changes information

Test Strip Port
Insert test strip here
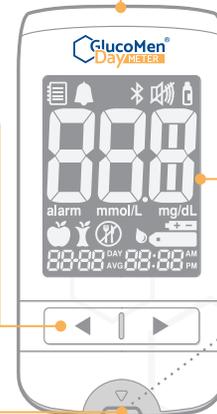
● Button
Turns the meter on/ off, confirms menu selections, and changes information

Display
Shows results and messages

Test Strip Ejector
Slide down to discard the used strips

GlucoMen® Day METER

alarm   mmol/L   mg/dL

/ 1.4 The GlucoMen® Day METER Glucose Meter display

1. Test results: test results displaying panel.
2. Memory recall mode: appears when test results stored in the memory are displayed.
3. PP2 alarm: appears when the post-meal alarm has been set.
4. Bluetooth symbol.
5. Mute symbol: appears only when the sound is set to off.
6. Control Solution flag: appears when the control solution test results are saved or displayed.
7. Decimal point: appears when the blood glucose measuring unit is set to mmol/L.
8. mmol/L, mg/dL: unit for measuring blood glucose.
9. Alarm: appears when the time alarm has been set.
10. Battery symbol: indicates meter battery is running low and needs to be replaced.
11. Blood insertion symbol: indicates meter is ready for the application of a drop of blood or control solution.
12. Pre-meal test flag: used for tests done before eating.
13. Post-meal test flag: used for tests done after eating.
14. Fasting test flag: used for tests done after fasting for at least 8 hours.
15. Month/Day/Hour/Minute.

NOTE: It is recommended to check if the display screen on the meter matches the illustration above every time the meter turns on.
Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

/ 2 System Setup

/ 2.1 Inserting or replacing batteries

If this is your first use of the system, you have to install the batteries (two 3.0 V lithium batteries).
(1) Make sure the meter is turned off. Open the battery compartment. **(2)** If replacing batteries, remove the used batteries one at a time. Slip your index finger under the battery to lift and pull out as shown. **(3)** Insert two new batteries with the "**+**" side facing upwards and make sure the batteries are inserted firmly. **(4)** Place the cover on the battery compartment. Push it down until you hear the tab click into place.
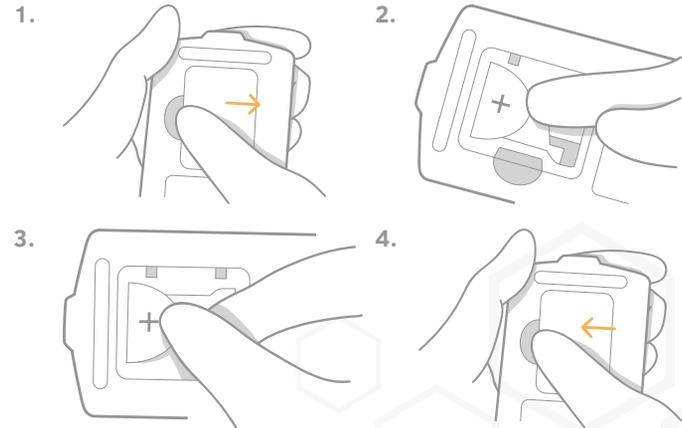
NOTE: Removing the meter batteries will not affect your stored results. However you may need to reset your meter settings.

/ 2.2 Setting up your system

Press and hold the ● button for 3 seconds to enter SET mode. After all settings are finished, press and hold the ● button for 3 seconds to turn off the meter.
Press the ◄ or ► button to change values. Press and hold the ◄ or ► button to scroll faster.

Entering SET Mode

Press and hold the ● button for 3 seconds to enter SET mode. After all the Segments flash across the screen, 'SET' will show up. Press the ◄ or ► button to select 'YES' and press the ● button to go to the next step.
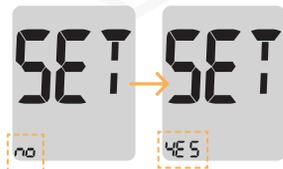
Setting Bluetooth

If you do not want to enable the Bluetooth, press the ● button when the screen shows on the right. The meter will go to next step (Year Setting).
Press the ◄ or ► button. The meter screen will display 'OFF', 'On', and 'PAIr' in turn. To switch on the Bluetooth, press the ● button when 'On' blinks on the screen, to switch off the Bluetooth, press the ● button when 'OFF' blinks on the screen. The symbol ✳ will appear on the screen when the Bluetooh feature is on.
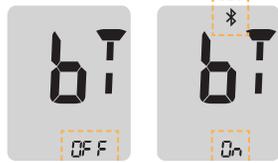
Pairing with GlucoMen® Day CGM system

The GlucoMen® Day METER Glucose Meter is able to transfer the glucose test results via Bluetooth to the GlucoMen® Day CGM smartphone App for the CGM system calibration.
To pair the GlucoMen® Day METER with the GlucoMen® Day CGM app follow the instructions reported in the GlucoMen® Day CGM User Guide.
Note: Ensure that devices are within the maximum Bluetooth range (10 meters).

Adjusting the Date and Time

Step 1: Setting the Year
Press the ◄ or ► button to adjust until the correct year appears. When the present year appears, press the ● button to confirm your selection and to go to the next step.

Step 2: Setting the Month
A number indicating the month will blink on the screen. Press the ◄ or ► button until the correct month appears. Press the ● button to confirm your selection and to go to the next step.

Step 3: Setting the Date
Press the ◄ or ► button until the screen displays the correct date. Press the ● button to confirm the date and to go to the next step.

Step 4: Setting the Time Format
The meter can be set in the AM/PM 12-hour or the 24-hour clock format.
Press the ◄ or ► button to select a format. The AM/PM symbol is not displayed in the 24-hour format. After selecting the format, press the ● button to go to the next step.

Step 5: Setting the Hour
Press the ◄ or ► button until the correct hour appears. After the hour is set, press the ● button to go to the next step.

Step 6: Setting the Minute
Press the ◄ or ► button until the correct minute appears. After setting the minute, press the ● button to go to the next step.

Setting the Sound On/OFF
On pressing the ◄ or ► button, the screen will display 'On' or 'OFF'. Press the ● button to confirm the selection. The meter will beep in the following instances if the sound is set to On:
• When you press a button to turn on the meter.
• When the test strip is inserted in the meter.
• When the blood sample is absorbed into the test strip and the test starts.

• When the test result is displayed.
• When you press and hold the ◄ button to set the post-meal (PP2) alarm.
• When it is time for a pre-set blood glucose test.

If the sound is set to OFF, none of the sound functions will work. After setting the sound, press the ● button to go to the next step.

NOTE: The 🔇 symbol is displayed only when the sound is set to OFF.

Other optional feature settings and procedures
Other optional settings are available:
• Expiration Date Indicator.
• Hypo Indicator.
• Alarms function.
• Post-meal alarm.

To set or use these additional optional features please refer to the Comprehensive User Guide, which is available on the website:
www.menarinidiagnostics.com

/ **3** Checking the system

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You may check your meter and test strips using the GlucoMen® Day METER Control Solutions.

The Control Solutions contain a known amount of glucose and can be used to check that the meter and the test strips are working properly.

Compare the result displayed on the meter to the control solution range printed on the test strip vial. Before using a new meter or a new vial of test strips, you may conduct a control solution test following the procedure on **pages 13–14**.

NOTE:
• Only use the GlucoMen® Day METER Control Solutions.
• Check the expiration date printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.
• Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20–25 ˚C).
• Before using the control solution, shake the bottle, discard the first few drops and wipe the tip clean.
• Close the control solution bottle tightly and store at a temperature between 8–30 ˚C.
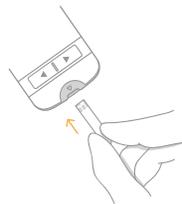
You may do a control solution test:
• When you want to practice the test procedure using the control solution instead of blood.
• When using the meter for the first time.

• Whenever you open a new vial or a new box of test strips.
• If the meter or test strips do not function properly.
• If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly.
• If you drop or damage the meter.

Control Solution Testing

Step 1 Inserting Test Strip
Insert a test strip into the meter's test strip port, with the contact bars facing upwards. Gently push the test strip into the port until the meter beeps. Be careful not to bend the strip while pushing it in. The ▨▬ symbol will show up.

Step 2 Activating Control Solution Test Mode
Press and hold the ▶ button for 3 seconds to activate the Control Solution Test Mode. This will also flag the control solution test result.
To undo the control solution flag, press and hold the ▶ button for another 3 seconds.

Step 3 Applying Control Solution to Test Strip
Shake the bottle before each test. Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth. Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown.

After the ☐ symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.

NOTE: The meter may switch off if the control solution sample is not applied within 2 minutes of the ☐ symbol appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 1.

Step 4 Waiting for the Result
The display segments will rotate clockwise and a test result will appear after the meter counts down from 5 to 1. The test result with control solution flag is stored in the memory but not included in the averages.

Step 5 Comparing the Result
Compare the result displayed on the meter to the range printed on the test strip vial.
The result should fall within the range.
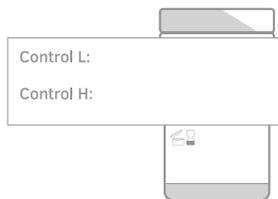
Control L:

Control H:

⚠ CAUTION

The range printed on the test strip vial is for the Control Solution only. It has nothing to do with your blood glucose level.

NOTE: The GlucoMen® Day METER Control Solution can be purchased separately. Please contact your authorised A.Menarini Diagnostics sales representative.

Repeat the control solution test if the test result falls outside of the range. Out of range results may occur in following situations:

Situations	Do This
• When the control solution bottle was not shaken well. • When the meter, test strip, or the control solution were exposed to high or low temperatures. • When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean. • When the meter is not functioning properly.	Repeat the control solution test by referring to the notes on pages 13-14 .
• When the control solution is past the expiration date printed on the bottle. • When the control solution is past its discard date. • When the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range, the test strip and meter may not be working properly. Do not use your system and contact the A.Menarini Diagnostics Customer Care number reported on the box.
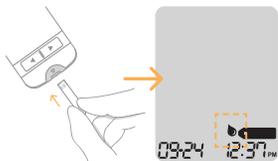
/ **4** Blood Glucose Testing

You will need a lancing device in order to collect a blood sample. You may use the lancing device that is included in the GlucoMen® Day METER Glucose Meter Set or any other medically approved lancing device.

Step 1
Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.

Step 2
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The ●▭ symbol will appear on the screen.

Step 3
Obtain a blood sample using the lancing device. Refer to the lancing device Instructions For Use how to prick your finger. You need a minimum volume of 0.4 microlitres for a blood glucose test with GlucoMen® Day METER test strip.
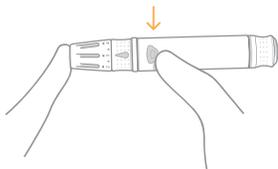
Step 4
After the ●▭ symbol appears on the screen, apply the blood sample to the narrow end of the test strip until the meter beeps. If the confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear. It is recommended to place the test strip vertically into the blood sample site as shown below.

Good Sample

Insufficient Sample
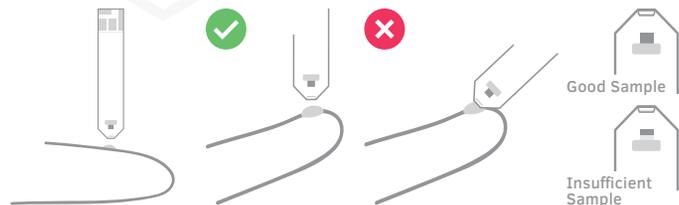
⚠ CAUTION

• Do not allow any foreign substances, such as dirt, blood, or water, to enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.
• Do not apply the blood sample directly to the test strip port.
• Do not apply the blood sample to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood sample may run down the surface of the test strip and flow into the test strip port.
• Do not store your meter in unsanitary or contaminated sites.

NOTE: The meter may switch off if the blood sample is not applied within 2 minutes of the ●▭ symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it, and start from Step 2.

Step 5

At this time, the display segments will rotate clockwise while the blood is going in. Test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in disposable containers. If the Bluetooth feature is activated, the meter will send the test result to the connected smartphone.

Test results

NOTE: To transmit glucose data to the GlucoMen® Day CGM smartphone App using the Bluetooth feature:
• The Bluetooth feature on the meter must be turned on.
• The meter and the smartphone must be paired.
• The GlucoMen® Day CGM must be launched.

The meter will transmit data in the following cases:
• When the strip is ejected after measuring,
• When the meter is turned on (only when untransmitted data exists).

Step 6

You can attach a flag to a blood glucose test result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press ◄ or ► button to select a pre-meal flag (🍎), a post-meal flag (🍴), or a fasting flag (⌛). When you remove the test strip while the desired flag is blinking, the test result is stored with the flag. If you do not want to add any flags on the test result, remove the strip after the test result is displayed.

| No flag | Pre-meal flag | Post-meal flag | Fasting flag |
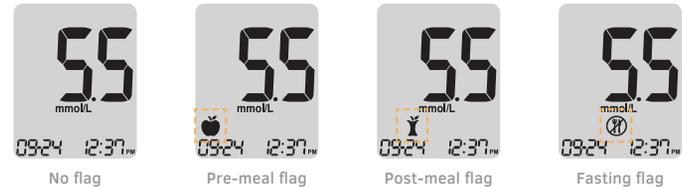
Step 7

Remove the strip using the ejector, and dispose of it following the local regulations.

Step 8

Dispose of the lancet following the local regulations.

⚠ **CAUTION**

The lancet is for single use only. Never share or reuse a lancet.

/ 5 Alternative Site Testing

/ 5.1 What is AST (Alternate Site Testing)?

Usually, we take the blood sample from the tip of the finger. However, since there are many nerve endings in the fingertip, it can be quite painful. When doing a glucose test, using different parts of the body such as the forearms and palms can reduce the pain during testing. This method of testing with different parts of the body is called Alternate Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.
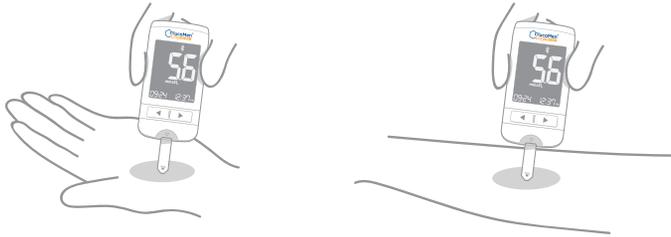
Alternate Site Blood Sampling (forearm and palm)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternate site sampling. Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes colour. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.4 μL) blood is drawn. Carefully lift the lancing device away from your skin.

/ 5.2 Things to Know When Using AST

Please read the following before testing at alternate sites (forearms and palms).
The capillary whole blood of the fingertips reflects changes in glucose levels more rapidly than in alternate sites. The test results from the fingertip testing and AST may differ due to factors such as lifestyle and ingested food which affect glucose levels.

Acceptable Situations for AST
When your blood glucose levels are stable:
• Fasting period.
• Before a meal.
• Before going to bed.

Situations Requiring Fingertip Test
When your blood glucose levels are unstable:
• During two (2) hours after a meal or exercise.
• When sick or when glucose levels seem quite lower than test value.
• When hypoglycemia is not well recognised.
• When insulin has the biggest effect.
• During two (2) hours after an insulin injection.

/ **5.3** AST Precautions

• Before using AST, please consult your healthcare professional.
• Do not ignore the symptoms of hyperglycaemia or hypoglycaemia.
• When the results of the test do not reflect your opinion, retest using a fingertip test. If the fingertip result still does not reflect the way you feel, please consult your healthcare professional.
• Do not rely on the AST results for changing your treatment method.
• The amount of glucose in alternate sites differs from person to person.

NOTE: • Results from alternate sites and fingertip samples may differ from each other as there is a time lag for the glucose levels to reach the same value. Use a fingertip for testing if you suffer from hypoglycaemia or have experienced hypoglycaemia shock or symptoms.
• If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, do not use that sample. Try puncturing again in a smoother area.

/ **6** HI and Lo messages

/ **6.1** HI Message

The meter displays blood glucose results between 1.1-33.3 mmol/L. 'HI' appears when the blood glucose level is greater than 33.3 mmol/L and indicates severe hyperglycaemia (much higher than normal glucose levels).
If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

/ **6.2** Lo Message

Lo' appears when a blood glucose test result is less than 1.1 mmol/L and indicates severe hypoglycaemia (very low glucose levels).
If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.

Reference intervals
Refer to the recommended reference intervals indicated by your healthcare professional.

NOTE: Please contact the A.Menarini Diagnostics Customer Care number reported on the box.

/ 7 Meter memory

The meter can save up to 1,000 test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored. The meter calculates and displays the averages of total test results, Pre-meal (🍎) test results, Post-meal test (🍸), and Fasting test results (🕮) from the last 1, 7, 14, 30 and 90 days.

/ 7.1 Viewing averages stored in memory

Press any button to turn the meter on. The current date and time will be displayed at the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day
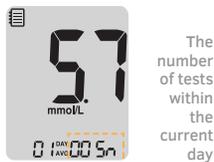
Step 2 Viewing Averages
Press the ◄ button to view 7, 14, 30 and 90-day average values and the number of Tests performed for the last test period.

◄ button
Average (1, 7, 14, 30, 90 days)
► button
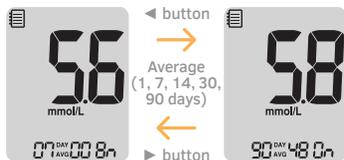
Step 3 Viewing Pre-meal Averages
Repeatedly press the ◄ button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed pre-meals with the (🍎) symbol for the last test period.

◄ button
Pre-meal average (1, 7, 14, 30, 90 days)
► button
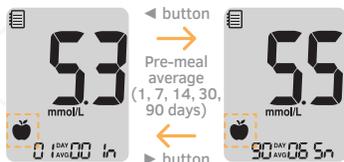
Step 4 Viewing Post-meal Averages
Press the ◄ button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed post-meals with the (🍸) symbol for the last test period.

◄ button
Post-meal average (1, 7, 14, 30, 90 days)
► button

Step 5 Viewing Fasting Averages
Press the ► button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed during fasting with the (🕮) symbol for the last test period.

◄ button
Fasting average (1, 7, 14, 30, 90 days)
► button

Step 6
Use the ► button to scroll back through the averages seen previously.
Press the ● button to turn off the meter.

NOTE: The control solution test results saved with the 🍼 symbol are not included in the averages.

/ 7.2 Viewing test results stored in memory

Press any button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.
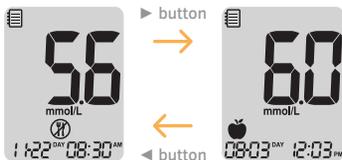

The number of tests within the current day

Step 2

Use the ▶ button to scroll through the test results, starting from the most recent and ending with the oldest.
Press the ◀ button to return to the results seen previously.
After checking the stored test results, press the ● button to turn off the meter.

▶ button

◀ button

NOTE: The control solution test results saved with the 🗋 symbol will be displayed with the 🗋 symbol when you review the stored test results.

/ 8 Understanding error messages

A used test strip was inserted.
> Repeat the test with a new test strip.

The blood or control solution sample was applied before the 🖿 symbol appeared.
> Repeat the test with a new test strip and wait until the 🖿 symbol appears before applying the blood or control solution sample.

The temperature during the test was above or below the operating range.
> Move to an area where the temperature is within the operating range (5–45 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.

The blood sample has abnormally high viscosity or insufficient volume.
> Repeat the test with a new test strip.

This error message may appear when a wrong blood glucose test strip is used instead of the GlucoMen® Day METER test strip.
> Repeat the test with a GlucoMen® Day METER test strip.

There is a problem with the meter.
> Do not use the meter. Contact the customer service reported on the meter box.

There is a problem with Bluetooth communication.
> Contact the customer service reported on the meter box.

An electronic error occurred during the test.
> Repeat the test with a new test strip. If the error message persists, contact the customer service reported on the meter box.

NOTE: Contact the A.Menarini Diagnostics Customer Care number reported on the GlucoMen® Day METER Glucose Meter set box.

/ 9 General troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing upwards. Check if the strip has been inserted completely into the test strip port. • Check if the appropriate test strip was used. • Check whether the batteries are inserted with the + side facing upwards. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled completely. • Repeat the test with a new test strip.
The test result does not match the way you feel.	• Repeat the test with a new test strip. • Check the expiration or discard date of the test strip. • Perform control solution test.

NOTE: If the problem is not resolved, please contact the A.Menarini Diagnostics Customer Care number reported on the GlucoMen® Day METER Glucose Meter set box.

/ 10 Performance Characteristics

The performance of GlucoMen® Day METER Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests following ISO 15197:2013 (EN ISO 15197:2015).

/ 10.1 Accuracy

The accuracy of the GlucoMen® Day METER system was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by diabetic patients at clinic centres.

System accuracy results for glucose concentration < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
117/186 (62.9 %)	181/186 (97.3 %)	186/186 (100 %)

System accuracy results for glucose concentration ≥ 5.55 mmol/L

Within ± 5 %	Within ± 10 %	Within ± 15 %
207/414 (50 %)	375/414 (90.6 %)	413/414 (99.8 %)

System accuracy results for glucose concentrations between 2.1 mmol/L and 29.5 mmol/L

Within ± 0.83 mmol/L and Within ± 15 %
599/600 (99.8%)

/ 10.2 Packed Cell Volume (Haematocrit)

The haematocrit levels (15-65 %) were successfully tested to evaluate the effect of haematocrit level on measurement of glucose concentration.

/ 10.3 Precision

The precision studies were performed in a laboratory using GlucoMen® Day METER system.

Within Run Precision
*Bloodav 2.1 mmol/L SD = 0.1 mmol/L
*Bloodav 4.2 mmol/L SD = 0.1 mmol/L
*Bloodav 7.2 mmol/L CV = 3.4 %
*Bloodav 11.4 mmol/L CV = 3.2 %
*Bloodav 17.9 mmol/L CV = 3.0 %
Between Run Precision
*Controlav 2.2 mmol/L SD = 0.1 mmol/L
*Controlav 6.4 mmol/L CV = 2.9 %
*Controlav 19.3 mmol/L CV = 3.0 %

This study shows that there could be variation of up to 3.4 %.

/ 10.4 Interferences

Paracetamol, ascorbic acid (vitamin C), uric acid and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate high results.

/ 10.5 User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results: 100 % within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 100 % within ±15 % of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

NOTE: Additional information about Performance Characteristics (Packed Cell Value data, Interferents table) are reported in the GlucoMen® Day METER Comprehensive User Guide available at: **www.menarinidiagnostics.com**

/ 11 Warranty

Your GlucoMen® Day METER Glucose meter is guaranteed 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® Day METER Glucose meter does not work for any reason (other than as described below), it will be replaced with a new meter, or substantial equivalent, free of charge.

The warranty is subject to the following exceptions and limitations:
• This warranty is only applicable to original purchaser.
• This warranty does not apply to units which malfunction or are damaged due to obvious tampering, misuse, alteration, neglect, unauthorized maintenance or failure to operate meter in accordance with the instructions.
• There is no other express warranty for this product. The option for replacement, described above, is the warrantor's only obligation under this warranty.

The original purchaser must contact the A.Menarini Diagnostics Customer Care number reported on the GlucoMen® Day METER Glucose Meter box.

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 disclose or sell your personal information with third-parties.
The information you voluntarily provide will be used to help us serve you better in the future.

Meaning of Symbols Used:

IVD	For in vitro diagnostic use
CE	This product fulfils the requirements for Directive 98/79/EC on in vitro diagnostic medical devices.
⚠	Cautions for safety and optimum product use
🗑	Do not discard this product with other household-type waste
⧖	Use by
⊘	Do not reuse
📖i	Consult instructions for use
🌡	Temperature limitation
CONT	Box Contents
EC REP	Authorised representative
LOT	Batch code
🏭	Manufacturer
SN	Serial number
REF	Catalogue number
⊞	Expiry date after first opening

/ **12.1** Cautions

• Keep the meter and testing supplies away from young children.
• Drying agents in the vial cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

/ **12.2** Limitations

• The GlucoMen® Day METER Test strips should be used with fresh capillary whole blood samples, or with fresh venous whole blood if drawn by healthcare professionals.
• Do not reuse test strips.
• Do not use test strips past the expiry or discard date.
• Store test strips in a cool and dry place at a temperature between 1-30 °C.
• Keep test strips away from direct sunlight or heat and do not freeze.
• Store test strips only in their original vial.
• Close the vial tightly after taking out a test strip for testing and use the strip immediately.
• Handle test strips only with clean and dry hands.
• Do not bend, cut, or alter test strips in any way.
• The unit of measurement is fixed and it cannot be changed by the user.
• Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiry date printed on the test strip box and vial label if the test strips are used according to its storage and handling methods.
• Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.

• Do not drop the meter or submit it to strong shock.

• Do not try to fix or alter the meter in any way.

• Strong electromagnetic radiation may interfere with the proper operation of this device. Keep the device away from sources of strong electromagnetic radiation, especially when measuring your blood glucose.

• Store all the meter components in the carrying case to prevent loss and help keep the meter clean.

/ **13** Meter Caring and Disposal

/ **13.1** Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the cloth or tissue in a small amount of alcohol. Do not use organic solvents such as benzene or acetone, household and industrial cleaners that may cause irreparable damage to the meter.

/ **13.2** Meter Disposal

Dispose of the meter following the local regulations.

/ 14 Specifications

Product specification

Measurement range	1.1–33.3 mmol/L
Sample size	Minimum 0.4 μL
Test time	5 seconds
Sample type	• Fresh capillary whole blood. • Fresh venous whole blood (healthcare professionals only).
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	103 x 54 x 15.9 (mm)
Weight	71.5 g (with batteries)

Bluetooth® technology	• Frequency range: 2.4–2.4835 GHz • Operating range distance: maximum 10 meters (unobstructed) • Operating channels: 40 channels • Security encryption: 128-bit AES (Advanced encryption standard)

The GlucoMen Day METER is in compliance with Directive 2014/53/EU on radio equipment. The full text of the EU Declaration of Conformity is available at the following internet address:
www.red.menarinidiagnostics.com

Operating ranges

Temperature	5–45 ˚C (41–113 ˚F)
Relative humidity	10–90 %
Hematocrit	15–65 %

Storage conditions

Glucose meter (with battery)	0–50 ˚C (32–122 ˚F)
Test strip	1–30 ˚C (34–86 ˚F)

NOTE

NOTE

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