Thank you for choosing the GlucoMen® areo 2K meter. We have designed this compact blood glucose and β-ketone meter for faster and easier testing of your blood glucose and β-ketone levels in fresh capillary whole blood. We hope it will be of great help in the management of your diabetes. This manual explains how to use your new meter. Before testing, carefully read through this manual and the package inserts that come with it: GlucoMen® areo Sensor, GlucoMen® areo β-Ketone Sensor, GlucoMen® areo Control, and GlucoMen® areo Ket Control. Pay particular attention to listed warnings and cautions. Please keep this manual at hand for future reference. If you have any questions, please contact A. Menarini Diagnostics for assistance (references at the end of this manual).

1. Intended use

Your GlucoMen® areo 2K meter, GlucoMen® areo Sensor, and GlucoMen® areo β-Ketone Sensor are in vitro diagnostic medical devices to quantitatively measure glucose and β-ketone levels in fresh capillary whole blood. They are intended for self testing to monitor and control blood glucose and β-ketone levels by people with diabetes mellitus; they can also be used in a clinical setting by healthcare professionals. They are not intended for diagnosis or screening of diabetes and DKA or for neonatal use. Do not alter your treatment on the basis of test results of this meter without previously consulting your doctor or healthcare professional.

2. System overview

2.1 Meter

FRONT

TEST STRIP PORT

ENTER ( ) BUTTON

UP/DOWN ( ▲▼ ) BUTTONS

BACK

RELEASE BUTTON

NFC ANTENNA

BATTERY HOLDER

DATA TRANSFER PORT

RELEASE BUTTON

Press this button to remove used test strip.

BATTERY HOLDER

Houses two CR2032 3V lithium coin cell batteries.

DATA TRANSFER PORT

Connection port for PC data cable and Bluetooth device from A. Menarini Diagnostics.

METER SCREEN

CLOCK/ALARM ICON

HYPO/HYPER ICONS

DROP ICON

WRONG TEMPERATURE ICON

MAIN DISPLAY AREA

UNIT OF MEASUREMENT

AVERAGE

MEMORY ICON:

indicates that you are using the memory (§6).

CLOCK/ALARM ICON:

“clock” appears while setting the time (§7.1); “alarm” appears while setting the acoustic reminder(s), and will be displayed if any alarm is on (§7.2).

HYPO/HYPER ICONS:

appear while setting the hypoglycaemic and hyperglycaemic thresholds and if your test results are below or above these values (§7.4).

DROP ICON:

blinks to indicate that the meter is ready for blood or control solution testing (§4.2, 4.3).

MAIN DISPLAY AREA:

displays test results, stored test values, result averages and messages.

UNIT OF MEASUREMENT:

shows the unit of measurement of your blood glucose and β-ketone meter (mg/dL or mmol/L for glucose, not changeable; mmol/L only for β-ketone).
3. Before testing

3.1 Caution when using the meter

Time and date are pre-set in the meter. Please make sure that time and date settings are correct before first use, and adjust them if needed. Always check the settings after changing the battery (§8.3).

![Insert this end into the meter](image)

**CAUTION**
- For accurate test results, allow the meter, test strips and control solution to adjust to the surroundings for 30 minutes before testing your blood glucose or β-ketone levels:
  - **Glucose test**
    - temperature: 5 to 45 °C (41 to 113 °F);
    - humidity: 20 to 90% RH;
  - **β-Ketone test**
    - temperature: 10 to 40 °C (50 to 104 °F);
    - humidity: < 85% RH.
- Do not store or use the meter where:
  - humidity: < 85% RH.
  - temperature: 10 to 40 °C (50 to 104 °F);
  - temperature: 5 to 45 °C (41 to 113 °F);
  - humidity: < 85% RH.
- Do not store or use test strips after their expiry date. The expiry date is either entered inside, even if dried afterwards.
- Do not use test strips after their expiry date. The expiry date is either entered inside, even if dried afterwards.
- Do not use test strips after their expiry date. The expiry date is either entered inside, even if dried afterwards.
- Do not use test strips after their expiry date. The expiry date is either entered inside, even if dried afterwards.
- For testing with GlucoMen® areo 2K meter use GlucoMen® area Sensor or GlucoMen® area β-Ketone Sensor only. Do not use other test strips, it causes inaccurate test results.
- Do not use test strips after their expiry date. The expiry date is either written on the test strip vial next to the symbol (glucose sensor) or on the foil pouch (β-ketone sensor).
- For accurate test results, allow the meter and test strips to adjust to the surroundings for at least 30 minutes before testing your blood glucose or β-ketone levels:
  - **Glucose test**
    - temperature: 5 to 45 °C (41 to 113 °F);
    - humidity: 20 to 90% RH.
  - **β-Ketone test**
    - temperature: 10 to 40 °C (50 to 104 °F);
    - humidity: < 85% RH.
- After first opening the vial, do not use the test strips beyond the time limit indicated on the label.
- The test strips are for single-use only. Do not use test strips that have already absorbed blood or control solution.
- Keep all unused GlucoMen® area Sensor test strips in the original vial and after having removed one, immediately close the cap tightly to preserve their quality. Do not transfer them into any other container.

4. Measuring your blood glucose levels

4.1 Blood sampling

For information on how to use the lancing device, read the relevant instructions for use.

**CAUTION**
- Wash the puncture site with soap and water and dry the site thoroughly before sampling blood.
- Do not share the same lancet or lancing device with anyone else to avoid the risk of infection.
- Always use a new lancet. Lancets are for single-use only. Do not reuse a lancet that has already been used.

4.1.1 Alternative site testing (AST)

This meter can test the glucose levels of blood from your fingertip, palm and forearm. However, test results from sites other than the fingertip may differ from fingertip measurements. Consult your doctor or healthcare professional before testing blood from the palm or forearm.

**Use blood from:**
- **If you are going to test:**
  - Fingertip, palm, forearm
    - Before meals.
    - Two hours or more after meals.
    - Two hours or more after exercise.

4.2 Testing your blood glucose

**a.** Insert a new GlucoMen® area Sensor test strip (white colour) into the test strip port. The drop icon starts blinking on the screen.

**b.** Apply the drops of blood to the tip of the test strip until the check window is full. A beeper sounds (if enabled) and a countdown timer starts on the screen.

**c. Read your test result.** You will hear a beep when the test result appears on the screen together with the glucose icon “Glu”.

**NOTE**
- For accurate test results, apply the drop of blood to the tip of the test strip within 20 seconds after puncturing.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood onto the test strip.
- Do not forcefully press the test strip into your puncture site.
- Do not touch the test strip once the meter has started the countdown.

3.2 Caution when using the test strips

**CAUTION**
- Do not share your meter with anyone else to avoid the risk of infection.
- Do not apply blood directly to the test strip port on the meter. A thermo sensor may represent a chocking hazard.
- Do not use the meter if it has been dropped in a liquid or liquids have entered inside, even if dried afterwards.
- Avoid hand contact with test strip port on the meter. A thermo sensor may represent a chocking hazard.
- Do not connect the data cable to the data transfer port during testing. The meter may be damaged, leading to inaccurate test results.
- Do not apply blood directly to the test strip port on the meter.
- Do not share your meter with anyone else to avoid the risk of infection.
- The meter complies with applicable electromagnetic emission requirements (EMC). However, do not perform measurements with this meter near mobile devices or electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
d. Press the release button to remove the test strip. The meter will switch off.

5. Measuring your blood β-ketone levels

5.1 Blood sampling

To perform a glucose control solution test, proceed as follows:

a. Insert a new GlucoMen® areo Sensor test strip into the test strip port.

b. Enable the CTL mode (§2.1).

The drop icon starts blinking on the screen and the Glucose icon starts (§4.2). As you are about to perform a test, a message written in bigger characters on the main screen.

To perform a glucose control solution test, proceed as follows:

b. Ketone test solution

If your own blood glucose is above a given threshold (to be set, §7.5), the ketone icon will start blinking at the bottom left hand corner of the display and an intermittent beep will sound, reminding the user that a blood β-ketone test would be recommended.

If you want to check the performance of the meter and GlucoMen® areo Sensor test strips when you first get them or any time you want to check their performance before a blood glucose test.

For accurate test results, allow the meter, test strips and control solution to adjust to the surroundings for at least 30 minutes before running the control test:

- temperature: 5 to 45 °C (41 to 113 °F);
- humidity: 20 to 90% RH.

Do not use the GlucoMen® areo Ket Control for testing the GlucoMen® areo Sensor test strips when you first get them or any time you want to check their performance before a blood glucose test.

NOTE

- To test your meter and GlucoMen® areo Sensor test strips only use the GlucoMen® areo Control (provided separately).
- Do not use the GlucoMen® areo Ket Control for testing the GlucoMen® areo Sensor: erroneous results would be obtained.

CAUTION

- Do not use control solutions after their expiry date. The expiry date is indicated on the control solution vial next to the © symbol.
- For accurate test results, allow the meter, test strips and control solution to adjust to the surroundings for at least 30 minutes before running the control test.
- Do not use the control solutions if 3 months or more have passed since first opening the vial.
- Do not drink the control solution. It is not intended for human consumption.
- Avoid contact of the solution with the skin and the eyes as this could cause inflammation.

CAUTION

- Do not use the GlucoMen® areo Control: erroneous results would be obtained.
- Do not touch the test strip once the meter has started the countdown.

NOTE

- The test will not start if you apply your control solution directly to the check window. The test starts when the meter detects the control solution. During the test the meter counts down from 5 to 1.
- Tightly close the control solution vial.
- Do not touch the test strip once the meter has started the countdown.

e. Check that your test result is within the acceptable range indicated on the label of the GlucoMen® areo Sensor test strip vial. If out of range, make sure that no procedural errors were made, then repeat the control solution test.

WARNING

- If the CTL mode has not been enabled before performing the control solution test, the result will be stored as a blood test and used for calculating averages.
- Always enable the CTL mode before conducting a control solution test or the results may fall outside the acceptable range. To enable the CTL mode, simultaneously press the UP/DOWN (△ / ▽) buttons for two seconds while the drop icon is blinking on the screen.
- Once CTL mode is enabled, CTL mark is displayed together with "ctl" message written in bigger characters on the main screen.

NOTE

- After a blood (not control) glucose test is performed with a valid result, you can mark the result as follows:
  - a. Start from point c of the glucose testing procedure (result displayed on the screen, §4.2).
  - Press △ until the markers icons start blinking. Press ▽ or ▼ to scroll through the icons (backwards or forwards) according to the following sequence:
    - Before meal marker.
    - After meal marker.
    - Exercise marker.
    - Check marker (General Purpose marker).
    - Void (Once confirmed it deselects any previously selected marker).

b. Press △ to confirm the marker you selected. You can select more markers (but only one when setting ◇ or ◇◇) by repeating steps a & b.

c. Return to point d of the glucose testing procedure (§4.2).

f. Press the release button to remove the test strip. The meter will switch off.

4.4 Marking test results

After a blood (not control) glucose test is performed with a valid result, you can mark the result as follows:

a. Start from point c of the glucose testing procedure (result displayed on the screen, §4.2).

b. Press △ until the markers icons start blinking. Press ▽ or ▼ to scroll through the icons (backwards or forwards) according to the following sequence:
   - Before meal marker.
   - After meal marker.
   - Exercise marker.
   - Check marker (General Purpose marker).
   - Void (Once confirmed it deselects any previously selected marker).

b. Press △ to confirm the marker you selected. You can select more markers (but only one when setting ◇ or ◇◇) by repeating steps a & b.

c. Return to point d of the glucose testing procedure (§4.2).

5.2 Testing your blood β-ketone

a. Insert a new GlucoMen® areo β-Ketone Sensor test strip (light purple colour) into the test strip port. The drop icon starts blinking on the screen and the β-ketone icon “Ket” will be shown at the bottom left hand corner of the display. If nothing appears on the screen, remove the test strip, insert it into the test strip port again and wait for the drop icon to start blinking.

b. Apply the drop of blood to the tip of the test strip until the check window is full. A beeper sounds (if enabled) and a countdown timer starts on the screen.

NOTE

- For accurate test results, apply the drop of blood to the tip of the test strip within 20 seconds after puncturing.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood onto the test strip.
- Do not forcefully press the test strip into your puncture site.
- Do not touch the test strip once the meter has started the countdown.

The GlucoMen® areo β-Ketone Sensor is not intended for alternative site testing (AST). Use only fresh capillary whole blood from your fingertip for testing.

To perform a glucose control solution test, proceed as follows:

a. Insert a new GlucoMen® areo Sensor test strip into the test strip port.

b. Enable the CTL mode (§2.1).

c. Gently shake the control solution vial before testing. Discard a drop before use. Squeeze a drop of control solution onto a clean, hard, dry surface.

d. Touch the control solution drop with the tip of the test strip until the check window is full. A beeper will sound (if enabled) as the countdown timer starts on the screen.

CAUTION

- Do not use the control solutions if 3 months or more have passed since first opening the vial.
- Disposal of biohazardous waste

If test results do not match with how you feel: Make sure you have performed the test correctly as explained in §4.2. Then, conduct a glucose control test to check that the system is working properly (§4.3). Repeat the test using a blood sample taken from a fingertip (do not use an alternative site). If the test result still does not match how you feel, contact your doctor or healthcare professional.

CAUTION

- If you still have test results that fall outside the acceptable range, stop using the system, and contact the A. Menarini Diagnostics customer service.

WARNING

If test results do not match with how you feel, contact your doctor or healthcare professional.

NOTE

- Do not share the same lancet or lancing device with anyone else to avoid the risk of infection.
- Always use a new lancet. Lancets are for single-use only. Do not reuse a lancet that has already been used.

The GlucoMen® areo β-Ketone Sensor is not intended for alternative site testing (AST). Use only fresh capillary whole blood from your fingertip for testing.

NOTE

- If you still have test results that fall outside the acceptable range, stop using the system, and contact the A. Menarini Diagnostics customer service.

CAUTION

- Do not use the control solutions if 3 months or more have passed since first opening the vial.
- Disposal of biohazardous waste

If test results do not match with how you feel, contact your doctor or healthcare professional.

NOTE

- Do not share the same lancet or lancing device with anyone else to avoid the risk of infection.
- Always use a new lancet. Lancets are for single-use only. Do not reuse a lancet that has already been used.

The GlucoMen® areo β-Ketone Sensor is not intended for alternative site testing (AST). Use only fresh capillary whole blood from your fingertip for testing.

NOTE

- If you still have test results that fall outside the acceptable range, stop using the system, and contact the A. Menarini Diagnostics customer service.

CAUTION

- Do not use the control solutions if 3 months or more have passed since first opening the vial.
- Disposal of biohazardous waste

If test results do not match with how you feel, contact your doctor or healthcare professional.

NOTE

- Do not share the same lancet or lancing device with anyone else to avoid the risk of infection.
- Always use a new lancet. Lancets are for single-use only. Do not reuse a lancet that has already been used.

The GlucoMen® areo β-Ketone Sensor is not intended for alternative site testing (AST). Use only fresh capillary whole blood from your fingertip for testing.

NOTE

- If you still have test results that fall outside the acceptable range, stop using the system, and contact the A. Menarini Diagnostics customer service.

CAUTION

- Do not use the control solutions if 3 months or more have passed since first opening the vial.
- Disposal of biohazardous waste

If test results do not match with how you feel, contact your doctor or healthcare professional.
To perform a β-ketone control test, proceed as follows:

a. Insert a new GlucoMen® areo β-Ketone Sensor test strip into the test strip port.

b. Gently shake the control solution vial before testing. Discard a drop of control solution onto a clean, hard, dry surface.

c. Touch the solution drop with the tip of the test strip.

d. Press the release button to remove the test strip. The meter will switch off.

NOTE

● The test will not start if you apply your control solution directly to the check window. The test starts when the meter detects the control solution. During the test the meter counts down from 8 to 1.

● Tightly close the control solution vial.

● Do not touch the strip once the meter has started the countdown.

● Conduct a control test if:
- your β-ketone test results do not match with how you feel;
- you want to check the performance of the meter and GlucoMen® areo β-Ketone Sensor test strips when you first get them or any time you want to check their performance before a blood β-ketone test.

● Make sure the meter is off (to turn the meter off hold [•] for 3 seconds while the drop icon is blinking on the screen).

● Press [•] for 2 seconds to turn the meter on and enter the memory recall mode (the “mem” icon appears on the screen and the “Glu” icon will blink).

● Press [•] to enter in the glucose results memory.

● The most recent test result appears on the screen. The screen also shows the “Glu” icon, the date and time of the test, and the corresponding markers.

● Press [•] or [•] to scroll through all the stored data.

● Press [•] for 5 seconds to switch the meter off.

6.2 Viewing glucose results averages

You can view the glucose results averages over the set intervals (1, 7, 14, 30, 60 or 90 days).

a. Follow steps a, b and c in §6.1.

b. Press [•] to enter the average mode (the “AVG” icon appears on the screen).

c. The 1-day average appears on the screen.

d. Press [•] to scroll through the averages.

● After reviewing the 90-day average, press [•] to return to the memory recall mode (step c of §6.1).

f. Hold [•] for 5 seconds to switch the meter off.

NOTE

● If there are no results in the memory, the screen displays “ooo”.

● If there are no results, the screen displays “ooo”.

● Keep [•] or [•] pressed to speed up the browsing through the results.

To perform a β-ketone control test solution test, proceed as follows:

a. Insert a new GlucoMen® areo β-Ketone Sensor test strip into the test strip port.

b. Gently shake the control solution vial before testing. Discard a drop of control solution onto a clean, hard, dry surface.

c. Touch the solution drop with the tip of the test strip until the check window is full. A beeper will sound (if enabled) as the countdown timer starts on the screen.

d. Press the release button to remove the test strip. The meter will switch off.

NOTE

● If there are less than 2 results in the memory for the averaged period, the screen displays “ooo”. If there are no results, the screen displays “ooo”.

● The averaging function equalises H1 results to 600 mg/dL (33.3 mmol/L) and LO results to 20 mg/dL (1.1 mmol/L).

6.3 Reviewing β-ketone past results

You can review past results stored in the memory. Your meter stores up to 730 glucose test results with dates, times and markers.

a. Make sure the meter is off (to turn the meter off hold [•] for 3 seconds until the screen switches off).

b. Press [•] for 2 seconds to turn the meter on and enter the memory recall mode (the “mem” icon appears on the screen and the “Glu” icon will blink).

c. Press [•] to enter in the glucose results memory.

d. The most recent test result appears on the screen. The screen also shows the “Glu” icon, the date and time of the test, and the corresponding markers.

e. Press [•] or [•] to scroll through all the stored data.

f. Press [•] for 5 seconds to switch the meter off.

NOTE

● If there are no results in the memory, the screen displays “ooo”.

● At the end of reviewing the individual test results, the screen displays “ooo”.

● Keep [•] or [•] pressed to speed up the browsing through the results.

6.4 Reviewing glucose past results averaged

You can view the glucose results averaged over the set intervals (1, 7, 14, 30, 60 or 90 days).

a. Make sure the meter is off (to turn the meter off hold [•] for 3 seconds until the screen switches off).

b. Press [•] for 2 seconds to turn the meter on and enter the memory recall mode (the “mem” icon appears on the screen and the “Glu” icon will blink).

c. Press [•] or [•] to enter the average mode (the “AVG” icon appears on the screen).

● The 1-day average appears on the screen.

● Press [•] to scroll through the averages.

● After reviewing the 90-day average, press [•] to return to the memory recall mode (step c of §6.1).

f. Hold [•] for 5 seconds to switch the meter off.

NOTE

● If there are no results in the memory, the screen displays “ooo”.

● If there are no results, the screen displays “ooo”.

● The averaging function equalises H1 results to 600 mg/dL (33.3 mmol/L) and LO results to 20 mg/dL (1.1 mmol/L).
7. Meter setup

a. Make sure the meter is off (turn the meter off press \( \mathcal{D} \) for 3 seconds until the screen switches off).

b. Press \( \mathcal{D} \) for 4 seconds to enter the setup menu.

c. Press \( \mathcal{Y} \) or \( \mathcal{V} \) to scroll through the setting menus (see pictures below) and press \( \mathcal{D} \) to enter each single menu

\[
\text{SEL} \quad \mathcal{Y} \quad \mathcal{V} \quad \mathcal{D} \quad \text{SEL} \quad \mathcal{Y} \quad \mathcal{V} \quad \mathcal{D} \quad \text{SEL} \quad \mathcal{Y} \quad \mathcal{V} \quad \mathcal{D} \\
\]

\[\text{NOTE}\]
- At anytime during set up, you may either press \( \mathcal{D} \) to exit, or insert a test strip to perform a test. The changes made so far will be memorized by the meter.

7.1 Date/Time setup

Use \( \mathcal{Y} \) or \( \mathcal{X} \) to select the correct value. Press \( \mathcal{D} \) to confirm and move on to the next step: year, month, day, time format (12H, 24H), hour, minutes. After confirming the minutes (by pressing \( \mathcal{D} \)), return to the setting menus (step c §7).

\[\text{NOTE}\]
- Date is in the DD-MM format.

7.2 Alarm setup

You can set up to six alarms on your GlucoMen® areo 2K meter: three for glucose test remind, and three for \( \beta \)-Ketone test remind. When the alarm reaches the set time, the meter sounds for 30 seconds.

\[\text{CAUTION}\]
- Before setting the alarms please check that the time is properly set.

a. The display will show the alarm clock and the “Glu” icons, both blinking. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to scroll between glucose (“Glu” icon blinking) and \( \beta \)-Ketone (“Ket” icon blinking) alarm section. Press \( \mathcal{D} \) to confirm the selection and move on to the next step. In the following steps either “Glu” or “Ket” icon will be shown, indicating the selected alarm section.

b. The display will show alarm 1 status (the default setting is OFF). You can turn it on by pressing \( \mathcal{Y} \) or \( \mathcal{X} \). Press \( \mathcal{D} \) to confirm the selection and move on to the next step.

c. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to select the hour. Press \( \mathcal{D} \) to confirm the selection and move on to the next step.

d. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to select the minutes. Press \( \mathcal{D} \) to confirm the selection and move on to the alarm 2 setting.

e. Set alarm 2 and 3 by following steps b to d. After you have finished setting all alarms, press \( \mathcal{D} \) to return to the setting menus (step c §7).

\[\text{NOTE}\]
- The alarm will have the format (12H, 24H) set for the time.

- Alarm settings will not be erased when changing the batteries.

7.3 Beeper setup

The beeper on your GlucoMen® areo 2K meter is preset to ON. You can adjust the beeper feature as follows.

a. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to turn the beeper ON or OFF.

b. Press \( \mathcal{D} \) to confirm and return to the setting menus (step c §7).

\[\text{WARNING}\]
- Turning off the beeper could mean you miss many important cues from your meter, such as confirmation or error messages.

7.4 hypo/hyper alarms setup

Your GlucoMen® areo 2K meter has an alarm feature that allows you to set your high (hyperglycaemia) and low (hypoglycaemia) blood glucose thresholds. Based on the values set, the screen will show “hypo” or “hyper”, depending on whether your blood glucose test result is below your low glucose or above your high glucose threshold values.

\[\text{WARNING}\]
- Consult your doctor or healthcare provider when setting the Hypo and Hyper values.

- Do not alter or stop your medication based on this feature, always consult your doctor or healthcare provider before altering or stopping medication.

You can set up the hypo and hyper threshold values as follows:

a. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to turn the hypo alarm ON/OFF.

b. Press \( \mathcal{D} \) to set the hypo alarm value (if ON).

c. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to select the desired value. Press and hold either \( \mathcal{Y} \) or \( \mathcal{X} \) to accelerate the numbering.

d. Press \( \mathcal{D} \) to confirm the selection and move on to the hyper alarm setup.

e. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to turn the hyper alarm ON/OFF.

f. Press \( \mathcal{D} \) to set the hyper alarm value (if ON).

g. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to select the desired value. Press and hold either \( \mathcal{Y} \) or \( \mathcal{X} \) to accelerate the numbering.

h. Press \( \mathcal{D} \) to confirm the selection and return to the setting menus (step c §7).

7.5 \( \beta \)-Ketone test warning setup

Your GlucoMen® areo 2K blood glucose and \( \beta \)-ketone meter has an additional warning feature that allows you to set a blood glucose threshold as a warning for \( \beta \) ketone testing. When the \( \beta \)-ketone test warning is turned ON, if your blood glucose is above the set threshold, the ketone icon will start blinking and an intermittent beep will sound, reminding the user that a blood \( \beta \)-ketone test would be recommended.

\[\text{WARNING}\]
- Consult your doctor or healthcare provider when setting the \( \beta \)-Ketone test warning value.

- Do not alter or stop your medication based on this feature, always consult your doctor or healthcare provider before altering or stopping medication.

You can set up the \( \beta \)-ketone test warning threshold value as follows:

a. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to turn the \( \beta \)-ketone test warning ON/OFF.

b. Press \( \mathcal{D} \) to set the blood glucose threshold value (if \( \beta \)-ketone test warning is ON).

c. Press \( \mathcal{Y} \) or \( \mathcal{X} \) to select the desired value (first setting: 200 mg/dL (11.1 mmol/L)). Press and hold either \( \mathcal{Y} \) or \( \mathcal{X} \) to accelerate the numbering.

d. Press \( \mathcal{D} \) to confirm the selection and return to the setting menus (step c §7).
8. Meter care

8.1 Storing your meter
After use, tightly close the caps of the test strip vial and control solution bottle to maintain their quality.
Pack your meter, test strips, control solutions and manuals into your carry case and store in a dry place. The correct storage temperature is -20 to 50 °C (-4 to 122 °F) for the meter and 4 to 30 °C (39,2 to 86 °F) for the test strips and control solutions. Do not freeze. Avoid heat, humidity and direct sunlight.

8.2 Cleaning your meter
Your meter does not need special cleaning. If your meter gets dirty, wipe it with a soft cloth moistened with mild detergent. To disinfect your meter after cleaning, wipe with a soft cloth moistened with either 75% ethanol alcohol or diluted household bleach (10% sodium hypochlorite solution).

8.3 Changing the batteries
When the low battery icon 🟢 appears on the screen, the batteries are getting low. Before using your meter, change the batteries. Past results remain in the memory even when the batteries are changed. Your meter uses two CR2032 3V lithium batteries. This type of battery is available in many stores. Keep spare batteries handy at all times.

NOTE
- With high blood glucose threshold (“hyper”) ON, the minimum settable β-ketone test warning threshold is “hyper” +10 mg/dL (+0,1 mmol/L).

7.6 NFC setup
The NFC function on your GlucoMen® areo 2K meter is preset to OFF and can be enabled as follows:
a. Press the ▲ or ▼ buttons to select ON or OFF.
b. Press ◼ to confirm and exit.

9. Troubleshooting

9.1 HI and LO messages
If the glucose test result is over 600 mg/dL (33,3 mmol/L) the HI icon will appear on the display.

If the glucose test result is less than 20 mg/dL (1,1 mmol/L) the LO icon will appear on the display.

If the β-ketone test result is over 8 mmol/L the blinking HI icon will appear on the display.

WARNING
- If the HI or LO message has appeared after glucose testing, please consult your doctor or healthcare professional before altering your treatment.
- If the HI message has appeared after β-ketone testing, please consult your doctor or healthcare professional before altering your treatment.
- If the HI or LO results are repeatedly displayed, but your doctor judges that they are not consistent with your conditions, please contact the A. Menarini Diagnostics customer service.

9.2 Error messages
System Hardware Error. Remove and reinsert the batteries to restart the meter, and repeat the test with a new strip. If the problem persists, please contact the A. Menarini Diagnostics customer service.

The test strip is damaged or has already been used or the blood sample was applied before the drop icon started to blink on the display. Remove the old test strip and repeat the test with a new one. Wait until the drop icon starts to blink before you begin.

Blood sample error. The blood sample did not fill the sample area of the strip during the measurement because the sample was not applied correctly or the volume was insufficient. Repeat the test with a new strip after correctly puncturing your finger (§4.1).

The strip was removed or disturbed during the countdown. Repeat the test with a new test strip.

Low battery. Change the batteries according to the instructions (§8.3).

The temperature was not within the recommended range. Repeat the measurement after at least 30 minutes, when the operating temperature has been restored.

9.3 Unexpected glucose test results
If the glucose test result is unusual compared to your previous test results or does not match with how you feel:
a. Repeat the measurement using a new test strip (§4.2).
b. Perform a control measurement using the GlucoMen® areo Control solution (§4.3).
c. Change the test GlucoMen® areo Sensor strip vial and repeat the measurement using a new test strip (§4.2).
d. If you are still uncertain about the test results, contact your doctor or healthcare professional.

**WARNING**
- In case of an unexpected reading, consult your doctor or healthcare professional before altering your treatment.
- If the test results continue to be unusual, please, contact the A. Menarini Diagnostics customer service.

### 9.4 Unexpected β-ketone test results
If the β-ketone test result is unusual compared to your previous test results or does not match with how you feel:

a. Repeat the measurement using a new test strip (§5.2).
b. Perform a control measurement using the GlucoMen® areo Ket Control solution (§5.3).
c. Repeat the measurement using a new test strip from a different foil pouch (§5.2).
d. If you are still uncertain about the test results, contact your doctor or healthcare professional.

**WARNING**
- In case of an unexpected reading, consult your doctor or healthcare professional before altering your treatment.
- If the test results continue to be unusual, please, contact the A. Menarini Diagnostics customer service.

### 10. Technical specifications

#### General specifications

- **Product:** GlucoMen® areo 2K
- **Manufacturer:** A. Menarini Diagnostics srl
- **Tested items:** Blood glucose level; blood β-ketone level.
- **Test strip coding:** No coding required.
- **Sample:** Fresh capillary whole blood.
- **Temperature compensation:** Automatic compensation using a built-in thermo sensor.
- **Batteries:** Two 3.0 V lithium batteries (CR2032).
- **Battery life:** A minimum of 900 tests or about 1 year (2-3 tests/day).
- **Memory:** 730 glucose and 100 β-ketone test results with markers, dates and times. When the memory is full, the new results will replace the oldest ones.
- **Data management:** Before/after meals, exercise, check markers.
- **Alarms:** Up to six settable acoustic alarms (3 for glucose, 3 for β-ketone measurements).
- **Data transfer:** Via dedicated USB cable or NFC (all results) or a Bluetooth device (glucose results only).
- **Averages:** Over 1, 7, 14, 30, 60, 90 days (for glucose results only).
- **Automatic turn off:** - After 90 seconds of inactivity before the test (sensor strip inserted into the meter, drop icon flashing). - After 60 seconds of inactivity after the test and Error messages Er2, Er3, Er4, HI and LO. - After 5 seconds for Error messages Er1, Temperature icon and Battery icon.
- **Dimensions:** 85,5 mm (L) x 56 mm (W) x 18,2 mm (H).
- **Weight:** 46 g (without batteries).
- **Meter Operating Conditions:** - Temperature: 5 to 45 °C (41 to 113 °F) for glucose testing; 10 to 40 °C (50 to 104 °F) for β-ketone testing. - Relative Humidity: 20 to 90% (no dew condensation) for glucose testing; < 85% for β-ketone testing.
- **Meter Storage Conditions:** - Temperature: 20 to 50 °C (<4 to 122 °F). - Relative Humidity: 20 to 90%.
- **Control Solutions Storage Temperature:** 4 to 30 °C (39,2 to 86 °F).
- **Operating environment:** The meter complies with applicable electromagnetic emission requirements (EMC).

#### Glucose measurement specifications

- **Unit of measurement:** mg/dL (mmol/L)
- **Test range:** 20 - 600 mg/dL (1.1 - 33.3 mmol/L).
- **Haematocrit range:** 10 - 70 % (haematocrit compensated).
- **Test strip:** GlucoMen® areo Sensor
- **Sample size:** Minimum 0,5 μL
- **Test time:** 5 seconds.
- **Assay method:** Electrochemical, Glucose Oxidase (GOD, Aspergillus niger sourced) based method. Mediator: Hexacyanoferrate(III) ion.

#### β-Ketone measurement specifications

- **Unit of measurement:** mmol/L
- **Test range:** 0,1 - 8,0 mmol/L
- **Haematocrit range:** 20 - 60 % (haematocrit compensated).
- **Test strip:** GlucoMen® areo β-Ketone Sensor
- **Sample size:** Minimum 0,8 μL
- **Test time:** 8 seconds.
- **Assay method:** Electrochemical, β-Hydroxybutyrate Dehydrogenase based method. Mediator: 1,10-phenanthroline-5,6-dione.

#### Calibration and traceability:
- The results are equivalent to the plasma glucose concentration (capillary plasma referenced). The GlucoMen® areo 2K system is calibrated using capillary plasma values determined with a Yellow Springs 2300 analyser and a Yellow Springs 2300 analyser (YSI). The YSI analyser is calibrated (as a secondary reference measurement procedure) using a series of YSI standards (primary calibrators) which are taken from the NIST (National Institute of Standards and Technology, USA).

- **Test strip storage conditions:** - Temperature: 4 to 30 °C (39,2 to 86 °F) (both for unopened vial and after opening). - Relative Humidity: 20 to 90% (both for unopened vial and after opening).

- **Maximum radiofrequency power transmitted in the operating frequency band(s):** 0,67 mW
- **EU directive/classification:** 98/79/EC / Annex II, List B
- **Device standard:** EN ISO 15197:2015
11. Warranty

Your GlucoMen® areo 2K 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® areo 2K 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.

This warranty is subject to the following exceptions and limitations:
- this warranty is only applicable to the 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 of replacement, described above, is the warrantor’s only obligation under this warranty.

The original purchaser must contact A. Menarini Diagnostics: Telephone XXXXXXXXXXXX.

Should you wish to extend the warranty period for your meter, please refer to the same contact.

12. Symbols and abbreviations

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>📖</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>⚠️</td>
<td>Caution, consult instructions for use</td>
</tr>
<tr>
<td>📡</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>🟢</td>
<td>Use by</td>
</tr>
<tr>
<td>🟥</td>
<td>Manufacturer</td>
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<tr>
<td>📜</td>
<td>Batch code</td>
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<tr>
<td>🕰</td>
<td>In vitro diagnostic medical device</td>
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<tr>
<td>🗑</td>
<td>In vitro device for self-testing</td>
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<tr>
<td>📝</td>
<td>Serial number</td>
</tr>
<tr>
<td>🔄</td>
<td>Recyclable package</td>
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<tr>
<td>🏎</td>
<td>CE marking</td>
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<tr>
<td>🚨</td>
<td>Contamination risk due to the use of blood samples</td>
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<tr>
<td>🧪</td>
<td>Blood glucose and β-ketone meter</td>
</tr>
<tr>
<td>🔍</td>
<td>Significant additions or changes from previous user manual revision</td>
</tr>
<tr>
<td>☑️</td>
<td>Direct current (voltage)</td>
</tr>
<tr>
<td>🎯</td>
<td>Catalogue number</td>
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</tbody>
</table>

The meter complies with the requirements of Directive 98/79/EC on in vitro diagnostic medical devices and with the requirements of Directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment.

The 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.

A. Menarini Diagnostics S.r.l.
Via Sette Santi, 3
50131 Firenze - Italia

Distributed by:
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Date of issue: October 2018

GlucoMen® areo 2K
Made in Taiwan

GlucoMen® areo Sensor, GlucoMen® areo β-Ketone Sensor,
GlucoMen® areo Control and GlucoMen® areo Ket Control.
See relevant instructions for use