

GLUCOCARD™ SM

BLOOD GLUCOSE MONITORING SYSTEM

Operating manual

SELF-TESTING IVD



Thank you for choosing GLUCOCARD™ SM.

We have designed this compact blood glucose meter for faster and easier testing of your blood glucose. We hope our product will help you manage 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 the GLUCOCARD™ SM TEST STRIPS and GLUCOCARD™ SM CONTROL. Pay particular attention to listed warnings and cautions. Please keep this manual handy for future reference. If you have any questions, please contact A. Menarini Diagnostics on the numbers listed at the end of the manual.

Chapter 1 Introduction

1.1 Intended use

The GLUCOCARD™ SM meter and GLUCOCARD™ SM TEST STRIPS are for quantitatively measuring the glucose level in fresh capillary whole blood. They are intended for use outside of the body (*in vitro* diagnostic use) at home or in a clinical setting as an aid to monitor and control blood glucose levels.

Do not use them to diagnose diabetes. Also, **do not** alter treatment based on the test results of this meter without instructions from your doctor or healthcare professional.

1.2 Measurement principle

Glucose in the blood reacts with the reagent in the test strip and this produces a small electric current. The strength of this current is proportional to the concentration of glucose in the blood. The meter measures this current and calculates your blood glucose level.

1.3 What's included

- GLUCOCARD™ SM
- Carrying case
- Operating manual (this manual)
- Guide on Bluetooth connection
- GLUCOCARD™ SM TEST STRIPS
- Lancets
- Lancing device

Chapter 2 Before tests

2.1 Important health-related information

WARNING

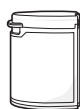
Do not use this meter for your blood glucose testing if you are being tested for xylose absorption.

These treatments may produce higher test results than your actual blood glucose level.

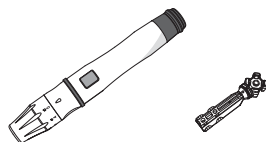
2.2 What you need for each test



a. GLUCOCARD™ SM (meter)



b. GLUCOCARD™ SM TEST STRIPS



c. Lancing device

d. Lancet

WARNING

Keep the meter, test strips and other items away from young children. Small items are choking hazards.

2.3 Cautions on using the meter

CAUTION

- For accurate test results, allow the meter to adjust to the surroundings:
 - Temperature: 8 to 40 °C (46 to 104 °F)
 - Humidity: 20 to 80% RH (Relative Humidity)
 for 30 minutes before testing your blood glucose.
- Do not store or use the meter where:
 - There are sharp temperature fluctuations.
 - Humidity is high enough to cause condensation (bathrooms, drying rooms, kitchen, etc.).
 - There is a strong electromagnetic field (microwave oven, cell phone, etc.).
- Do not use the meter after it has been dropped in liquid or liquids have entered inside, even if dried afterwards.
- Avoid hand contact with test strip slot on the meter. A thermo sensor is housed inside the meter to minimize errors.
- Do not connect the meter to a computer via USB cable during testing. The meter may be damaged, leading to inaccurate test results.
- Do not apply blood directly to the test strip slot on the meter.
- Do not share your meter with anyone to avoid the risk of infection.

2.4 Cautions on using the test strips

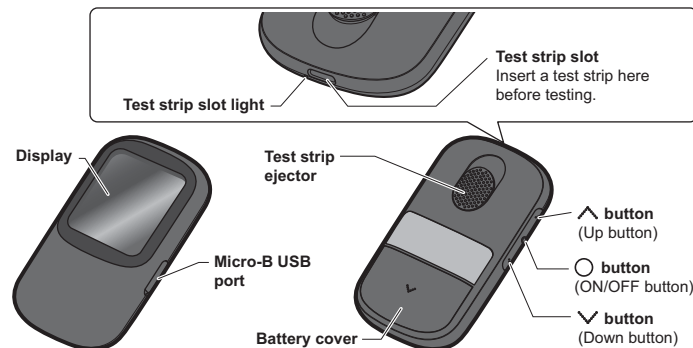
CAUTION

- Use only the GLUCOCARD™ SM TEST STRIPS for testing with the GLUCOCARD™ SM meter. **Do not** use other test strips as it causes inaccurate test results.
- **Do not** use test strips beyond their expiration date. The expiration date is written on the test strip bottle next to the "Use by" symbol.
- For accurate test results, allow test strips to adjust to the surroundings:
 - Temperature: 8 to 40 °C (46 to 104 °F)
 - Humidity: 20 to 80% RH (Relative Humidity)
 for 30 minutes before testing your blood glucose.
- **Do not** use the test strips if 6 months or more have passed since opening the laminated pouch.
- The test strips are for single use only. **Do not** use test strips that have already absorbed blood or control solution.

NOTE

Store test strips in their original bottle to maintain quality. **Do not** transfer them to other containers.

2.5 Meter parts



2.6 Display

At each start-up, the screen displays all segments, indicating the correct functioning of the meter.

NOTE

After 30 seconds of inactivity, the display will dim slightly. It will brighten again when next used.

Wireless communication setting symbol
Appears when you set up the wireless communication (BLE = Bluetooth Low Energy).

Setting symbol:
Appears when you set up the meter.

Memory symbol:
Appears when you are reviewing a past result from the meter memory.

Past results symbol

Result average symbol

High blood sugar (high value) warning flag

Low blood sugar (low value) warning flag

Alarm symbol

Delete flag

Thermometer symbol

Before-meal flag:

After-meal flag:

MEM SET BLE

ALL AVG

MEM SET BLE

MEM SET BLE

MEM SET BLE

MEM SET BLE

MEM SET BLE

MEM SET BLE

MEM SET BLE

Blood symbol:
Appears when the meter is ready for testing.

Bluetooth symbol:
Flashes during wireless communication

Hospital device icon

Personal device icon

Time symbol

Date symbol

Beeper volume symbol

Battery symbol

Sound mute symbol

Control test flag

Before bedtime flag

mg/dL

mg/dL

mg/dL

mg/dL

mg/dL

mg/dL

mg/dL

mg/dL

mg/dL

mg/dL

2.7 Inserting test strips into the meter

Follow the steps below to test your blood glucose level.

1. With clean, dry hands, remove 1 test strip from the bottle.

Do not bend the test strip.

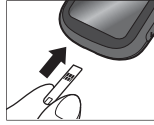
NOTE

- Tightly close the bottle immediately after taking out a test strip.
- Do not apply blood to the test strip before inserting it into the meter.

2. Insert the test strip fully into the test strip slot.

The meter turns on. Check that a full display appears as shown in paragraph 2.6.

After the most recent test result appears, the blood symbol flashes on the screen.



If nothing appears on the screen, remove the test strip and insert it back into the test strip slot.

NOTE

If the thermometer symbol appears on the screen, see chapter 10 "Troubleshooting".



CAUTION

- If any part of the display screen is missing (see 2.6), call your distributor.
- If you cannot test your blood glucose due to a problem with your meter or test strips, promptly contact your healthcare professional and distributor.

Next ...

Go to chapter 3 "Blood sampling". Draw blood and apply it to the test strip no more than 5 minutes after you insert the test strip into the meter. Otherwise, the meter turns itself off.

Chapter 3 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 (avoid disinfectants). Dry the site thoroughly before sampling blood.
- Do not share the same lancet or lancing device with anyone to avoid the risk of infection.
- Always use a new lancet. Lancets are for single use only. Do not reuse a lancet that you have already used.

3.1 Alternative site testing (AST)

This meter can test the glucose level of blood from your fingertip, palm, forearm or upper arm. However, test results from sites other than the fingertip may differ from a fingertip measurement. Consult your doctor or healthcare professional before testing blood from the palm, forearm or upper arm.

| Use blood from: | If you are going to test: |
|---------------------------------------|---|
| Fingertip, palm, forearm or upper arm | <ul style="list-style-type: none"> ■ Before meals ■ Two hours or more after meals ■ Two hours or more after exercise |
| Fingertip | <ul style="list-style-type: none"> ■ When there is the possibility of blood glucose level changing rapidly (e.g. after meals or exercise) ■ When experiencing symptoms of hypoglycemia such as perspiration, cold sweats, a floating sensation or trembling ■ When immediate testing is needed for suspected hypoglycemia ■ When in poor physical condition such as having a cold, etc. |

Chapter 4 Testing your blood glucose

1. Make sure that the blood symbol is flashing on the screen.

If nothing appears on the screen, remove the test strip and insert it back into the slot. Then, wait until the blood symbol starts flashing.

2. Touch the tip of the test strip to the drop of blood.

Let the test strip draw up blood until the dark-colored check window is filled with blood.

Accurate test results will not be obtained if you apply your blood to the check window directly.



The meter counts down. After 5 seconds, a beep sounds and the test result and date/time are shown.

NOTE

- For accurate test results, touch the test strip to your blood immediately after obtaining a sufficiently large blood drop. This is normally achieved within 20 seconds.
- Use only a round drop of blood. Wipe away smeared blood.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood on the test strip.
- Do not press the test strip against your puncture site with force.
- Do not add any extra blood. It may cause inaccurate test results.
- Do not touch the test strip until the test result appears.

3. Read your test result.

The meter stores this test result with the test date and time in the memory.



WARNING

Test results are shown in mg/dL. You cannot change the unit of measure. If, by any chance, the results appear in mmol/L, contact your distributor immediately. Using mmol/L may cause you to misread test results and lead to incorrect treatment.

CAUTION

■ If "Lo" or "Hi" appears on the screen:

Repeat the test. If "Lo" or "Hi" still appears, contact your doctor or healthcare professional. "Lo" appears if your test result is less than 10 mg/dL. "Hi" appears if your test result is more than 600 mg/dL.

■ If test results do not match how you feel:

Make sure you performed the test properly as explained in chapters 2 to 4. Then, do a control test to check that there are no problems with the meter or test strips. If you tested blood from the palm, forearm or upper arm, repeat the test with blood from a fingertip. If test results still do not match how you feel, contact your doctor or healthcare professional.

- Do not ignore test results. Do not alter your blood glucose management or treatment without consulting your doctor or healthcare professional. It is important to follow their instructions.

4. Remove the used test strip.

Point the test strip down. Slide the test strip ejector to eject the test strip. The meter turns itself off.

NOTE

When the wireless communication is ON, test results will be transmitted automatically.

Disposal of biohazardous waste

Test strips and lancets qualify as biohazardous waste once used to test blood glucose. After use, dispose of them according to your local regulations on biohazardous waste.

Chapter 5 Managing your test results

5.1 Flagging test results

Flags help you categorize and identify results.

1. Leave the test strip in the meter after the test result appears on the screen.
2. Press the \bigcirc button until the flag you want appears.



| | | | | |
|----------------|--|--|---|---|
| No flag | Before-meal flag For results obtained before eating. | After-meal flag For results obtained after eating. | Before bedtime flag For results obtained before sleeping. | Delete flag For inaccurate results. Not part of your result averages. |
|----------------|--|--|---|---|

3. Point the test strip down. Slide the test strip ejector to eject the test strip. The meter turns itself off.

5.2 Reviewing past results

You can review past results stored in the memory. Your meter stores up to 500 test results. New results beyond the 500th overwrite previously stored results in the order of oldest first.

1. Make sure the meter is off.
2. Hold down \bigcirc button for 2 seconds to turn on the meter.
3. Make sure "MEM" is flashing, and press \bigcirc button.
4. When "ALL" flashes, press \bigcirc button.
The meter displays the most recent test result stored in the memory. Three bars "---" appear when there is no past result.

NOTE

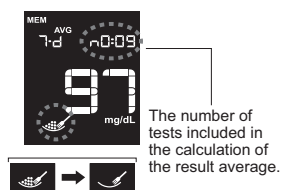
When the wireless communication is ON, the current receiving device is displayed before past results. See "Transmitting all test results" in chapter 7 for details.

5. View the test result you want.
To go back to the previous result, press \wedge button.
To go to the next result, press \vee button.
To scroll through results, hold down \vee or \wedge button.
6. To turn off the meter, hold down \bigcirc button for 3 seconds.

5.3 Viewing result averages

You can view average values of past results.

1. See steps 1, 2 and 3 in paragraph 5.2.
2. Press \wedge button to make "AVG" flash.
3. When "AVG" flashes, press \bigcirc button.
The result average changes in the order of 7-, 14-, 30-, 60- and 90-day each time \wedge button is pressed.
Three bars "---" appear when there is no past result to be included in the average calculation.



4. To view the averages with a flag, press \bigcirc button.
5. To turn off the meter, hold down \bigcirc button for 3 seconds.

5.4 Deleting all test results

You can delete all test results from the memory. Remember that results cannot be retrieved once deleted.

1. See steps 1, 2, 3 and 4 in paragraph 5.2.
2. Hold down both \vee and \wedge buttons for 2 seconds. "DEL" flashes (to cancel the operation at this point and return to the previous level, hold down the \bigcirc button for 1 second).

3. Hold down \wedge button and \bigcirc button together for 3 seconds to delete all test results (a long beep sounds and "---" appears).

4. To turn off the meter, hold down \bigcirc button for 3 seconds.

5.5 Downloading test results

Test results stored in the GLUCOCARD™ SM meter's memory can be downloaded to GlucoLog® software and apps by A. Menarini Diagnostics using either BLE communication (Bluetooth 4.0) or a standard Micro-B USB cable. GlucoLog® software and apps are supplied separately.

For information on how to set the meter for Bluetooth communication, see chapter 7 of this manual.

For additional information, consult the guide on Bluetooth connection provided.

When the meter is connected with a USB cable, "USB" blinks on the display.



NOTE

- Set the connection using electrical and electronic equipment (cable, computer, etc.) that is compliant with applicable requirements.
- To prevent software errors, which could lead to accidental data loss, download test results to GlucoLog® software and apps only.

Chapter 6 Meter setup

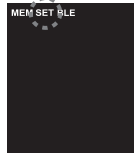
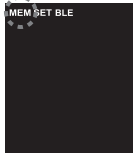
Your meter is set up as below at first use. To change the settings, see the setup mode flowchart below.

- Alarm: Off
 - HYPO: Off
 - HYPER: Off
 - Time: Current local time (default format: 24 h)
 - Date: Current local date (default format: day - month)
 - Beeper volume: High(3)
 - BLE: Off
- (See chapter 7 "Using the wireless communication function" to change the "BLE" settings.)

Setup mode

SET mode selection

1. Hold down button for 2 seconds to turn on the meter.



2. Press button. 3. Press button.

- To follow the gray arrows (), press button.
- To follow the black arrows (), press button.
- To change the settings or numbers in *italic*, press or button.
- To scroll through the numbers, hold down or button.
- To cancel a setting and return to the previous level, hold down button for 1 second.
- To turn the meter off (in any screen), hold down button for 3 seconds.

Alarm



1. Select an alarm number. 2. Turn on the alarm. 3. Set the hour. 4. Set the minute.

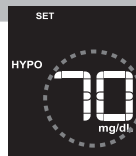
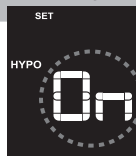


To the top of the alarm setting.

HYPO



1. Turn on the HYPO flag. 2. Set the threshold value.



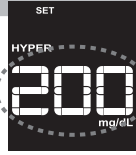
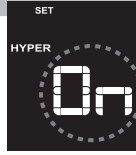
A HYPO flag appears when your test results are below the threshold value.

To the top of the HYPO setting.

HYPER



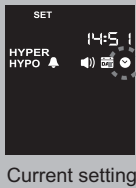
1. Turn on the HYPER flag. 2. Set the threshold value.



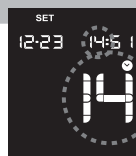
A HYPER flag appears when your test results are above the threshold value.

To the top of the HYPER setting.

Time

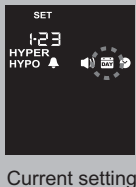


1. Select a time format. 2. Set the hour. 3. Set the minute.

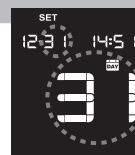
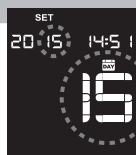


To the top of the time setting.

Date



1. Set the year. 2. Select a date format. 3. Set the month. 4. Set the day.

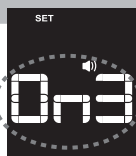


To the top of the date setting.

Beeper volume



1. Select a setting.



*On1: Low
On2: Normal
On3: High
OFF: Off*

To the top of the beeper volume setting.

Chapter 7 Using the wireless communication function

This chapter provides information on how to set the meter (transmitting device) for wireless communication via BLE. Before starting communication, also check the instructions of your receiving device (smartphone, tablet, etc.).

When the wireless communication function is on, test results will be transmitted automatically after measuring blood glucose and removing the test strip (the Bluetooth symbol will flash). The meter will search for the receiving device (max. 30 seconds) and will turn itself off after transmitting data. If transmission fails, check the settings of your receiving device.

It is also possible to transmit manually all previous test results whenever needed (e.g. when a new receiving device is registered, or when the usual receiving device is not present at the time of measurement, or its battery ran out). For this function, see "Transmitting all test results" below.

Wireless communication setup mode

BLE mode selection

1. Hold down the \bigcirc button for 2 seconds to turn on the meter.



2. Press ∇ button.



3. Press \bigcirc button.

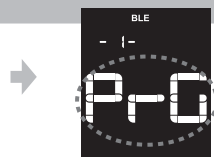
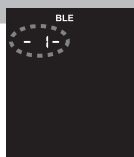


Setting at first use

- To follow the gray arrows (\Rightarrow), press \bigcirc button.
- To select among different options, use the \wedge ∇ buttons.
- To cancel a setting and return to the previous level, hold down the \bigcirc button for 1 second.
- To turn the meter off (in any screen), hold down the \bigcirc button for 3 seconds.

Pairing a new receiving device and turning the wireless communication ON

1. Select a number (1-2-3) for the receiving device (\wedge ∇).



NOTE: It is possible to register up to 3 receiving devices.

2. Select "PrG".
3. Pairing starts automatically. Check the settings of your receiving device to finalize the pairing procedure.



SUCCESS

FAILURE

4. Select an icon (\wedge ∇).



It is possible to identify each receiving device with an icon: select between the options ("personal device" icon, "hospital device" icon, no icon) using the \wedge ∇ buttons.

Selection of a different receiving device

1. Select the number of the receiving device (\wedge ∇).



2. Select "On" (\wedge ∇).



3. Edit the icon assigned (optional) (\wedge ∇).



To the BLE mode selection.

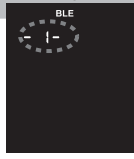
NOTE: It is possible to turn the wireless communication on only for one receiving device at a time. The last paired receiving device is set automatically on.



The selected receiving device is turned on automatically. Its number and icon will appear on the mode selection screen with the sign "On".
Your meter and device are now ready for wireless communication.

Deletion of a receiving device

1. Select the number of the receiving device (\wedge ∇).



2. Select "DEL" (\wedge ∇).



3. Select "YES" (\wedge ∇).



To the BLE mode selection.

Turning the wireless communication OFF

1. Select "OFF" (\wedge ∇).

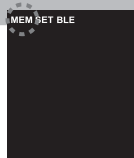


To the BLE mode selection.

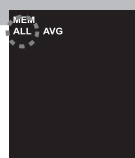
Transmitting all test results

This function is accessible from the MEM mode and only when wireless communication is ON

1. Select "MEM" (\wedge ∇).



2. Select "ALL" (\wedge ∇).



3. Confirm the number of the receiving device (\wedge ∇).



Wireless communication starts automatically.

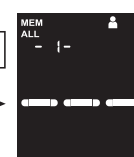


SUCCESS

FAILURE



Back to step 3.



Back to step 3. Check the settings of your receiving device.

Chapter 8 Control test

This meter checks itself every time you insert a test strip. You do not need to run frequent control tests. Do a control test if:

- You suspect the meter or test strips are not working properly.
- You dropped the meter.
- You damaged the meter.
- Your test results do not match how you feel.
- You want to check performance of the meter and test strips before a blood glucose test.

NOTE

Use only the GLUCOCARD™ SM CONTROL to test your meter and test strips.

CAUTION

- **Do not** use control solutions beyond their expiration date. The expiration date is written on the control solution bottles next to the "Use by" symbol.
- Leave the meter, test strips and control solution at 8 to 40 °C (46 to 104 °F) and 20 to 80% RH for at least 30 minutes before running the control test.
- **Do not** drink control solution. It is not for human consumption.
- Avoid contact with skin and eyes. Contact may cause inflammation.

1. See steps 1 and 2 in paragraph 2.7.

2. Make sure that the blood symbol is flashing on the screen.



3. Place a drop of control solution on a clean flat surface. Touch the tip of the test strip to a drop of control solution.

Accurate test results will not be obtained if you apply the control solution to the check window directly.



The meter counts down. After 5 seconds, a beep sounds and the test result, date/time and control test flag are shown.

NOTE

- Tightly close the control solution bottle.
- **Do not** touch the test strip until the test result appears.

4. Make sure the control test flag is on.



The meter automatically recognizes and associates the control test flag with the measurement results.

CAUTION

If the control test flag is not on, stop using your meter, test strips and control solutions, and contact your distributor.

5. Check that your test result is within the acceptable range.

The acceptable range is shown on the label of test strip bottles. If within range, the meter and the test strip are working properly. If out of range, test the control solution again.

CAUTION

If you still have test results that are out of the acceptable range, stop using your meter, test strips and control solutions, and contact your distributor.

6. Point the test strip down. Slide the test strip ejector to eject the test strip.

The meter turns itself off.

Chapter 9 System care

9.1 Storing your system

After use, tightly close the caps of the test strip bottle and control solution bottle to maintain their quality.

Store your meter, test strips, control solutions and manuals in your carrying case and keep this in a dry location. The correct storage temperatures are 0 to 50 °C (32 to 122 °F) for the meter, 1 to 30 °C (34 to 86 °F) for test strips, and 2 to 30 °C (36 to 86 °F) for control solutions. Do not freeze. Avoid heat, humidity and direct sunlight.

CAUTION

To obtain accurate test results:

- **Do not** use test strips or control solutions if their bottles are broken or have been left open.
- **Do not** use the test strips or control solutions beyond their expiration dates.

9.2 Cleaning your meter and lancing device

Your meter and lancing device do not need special cleaning. If your meter and lancing device get dirty, wipe them with a soft piece of cloth moistened with water. To disinfect these items after cleaning, wipe with a soft cloth moistened with 70% ethanol, 70% isopropanol or diluted household bleach (0.05% sodium hypochlorite solution).

9.3 Changing the batteries

When the battery symbol appears permanently on the screen, the batteries are getting low (approximately 100 tests can be performed). Before using your meter, change the batteries. Date and time settings will not be cancelled if you insert new batteries within 30 seconds. Past results remain in the memory even when the batteries are changed.



NOTE

Your meter uses two 1.5V alkaline LR03/AAA batteries. This type of battery is available in many stores. Keep spare batteries handy at all times.

1. Make sure the meter is off.

2. Push firmly to slide and open the battery cover.



3. Remove the old batteries.

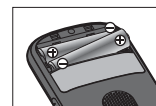
NOTE

Do not use sharp objects that may damage the meter.

4. Insert two AAA alkaline batteries in the correct direction.



5. Close the battery cover.



NOTE



The meter may enter date setting mode the next time it is turned on. In this event, set the correct date and time. See the setup mode flowchart in chapter 6.

Dispose of old batteries according to your local environmental regulations.



Chapter 10 Troubleshooting

| Error message | What it means | What to do |
|---|--|--|
| E01 (strip issue) | <ul style="list-style-type: none"> The insertion portion (electrode) of the test strip is dirty. A used test strip is inserted into the meter. A different type of test strip is inserted into the meter. The test strip is wet or contaminated by water. | Repeat the test with a new test strip. |
| E04 (empty battery) | The batteries are almost dead. Test results and changes made in the setup mode are not stored in the memory. | Change the batteries. See paragraph 9.3. |
| E06 (environment conditions issue) | The operating environment is not right for testing. | <ul style="list-style-type: none"> Leave the meter and test strips somewhere where the temperature is 8 to 40 °C (46 to 104 °F) and humidity is 20 to 80% RH for at least 30 minutes. Remove the test strip and insert it back into the slot. Test your blood only after the error and the thermometer symbol disappear. <p>If the error still appears on the screen, contact your distributor.</p> |
| E07 (temperature fluctuation issue) | There was a sharp change in the surrounding temperature. | |
| E11, E21, E22 (meter issue) | There is a problem with the inside of the meter. | Contact your distributor. |
| E13 (strip filling issue) | <ul style="list-style-type: none"> The test strip touched blood again after the test started. The test strip inside the meter moved during testing. The blood was not correctly drawn into the test strip. There was an insufficient amount of blood to perform the test. The test strip is wet or contaminated by water. | Repeat the test with a new test strip. |
| E14 (sample issue) | <ul style="list-style-type: none"> The insertion portion (electrode) of the test strip is dirty. | Repeat the test with a new test strip. |
| | <ul style="list-style-type: none"> Hematocrit range is out-of-specification. Sample type is out-of-specification. | Repeat the test using a suitable sample (see paragraph 11.1). |
| E23 (temperature verification issue) | The meter could not detect the surrounding temperature correctly. | See "What to do" for E06/E07. |

| Symbol | What it means | What to do |
|--|---|---|
|  | <ul style="list-style-type: none"> The batteries are getting low (approx. 100 tests can be performed). | Change the batteries (if the symbol is displayed permanently). See paragraph 9.3. |
|  | <ul style="list-style-type: none"> The surrounding temperature is too low or too high. The meter has not adjusted to the surrounding temperature. | <p>Leave the meter and test strips somewhere where the temperature is 8 to 40 °C (46 to 104 °F) and humidity is 20 to 80% RH for at least 30 minutes. Remove the test strip and insert it back into the slot. Test your blood only after the thermometer symbol disappears.</p> <p>NOTE Your meter can test your blood even when the thermometer symbol is displayed, but this may produce inaccurate test results. These results are stored along with the thermometer symbol and cannot be part of your result averages.</p> |

Chapter 11 Technical information

11.1 Specifications

| | |
|-------------------------------|--|
| Product | GLUCOCARD™ |
| Model | SM |
| Test item | Blood glucose level |
| Sample | Fresh capillary whole blood |
| Sample size | 0.3 µL |
| Assay method | Electrochemical, flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH) based method. Mediator: hexaammineruthenium(III) chloride, 1-Methoxy PMS. |
| Calibration | The results are equivalent to plasma glucose concentration (capillary plasma referenced) |
| Test strips | GLUCOCARD™ SM TEST STRIPS |
| Test strip coding | Auto Coding |
| Unit of measurement | mg/dL |
| Test range | 10 to 600 mg/dL |
| Hematocrit range | 20 to 70% (hematocrit compensated) |
| Test time | 5 seconds |
| Temperature compensation | Automatic compensation using built-in thermo sensor |
| Battery | 1.5 V alkaline LR03/AAA battery × 2 (the meter is shipped with the batteries loaded) |
| Battery life | Approximately 1,000 tests or approximately 12 months (counting 3 tests/day), with Bluetooth transmission after each test. The actual number of tests may be lower depending on conditions of use, environment conditions and individual variability. |
| Power consumption | 0.1 W (Max.) |
| Memory capacity | 500 test results |
| Data transmission | Yes (USB and Bluetooth 4.0) |
| Auto power off | 2 minutes after last user operation (5 minutes when waiting for blood application) |
| Operating environment | Temperature: 8-40 °C (46-104 °F) Humidity: 20-80% RH (no condensation) |
| Test Strip storage conditions | Temperature: 1-30 °C (34-86 °F) Humidity: 20-80% RH |
| Meter storage conditions | Temperature: 0-50 °C (32-122 °F) Humidity: 20-80% RH |
| Expected Meter life | 3 years |
| Dimensions | L94.0 x W57.0 x 18.5 mm (L3.7 x W2.2 x 0.7 inches) |
| Weight | Approx. 70 g (2.47 ounces) |

11.2 Product safety information

The meter complies with applicable electromagnetic emission requirements (EMC). However, do not perform a glucose measurement 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.

Electromagnetic interference (EMI)

This meter complies with CISPR 11:2003, Class B (Radiated Only). It emits low levels of energy that are not likely to interfere with nearby electronic equipment.









Static electricity and radiated magnetic field immunity

This meter clears immunity requirements for Level 3 electrostatic discharge set forth in IEC 61000-4-2. This meter clears immunity requirements for radio frequency interference in the 80 MHz to 2.5 GHz range (3 V/m) set forth in IEC 61000-4-3.

11.3 Disposing of your meter

The meter qualifies as biohazardous waste once used to test blood glucose. When no longer needed, remove the batteries and dispose of the meter according to your local regulations on biohazardous waste. This meter is not subject to requirements of European Directive 2002/96/EC (Directive on Waste Electrical and Electronic Equipment (WEEE)).

11.4 Specifications

| Symbol | Description |
|---|---|
|  | Storage temperature limitation |
| IVD | In Vitro Diagnostic Medical Device |
|  | Manufacturer |
|  | Biological risks |
|  | Caution, consult instructions for use |
| LOT | Batch code |
|  | Use by |
| CE 0 1 2 3 | This product complies with Directive 98/79/EC |
| SELF-TESTING | Suitable for self testing |
| EC REP | Authorized Representative in the European Community |
| SN | Serial number |
|  | Consult instructions for use |
| Blood Glucose Meter | Blood glucose meter |
|  | Significant additions or changes from previous user manual revision |
|  | Direct current (voltage) |
| REF | Catalogue number |

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GLUCOCARD™ SM
 Made in Philippines

GLUCOCARD™ SM TEST STRIPS,
 GLUCOCARD™ SM CONTROL
 See relevant instructions for use