GLUCOFIX® TECH

User Manual

Read this user manual carefully
before you start testing

A.MENARINI
diagnostics

CUSTOMER SERVICE

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

This number is not for emergency or medical information.

E-mail: myglucomen@menarinidiag.co.uk
Web site: www.glucomen.co.uk

Date of Issue: January 2019

INTRODUCTION

Thank you for choosing the GLUCOFIX® TECH meter.

We have designed this compact blood glucose meter for faster and easier testing of your blood glucose and 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: GLUCOFIX® TECH Sensor and GLUCOFIX® TECH 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 for assistance (references on page 2 or at the end of this manual).

IMPORTANT INFORMATION!

Notes, Cautions and Warnings:

Notes: *provide helpful operating information.*

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

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

CONTENTS

UK

CONTENTS

1. INTENDED USE

Your GLUCOFIX® TECH meter and GLUCOFIX® TECH Sensor are *in vitro* diagnostic medical devices to quantitatively measure the glucose level in fresh capillary whole blood.

They are intended for self testing to monitor and control blood glucose 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 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.

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.

2. SYSTEM OVERVIEW

2.1 GLUCOFIX® TECH Meter

FRONT

BACK

2. SYSTEM OVERVIEW

TEST STRIP PORT ..... Test strip should be inserted here.

ENTER (⏻) BUTTON ..... Press and hold ⏻ for 2 seconds to access meter memory (§5.1) or simultaneously press ⏻ and ▲ for 2 seconds to enter setup menu while not testing (§6).

UP/DOWN (▲/▼) BUTTONS .... Press ▲ or ▼ to scroll through different options and/or values.

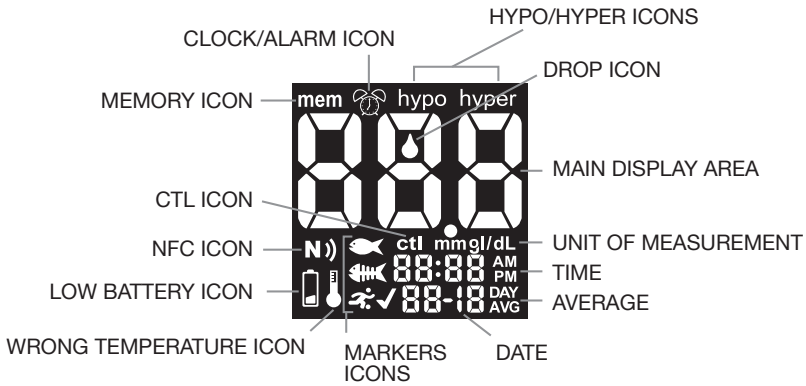
RELEASE BUTTON ..... Press this button to remove used test strip.

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.

2. SYSTEM OVERVIEW

METER SCREEN



2. SYSTEM OVERVIEW

MEMORY ICON: Indicates that you are using the memory (§5).

CLOCK/ALARM ICON: "Clock" appears while setting the time (§6.1); "alarm" appears while setting the acoustic reminder(s), and will be displayed if any alarm is on (§6.2).

HYPO/HYPER ICONS: Appear while setting the hypoglycaemic and hyperglycaemic thresholds and if your test results are below or above these values (§6.4).

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 meter (mg/dL or mmol/L, not changeable).

TIME: Shows time (HH:MM 12H am/pm or 24H format).

AVERAGE: Shows the period related to the displayed average (1, 7, 14, 30, 60 or 90 days – §5.2).

DATE: Shows the date (DD-MM format).

MARKERS ICONS: Displayed while marking a test result (§4.4) or reviewing a marked result.

2. SYSTEM OVERVIEW

Before meal marker.

After meal marker.

Exercise marker.

Check marker.

WRONG TEMPERATURE ICON: Appears while testing outside the allowed temperature range.

LOW BATTERY ICON: Appears when the battery needs to be replaced (§7.3).

NFC ICON: Displayed while setting the NFC (Near Field Communication) function (§6.5) and when this function is enabled; blinks while data are transmitted via NFC (§5.3.1).

CTL ICON: Indicates a control solution test (§4.3).

2.2 Test strip

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 (§7.3).

⚠ 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 levels:
  - temperature: 5 to 45 °C (41 to 113 °F);
  - humidity: 20 to 90% RH (Relative Humidity).
- Do not store or use the meter where:
  - there are sharp temperature fluctuations;
  - humidity is high and causes condensation (bathrooms, drying rooms, kitchen, etc.);
  - there is a strong electromagnetic field (close to a microwave oven, cell phone, etc.).
- Keep the meter out of the reach of children. Coin batteries may represent a choking 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 is housed inside the meter to minimize any errors.

3. BEFORE TESTING

- 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 a glucose measurement with this meter near mobile devices or electrical or electronical equipments that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

3.2 Caution when using the Test Strips

⚠ CAUTION

- For testing with GLUCOFIX® TECH meter use GLUCOFIX® TECH 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 written on the test strip vial next to symbol .
- 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 levels:
  - temperature: 5 to 45 °C (41 to 113 °F);
  - humidity: 20 to 90% 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 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

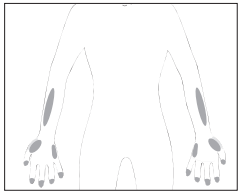
For information on how to use the lancing device, read the relevant instructions for use.

⚠ 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.
Fingertip	• When there is the possibility of your blood glucose levels changing rapidly (e.g. after meals or exercise). • When experiencing symptoms of hypoglycaemia such as perspiration, cold sweats, a floating sensation or trembling. • When immediate testing is needed for suspected hypoglycaemia. • When in poor physical condition, such as with a head cold, etc.

4.2 Testing your Blood Glucose

a. Insert a new test strip into the test strip port. **The drop icon starts blinking on the screen**. 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 blood drop 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.

4. MEASURING YOUR BLOOD GLUCOSE LEVELS

⚠ 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.

c. **Read your test result**. You will hear a beep when the test result appears on the screen.

⚠ 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 1.1 mmol/L “HI” appears if your test result is more than 33.3 mmol/L.
- The “hypo” or “hyper” icons may appear depending on the threshold limit you have set (§6.4).
- **If test results do not match how you feel:**
  Make sure you have performed the test correctly as explained in §4.2. Then, conduct a 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.

- **Do not** ignore test results. **Do not** alter your blood glucose management or treatment without first consulting your doctor or healthcare professional.

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

⚠ **CAUTION**

- When ejecting the used test strip, point your meter downwards and away from others.
- **Disposal of Biohazardous Waste.**
  Used test strips and lancets are biohazardous waste. They must therefore be disposed according to local regulations on biohazardous waste.

4.3 Control Test

Conduct a control test if:

- you suspect the meter or test strips are not working properly;
- the meter has been dropped;
- the meter is damaged;
- your test results do not match how you feel;
- you want to check the performance of the meter and test strips when you first get them or any time you want to check their performance before a blood glucose test.

4. MEASURING YOUR BLOOD GLUCOSE LEVELS

⚠ NOTE

To test your meter and test strips only ever use the GLUCOFIX® TECH Control control solutions (provided separately).

⚠ CAUTION

- **Do not** use control solutions after their expiry date. The expiry date is indicated on the control solution vial next to ⌛ 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:
  - temperature: 5 to 45 °C (41 to 113 °F);
  - humidity: 20 to 90% RH.
- 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.

To perform a control solution test, proceed as follows:

a. Insert a new test strip into the test strip port. **The drop icon starts blinking on the screen**. 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. **Enable the CTL mode** (§2.1).

⚠ 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 enabled 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.

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.

⚠ 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.

4. MEASURING YOUR BLOOD GLUCOSE LEVELS

e. **Check that your test result is within the acceptable range** indicated on the label of the test strip vial. If out of range, repeat the control solution test.

⚠ **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.

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). 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. MANAGING YOUR TEST RESULTS

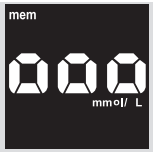
5.1 Reviewing past results

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

> ⚠ **WARNING**
>
> Please make sure that the time and date are correct before the first use, and adjust them if needed (§6.1). If the time and date settings are not correct the meter will memorize the test results in the wrong order.

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).
c. The most recent test result appears on the screen. The screen also shows the date and time of the test and the corresponding markers.
d. Press ▲ or ▼ to scroll through all the stored data.
e. Press ⏻ for 3 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.



5.2 Viewing results averages

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

a. Follow steps **a** and **b** in §5.1.
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.
e. After reviewing the 90-day average, press ⏻ to return to the memory recall mode (step **c** of § 5.1).
f. Hold ⏻ for 3 seconds to switch the meter 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 HI results to 33.3 mmol/L and LO results to 1.1 mmol/L.

5.3 Data transmission

Test results stored in the GLUCOFIX® TECH meter’s memory can be also downloaded to GlucoLog® software or apps by means of either NFC, a dedicated cable, or a Bluetooth dongle distributed by A. Menarini Diagnostics only.

⚠ NOTE
- GlucoLog® software and apps, data cable, and Bluetooth dongles are supplied separately. See relevant user manuals for instructions on how to download data.

5.3.1 NFC Transmission

For data transmission by means of NFC the NFC function must be enabled on the GLUCOFIX® TECH meter (§6.5) and an NFC equipped device (such as a Smartphone) with GlucoLog® apps.

a. Activate the NFC transmission on the GlucoLog® app of the NFC equipped device.

b. Bring the GLUCOFIX® TECH NFC antenna close (< 1 cm) to the antenna in the NFC equipped device.

⚠ NOTE
- Data will be transmitted even when the meter is switched off or in memory recall mode.

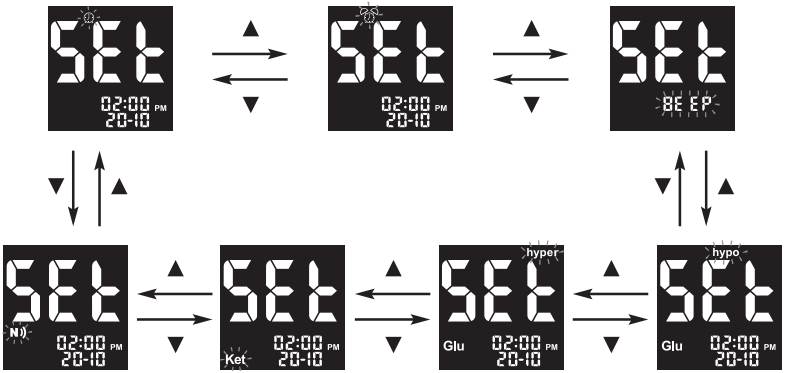
c. Data transmission will start automatically (the GLUCOFIX® TECH meter will turn on and the **N**)) blinking icon will be displayed on the screen).

d. After downloading the data, the meter switches off automatically.

⚠ WARNING
- Data transmission via NFC may decrease battery life.

5. MANAGING YOUR TEST RESULTS

a. Make sure the meter is off (to turn the meter off press ⏻ for 3 seconds until the screen switches off).
b. Simultaneously press ⏻ and ▲ for 2 seconds to enter the setup menu.
c. Press ▲ or ▼ to scroll through the setting menus (see pictures below) and press ⏻ to enter each single menu.



6. METER SETUP

⚠ NOTE
- At anytime during set up, you may either press ⏻ to exit, or insert a test strip to perform a test. The changes made so far will be memorized by the meter.

6.1 Date/Time setup

Use ▲ or ▼ to select the correct value. Press ⏻ to confirm and move on to the next step: year, month, day, time format (12H, 24H), hour, minutes.
After confirming the minutes (by pressing ⏻) return to the setting menus (step **c** §6).

⚠ NOTE
- Date is in the DD-MM format.

6.2 Alarm setup

You can set up to six alarms on your GLUCOFIX® TECH meter: three for glucose test remind, and three for β-Ketone test remind. When the alarm reaches the set time, the meter sounds for 30 seconds.

⚠ NOTE
- Press ⏻ or insert a test strip to stop the acoustic meter alarm (the alarm will remain set).

⚠ 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 ▲ or ▼. to scroll between glucose (“Glu” icon blinking) and β-Ketone (“Ket” icon blinking) alarm section. Press ⏻ 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 ▲ or ▼ to select the hour. Press ⏻ to confirm the selection and move on to the next step.
c. Press ▲ or ▼ to select the hour. Press ⏻ confirm the selection and move on to the next step.
d. Press ▲ or ▼ to select the minutes. Press ⏻ 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 ⏻ to return to the setting menus (step **c** §6).

⚠ NOTE

- The alarm will have the format (12H, 24H) set for the time.
- Alarm settings will not be erased when changing the batteries.

6.3 Beeper setup

The beeper on your GLUCOFIX® TECH meter is preset to ON. You can adjust the beeper feature as follows.

a. Press ▲ or ▼ to turn the beeper ON or OFF.

b. Press ⏻ to confirm and return to the setting menus (step **c** §6).

⚠ **WARNING**

- Turning off the beeper could mean you miss many important cues from your meter, such as confirmation or error messages.

6.4 Hypo/hyper alarms setup

Your GLUCOFIX® TECH 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.

⚠ **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 ▲ or ▼ to turn the hypo alarm ON/OFF.
b. Press ⏻ to set the hypo alarm value (if ON).
c. Press ▲ or ▼ to select the desired value. Press and hold either ▲ or ▼ to accelerate the numbering.
d. Press ⏻ to confirm the selection and move on to the hyper alarm setup.
e. Press ▲ or ▼ to turn the hyper alarm ON/OFF.
f. Press ⏻ to set the hyper alarm value (if ON).
g. Press ▲ or ▼ to select the desired value. Press and hold either ▲ or ▼ to accelerate the numbering.
h. Press ⏻ to confirm the selection and return to the setting menus (step **c** §6).

6.5 NFC setup

The NFC function on your GLUCOFIX® TECH 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.

7. METER CARE

7.1 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.

⚠ 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 after their expiry dates.

7.2 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).

7.3 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.

7. METER CARE

Your meter uses two CR2032 3V lithium batteries. This type of battery is available in many stores. Keep spare batteries handy at all times.
You do not need to set the date and time if you insert new batteries within 2 minutes after removing the old ones.
If batteries replacement takes longer than 2 minutes, the meter will automatically require to reset Date and Time before any operation (see 6.1).

Replace the batteries as follows:
a. Make sure the meter is switched off.
b. Remove the battery cover at the rear of the meter.
c. Remove the batteries.
d. Fit the new batteries into the battery holder with the "+" pole facing upwards.
e. Close the battery holder.

⚠ WARNING

- If the batteries are inserted upside down, the meter will not operate.
- The meter clock may stop if you touch the metal parts inside the meter with your hands or metal.
- If you replace batteries after 2 minutes and do not set the time, all subsequent test results will be stored with the incorrect date and time.
- Dispose of old batteries according to local environmental regulations.

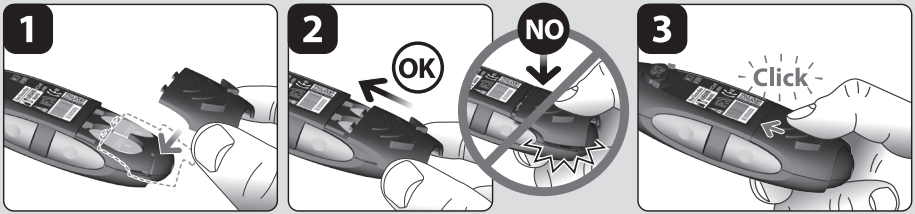
7. METER CARE

⚠ CAUTION

- Improper use may cause explosion or leakage of flammable liquid.
- Do not expose the battery to extremely high temperatures.
- Do not expose the battery to extremely low air pressure.

⚠ NOTE

- **Correct closing of the battery compartment.**



8.1 HI and LO messages

If the test result is over 33.3 mmol/L the HI icon will appear on the display.

If the test result is less than 1.1 mmol/L the LO icon will appear on the display.

⚠ WARNING

- If the HI or LO message has appeared, please consult your doctor or a healthcare professional before altering your treatment.
- If the HI or LO icons are displayed repeatedly, even though your blood glucose levels should not be high or low according to your doctor, please contact the A. Menarini Diagnostics customer service.

8.2 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 (§7.3).
	The temperature was not within the recommended range. Repeat the measurement after at least 30 minutes, when the operating temperature has been restored.

8.3 Unexpected test results

If the test result is unusual compared to your previous test results:

a. Repeat the measurement using a new test strip (§4.2).

b. Perform a control measurement using the GLUCOFIX® TECH Control control solution (§4.3).

c. Change the test 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. TECHNICAL SPECIFICATIONS

Product:	GLUCOFIX® TECH
Manufacturer:	A. Menarini Diagnostics S.r.l.
Tested item:	Blood Glucose level
Unit of measurement:	mmol/L
Test Range:	1.1 – 33.3 mmol/L
Haematocrit range:	10 – 70% (haematocrit compensated)
Test strip:	GLUCOFIX® TECH Sensor
Test strip coding:	No coding required
Sample:	Fresh capillary whole blood
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

9. TECHNICAL SPECIFICATIONS

Calibration and traceability:	The results are equivalent to the plasma glucose concentration (capillary plasma referenced). The GLUCOFIX® TECH system is calibrated using capillary plasma values determined with 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)
Temperature compensation:	Automatic compensation using a built-in thermo sensor
Batteries:	Two 3.0 V lithium batteries (CR2032)
Battery life:	A minimum of 1000 tests or about 1 year (2-3 tests/day)
Memory:	730 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 available
Alarms:	Up to three settable acoustic alarms
Data transfer:	Via dedicated data cable, NFC, or a Bluetooth device
Averages:	Over 1, 7, 14, 30, 60, 90 days

9. TECHNICAL SPECIFICATIONS

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 - 45 °C (41 - 113 °F). - Relative Humidity: 20 - 90% (no dew condensation).
Meter Storage Conditions:	- Temperature: -20 – 50 °C (-4 – 122 °F). - Relative Humidity: 20 - 90%.
Test strip Storage Conditions:	- Temperature: 4 - 30 °C (39.2 - 86 °F) (both for unopened vial and after opening). - Relative Humidity: 20 - 90% (both for unopened vial and after opening).
Control Solution Storage Temperature:	4 - 30 °C (39.2 - 86 °F)

9. TECHNICAL SPECIFICATIONS

Operating environment:	The meter complies with applicable electromagnetic emission requirements (EMC)
Operading radio frequency band(s):	13.56 MHz
Maximum radiofrequency power transmitted in the operating frequency band(s):	0.0042 mW
EU directive/ classification:	98/79/EC / Annex II, List B
Device Standard:	EN ISO 15197:2015

10. WARRANTY

Your GLUCOFIX® TECH 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 GLUCOFIX® TECH 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: Tel. (UK) 0800 243667 - (Republic of Ireland) 1800 709903 - (Northern Ireland) 0800 7837286.
Should you wish to extend the warranty period for your meter, please refer to the same contact.

11. SYMBOLS AND ABBREVIATIONS

	Consult instructions for use
	Caution, consult instructions for use
	Temperature limitation
	Use by
	Manufacturer
LOT	Batch code
IVD	*In vitro* diagnostic medical device
SELF-TESTING	*In vitro* device for self-testing

SN	Serial number
	Recyclable package
CE	CE marking
	Contamination risk due to the use of blood samples
Blood Glucose Meter	Blood glucose meter
	Significant additions or changes from previous user manual revision
	Direct current (voltage)
REF	Catalogue number

A. MENARINI DIAGNOSTICS Srl
Via Sette Santi, 3
50131 Firenze - Italia

51415 - 02/20

UK

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

GlucoMen® Careline:
(UK) 0800 243667
(Republic of Ireland) 1800 709903
(Northern Ireland) 0800 7837286

Email: myglucomen@menarinidiag.co.uk
www.glucomen.co.uk

GLUCOFIX® TECH
Made in Taiwan

GLUCOFIX® TECH Sensor and
GLUCOFIX® TECH Control
See relevant instructions for use

A.MENARINI diagnostics

CE 0123

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

Description	GLUCOFIX® TECH - U.MANUAL - UK
Code	51415
Rev	02/20
Size (mm)	150 x 102

Colours Used
CMYK
PANTONE 877 C

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

PLEASE READ THIS IMPORTANT INFORMATION: Please ensure this proof matches your Artwork requirements.
Please check ALL aspects of the proof i.e. text, font, spelling, colours, size, construction, copy position, barcode, pharma codes, orientation of graphics etc.

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

INDICAZIONI STAMPA - USER MANUAL BOOKLET

composto da: 40 pagine interne stampate ad 1 colore (k 100) in b/v
+ 4 pagine di coperta stampata a 5 colori in bianca e 1 colore in volta (k 100)