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Gluc_oR_x Q Blue

Blood Glucose Monitoring System

Owner's Manual



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Dear GlucoRx Q Blue System Owner

Thank you for choosing the GlucoRx Q Blue Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before you begin, please read the following contents thoroughly and carefully. If you have other questions regarding this product, please contact the GlucoRx Customer Care or place of purchase.

Intended Purpose

The GlucoRx Q Blue Blood Glucose Monitoring System consists of the GlucoRx Q Blue Blood Glucose Meter (TD-4125), the GlucoRx Q Blue Blood Glucose Test Strips (TD-4304) and the GlucoRx Q Control Solution (TD-4908).

The system is intended for use outside the body (*in vitro* diagnostic use) to quantitatively measure the biochemical parameter - blood glucose in fresh capillary whole blood. It is for self-testing or for near-patient testing by healthcare professionals. It is intended for *in vitro* diagnostic use by healthcare professionals in clinical settings and by people with diabetes for self-testing.

Near-patient testing may also use the test strips for blood glucose measurement in capillary whole blood

Glucose measurements are indicated to monitor diabetes mellitus.

Lancing Device and Lancet

The lancing device and the sterile lancet are intended to obtain capillary blood for testing purposes from the sides of the fingertips and from alternative sites, such as the palm, the upper arm and the forearm. The sterile lancet is to be disposed of and is for single use only. The sterile lancet and the lancing device are for use only on a single patient in a home setting.

Control Solution

The blood glucose control solution is intended for checking that the meter and blood glucose test strips are respectively working together properly. It is for self-testing or near-patient testing by healthcare professionals. It is intended for *in vitro* diagnostic use by healthcare

professionals in clinical settings and by people for self-testing.

Contraindications

There are no known contraindications for the meter, although care should be taken when considering using the meter according to the warnings, precautions and limitation of use.

The lancing device should be used only on a single patient, not on multiple patients. Use on multiple patients may cause infections from residual blood.

Test Principle

The test is based on the measurement of electrical current generated by the reaction of the biochemical parameters with the reagent of the strip.

⚠Warnings and Precautions

Please read the following carefully before use:

1. Use this device only for the intended use described in this manual.
2. Do not use accessories that are not specified by the manufacturer.
3. The GlucoRx Q Blue Blood Glucose Monitoring System should only be used with GlucoRx Q Blue test strips. Using other test strips with this meter can produce inaccurate results.
4. Do not use the device if it is not working properly or is damaged.
5. This device does not serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
6. The user should not take any decision of medical relevance without first consulting his or her medical practitioner. When the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so.
7. Keep the device and testing equipment away from children. Small parts such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
8. The presence of synthetic materials (synthetic clothing, carpet, etc.) may cause damaging static discharges that lead to erroneous

results.

9. Do not use this device in close proximity to sources of strong electromagnetic radiation as these may interfere with the accurate operation.
10. Remove the battery from the unused meter to avoid battery leakage.
11. Proper maintenance and control solution tests are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact GlucoRx Customer Care or place of purchase for assistance.
12. We do not recommend using this product on severely hypotensive individuals or patients in shock. Severe dehydration and excessive water loss may also cause inaccurate readings. Please consult a healthcare professional before use.
13. Only use fresh whole blood sample. Using any body substances other than blood will lead to incorrect results.
14. If your test results are significantly different from what you expect, inconsistent with your symptoms or at unusually high or low levels, please repeat the test with a new test strip or contact your healthcare professional.
15. If the device is used in a manner not specified within this manual, the protection provided by the device may be impaired.
16. Other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitised objects.
17. If any serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
18. For the summary of safety and performance, please reference the EUDAMED website.

Lancing Device and Lancet

1. Possible skin infection present at the sample site.
2. Never share a lancet and the lancing device.
3. Do not reuse lancets. Always use a new, sterile lancet for testing. The used lancet may potentially be biohazardous. Discard it

according to your local regulations.

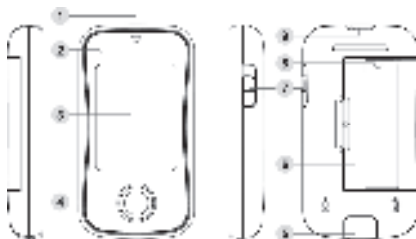
4. If the lancing device is being operated by a second person who is providing testing assistance to the user, the lancing device should be cleaned and disinfected prior to use by the second person. The second person must wear protective gloves for all the steps when providing testing assistance.
5. Always keep the lancing device and the lancet with all its components away from children.
6. Do not use if the sterile lancet package is damaged.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Product Overview

The contents included in the kit depend on the package. Check the components in the kit and quantity of each item. Test strips, control solution, sterile lancets and lancing device may be purchased separately. Please make sure you have those items needed for a test beforehand. If any item is missing or damaged, contact GlucoRx Customer Care for assistance.

Meter



1. Strip Indication Light

Red: Blood Glucose result fallen outside the target range

2. Bluetooth Indication Light

3. Display Screen

4. Main Button (M)

Enter the meter memory and silence a reminder alarm.

Select or change parameters.

5. Data port

Download test results with a cable connection.

6. Battery Compartment

7. Test Strip Ejector

Eject the used strip by pressing this ejector.

8. Set Button (S)

Enter and confirm the meter settings.

9. Test Strip Slot

Insert test strip here to turn the meter on for testing.

Test Strip

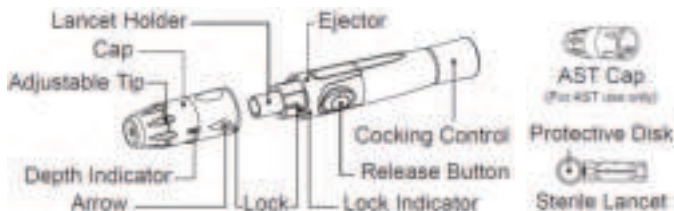


1. Absorbent Hole
2. Confirmation Window
3. Test Strip Handle
4. Contact Bars

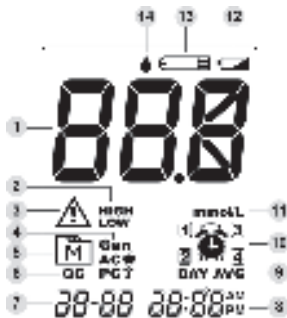
Control Solution



Lancing Device and Lancet (For self-testing)



Display Screen



- | | |
|-----------------------|---|
| 1. Test Result | 2. High/Low Indicator |
| 3. Error Message | 4. Measuring Mode
Gen – any time of day
AC – before meal
PC – after meal |
| 5. Memory Mode | 6. QC mode
QC – control solution test |
| 7. Date | 8. Time |
| 9. Day Average | 10. Alarm Symbol |
| 11. Measurement Unit | 12. Low Battery Symbol |
| 13. Test Strip Symbol | 14. Blood Drop Symbol |

Before Testing

Get all accessories ready and follow the preparation steps below before testing.

Setting the Meter

Set up your meter with the correct date, time, desired measurement unit, personal target range, etc. for better health management. Date and time could be synced with the paired device by data transmission.

Entering the Setting Mode

Start with the meter off (no test strip inserted). Press **S**. The following settings are set up in sequence:

1. Date

With the YEAR / MONTH / DAY flashing in sequence, press **M** to select the number. Press **S**.

2. Time format and time

Press **M** to select the desired time format (12h or 24h). Press **S**. With the HOUR / MINUTE flashing in sequence, press **M** to select the number. Press **S**.


3. Blood glucose's target range

The sequence of the low and high target range setting is: Gen low → Gen high → AC low → AC high → PC low → PC high. Press **M** to select target number for each testing mode. Press **S**.

NOTE

◆ The meter comes with a set of default target range. Please consult your doctor to determine a target range that works best for you.

4. Reminder alarm

Your meter has 4 reminder alarms. The meter will display “OFF” and “”. If you do not want to set an alarm, press **M** to select “OFF”, and then press **S** to skip this step. Or select “On” and press **S** to proceed. With the HOUR / MINUTE flashing in sequence, press **M** to select the correct HOUR / MINUTE. Press **S** and go to the next alarm setting.

NOTE

When the alarm beeps, press **M** to switch it off.

Prepare the Lancing Device for Blood Glucose Tests

To set up the lancing device, you need: lancing device and lancet.

1. Twist and pull off the cap of the lancing device.
2. Insert a lancet into the lancet holder of lancing device and push down firmly until it is fully secured.
3. Twist off the protective disk of the lancet.
4. Replace the cap onto the lancing device.
5. Hold the cap and select the depth of penetration by turning the adjustable tip. The longer the length of indicator line, the greater the

depth of penetration.

6. Pull the cocking control back until it clicks. You will see a colour change inside the release button when it is ready. If it does not click, the device may have been cocked when the lancet was inserted.

Alternative Site Testing (AST)

Testing on sites other than the fingertip is referred to as alternative site testing (AST). Please consult your healthcare professional before you perform AST.

Substitute the lancing device cap with the AST cap for alternative site testing. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, or hand, avoid lancing the areas with obvious veins in order to prevent excess bleeding. AST cap is reusable; do not throw away the AST cap after each use.

The following times are recommended to perform AST:

- In a pre-meal or more than 2 hours after the last meal.
- Two hours or more after taking insulin.
- Two hours or more after exercise.


Perform Blood Glucose Tests

The meter provides you with three measuring modes: General (any time of day), AC (before meal), PC (after meal).

Before collecting a drop of blood

- ◆ Wash and dry your hands before you start.
 - ◆ Rub the puncture site for about 20 seconds before penetration.
-

To perform a blood glucose test by self-testing, you need: meter, test strip, lancing device and lancet.

- 1. Turn on the meter by inserting a test strip:** Wait for the meter to display the flashing “”.
- 2. Select the appropriate measuring mode by pressing M (For blood glucose: Gen / AC / PC).**
- 3. Prick the puncture site:** Hold the pre-set lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick the puncture site.
- 4. Obtain a blood sample:** Gently squeeze the punctured site to squeeze out the first drop of blood and wipe it off. Then obtain

another drop of blood and use it as the sample for the test. Be careful not to smear the blood sample.

- 5. Apply the sample:** Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Make sure the absorbent hole of the test strip comes into contact with the blood sample but not the skin. Hold the meter still until the confirmation window of the test strip is completely filled. Confirmation window should be completely filled if enough blood has been applied.

NOTE

- ◆ Do not put blood on top of the test strip.
 - ◆ Always apply a blood sample after the test strip is inserted into the meter.
 - ◆ Do not hold the test strip parallel to the finger for absorption.
 - ◆ If you do not apply a blood sample to the test strip within 3 minutes; the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
 - ◆ The confirmation window should be filled with blood before the meter starts counting down.
-

- 6. Read your result:** Place the meter flat on the table and wait for the test result display. Do not move the meter during the countdown.
- 7. Remove the used test strip:** Remove the test strip and dispose of them carefully according to your local regulations.
- 8. Remove the used lancet:** Remove the sterile lancet by twisting the lancing device cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface and pushing the exposed tip into the protective disk. Slide the ejector forward to remove the used lancet and dispose of the lancet according to your local regulations.

Result Reading with Display Messages

Lo: test result is below the measurement range.

Hi: test result is above the measurement range.

A value display with Lo: blood glucose result is below the target range.

A value display with Hi: blood glucose result is above the target range.

 **with High:** blood glucose result ≥ 13.3 mmol/L (240 mg/dL).

The default target range of blood glucose in each mode

Gen: 3.8 to 6.6 mmol/L (70 to 119 mg/dL)

AC: 3.8 to 7.1 mmol/L (70 to 129 mg/dL)

PC: 3.8 to 9.9 mmol/L (70 to 179 mg/dL)

Quality Control Tests


If you are concerned that the meter or test strips are not working properly, you can check the performance of the meter, test strips and your technique by comparing the control solution results with the range printed on the test strip package.

Perform a Control Solution Test when:

- you suspect the meter or test strips are not working properly;
- your test results are not consistent with how you feel, or if you think the results are not accurate;
- to practice the testing process; or
- you have dropped or think you may have damaged the meter.

To perform a control solution test, you will need: meter, test strip and control solution.

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display a flashing “”.

2. Press M to mark this test as a control solution test

With “QC” displayed, the meter will store your test result in memory under “QC”.

NOTE

When doing the control solution test, you have to mark it so that the test result will not mix with the blood glucose test results stored in the memory.

3. Apply the control solution

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the test strip absorbent hole to the droplet. Once the confirmation window fills completely, the meter will start counting down.

4. Read and compare the result

Compare the displayed number with the range printed on the test strip vial or foil packet and it should fall within range. If not, please read the instructions again and repeat the control solution test.

NOTE

- ◆ The control solution range printed on the test strip vial or foil packet is for control solution use only. It is not a recommended range for your blood glucose test levels.
-

Out-of-range Result


Results that fall outside the expected range may indicate:

- An error in the way you are doing the test.
- Expired test strips and/or control solution.
- A problem with the meter.
- Control solution that is too warm or too cool.
- Failure to shake the control solution vial vigorously.


If you are still unsure of the problem, please contact GlucoRx Customer Care for assistance.

Review Test Results

To enter memory mode, start with the meter switched off.

1. Press and release **M**. “” will display with the latest result.
2. Press **M** to scroll through all the test results stored in the meter.

Reviewing Blood Glucose Average Results

1. Press and release **M**. “” will display with the latest result.
2. Press and hold **M** to enter day average memory with “DAY AVG” display on the screen.
3. Press **M** to review 7-, 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC and PC.

NOTE

- ◆ Any time you wish to exit the memory mode, press and hold **M** for 3 seconds.
 - ◆ Control solution results are not included in the day average.
-

Data Transmission

Data Transfer to a Computer

You can use the Health Care Management System to view test results on a **Windows 10 (or above)** computer. Connect to a computer via cable, Bluetooth and visit GlucoRx's website at www.glucorx.co.uk to find the appropriate Health Care Management System for this meter.

Data Transfer to a Mobile Device

You can transfer test results from the meter to the compatible app on your mobile device via Bluetooth. For the requirement of OS version, please find it on App Store or Google Play when you download the app. Follow the Quick Start Guide (For Bluetooth Pairing) and instructions in the app for pairing.

Bluetooth Indicator on the Meter

Flashing Blue: The Bluetooth function is on and waiting for connection.

Solid Blue: The Bluetooth connection is established.

NOTE

- ◆ The meter will be unable to perform a test while it is in transfer mode.
 - ◆ Please make sure your device supports Bluetooth Smart Technology, the Bluetooth setting on your device is turned on and the meter is within the receiving range before transferring the data.
 - ◆ The Bluetooth functionality is implemented in different ways by various mobile device manufacturers; compatibility issue between your mobile device and the meter may occur. The additional connection with other equipment to IT-network may cause previously unidentified risks to patients, operators or third parties. These risks should be identified, analysed, evaluated and controlled.
 - ◆ The changes of IT-network include configuration, the connection of additional items, disconnection items and the update and upgrade of the monitor, which could introduce risks and require additional analysis.
-

Maintenance

Meter Storage and handling

- ▶ Always store or transport the meter in its original storage case.
- ▶ Avoid dropping the meter or heavy impact.
- ▶ Avoid direct sunlight or high humidity.
- ▶ Store the meter at -20°C to 60°C (-4°F to 140°F), 10% to 93% R.H. (non-condensing).

Meter Cleaning and Disinfecting

Wipe the meter exterior with soft damp cloth or mild cleaning agent, then dry the device with soft dry cloth. Do not use organic solvents (except isopropanol and ethyl alcohol) to clean the meter. Do not rinse or immerse in water or other liquids. Always disinfect the surfaces of the meter with cotton moistened with 70% isopropanol or ethyl alcohol after taking a test. Avoid getting any moisture into any openings (e.g. test strip port, battery compartment).


Meter Disposal

The used meter should be treated as a contaminated item that may carry a risk of infection during measurement. This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.



Batteries

The meter will display the messages below to alert you when the meter power is getting low.

1. When the “ ” symbol appears along with display messages: The meter is functioning properly and the result remains accurate, but it is time to change the batteries.
2. When E-b display: The power is too low to perform a test. Please change the batteries immediately.

Properly dispose of the batteries according to your local environmental regulations.

Lancing Device, Lancet Storage and Handling

- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Store the lancing device only without a lancet inserted.
- Store the lancing device at -20°C to 60°C (-4°F to 140°F), 10% to 93% R.H.
- Store the sterile lancet at -10°C to 50°C (14°F to 122°F), 0% to 80% R.H.

Lancing Device and Cap Cleaning and Disinfecting

The disposable lancet is intended for single use only. The lancing device is reusable. To clean the lancing device and the cap, use mild soap and water to wipe and clean the lancing device. Do not rinse the device under water.

Disinfect the cap by placing it in 70% alcohol for 10 minutes and then allow it to air dry. Do not place the device in a dishwasher or use detergents.

Control Solution Storage and Handling

- Check the expiry date on the vial. Do not use it if expired.
- Refer to the period after opening on the control solution vial. Record the first opening date on the vial.
- Tightly close the control solution and store at room temperature at 2°C to 30°C (36°F to 86°F), 10 to 90% R.H. Do not freeze.

Performance Characteristics

For more information, please refer to the test strip insert.

System Troubleshooting

If you follow the recommended action but the problem persists, please call GlucoRx Customer Care.

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	The battery is too low.	Replace the battery immediately.

E-U	A used test strip is inserted.	Repeat with a new test strip.
E-t	Ambient temperature is above or below system operation range.	Repeat the test after the meter and test strip are within the operation temperature range.
E-0, E-A E-E, E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact GlucoRx Customer Care for assistance.
E-F	Test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact GlucoRx Customer Care for assistance.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact GlucoRx Customer Care.



















2. If the test does not start after applying the sample:







POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off.	Repeat the test with a new test strip. Apply sample only when flashing “▲” appears on the display.
Defective meter.	Please contact GlucoRx Customer Care.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution thoroughly and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Perform the test with a proper stored control solution.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact GlucoRx Customer Care.
Improper working of meter and test strip.	Please contact GlucoRx Customer Care.

Symbol Information

SYMBOL	REFERENT	SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device		Manufacturer
	Serial number		Date of manufacture
	Model number		Direct current
	Temperature limit		Humidity limitation
	Caution		RoHS compliance
	Sterilised using irradiation		Unique device identifier
	Medical device		Batch code
	Importer		Use-by date
	Do not reuse		UKCA mark

	Authorised representative in the United Kingdom		Consult instructions for use or consult electronic instructions for use
	CE Mark		Authorised representative in the European Community
	Do not use if package is damaged and consult instructions for use		
	This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.		

Specifications

Dimension: 97 (L) x 52 (W) x 16 (H) mm

Weight: 47.8 g (without batteries)

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD with backlight

Memory: 1000 measurement results

External Output: RS-232 and Bluetooth

Operating Conditions: 10°C(50°F)~40°C(104°F), 10~85% RH (EU)

For indoor use.

Refer to the test strip manual for operating altitude.

Sample Size and Reaction Time: 0.5 µL, 5 seconds

Measurement Units: mmol/L

Measurement Range: 1.1~33.3mmol/L (20~600mg/dL)

Shelf Life: 5 years

Degree of Pollution: Pollution degree 2

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6



TD-4125



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For self-testing.

For near-patient testing.