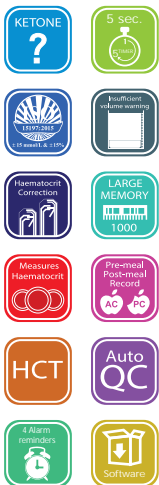
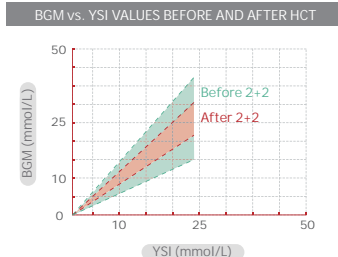
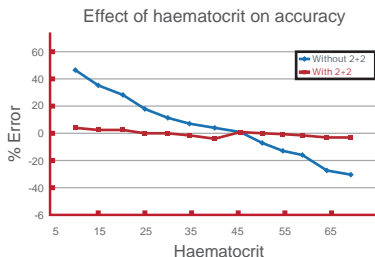


This changes Everything.....

Haematocrit Correction Technology (HCT)

GlucoRx HCT Glucose test strips use advanced GDH-FAD enzyme technology with 2+2 (AC and DC) Bio Signal. AC signal works to measure the haematocrit result, and DC measures glucose. Meter then modulates glucose level according to haematocrit value.



Features

- Ketone testing & warning
- Exceeds EN ISO 15197:2015 Accuracy criteria
- Haematocrit Correction Technology
- Measures Haematocrit (0 - 70% haematocrit range)
- 4 Alarm reminders
- 5 second glucose results
- Insufficient volume warning
- Stores 1000 readings, fulfilling DVLA memory requirements
- Meal markers
- Auto QC tagging
- PC download facility; Diasend compatible.

GlucoRx HCT

BLOOD GLUCOSE & KETONE MONITORING SYSTEM

Measures Blood Glucose, Ketone & Haematocrit



Specifically for Type 1 diabetics
(also suitable for use in newborn babies and pregnancy)

Use with GlucoRx HCT Glucose Test Strips,
GlucoRx HCT Ketone Test Strips and GlucoRx Lancets.

Dear GlucoRx HCT System Owner:

Thank you for purchasing the **GlucoRx HCT** Blood Glucose & Ketone Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

The System measures both blood glucose and β -ketone. Regular monitoring of your blood glucose and β -ketone levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **GlucoRx HCT** Blood Glucose & Ketone Monitoring System to easily monitor your blood glucose and β -ketone levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact GlucoRx Customer care on 01483 755133.

Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) and β -hydroxybutyrate (ketone) in fresh whole blood samples from the finger. It should not be used for the diagnosis of or screening for diabetes mellitus.

The test for haematocrit (HCT) as part of the system, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in capillary whole blood as an aid in monitoring the status of total volume of red blood cells. The test reading of haematocrit (HCT) is used only to determine whether the blood test sample is within the acceptable range of blood glucose system. It should not be used for the diagnosis of anaemia or erythrocytosis.

IMPORTANT SAFTY INSTRUCTIONS

READ BEFORE USE

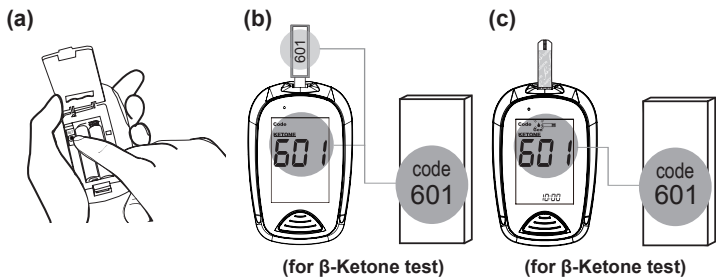
1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. This device does **NOT** serve as a cure for any symptoms or diseases.
The data measured is for reference only. Always consult your doctor to have the results interpreted.
5. The blood glucose test strip can be used for the testing of newborns; The β -ketone test strip must not be used for the testing of newborns.
6. Before using this device to test blood glucose or β -ketone, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
7. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
8. Do Not use this instrument in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment. That may cause incorrect operation or damage to the device.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with accurate operation.
10. Proper maintenance and periodic control testing are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact GlucoRx Customer care on 01483 755133.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

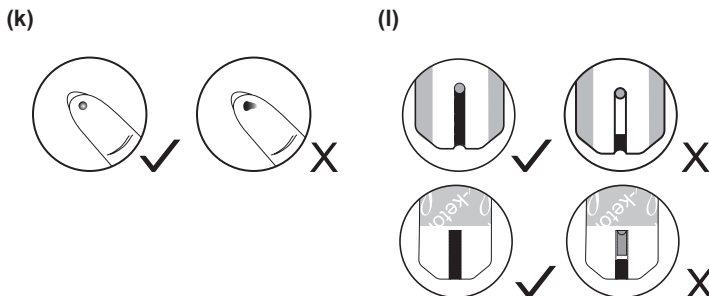
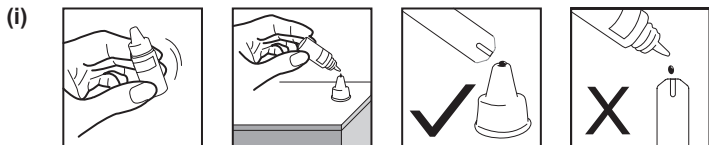
TABLE OF CONTENTS

BEFORE YOU BEGIN	09
Important Information	09
Contents of System	10
Meter Overview	11
Display Screen	12
Test Strip	12
SETTING THE METER	13
THE MEASURING MODES	14
BEFORE TESTING	15
Calibration	15
How to Code Your Meter (for β -Ketone Test)	15
Checking the Code Number	15
Control Testing	16
Performing a Control Test	17
TESTING WITH BLOOD SAMPLE	18
Preparing the Lancing Device for Blood Testing	18
Preparing the Puncture Site	18
Performing a Blood Glucose or β -Ketone Test	19
METER MEMORY	21
Reviewing Test Results of Blood Glucose or β -Ketone	21
Reviewing Blood Glucose Day Average Results	21
DOWNLOADING RESULTS ONTO A COMPUTER	22
MAINTENANCE	23
Battery	23
Caring for Your Meter	24
Caring for Your Test Strips	24
Important Control Solution Information	25

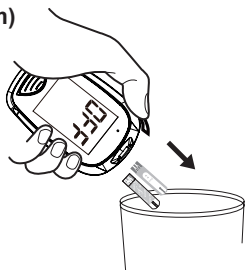
SYSTEM TROUBLESHOOTING	26
Result Readings	26
Error Messages	27
Troubleshooting	28
DETAILED INFORMATION	29
SYMBOL INFORMATION	30
SPECIFICATIONS	31



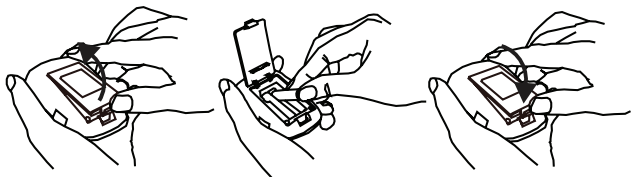
(d) (e) (f) (g) (h)



(m)



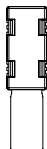
(n)



(j)



(o)



(p)



BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose or β -ketone results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose or β -ketone. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or β -ketone test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Please consult your healthcare professional before use.
- The measurement unit used for indicating the concentration of blood or plasma glucose will have molarity (mmol/L). The approximate calculation rule for conversion of mmol/L in mg/dL is:

mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example:

1) $120 \text{ mg/dL} \div 18 = 6.6 \text{ mmol/L}$

2) $7.2 \text{ mmol/L} \times 18 = 129 \text{ mg/dL}$ approximately.

Contents of System

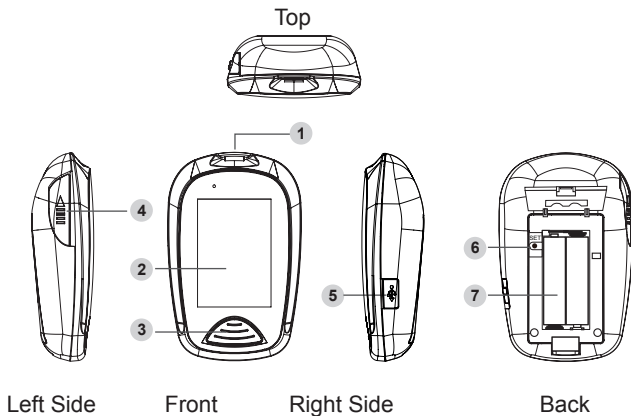
Your new GlucoRx HCT System kit includes:

- **A meter**
- **Owner's manual**
- **Protective wallet**
- **Quick start user guide**
- **Daily log book**
- **Warranty card**
- **Lancing device**
- **Batteries**
- **Glucose test strips vial**
- **Single foil ketone test strip**
- **Blood glucose control solution**
- **β -Ketone control key**
- **Lancets**

NOTE:

If any items are missing from your kit or opened prior to use, please contact GlucoRx Customer care on 01483 755133.

Meter Overview



1 Test Strip Slot

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

2 Display Screen

3 Main Button (M)

Enter the meter memory

4 Test Strip Ejector

Eject the used strip by pushing up this button.

5 Data Port

Download test results with a cable connection.

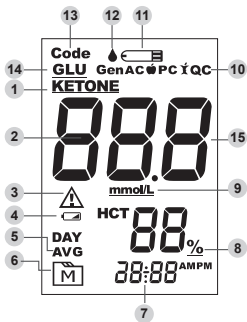
6 SET Button (S)

Enter and confirm the meter settings.

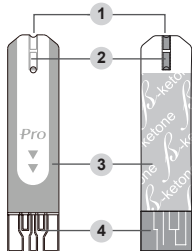
7 Battery Compartment

Display Screen

- 1 Ketone Symbol / Ketone Warning
- 2 Glucose Level / Ketone Level
- 3 Error Warning
- 4 Low Battery Symbol
- 5 Day Average
- 6 Memory Symbol
- 7 Time / Date
- 8 HCT Level
- 9 Glucose / Ketone Measurement Unit
- 10 Measurement Modes
Gen – any time of day
AC – before meal
PC – after meal
- 11 Test Strip Symbol
- 12 Blood Drop Symbol
- 13 Code
- 14 Glucose Symbol
- 15 Alarm reminder (characterised as "AL1", "AL2", "AL3", "AL4" in the middle of meter display)



Test Strip



(for glucose test)

(for ketone test)

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

ATTENTION:

The front side of test strip should face up when inserting test strip.

Test results may be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

The **GlucoRx HCT** monitor should only be used with **GlucoRx HCT** Glucose or β -Ketone Test Strips. Using other test strips with this meter can produce inaccurate results.

SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press **S**.

1. Setting the date

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** until the correct year/month/day appears. Press **S**.

2. Setting the time format

Press **M** to select the desired time format --- 12h or 24h. Press **S**.

3. Setting the time

With the HOUR / MINUTE flashing in sequence, press **M** until the correct hour/minute appears. Press **S**.

4. Setting the buzzer

With the buzzer displays, press **M** to switch between “On” and “OFF”. Press **S**.

5. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display “OFF” and “AL1”. If you don’t want to set an alarm, press **S** to skip this step; Or press **M** to select “On”, then press **S**.

With the hour/minute flashing in sequence, press **M** to select the correct hour/minute. Press **S** and go to the next alarm setting.

NOTICE:

When the alarm is beeping: Press M to silence it or press and hold M to switch it off. Otherwise, it will beep for 2 minutes then switch off.

6. Setting the backlight

The default setting for meter backlight ("8L") is set to ON. Press **M** to switch between "On" and "OFF". Press **S**.

Congratulations! You have completed all settings!


NOTE:

- These parameters can **ONLY be changed** in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE MEASURING MODES


For Blood Glucose Testing

This meter provides you with three modes for measuring blood glucose: GEN (General), AC, and PC. You can switch between each mode by:

1. Start with the meter switched off. Insert a blood glucose test strip to turn on the meter. The screen will display a flashing "  ", "GEN" and "HCT".
2. Press **M** to switch between GEN (General), AC, and PC modes.

For β -Ketone Testing

This meter provides you with one mode for measuring β -ketone.

Start with the meter switched off. Insert a β -ketone test strip to turn on the meter. The screen will display a flashing "  ", "Gen" and "KETONE".

BEFORE TESTING

Calibration

You must calibrate the meter every time you begin to use a new vial of β -Ketone test strips by setting the meter with the correct code.

Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on your individual foil packet.

How to Code Your Meter (for β -Ketone test)(b)

1. Insert the code strip when the monitor is off. Wait until the code number appears on the display.

NOTICE:

Make sure the code number on display, and individual foil packet are the same. The code strip should be within the expiry date, otherwise an error message may appear.

2. Remove the code strip, the display will show “OK”. This tells you that the meter has finished coding and is ready for β -ketone testing.

Checking the Code Number (c)

You need to make sure that the code number displayed on the meter matches the number on your ketone test strip vial or individual foil packet before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and repeat the calibration procedure. If the problem persists, contact GlucoRx Customer care on 01483 755133 for help.

NOTICE:

The codes used in this manual are examples only; your meter may display a different ketone code.

WARNING:

- It is important to make sure that the LCD displayed code is the same as the code on your ketone test strip vial or individual foil packet before testing. Failure to do so will get inaccurate results.
- The code number for β -Ketone strip is three-digits; please ensure you are using the correct strips for the test.
- If the LCD displayed code is not the same as the code on your ketone individual foil packet, and the code number cannot be updated, please contact GlucoRx Customer care on 01483 755133 for assistance.

Control Testing

Our Glucose Control Solution contains a known amount of glucose that reacts with the glucose test strips and is used to ensure your meter and glucose test strips are working together correctly.

Do a control test when:


- you first receive the meter,
- at least once a week to routinely check your meter and test strips,
- you begin using a new vial or new individual foil packet of test strips,
- you suspect your meter or test strips are not working properly,
- your blood glucose or ketone test results are not consistent with how you feel, or if you think the results are not accurate,
- practicing the testing process, or
- you have dropped or think you may have damaged your meter.

Test strips **(e)**, control solution **(f)**, lancing device **(g)** or sterile lancets **(h)** may not be included in the kit (please check the contents in your product box). They can be obtained separately from GlucoRx Customer care (telephone 01483 755133). Please make sure you have all items needed for a blood glucose or ketone test beforehand.

Performing a Control Test For Blood Glucose Control Test

To perform a blood glucose control solution test, you will need: **(d)**, **(e)** and **(f)**.

1. Insert the glucose test strip to turn on your meter

Wait for the meter to display a flashing “”, “Gen” and “HCT”.

2. Apply blood glucose control solution (i)

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 absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

3. Read and Compare the Result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

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



NOTICE:

To avoid contaminating the control solution, do not directly apply control solution onto a strip.

For β -ketone Control Test

To perform a β -ketone control test, you will need: **(d)** and **(o)**.

1. Insert Ketone Control Key (p)

Insert the ketone control key into your meter. The meter displays the following: code number, “KETONE”, “” and a flash “”.

2. Turn on the switch on the front side of the ketone control key.

3. Read and compare the result

After counting down to 0, the control test result will appear on the display. Compare this result with the range printed on your individual foil packet and it should fall within this range. If not, please read the instructions again and repeat the control test. With the β -ketone control test, make sure you turn off the switch on the front side of the ketone control key after removing it from your meter.

NOTE:

- There is no HCT display function while the meter is in QC mode.
- The control test range printed on the test strip vial or individual foil packet is for control testing use only. It is not a recommended range for your blood glucose or ketone level.
- See the **MAINTENANCE** section for important information about your control solution.

TESTING WITH BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- Never share a lancet or the lancing device. GlucoRx Lancing device is **for self-use only**.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the accuracy of the glucose or β -ketone value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose or β -ketone concentration than blood from the finger. If the puncture site was rubbed prior to blood extraction, the difference is significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- Select the puncture site at fingertips.

- Hand wash the puncture site with warm water and dry thoroughly before testing
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.
- **Fingertip testing (j)**
Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger; a click indicates that the puncture is complete.

NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
 - It is recommended that you discard* the first drop of blood as it may contain tissue fluid, which may affect the test result.
- * WHO Guidelines on drawing blood: best practices in phlebotomy, 2010 - Section 7.2.2.

Performing a Blood Glucose or β -Ketone Test


To perform a blood glucose or β -ketone test, you will need: **(d)**, **(e)**, **(g)** and **(h)**.

1. Insert the test strip to turn on the meter

Wait for the meter to display “” and a flash “”,

2. Select the appropriate measuring mode by pressing **M** (for glucose test)

3. Obtaining a blood sample (k)

Use your pre-set lancing device to puncture the desired site. Wipe off the first drop of blood with a clean cotton swab. The size of the drop should be at least as big as  (actual size), which is **1.0** microliter (μL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

4. Apply the sample (l)

Gently apply the drop of blood to the absorbent hole of the test strip at

a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against your test strip or try to smear the blood.
- 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 begins to count down. If there is insufficient blood volume in the test strip confirmation window, you can apply more blood to the same strip as long as you see the blinking blood drop symbol displayed on the meter screen (before countdown begins). The meter will give an 'E-F' error message within a few seconds if there is still underfill, in which case discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your health care professional or GlucoRx Customer care on 01483 755133 for assistance.

5. Read your result

The result of your blood glucose test with HCT level or the result of your β -ketone test will appear after the meter counts down to 0. The blood glucose result with HCT level or the β -ketone result will be stored in your memory automatically.

6. Eject the used test strip (m)

Eject your test strip by pushing the eject button on the side. Use a sharps bin to dispose of used test strips. The meter will switch itself off automatically.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING:

The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.

METER MEMORY

This meter stores the **1000** most recent blood glucose test results along with respective HCT values, dates and times or β -ketone test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results

1. Press and release **M**.

“**M**” will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with HCT value, date, time and the measuring mode or you will see the last β -ketone result along with date, time and the measuring mode.

2. Press M to recall the test results stored in the meter. **After the last glucose or β -ketone test result, press M again and the meter will switch off.**

Reviewing Blood Glucose Day Average Results

1. Press and release M. When “**M**” appears on the display, keep pressing **M** for 3 seconds until the flashing “**DAY AVG**” appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.

2. Press M to review 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, then PC.

3. Exit the meter memory. Keep pressing the **M** and the meter will switch off after displaying the last test result.

NOTE:

- Any time you wish to exit the memory, keep pressing **M** for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control test results are **NOT** included in the day average.

DOWNLOADING RESULTS ONTO A COMPUTER

Data Transmission Via Cable

You can use your meter with a USB cable and the GlucoRx Healthcare Software System to view test results with HCT levels on your personal computer. To learn more about the GlucoRx Healthcare Software System or to obtain a USB cable separately, please contact GlucoRx Customer care on 01483 755133 for assistance.

1. Obtaining the required cable and installing the software

To download GlucoRx Healthcare Software System, please visit GlucoRx's website www.glucorx.co.uk.

2. Connecting to a personal computer

Connect the cable to a USB port on your computer. With the meter switched off, connect the other end of the USB cable to the meter data port. "USb" will appear on the meter display, indicating that the meter is in communication mode.

3. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with the date and time. Remove the cable and the meter will automatically switch off.

NOTE:

While the meter is connected to the PC, it is unable to perform a blood glucose or β -ketone test.




MAINTENANCE

Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

Low Battery Signal

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

1. The “” **symbol appears** along with display messages: The meter is functional and the result remains accurate, but it is time to change the batteries.
2. The “” **symbol appears with E-b and ** : The power is not enough to do a test. Please change the batteries immediately.

Replacing the Battery (n)

To replace the batteries, make sure the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover. If the batteries are inserted correctly, you will hear a “beep” afterwards.

NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries may leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

Cleaning

- To clean the meter exterior, wipe it with a disinfecting wipe (Example: Micro-Kill Plus™) to clean exposed surfaces thoroughly and remove any visible dirt, blood or any other body fluid with the wipe. Then dry the device with a soft, dry and clean cloth. Do **NOT** rinse the meter with water.
- Do **NOT** use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

A used meter should be treated as contaminated and may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions for blood glucose and β -ketone test strips: 2°C to 30°C (35.6°F to 86°F) below 85% relative humidity. Do **NOT** freeze.
- Store your blood glucose test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a glucose test strip from its vial, immediately close the vial cap tightly.

- Touch the glucose and ketone test strips with clean and dry hands.
- Use each test strip immediately after removing it from the vial or individual foil packet.
- Do not use test strips beyond their expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.


Important Control Solution Information

- Use only GlucoRx control solution with your meter.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do **NOT** freeze.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, please call GlucoRx Customer care on 01483 755133.

Result Readings (for glucose test)

MESSAGE	WHAT IT MEANS
Lo	Your blood glucose level is below 0.5mmol/L
	When your blood glucose level is between 15 mmol/L and 38.9 mmol/L like the example shown, the result will flash on the screen. This warns you that you may have high ketones. Please also check your blood ketone level.
Hi	Your blood glucose level is above 38.9mmol/L

Result Readings (for β -ketone test)

MESSAGE	WHAT IT MEANS
Lo	Your blood ketone level is below 0.1mmol/L. (please see below 'Interpretation' table)
Any result between 0.1 and 8mmol/L (for example 0.6mmol/L)	Your blood ketone level is between 0.1mmol/L and 8mmol/L. (please see below 'Interpretation' table)
Hi	Your blood ketone level is above 8mmol/L. (please see below 'Interpretation' table)

How to interpret blood Ketone results

(Reference: adapted from Information provided in The Balance Guide to Meds & Kit, 2011 - 2012, p15)

Your Ketone reading	Interpretation
Below 0.6mmol/L	This is normal
Between 0.6 and 1.5 mmol/L	You may require medical assistance; contact your Diabetes healthcare team for advice.
Above 1.5mmol/L	Risk of Diabetic ketoacidosis; call your Diabetes healthcare team immediately.

Error Messages


MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the batteries are too low.	Replace the batteries immediately.
E-C	Appears when the wrong code strip is inserted or other coding errors.	Check if the code numbers on the display and ketone foil packet are the same. If the problem persists, please contact GlucoRx Customer care on 01483 755133 for help.
E-2	Expired code strip.	Repeat the test with a new lot of test strip.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
E-0, E-A, E-E	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact GlucoRx Customer care on 01483 755133 for assistance.
E-F	Appears when 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 on 01483 755133 for help.

Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
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 on 01483 755133.

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 (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing “  <p>3. If the control testing result is out of range:</p>

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 vigorously 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.	Control solution, meter, and test strips should be at room temperature 20°C to 25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact GlucoRx Customer care on 01483 755133.
Improper working of meter and test strip.	Please contact GlucoRx Customer care on 01483 755133.

DETAILED INFORMATION

The meter provides you with plasma equivalent results.

Time of day	Normal blood glucose range for people with diabetes (mmol/L)
Fasting and before meal	4 to 7 mmol/L
2 hours after meals<	9 mmol/L








Source: Diabetes UK. Blood glucose target. Balance: No.234, 2010 April. P.69





The β -Ketone test measures Beta-Hydroxybutyrate (β -OHB), the most important of the three β -Ketone bodies in the blood. Normally, levels of β -OHB are expected to be less than 0.6 mmol/L.

β -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β -Ketone result is "Lo", repeat the β -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication programme. If your β -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your β -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

Please consult your doctor to determine a target range that works best for you.

SYMBOL INFORMATION

SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use
	Temperature limitation
	Use by
	Batch code
	Humidity limitation
	CE mark

SYMBOL	REFERENT
	Manufacturer
SN	Serial number
	Authorised representative in the European Community
	Caution, consult accompanying documents
	Collection for electrical and electronic equipment

SPECIFICATIONS

Model No.: TD-4279

Dimension & Weight: 96 (L) x 61 (W) x 26 (H) mm, 67.2 g

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD

Memory: 1000 measurement results with respective date and time

External Output: USB

Auto electrode insertion detection

Auto sample loading detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature Warning

Operating Condition:

10°C to 40°C (50°F to 104°F), below 85% R.H. (non-condensing)

Meter Storage / Transportation Conditions:

-20°C to 60°C (-4°F to 140°F), below 95% R.H.

Strip Storage / Transportation Conditions:

2°C to 30°C (35.6°F to 86°F), below 85% R.H.

Measurement Units: mmol/L

Measurement Range: 0.5 to 38.9 mmol/L for glucose test and
0.1~8.0 mmol/L for β -ketone test

Expected service life: 5 years

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

Distributed by GlucoRx Ltd.

Unit 1C Henley Business Park, Pirbright
Road, Guildford, Surrey, GU3 2DX, UK

Website: www.glucoRx.co.uk

Customer care number: 01483 755133

 **TaiDoc Technology Corporation**

B1-7F, No. 127, Wugong 2nd Rd.,

Wugu Dist., 24888 New Taipei City, Taiwan

www.taidoc.com

 **MedNet GmbH**

Borkstraße 10, 48163 Münster, Germany

For self-testing

 CE 0123 IVD