

BLOOD GLUCOSE MONITORING SYSTEM







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311-4277100-009

Dear GlucoRx Nexus System Owner:

Thank you for purchasing the **GlucoRx Nexus** Blood Glucose 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.

Regular monitoring of your blood glucose 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 Nexus** Blood Glucose Monitoring System to easily monitor your blood glucose levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact your place of purchase or call the local customer service.

IMPORTANT SAFETY PRECAUTIONS READ BEFORE USE

- 1. Use the device only for the intended use described in this manual.
- 2. Do not use accessories which are not supplied by the manufacturer.
- 3. Do NOT use the device if it is not working properly or if it is damaged.
- 4. Do not use the equipment in places where aerosol sprays are being used, or where oxygen is being administered.
- 5. Do NOT under any circumstances use on newborns or infants.
- 6. 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.
- 7. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all quality control checks as directed.
- 8. Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets, and vial caps are choking hazards.
- 9. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may give damaging static discharges that may cause erroneous results.
- 10.Do not use this instrument in close proximity to sources of strong electromagnetic radiation as these may interfere with its accurate operation.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

TABLE OF CONTENTS

IMPORTANT SAFETY PRECAUTIONS	5
BEFORE YOU BEGIN	8
Important Information	8
Intended Use	9
Test Principle	9
Contents of System	10
Meter Overview	11
Display Screen	12
Test Strip	13
Setting the Meter	14
THE FOUR MEASURING MODES	17
BEFORE TESTING	18
Control Solution Testing	18
Performing a Control Solution Test	18
GETTING A BLOOD SAMPLE	21
Overview of the Lancing Device	21
Setting up the Lancing Device	21
Preparing the Puncture Site	23
Performing a Blood Glucose Test	24
METER MEMORY	27
Reviewing Test Results	27
Reviewing Blood Glucose Day Average Results	28
Downloading Results onto a Computer	30
MAINTENANCE	31

Battery	31
Caring for Your Meter	33
Caring for Your Test Strips	33
Important Control Solution Information	34
SYSTEM TROUBLESHOOTING	35
Result Readings	35
Error Message	36
Troubleshooting	37
DETAILED INFORMATION	38
Reference Values	39
Comparing Meter and Laboratory Results	39
SYMBOL INFORMATION	41
SPECIFICATIONS	42

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 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 capillary whole blood sample to test your blood glucose. Using other substances will give incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all instructions described in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemichyperosmolar state, with or without ketosis. Please consult your healthcare professional before use.

Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by health care professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples from the finger.

It should not be used for the diagnosis of diabetes, or testing on newborns.

Professionals may test with capillary and venous whole blood; home use is limited to capillary whole blood testing.

Test Principle

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample

Contents of System

Your new GlucoRx Nexus system kit includes:

- 1 Meter
- 2 Owner's Manual
- **3** Warranty Card
- 4 Quick Start User Guide
- 5 Daily Log Book
- 6 Protective Wallet

- 7 Lancing Device
- 8 2 x 1.5V AAA Alkaline Batteries
- 9 Control Solution
- 10 Test Strips
- 11 Lancets



Test strips, control solutions, or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately.

NOTE

If any items are missing from your kit or opened prior to use, please contact your local customer services or place of purchase for assistance.

Meter Overview



1 TEST STRIP EJECTOR

Eject the used strip by pushing this button up.

2 DISPLAY SCREEN

3 M BUTTON

Enter the meter memory and silence a reminder alarm.

4 TEST SLOT

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

5 DATA PORT

Download test results with the cable connection.

6 SET BUTTON

Enter and confirm the meter settings.

7 BATTERY COMPARTMENT

8 STRIP INDICATION LIGHT

Display Screen



- 1 Blood Drop Symbol
- 2 Test Result
- 3 Ketone Warning
- 4 Error Message
- **5** Memory Mode Symbol
- 6 Control Solution Mode
- 7 Measuring Mode
- 8 Test Strip Symbol

- 9 Low Battery Symbol
- **10 Measurement Unit**
- **11** Reminder Alarm
- 12 Day Average
- 13 Time
- 14 Date

Test Strip

Absorbent Hole

Apply a drop of blood here. The blood will be automatically absorbed.

- Confirmation Window

This shows if enough blood has been applied to the absorbent hole of the test strip.

Test Strip Handle

Hold this part to insert the test strip into the slot.

Contact Bars

Insert this end of the test strip into the meter. Push it in firmly until it will go no further.



NOTE

The GlucoRx Nexus meter should only be used with GlucoRx Nexus 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. Make sure you complete the steps below and have your desired settings saved.

To Enter the Setting Mode

Start with the meter off (no test strip inserted). Press SET to turn on the meter.

1. Setting the date

With the year flashing, press and release M button to choose the correct year. Press SET.

With the month flashing, press and release M button to choose the correct month. Press SET.

With the date flashing, press and release M button to choose the correct date. Press SET.









2. Setting the time format

Press M button to select the desired time format --- 12h or 24h. Press SET.



4. Deleting the Memory.

With "dEL" and a flashing " $\boxed{\mathbb{M}}$ " symbol on the display, press M button and select "No" to keep the results in memory then press SET to skip.

To delete all the results, press M button and select "Yes" then press SET to confirm. "OK" and " $\boxed{\mathbb{M}}$ " are displayed on the meter, which indicates that all data stored is deleted.



8-10 IG÷00ª

5. Setting the reminder alarm

You may set up any or all of the reminder alarms

(1-4). The meter displays "On" or "OFF" and " (1-4). The meter displays "On" or "OFF" and " (1-4), press M button to turn on or turn off to set the first reminder alarm.

Press M button to select "On", then press SET to set the hour. When the hour is flashing, press M button to add an hour. Press SET to confirm and go to minutes, press M button to add one minute. Hold M button longer to add faster. Press SET to confirm and go to the next alarm setting.



If you do not want to set an alarm, press SET to skip this step.

If you want to turn off an alarm, find the alarm number by pressing SET in the setting mode, press M button to change from "ON" to "OFF".



At the time of your alarm, the meter will beep and automatically turn on. You can press M button to silence the alarm and insert a test strip to begin testing. If you do not press M button, the meter will beep for 2 minutes then switch off. If you do not want to test at this time, press M button to switch off the meter.

Congratulations! You have completed all settings!



THE FOUR MEASURING MODES

The meter provides you with four modes for measuring General, AC, PC and QC.

Modes	Use when
General (displays as "Gen")	any time of day, regardless of time since last meal
AC	no food intake for at least 8 hours
PC	2 hours after a meal
QC	testing with the control solution

You can switch between each mode by:

1. Start with the meter switched off. Insert a test strip to turn on the meter, the screen will display flashing blood drop and "Gen".



2. Press M button to switch between General, AC, PC and QC.



BEFORE TESTING

Control Solution Testing

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

Do a control solution test when:

- you first receive the meter,
- at least once a week to routinely check the meter and test strips,
- you begin using a new vial of test strips,
- you suspect the meter or test strips are not working properly,
- your blood glucose 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 the meter.

Performing a Control Solution Test

1. Insert the Test Strip to Turn on the Meter

Insert the test strip into the meter. Wait for the meter to display the test strip and blood drop symbols.



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

If you press M button again, the "**QC**" will disappear and this test is no longer a control solution test.



3. Apply Control Solution.

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze another drop and place it on the tip of the vial cap.

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



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





4. Read and Compare the Result

After counting down to 0, the test result of control solution 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 instructions again and repeat the control solution test.



Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Contact your local customer service or place of purchase for help.

NOTE

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the Maintenance section for important information about your control solutions.

GETTING A BLOOD SAMPLE

Overview of the Lancing Device



If your lancing device differs from the one shown above, please refer to the manufacturer's manual to ensure proper usage.

NOTE

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- 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.

Setting up the Lancing Device

- 1. Pull the cap off the lancing device.
- 2. Insert a lancet into the lancet holder and push down firmly until it is fully secured.



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3. Twist the protective disk off the lancet.

4. Replace the cap by aligning the arrow on the cap with the release button.

5. Select the depth of penetration by turning the adjustable tip in either direction so that the arrow on the cap points to the desired depth.

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.

The lancing device is now ready for use. Set aside for later use.









Preparing the Puncture Site.

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the glucose value obtained.

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

* Wash and dry your hands before starting.

- * Select the puncture site at fingertips.
- * Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**
- * Rub the puncture site for about 20 seconds before penetration.

Fingertip testing

Press the lancing device's tip firmly against the side of your fingertip. Press the release button to prick your finger, then 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 (hard/thick skin).
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a Blood Glucose Test

1. Insert the Test Strip to Turn on the Meter

Wait for the meter to display the test strip \bigcirc and blood drop \blacklozenge symbols with Gen preset.



2. Select the appropriate measuring mode by pressing M button.

For selecting the measuring mode, please refer to the "FOUR MEASURING MODES" section.

3. Obtain a Blood Sample

Use the pre-set lancing device to puncture the desired site. After penetration, discard the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample.

The volume of blood sample must be at least 0.5 microliter (μ L) of volume. (. actual size).



4. Apply the Sample

Hold the blood drop to touch the absorbent hole of the test strip. Blood will be drawn in and after the confirmation window is completely filled, the meter begins counting down.



NOTE

- Do not press the site against the 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. NEVER try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your healthcare professional or the local customer service for assistance.

5.Read the Result

The result of your blood glucose test will appear after the meter counts to 0. This reading will automatically be stored in the memory.

6. Eject the Used Test Strip and Remove the Lancet

To eject the test strip, point the strip at a sharp disposal container. The meter will turn itself off automatically after the test strip is ejected

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

The meter stores the 1000 most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter off.**

Reviewing Test Results

1. Press and release M button.

(M) will appear on the display. Press M button again, and the first reading you see is the last blood glucose result along with date, time and the measuring mode.

2. Press M button to recall the test results stored in the meter with each press.

Image: Second second



3. Exit the meter memory

After the last test result, press M button again and the meter will turn off.



If the meter is left idle for more than 5 seconds after entering the memory mode, the meter then will display the flashing test strip symbol on the LCD. This indicates that you can insert a test strip and initiate a blood glucose test.

Reviewing Blood Glucose Day Average Results

1. Press and release M button

When m appears on the display, keep pressing M button for 3 seconds until the flashing " may ave " appears. Release M button and then your 7-day average result measured in general mode will appear on the display.



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

For example:



2. Exit the meter memory

Keep pressing M button and the meter will turn off after displaying the last test result.



NOTE

- Any time you wish to exit the memory, keep pressing M button for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.
- If using the meter for the first time, "---" displays when you recall the test results or review the average result. It indicates that there is no test result in the memory.



Downloading Results onto a Computer

You can use the meter with a USB cable and the Health Care Software System to view your test results on your personal computer. To learn more about the Health Care Software System or to obtain a USB cable separately, please contact your local customer services or the place of purchase for assistance.

1. Obtaining the required cable and installing the software

For downloading Health Care Software System, please visit the GlucoRx website: http://www.glucorx.co.uk.

2. Connecting to a personal computer

Connect the cable to a USB port of your computer. With the meter turned 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

Follow the instructions provided in the software to transmit data. Results with date and time will be transmitted. Remove the cable and the meter will automatically turn off.

WARNING

While the meter is connecting to the PC, it is unable to perform a blood glucose test.

MAINTENANCE

Battery

Your meter comes with two1.5V AAA size alkaline batteries.

Low Battery Signal

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

1. The I 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 car symbol appears with E-b, error message and low:

The power is not enough to do a test. Please change the batteries immediately.

Replacing the Battery

To replace the battery, make sure that 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 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 memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might 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

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

► Cleaning

- 1. To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do NOT rinse the meter with water.
- 2. Do NOT use organic solvents to clean the meter.

► Meter Storage

- Storage condition: -20°C~60°C (-4°F~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.

Caring for Your Test Strips

- Storage conditions: 2°C~32°C (35.6°F~89.6°F), below 85% relative humidity. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first open it. Discard remaining test strips after 3 months.

- Do not use test strips beyond the 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 TaiDoc control solutions 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-25°C / 68°F-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 and 30°C (36°F and 86°F). Do NOT freeze.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair by yourself and never try to disassemble the meter under any circumstances.

Result Readings

Appears	When Glucose
Lo	<1.1mmol/L (20mg/dL)
KETONE?	≧15mmol/L (270mmol/L)
H,	>33.3mmol/L (600mg/dL)

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E - 5 A	Appears when the batteries cannot provide enough power for a test.	Replace the batteries immediately.
E - U	Appears when a used test strip is inserted.	Repeat with a new test strip.
<u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u>	Problem in operation.	Repeat the test with a new test strip. If the meter still does not work, please contact customer services for assistance
E - F A	Appears when test strip is removed while counting down. You may have not followed the instructions correctly.	Review the instructions and repeat test with a new test strip. If the problem persists, please contact your local customer services for help.
E - E A LOW	Appears when ambient temperature is below system operation range.	System operation range is
E - L A HEH	Appears when ambient temperature is above system operation range.	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.

Troubleshooting

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

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 customer services.

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 (2 minutes after last user action).	Repeat the test with a new test strip.
	Apply sample only when flashing " ▲ " appears on the display.
Defective meter.	Please contact customer services.

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 vigor- ously 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 tempera- ture (20°C-25°C / 68°F-77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.

DETAILED INFORMATION

Reference Values

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%^{*1}. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal blood glucose range for people with diabetes (mmol/L)
Fasting and before meal	4 to 7 mmol/L (72 to 126 mg/dL)
2 hours after meals	< 9 mmol/L (162 mg/dL)

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

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

*1: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

Comparing Meter and Laboratory Results

The meter provides you with plasma equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before going to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

While staying at the lab:

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a greytop test tube.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten , exercised, taken medication, or experienced stress*². In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 3.9 mmol/L (70 mg/dL) higher than blood drawn from a vein (venous sample) used for a lab test*³. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

References

- *2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.
- *3: Sacks, D.B.: "Carbohydrates. " Burtis, C.A., and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

SYMBOL INFORMATION

Symbol	Referent
IVD	In vitro diagnostic medical device
2	Do not reuse
i	Consult instruction for use
*	Keep away from sunlight
Ť	Keep dry
-	Temperature limitation
	Use by/ Expiry date
[LOT]	Batch code
	Manufacturer
SN	Serial number
	Caution, consult accompanying documents
EC REP	Authorised representative in the European Community
CE ₀₁₂₃	CE mark
	Do not use if package is damaged
ЗМ	Use within 3 months after first opening
STERILE R	Sterilised using irradiation

SPECIFICATIONS

Model No.: TD-4277

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 Cable

Auto electrode inserting detection

Auto sample loading detection

Auto reaction time count-down

Auto shutdown after 3 minutes of idleness

Temperature Warning

Operating condition: 10°C to 40°C (50°F to 104°F), below 85% R.H. (no condensing)

Storage/Transportation condition: -20°C to 60°C (-4°F to 140°F), 95% R.H.

Measurement units: mmol/L

Measurement range: 1.1 to 33.3 mmol/L (20 to 600 mg/dL)

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

