

Blood Glucose Monitoring System

EN Instruction Manual

GlucoTea

1. Before you begin

Please read this before using.

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children or people with disabil-2.Use the device only for the intended use described in this user guide.

3.Do not use test strips and control solutions which are not supplied by the manufacturer.

4.Do not use the device if it is not working properly, or if it has suffered any damage.

5.Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.

IVD The system is intended for use outside the body (*in vitro* diagnostic use only). It should be used only for self-testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. The system should not be used for the diagnosis of diabetes or for the testing of newborns.

Principle of Measurement

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The Microlife GlucoTeq meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L)

△ Caution

1. The user should not take any decision of medical relevance without first consulting his or her medical

2.Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.

3. High altitudes above 3,402 meter (11,161 ft) may affect the test results. 4.Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results. Do not

test outside of these temperature ranges. 5.Do not perform servicing and maintenance while the meter is in use.

6. Modification of this equipment is not allowed. If the equipment is used in a manner not specified by

the manufacturer, the protection provided by the equipment may be impaired.

7.Do not use this meter near cellular or cordless telephones in a call, walkie-talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

△ Important Health-Related Information

1.Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.

2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.

3. Test results below 60 mg/dL (3.3 mmol/L)*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)*2 indicates high blood glucose (hyperglycemia). If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.

4. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

5. Abnormal red blood cell counts may cause false results. Please consult your healthcare professional if you do not know your hematocrit level. 6.Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from thera-

peutic treatments (ascorbic acid, acetaminophen) will not significantly affect Microlife GlucoTeq results. However, elevated concentrations of these substances may affect test results. The compounds listed in the table were found to have no affect at the concentration indicated.

Compounds	Concentrations higher than the following values may cause inaccurate results
Acetaminophen	8.0 mg/dL (0.53 mmol/L)
Ascorbic Acid	5.0 mg/dL (0.28 mmol/L)
Aspirin	60 mg/dL (3.33 mmol/L)
Bilirubin	90 mg/dL (1.54 mmol/L)
Cholesterol	500 mg/dL (12.9 mmol/L)
Creatinine	5.0 mg/dL (0.44 mmol/L)
Dopamine	2.0 mg/dL (0.11 mmol/L)
EDTA	360 mg/dL (12.3 mmol/L)
Galactose	900 mg/dL (50 mmol/L)
Gentisic Acid	5.0 mg/dL (0.32 mmol/L)
Glutathione	53 mg/dL (1.72 mmol/L)
Haemoglobin	500 mg/dL (0.08 mmol/L)
Heparin	8,000 U/dL
Hydroxyurea	3.0 mg/dL (0.39 mmol/L)
Ibuprofen	50 mg/dL (2.42 mmol/L)
Icodextrin	13 mg/dL (0.01 mmol/L)
L-dopa	10 mg/dL (0.51 mmol/L)
Maltose	900 mg/dL (26.3 mmol/L)
Methyldopa	3.0 mg/dL (0.13 mmol/L)
Pralidoxime Iodide	25 mg/dL (0.94 mmol/L)
Salicylate	60 mg/dL (4.34 mmol/L)
Tolazamide	100 mg/dL (3.21 mmol/L)
Tolbutamide	400 mg/dL (14.8 mmol/L)
Triglycerides	2,000 mg/dL (22.6 mmol/L)
Uric Acid	8.0 mg/dL (0.48 mmol/L)
Xylose	100 mg/dL (6.66 mmol/L)
REFERENCE:	·

Kahn, R. and Weir, G.: Joslinis Diabetes Mellitus, 13thed Philadelphia: Lea and Febiger (1994), 489. *1 Krall, L.P. and Beaser, R. S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263. *2

2. Getting to know your System

The Microlife GlucoTeq Glucose Monitoring System

The Microlife GlucoTeq system uses the latest technology to provide you with easy and comfortable testing. The system requires only 0.5uL blood sample to complete the testing in only 5 seconds. Please review the contents of your purchase to confirm that all the components are included as listed on the side of your meter box.

1 Illuminated Test Strip Slot

Insert the test strip here. The meter will turn on automatically and the slot LED light will illuminate. To track the position of test strip slot without strip inserting, press main button and the slot LED light will be flashing.

(2) LCD Display Guides you through the test using symbols and simple messages.

(3) Main Button

Turns the meter on or performs other functions

described in this user guide.

(4) Data Port Allows you to transfer the information stored in the meter to a computer to view, analyze and print.

(5) Set Button

Located on the back of the meter, inside the battery compartment; used to set up the meter.

vou start testing.

or tear the label off.

(6) Battery Compartment Holds ONE 3V Lithium battery (battery type CR2032). Please install battery into meter before

7 Meter Label Each meter has its unique number on it. Do not alter



GlucoTeq - BGM 200

② Do not reuse

Lot number

T Keep dry

C € 0123

9443 Widnau

www.microlife.com

Switzerland

Explanation of Symbols

IVD For In vitro diagnostic use

i Please consult instructions for use

Temperature limitation

Use by / Expiry date Manufacturer

Caution, consult accompanying document Keep away from sunlight

Humidity limitation **ECREP** EU representative This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.

Do not use if package is damaged Distributor Microlife AG

Wholecare Biomedical Corporation Espenstrasse 139 8F, 443, RuiGang Road, NeiHu Taipei, 11492, Taiwan

SN Serial number

ECREP Medical Device Safety Service GmbH (MDSS GmbH) Schiffgraben 41 30175 Hannover / Germany

C € 0123

microlife

Overview

1.Before you begin

2.Getting to know your system

8. Caring for your meter and test strip

3. Prepare for blood sampling

4. Performing blood test

5. Alternative site testing

6.Control solution testing 7.Memory recall

10.System Troubleshooting

11.Performance Characteristics

9.Specifications

12.Guarantee

(8) Contact Bars Insert this end of the test strip into the meter. Push it in firmly until it will not go any further. (9) Test Strip Handle

slot on the meter. 10 Confirmation Window

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

Shows whether enough blood has been drawn into the test strip's absorbent channel. (1) Absorbent Channel

Apply a drop of blood and it will be drawn in auto-

Test Result Area Displays test results. 88:88 M 88-88 (13) © Appears when test result is

lower than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10 mmol/L). © Appears when test result is within the range of 70 to 120 14 mg/dL (3.9 mmol/L to 6.7

mmol/L) **Ketone Symbol** Appears when test result is higher than 240 mg/dL (13.32 mmol/L) Alarm Symbol

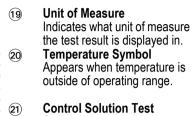
Appears when you are setting alarms. Test Strip Symbol

Appears when the meter is in

Blood Drop Symbol Flashes when sample should be applied.

testing mode.

Low Battery Symbol Appears when the battery power is low.



microlife

Symbol Shows that you are in control solution mode.

Memory Symbol Appears when you review the memory.

After Meal Indicates that your test is an After Meal test.

Before Meal Indicates that your test is a Before Meal test. Date

Time

⚠ If any part of the display is not working, contact your local distributor for help.

Microlife GlucoTeq meters come with one (1) CR2032 lithium battery. The battery is manufactured in a charged state and not designed for recharging. Recharging the battery can cause battery leakage, or in some cases, high pressure rupture. ⚠ Warning: Batteries can explode or leak and cause burns if installed backwards, disassembled,

charged or exposed to water, fire or high temperatures.

Low Battery

The meter will alert you when the power is getting low by displaying two different messages: •When the battery symbol (18) appears alone on the display, the meter is functional and the results remain accurate, but you should change the battery as soon as possible.

•When the battery symbol (18) appears together with the **«E-b»** symbol on the display, the battery does not have enough power for a test. You must change the battery before using the meter.



STEP 1: With the meter off, press the mark on the battery cover and slide up to open the cover.

by pressing on the buckle beside

the battery and gently pulling it at

the same time.



STEP 3: Replace with a new battery. Be sure to align the battery properly with the positive (+) side up.

STEP 4: Close the battery cover. If the meter does not power on and enter setting mode after you have replaced the battery, check that the battery is correctly

Replacing the battery does not affect the meter's memory (previous test results stored in memory). However, the date, time and unit settings may need to be updated; update the settings by following the steps in «Setting Time and Date»

As with all small objects, the battery should be kept away from small children. If the battery is swallowed, seek medical assistance immediately. Remove the battery if you are not going to use the device for a long period of time (i.e. 3 months or more), or the battery might leak chemicals.

Please discard the product or the batteries properly according to the regulations of your country.

Setting Mode

Please install battery first and complete the setting before you begin to test. STEP 4: Set the Date



15:00_~50 03

STEP 1: Enter Setting Mode If your meter is off, press the SET button (5) located in the battery compartment. The meter is now in the setting mode.

STEP 2: Set the Year



(3) to advance the date. With the correct date on the display, press the SET button (5) and the time will appear on the display with the hour segment flashing. STEP 5: Set the Hour Press and release the main button (3) to advance the hour. With the correct hour on the display, press the **SET** button (5)

and the minutes segment will

Press and release the main button



month segment flashing. STEP 3: Set the Month Press and release the main button (3) to advance the month. With the correct month on the display, press the **SET** button (5) and the date segment will start flashing.

Fig. A **STEP 7:** Set the Alarm

Press and release the main button

(3) to advance the year. With the

correct year on the display, press

the **SET** button (5) and the date

will appear on the display with the



start flashing. **STEP 6:** Set the Minutes Press and release the main button(3) to advance the minutes. With the correct minutes on the display, press the **SET** button (5) and the «OFF» will start flashing



will be displayed during the alarm setting. 1 - Press the main button 3 to turn the alarm ON (Fig.A) or OFF (Fig.B).

The meter allows you to set 4 different alarms with an order from 1 to 4. 1

2 - Press **SET** button (5) to move to hour setting for alarm. (Fig.C) Use the



3 - Press **SET** button to set the next alarm. 4 - Repeat step 1-3 to set the second, third and fourth alarm. After completing fourth alarm, the AC/PC will start flashing.

Press SET button (5) again to set the minute. (Fig.D).

main button (3) to set your desired hour.



ÜΠ

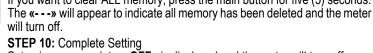
Fig. D

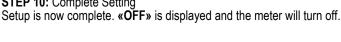


STEP 8: Set AC/PC Press and release the main button (3) to select ON/OFF. With the correct setting, press the SET button 5 for confirmation.



STEP 9: Delete Memory If you do not want to clear the memory, press the SET button again to skip If you want to clear ALL memory, press the main button for five (5) seconds.





3. Prepare for blood sampling

If your lancing device did not come with a lancing device insert, the following information shall take the place of the insert.

Microlife LD-100 Lancing Device

Your lancing device and lancets are used for obtaining blood samples from the puncture site (1) A stylish, slim and ergonomic design is very

convenient and user friendly. (2) Big window to show the penetration depth with numeric display which is easy for the user to

3 Big release button, comfortable and easy to operate.

4 Patented feature of lancet ejection by one thumb pushing with only one hand operation. (5) Patented safety switch design:

when the cap is closed, it allows only load but lock the function of lancet ejection. When cap is open, it allows lancet ejection but release the trigger automatically to prevent accidental pricking.

6 Depth adjustable cap (7) Release button

(8) Plunger 9 Hub

10 Clear cap (optional)

11) Disposable lancet (optional)

Special Features •Intended Use: The lancing device is intended for use by a single person with the lancet puncturing

through the skin for collecting blood sample. •Safety Switch design: when the depth adjustable cap is open, the trigger will be relieved automatically which prevents users from being pricked if you are not intended to start the test. You can eject the used

disposable lancet on one hand operation by pushing the plunger with your thumb at this status. •When the cap is closed, it will lock the lancet eject function and prevent the lancet from being removed when you are intended to start the test. •Stable and sophisticated structure design ensures almost no vibration, so that the lancet pricking is

steadier with almost no pain. It lowers the psychological pressure of users very much and let people

recover the test frequencies which recommended by HCPs. •A stylish, slim and ergonomic design is very convenient and user friendly.

•Clear indication for depth penetration (numeric display): easy to read and adjust for users.

⚠ Important Lancing Device and Lancets Information

1.Lancet is for single use only. 2. Keep lancing device and lancets clean.

3.Use caution when removing the used lancet from the device and when disposing the used lancet.

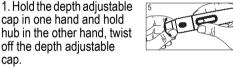
The meter and lancing device are for single patient use.

Do **NOT** share them with anyone including family members.

Do **NOT** use on multiple patients.



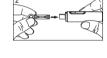
cap in one hand and hold hub in the other hand, twist off the depth adjustable cap.



portion of the depth adjustable cap until the number matched to the window. Settings are based on skin type.«1,2» are for soft or thin skin. «3,4» are for average skin. «5,6» are for thick or

5. Select a depth of pene-

tration by rotating the top



2. Insert a new disposable lancet firmly into the lancet holder.



6. Hold the hub in one hand and push on the plunger in the other hand. The device will be cocked. Release the plunger; it will go back to its original position near the hub.

calloused skin.



Twist off and set aside the protective cover of the disposable lancet.

2. Insert Test Strip:

5. Apply Blood Sample:

contamination

The Lancing device is made by MEDIFUN CORPORATION No.8, Shuyi Rd., South Dist., Taichung City, 40241, Taiwan (R.O.C.) 4. Replace the depth

adjustable cap 4. Performing a Blood Test



1. Wash Your Hands and the Puncture Site:

Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.



test strip slot first. Push the test strip as far as it will go without bending it. The meter turns on automatically. *To track the position of test strip slot, press main button and the slot LED light will flashing.

removing test strips. Insert a test strip with the contact bar end entering into the

Remove a new test strip from vial. Be sure to tightly replace vial cap after



3. Select and Lance a Puncture Site: Hold the prepared lancing device firmly against the side of your fingertip. Press the release button. NOTE: If you want to do alternative site testing, please refer to the «About Alternative Site Testing (AST)» section. Please consult your healthcare professional before obtaining blood from site other than your fingertip.



4. Obtain a Blood Sample: Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.5 µL of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.



bent channel of the test strip where it meets the narrow channel. Blood will be drawn into the test strip. If the test strip confirmation window is full, you will hear 6. Read Your Result:

When the meter shows the «♠» symbol, apply blood to the opening of the absor-



7. Turn Off the Meter: This blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used test strip carefully to avoid



After use, put the Protective Cap back onto the exposed needle of the lancet.



Slide the Lancet Ejector forward and dispose the used lancet in an approved container. Dispose the used lancet according to your country's safety regulations. Replace the Lancing Device Cap.



After the meter counts down from 5 to 1, your blood glucose test result appears along with the unit of measure, date and time.

8. Remove the Adjustable Comfort Tip:



9. Dispose the used lancet correctly:



5. Alternative Site Testing (AST)

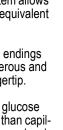
There are important limitations for doing AST. Please consult your healthcare professional before you perform AST.

What is AST?

Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The system allows you to test from the palm, forearm, upper arm, calf or thigh, with equivalent results to fingertip testing.

What is the advantage? Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous and you will not feel as much pain as you will experience at the fingertip. When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.



Use AST only:

1.In a pre-meal or fasting state (more than 2 hours since the last meal).

- 2.Two hours or more after taking insulin.
- 3.Two hours or more after exercise.
- 4. During steady state blood glucose conditions.

Do NOT use AST if:

1. You have reason to believe you have hypoglycemia or hyperglycemia.

- 2. Your routine glucose results are often fluctuating.
- 3. The test result is to be used to calibrate continuous glucose monitors (CGMs).
- 4. The test result is to be used for insulin dose calculations.

How to increase the blood volume?

Increase the blood flow by rubbing the puncture site for more than 20 seconds before extracting blood. This helps to reduce the risk of insufficient blood sample for a blood glucose test.

6. Control Solution Testing

If your Microlife control solution did not come with Microlife Control Solution instructions, the following information shall take the place of the instructions.

Microlife Control Solution contains a known amount of glucose that reacts with Microlife GlucoTeq Blood Glucose Test Strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you can make sure that the meter and the test strips are working properly together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

The standard GlucoTeq Blood Glucose Monitoring System DOES NOT contain the control solution. To purchase Microlife Control Solution, please contact your local distributor.

△ Important Information:

•Use only Microlife Control Solution with your Microlife GlucoTeg meter.

•Check the expiration date on the bottle. Do not use if expired.

•Use within a period of 90 days from the date that you first open it. Record the discard date on the control solution bottle when you first open it to serve as a reminder to discard after 90 days. •The control solution ranges are printed on the label of the Microlife Blood Glucose Test Strip vial. They

When your blood glucose test results are not consistent with how you feel, or when you think your

are not recommended target ranges for your blood glucose.

•For in vitro diagnostic use.

•Do not add any liquid to the Microlife Control Solution.

Do not take internally or inject.

Why Perform a Control Solution Test:

•To ensure that your meter and test strips are working properly together.

To allow you to practice testing without using your own blood.

When to Use:

Whenever you suspect that the meter or test strips are not working properly.

results are not accurate. When test strips have been exposed to extreme environmental conditions.

 If you drop the meter. **Performing a Control Solution Test**

Start with the meter off.

STEP 1: Wash your Hands. Wash your hands with mild soap and water before performing any test.

Be sure to dry them thoroughly. STEP 2: Insert Test Strip

Insert a test strip with the contact bar end entering into the test strip slot first. Push the test strip as far as it will go without bending it. The meter turns on automatically. **STEP 3: Mark as a Control Solution Test**

After the «♦» symbol appears on the display, press and hold the main button for 5 seconds and a & symbol appears on the display. With the symbol on the display, the meter will not store your test result in the memory. If you decide not to perform a control solution test, press and hold the main button for 5 seconds again and the a symbol will disap-



1. Check the expiration and discard dates on your control solution and test strip vials.

2. Shake the control solution bottle well, then remove cap 3. Squeeze the bottle and discard the first drop then wipe the

dispenser tip with clean tissue paper or cotton.

4. Squeeze the bottle again to get a second drop onto a clean, nonabsorbent surface or on your clean fingertip.

5. Bring the tip of the test strip to touch the drop of solution until the

meter beeps.

To avoid contaminating the control solution with the content of the test strip, DO NOT DIRECTLY APPLY CONTROL SOLU-TION ONTO THE TEST STRIP.

STEP 5: Check if the Test Result is in Range.

After five (5) seconds, the control solution test result appears on the display. Compare the test result with the range printed on the test strip vial. Each vial of Microlife GlucoTeq Blood Glucose Test Strips may have a different control solution range. The result should fall within the printed range on the test strip vial.

△ Caution

7. Memory Recall

Do not use test strips or control solution that have exceeded the discard date, are expired or have been damaged. Your results

The Microlife GlucoTeq meter stores a maximum of the 500 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14, 28, 60 and 90-day averages of your blood glucose test results. You can review the individual or average test results by entering the memory

Recall the memory

STEP 1: Enter the Memory Mode While the meter is turned off, press and hold the main button to turn the meter on. Press the main button again to enter memory mode.

The 7-day average will appear, indicating that you are in the memory mode. When using the meter for the first time or when the memory has been deleted, «- - -» appears, indicating there are no test results in the meter memory.

STEP 2: Recalling Average Test Results

If you continue to press the main button, the 7, 14, 28, 60 and 90-day averages will appear in order. You can then review the last 500 individual test results in memory. The 7-day average is calculated from the blood glucose results obtained during the last 7 days. It also indicates how many blood glucose tests have been performed within this period, e.g., 21 (21 tests in the last 7 days).



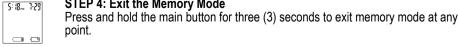
★ The 14-day average is calculated from the blood glucose test results obtained during the last 14 days. It also indicates how many blood glucose tests have been performed, e.g., 41 (41 tests in the last 14 days).

The 28, 60, 90-day averages show the same information. 5:48... 1:29 STEP 3: Recalling Individual Test Results



After the 90-day average, the most recent test result with date and time will be shown. After the 90-day average, the most recent test result with date and time will be Press the main button once and the next most recent test result will appear. Each time you press and release the main button, the meter will recall up to your last 500 test results in order. When the memory is full, the oldest test result is deleted as the newest is added. After reaching the last individual result, press the main button and

> the meter turns off. **STEP 4: Exit the Memory Mode**



If you do not press any buttons for one (1) minute, the meter will display **«OFF»** and turn off auto-

«Hi» and «Lo» test results are not included in the averages.

8. Caring For Your Meter And Test Strip To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your

Your meter does not require special maintenance. As long as no blood or control solution comes in

hands thoroughly before use.

direct contact with the meter, there is no special cleaning required. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then

dry the device with a soft and dry cloth. Do not flush with water.

Do not use organic solvents to clean the meter. Your meter is a precision instrument. Please handle it with care.

Storage 1. Meter Storage

•Storage condition: -20 °C~50 °C (-4 °F~122 °F), below 90 % relative humidity.

 Avoid dropping and strong impact. Avoid direct sunlight and humidity.

•Storage condition: 4 °C~40 °C (39 °F~104 °F), and 10~85 % relative humidity. Do not freeze. •Store your test strips in their original vial only. Do not transfer to other 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 replace the vial cap and close it tightly. •You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.

•Use each test strip immediately after removing it from the vial.

•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 can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

3. Control solution storage

•Storage condition: Store the control solution tightly closed at temperatures between 4 °C (39 °F) and 30 °C (86 °F). Do not freeze.

9. Technical Specifications

Model Name: GlucoTeq **Assay Method:** Electrochemical biosensor **Test Sample:** Capillary whole Blood **Test Result:** Referenced to plasma glucose value **Alternative Site Testing:** YES (palm, forearm, upper arm, calf, or thigh)

Sample Size: $0.5 \,\mu$ L **Measuring Time:** 5 seconds Measurement range: 20~600 mg/dL **Acceptable Hematocrit**

20~60 % Range:

Operating conditions: 10 °C~40 °C (50 °F~104 °F), between 10 - 85 % R. H. Storage/Transportation Meter: -20 °C~50 °C (-4 °F~122 °F), below 90 % R. H. Strip: 4 °C~40 °C (39 °F~104 °F), between 10~85% R. H. **Condition:**

500 test results with time and date **Memory Capacity: Average Calculation:** 7, 14, 28, 60, and 90 days **Power Supply:** 1 CR2032 lithium battery **Battery lifetime:** Approximately 1000 tests Automatic shut-off: In 3 minutes **Dimensions:** 98 x 54 x 16.4 mm

Weight: approximately 49 g (including battery)

10.System Troubleshooting

Special messages and error messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error

In the event of a problem, refer to the information under «Actions» in the «Error Messages» section. If you continue to have a problem, please refer to the «Troubleshooting Guide» section. If you follow the actions recommended but the problem is not resolved, please contact your local distributor for assistance.

tarioo.	
Message	What it means
LO	«Lo» appears when your result is below the measurement limit, which is less than 20 mg dL (1.1 mmol/L). «Lo» indicates hypoglycemia (low blood glucose). You should immediately consult your healthcare professional.
HI	«HI» appears when your result is above the measurement limit, which is higher than 600 mg/dL (33.3 mmol/L). You should immediately consult your healthcare professional.
Error Message	Description
E-P	What it means: Appears when the batteries cannot provide enough power for a test. Action: Replace the battery immediately.
E-U	What it means: Appears when inserting a used test strip. Action: Test with a new test strip. If the problem persists, please contact your local distributor.
E-F	What it means: Appears when the temperature is out of the system operating range (10 °C~40 °C (50 °F~104 °F)). Action: Repeat the test after the meter and test strip are within the operating temperature range.

Only the most common error messages are listed. If your meter displays an error message that is not listed, please contact your local distributor.

Troubleshooting Guide

Ine meter does not display a message after inserting a test strip		
Probable Cause	Actions	
Battery exhausted	Replace the battery.	
Battery incorrectly installed or absent	Check that the battery is correctly installed.	
	Insert the test strip correctly with the bar end entering into the test strip slot first.	
Defective meter	Please contact your local distributor for assistance.	

I he test does not start after applying the sample		
Probable Cause	Actions	
Insufficient blood sample	Repeat the test using a new test strip with a larger blood sample.	
Defective test strip	Repeat the test with a new test strip.	
Sample applied after automatic shut-off (3 minutes after user action)	Repeat the test with a new test strip. Apply sample only when the « • » symbol appears on the display.	
Defective meter	Please contact your local distributor for assistance.	

AThe control colution toot is out of ron

In the control solution test is out of range			
Probable Cause	Actions		
Error in performing the test	Read the instructions thoroughly and repeat the test again.		
Control solution bottle not shaken well	Shake the control solution bottle vigorously and repeat the test again		
Expired or contaminated control solution	Check the expiration date and the discard date of the control solution.		
Control solution that is too warm or too cold	Control solution should come to room temperature (between 4 °C (39 °F) and 30 °C (86 °F)) before testing.		
Test strip deterioration	Please repeat the test with a new test strip.		
Meter malfunction	Please contact your local distributor for assistance.		

11.Performance Characteristics

Low 45-75 mg/dL

High 200-300 mg/dL

Standard deviation (SD) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and coefficient of variation (CV) for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L) is ≤ 5.0 mg/dL (0.278 mmol/L) and ≤ 5.0%, respectively.

Intermediate precision

Control S	Solution Level			Normal		High	
30-50 mg/dL (1.6~2.7 mmol/L)		.6~2.7 mmol/L)	96~144 mg/dL (5.3~8.0mmol/L)		280~420 mg/dL (15.5~23.3mmol/L)		
		mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L
Pooled	Mean	44.6	2.48	100.0	5.55	351.8	19.52
	SD	3.0		2	.9	8	.1
	CV (%)	6	.7%	2.9	9%	2.3	3%

111-150 mg/dL (6.1-8.3 mmol/L)

mg/dL mmol/L

2.9%

132

7.33

151-250 mg/dL (8.3-13.8 mmol/L)

mg/dL mmol/L

221.4 12.29

6.8

3.1%

251-400 mg/dL (13.8-22.2 mmol/L)

mg/dL mmol/L

98

2.8%

349.1

19.38

SD 3.2 CV (%) 7.1%

30-50 mg/dL (1.6~2.7mmol/L)

mg/dL mmol/L

concentrations at or above 100 mg/dL (5.55 mmol/L).

51-110 mg/dL (2.8-6.1 mmol/L)

mg/dL mmol/L

101.1 5.61

3.2

3.2%

Repeatability

Blood Glucose

Pooled Mean

	For glucose concentration <100 mg/dL	(5.55 mmol/L)		
Within±5 mg/dL (Within±0.28mmol/L)	Within±10 mg/dL (Within±0.56mmol/L)	Within±15 mg/dL (Within±0.83mmol/L)		
109/204 (53.4%)	183/204 (89.7%)	204/204 (100%)		
<u>'</u>	For glucose concentration ≥100 mg/dL	(5.55 mmol/L)		
Within±5%	Within±10%	Within±15%		
192/396 (48.5%) 310/396 (78.3%)		380/396 (96.0%)		
For gluc	ose concentrations between 41.5 mg/dL (2.3 mmol	/L) and 525 mg/dL (29.17 mmol/L)		
Within ±15 mg/dL (0.83 mmol/L) or ±15%				
	584/600 (97.3%)			

The Microlife GlucoTeq Blood Glucose Monitoring System meets the requirements for System Accuracy as stated in ISO 15197:2013.

User Performance

A study evaluating glucose values from fingertip, palm, forearm, upper arm, calf, and thigh capillary blood samples obtained by 100 lay persons showed the following results: 100% within ± 15 mg/dL (± 0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and ≥ 95% within ±15% of the medical laboratory values at glucose

12.Guarantee

This device is covered by a 5 year guarantee from the date of purchase. During this guarantee period, at our discretion, Microlife will repair or replace the defective product free of charge.

The above warranty will be valid when following conditions are completed:

•The complete device is returned to authorized after-sale center. •The original purchase invoice is returned with the returned device.

The following shall be excluded from or not covered by the warranty: 1. Accessories (lancing device, pouch) and consumables (batteries, test strips, lancets).

2. Parts that are subjected to wear and tear, including without limitation to LCD screen, flip cover, etc).

3. Packaging materials and wearing parts. 4. Regular check and maintenance (calibration).

5.Damage caused by incorrect application or non-compliance with the instructions for use (including but not limited to improper storage).

Damage caused by accident or negligence (including but not limited to battery leakage).

7. Damage cause by force majeure.

8. The device has been unauthorized modified, altered or disassembled. 9. The serial number on meter is removed/ made illegible or tampered. EXCEPT AS THE ABOVE LIMITED WARRANTY, NO OTHER WARRANTIES, EXPRESS OR

These terms shall be without prejudice to the rights of the consumer in accordance with applicable national law.

IMPLIED, ARE MADE. THE INDEMNITY OR COMPENSATION ARISING OUT OF OR IN

CONNECTION WITH THE WARRANTY SHALL BE ONLY LIMITED TO THE VALUE OF THE

Should guarantee service be required, please contact the dealer from where the product was purchased, or your local Microlife service. You may contact your local Microlife service through our

www.microlife.com/support

Repair or replacement will not prolong or renew the original warranty period of the device.