GlucoLeader™ Enhance 2

Blood Glucose Monitoring System

3K-02-XXXXXX V3

Please read this User Guide before using your GlucoLeader™ Enhance 2 Blood Glucose Meter. If you have any questions or enquiries, please contact us or your local distributor.

INTRODUCTION

Thank you for selecting GlucoLeader™ Enhance Blood Glucose Monitoring System. This system was produced in close association with diabetes healthcare professionals, most importantly, people with diabetes.

ABOUT GlucoLeader™ Enhance SYSTEM

Intended Use

The GlucoLeader™ Enhance Blood Glucose Monitoring System (The GlucoLeader™ Enhance 2 System) is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood by people with diabetes or by healthcare professionals for monitoring blood glucose at home or in healthcare facilities. The device is indicated for professional use and over-the-counter sales. The GlucoLeader™ Enhance 2 System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

About the System

The GlucoLeader™ Enhance 2 System are designed to pursuit the accuracy in blood glucose monitoring to provide you with easy and comfortable testing. The system requires 0.8μL of blood sample and 5 seconds for the test to complete.

The GlucoLeader™ Enhance 2 System consists of

1) GlucoLeader™ Enhance 2 Blood Glucose Meter
2) GlucoLeader™ Enhance 2 Lancing Device
3) GlucoLeader™ Enhance 2 Blood Glucose Test Strips (Optional)
4) GlucoLeader™ Enhance 2 Control Solution. (Optional)
5) GlucoLeader™ Enhance 2 Check Strip (Optional)

These products are intended to be used together to get accurate blood glucose test results. Do not use other test strips or glucose control solutions with your meter.

Important Information

IVD The GlucoLeader™ Enhance 2 System is intended for *in vitro* diagnostic use with capillary and venous whole blood or for testing newborn infant (neonatal testing). The system should not be used for diagnosis of diabetes.

⚠Caution

1. The user should not take any medical relevant decision without first consulting medical practitioner.
2. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
3. Severe dehydration or excessive water loss may cause false, high results. Call your doctor right away if you suspect suffering from dehydration.
4. A sample with large amount of reducing substances such as Acetaminophen(>10mg/dL), Cholesterol(>500mg/dL), Bilirubin(>10mg/dL), Glutathione(>23mg/dL) and Uric Acid(>5mg/dL) may cause the result slightly higher than the actual glucose level.
5. A red blood cell count (hematocrit) that is either very high (over 70%) or very low (under 10%) can cause false result.
6. High altitudes above than 2,750 meter (8,800 feet) may affect the test results.
7. Temperatures outside the range of 8°C to 44°C (46.6°F to 111.2°F) may affect the test results.
8. Do not modify this meter.
9. Do not perform maintenance and servicing when using the meter.
10. Remove the battery if the meter will not be used for a long time.

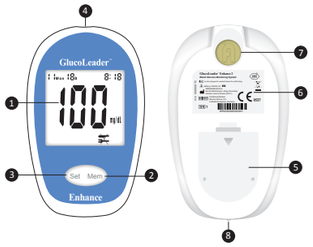
Limitations:

1.For single-patient use only.
2.For self-testing.
3.For over the counter use.
4.The patient is an intended operator.

NOTE: PLEASE MAKE SURE THAT ALL PRODUCTS LISTED ON THE "CONTENTS" OF THE BOX ARE CONTAINED IN THE PACKAGE BEFORE USING THIS SYSTEM. IF YOU FIND ANY IMPERFECTION IN OUR PRODUCTS, PLEASE RETURN THE WHOLE SYSTEM TO THE PLACE OF PURCHASE.

BLOOD GLUCOSE METER

Study this diagram and become familiar with all the parts of your GlucoLeader™ Enhance 2 Blood Glucose Meter.



1. **DISPLAY**: The large, easy to read display shows the test results, messages, blood glucose results stored in memory, time and date.
2. **Mem BUTTON**: Press Mem button to enter memory mode to recall the information stored in meter's memory.
3. **Set BUTTON**: Press Set button to enter date and time setting.
4. **STRIP SLOT**: Holds a GlucoLeader™ Enhance 2 Blood Glucose Test Strip or Check Strip in place when you perform blood glucose test or perform check test.
5. **BATTERY COMPARTMENT**: Holds one 3V Lithium battery. The battery is not yet installed into meter when new purchasing. Before using the meter, please install the battery first.
6. **Meter SN Label**: The label shows the meter serial number and FCC ID.
7. **EJECTION BUTTON**: For a easy ejection of the test strip.
8. **DATA PORT**: Allows you to transfer the information stored in the meter's memory to a smartphone to view, analyze. (The smart cable should be purchased separately.)

FCC Regulations:

15.19(a)(3):

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

15.105(b):

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/ TV technician for help.

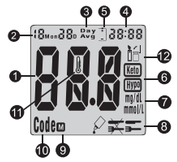
Exposure to Radio Frequency Radiation

Exposure to Radio Frequency Radiation

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meet FCC radio frequency(RF) Exposure Guidelines.

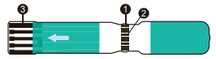
This equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

METER LCD WINDOW



1. **TEST RESULT**
2. **DATE**: Month/date.
3. **DAY AVG**: Appears when the meter is in the memory mode while recalling 7/14/21/28 day test averages.
4. **TIME**: The meter is programmed for a 24 hour period format.
5. **BATTERY SYMBOL**: Appears when battery is low.
6. **Keto Hypo SYMBOL**: When the result is over 320mg/dL(17.7 mmol/L) or below 70mg/dL (3.9 mmol/L), the symbols will appear and "beeping" alarms the patients of abnormal glucose level.
7. **mg/dL mmol/L**: The meter has two units of measurement (mg/dL or mmol/L) to choose from.
8. **SYMBOL:** The test can be adjust and stored into 3 types of test modes - BEFORE MEAL TEST (AC), AFTER MEAL TEST (PC), and GLUCOSE CONTROL SOLUTION TEST (QC)
9. **M**: **M** appears to indicate memory mode when reading previous results.
10. **CODE**:Code appears to indicate code NO. when ready to test.
11. **THERMOMETER SYMBOL**: Appears when ambient temperature is above or below the acceptable range needed for testing.
12. **STRIP SYMBOL**: Appears when the test strip is inserted and meter is ready for blood testing.

GlucoLeader™ Enhance 2 BLOOD GLUCOSE TEST STRIP



1. Aperture: It absorbs the blood from either side of the test strip.
2. Blood Reaction Zone: It must be filled with blood entirely.
3. Meter Contact: The value of the test result will be transmitted from blood Reaction Zone into the meter through this Meter Contact.

NOTE 1: NEVER APPLY BLOOD SAMPLE TWICE IN THE SAME STRIP. PLEASE REPEAT THE TEST USING A NEW TEST STRIP WITH A LARGER BLOOD DROP.

NOTE 2: IF THE AMOUNT OF BLOOD APPLIED WAS TOO SMALL, AN ERROR CODE "E42" WILL APPEARS WHICH SHOWS THE BLOOD IS NOT ENOUGH. PLEASE DO NOT ADD BLOOD IN THE SAME STRIP. PLEASE REVIEW THE ERROR CODE TABLE AND PROBLEM SOLVING GUIDE SECTION.

⚠IMPORTANT TEST STRIP INFORMATION

1. GlucoLeader System measures the amount of glucose in capillary and venous whole blood. Blood can be applied to the front of the test strip and is automatically drawn to the test strip through capillary and venous action.
2. GlucoLeader Blood Glucose Test Strips are intended for in vitro diagnostic use with capillary and venous whole blood or GlucoLeader Glucose Control Solution. Results will not be accurate if used with plasma or serum samples.
3. Do not use test strips beyond the expiration date indicated on the strip vial label.
4. Use test strips within 90 days after first opening the vial cap. Record the discard date on the vial when you open a new vial of test strips.
5. Blood Glucose Test Strip can be damaged by heat and light. Keep them sealed in the original vial.
6. +2°C (35.6°F) +30°C (86°F) Store test strip in the original container within the range of 50°F to 104°F(10°C to 40°C). Do not refrigerate.
7. Do not use damaged test strips in any way. Use test strip immediately after taking it out from the vial or foil packet; replace the vial cap and close it tightly.
8. Do not transfer test strips to a new vial. Always carry test strips in their original vial.
9. Do not place in direct heat or sunlight.
10. Do not carry loose test strips in your carrying case.
11. Test strips are for single use only.

GlucoLeader™ GLUCOSE CONTROL SOLUTION (OPTIONAL)

GlucoLeader™ Glucose Control Solution is used to check if the GlucoLeader™ Enhance 2 Blood Glucose Meter and Test Strip are working correctly as a system.

It can be used in two ways:

1. To practice the test procedure
2. To make sure that the GlucoLeader™ Enhance 2 Blood Glucose Meter and Test Strips are working together properly.

⚠ IMPORTANT INFORMATION

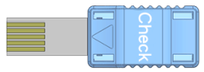
1. Do not use glucose control solution beyond the expiration date indicated on the bottle label.
2. The discard date for glucose control solution is 90 days after first opening. Record the discard date on the bottle when you open a new bottle of glucose control solution.
3. +10°C (50°F) +30°C (86°F) Store the glucose control solution closed at temperatures between 10ºC (50ºF) and 30ºC (86ºF).

PERFORM CONTROL TEST

1. Insert a new test strip into the strip slot, the meter will activate.
2. The last code number will appear on the screen. Compare the code number shown on the screen against the code number on the test strip vial. If the two numbers match, you may begin test, otherwise consult Section "CODING YOUR METER" of this user guide to code your meter first.
3. Gently shake the glucose control solution and apply a drop to the aperture of strip. Make sure that the glucose control solution has saturated the blood reaction zone.
4. Test result will show up in 5 seconds. The result should correspond to the range printed on the label of strip vial used.

NOTE: REPEAT TEST IF THE RESULT FALLS OUTSIDE THE CONTROL RANGE. IF YOU CONTINUE TO GET THE RESULT FALLING OUTSIDE THE CONTROL RANGE, YOUR METER AND STRIP MAY NOT BE WORKING PROPERLY. DO NOT USE THE SYSTEM TO TEST YOUR BLOOD UNTIL YOU GET A TEST RESULT FALLS WITHIN THE CONTROL RANGE. CONSULT YOUR LOCAL DISTRIBUTOR FOR HELP.

GlucoLeader™ Enhance 2 CHECK STRIP(OPTIONAL)



The GlucoLeader™ Enhance 2 Check Strip can be used in 2 ways:

1.To check that the meter is operating properly. Use when performing quality control check on your meter.

2.To delete all test memories.

How to check meter by check strip

Step 1: Insert the check strip into strip slot with label side up as above.
Step 2: You should obtain an "OK" reading within 10 seconds, which means your meter is working properly.
Step 3: Remove the check strip to exit. Meter will automatically turn off.

NOTE: IF YOU DO NOT GET "OK" READING BUT APPEAR OTHER ERROR MESSAGE, TURN OFF THE METER BY REMOVE CHECK STRIP FROM THE METER. THEN REPEAT THE TEST. IF THE SECOND RESULT PERSISTS, CONSULT YOUR LOCAL DISTRIBUTOR FOR HELP.

HOW TO DELETE MEMORY

1. Insert check strip into strip slot with label side up.
2. After "OK" displayed, press Mem button until flashing "dEL" shows up with a beep sound.
3. Press and hold the Set button until you hear a beep sound, Meter will display "OK" before turning off and all the memory has been deleted successfully.
4. Remove the check strip from the meter.

SETTING METER PARAMETERS

SETTING TIME & DATE

When you first time installing the battery into the meter or when replacing a battery, the meter will automatically enter to the setting mode. Please set correct time and date before you begin testing.

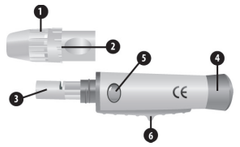
How to set time and date

1. Press Set button for 2 seconds to turn on the meter. The meter will enter to the setting mode automatically.
2. At the beep sound, the year "12" will flash(It mean 2012). Press Set button to select the desired month.
3. Press Mem button to confirm and shift to the next setting.
4. Repeat above steps to set the day, hour and minute by Set & Mem buttons. After minute is set, the meter will display "OK" before turning off.

NOTE: WHILE SETTING THE TIME AND DATE, YOU CAN EXIT THE SETTING MODE ANYTIME BY PRESS Mem BUTTON FOR 3 SECONDS.

PREPARE FOR BLOOD SAMPLING

ADJUSTABLE LANCING DEVICE



1. Depth Adjustment Cap
2. Depth Selector
3. Lancet Holder
4. Cocking Control
5. Release Button
6. Ejection Button

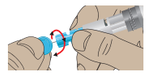
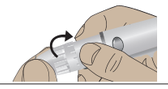
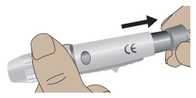
LANCET

1. Protective cap

Important Information

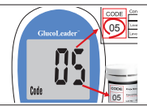
1. Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Be cautious when removing the used lancet from the device and when disposing the used lancet.
4. The lancing device and lancets are in conformity with MDD 93/42/EEC. Refer to product labels for contact information of manufacturer and CE marking.

SET LANCING DEVICE

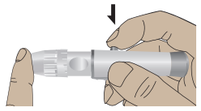
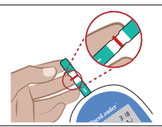
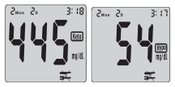
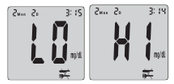
1. Remove the depth adjustment cap. Insert a lancet into the lancet holder and push down until it is fully seated	
2. Twist off the protective cap until it separates from the lancet.	
3. Replace the depth adjustment cap and set the puncture depth to the desired number. **NOTE: The shorter the scale the shallower the puncture.**	
4. Pull back the cocking control until it makes a click, press release button for penetration. If it does not click, the device may have been cocked when the lancet was inserted. Please contact local distributor.	

CODING YOUR METER

Before you use your meter for the first time and every time you open a new box of test strips, you need to set the meter to “match” the strips. This is called coding.

1. Insert the test strip into the strip slot, the meter will activate. The last code number will appear on the screen.	
2. Compare the code number shown on the meter display against the code number on the test strip vial. If the two numbers match you may begin blood testing. Otherwise continue to the next step.	
3. Press Mem button until you hear the sound of buzzer and the code value flashes, press Set or Mem button to obtain the code number indicated on the new test strip vial.	
4. Upon obtaining the right code number, wait to flash 3 times to validate the change. When the symbol flashes, you are ready to perform a test. **NOTE: THE NEW SETTING CODE NUMBER IS ALSO DISPLAYED ON THE SCREEN.**	

PERFORMING BLOOD TEST

1. Wash your hands in warm, soapy water. Rinse and dry completely.	
2. Remove new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically.	
3. Check the code number on the meter matches the number is on the pouch, and also the individually wrapped strip. If the 2 numbers match, you may begin blood testing. Otherwise refer to previous section to code your meter first.	
4. When the symbol flashes, you are ready to perform a test.	
5. Hold the prepared lancing device firmly against the side of your finger. Press the release button. Gently massage your finger to obtain the required blood volume. To perform the test, you need only 0.8uL of blood sample resting on your finger.	
6. Apply the blood sample to the right or left aperture of test strip in a way that comfortable for you. Make sure that the blood drop has saturated the test confirmation window. When blood is applied to the strip, a line moves on the screen until measurement is completed.	
7. Test result will show up in 5 seconds. If a count down number not appear, an error code “E42” will appears which shows the blood is not enough. Please do not add blood in the same strip. Please review the error code table and problem solving guide section. Before removing strip from the meter, you can press Set button to set the test as BEFORE MEAL TEST (AC), or AFTER MEAL TEST (PC), or a CONTROL SOLUTION TEST (QC). If not setting, the default of the meter is BEFORE MEAL TEST (AC).	
8. If the test is been done in 2 hours after meal, press Set button to change the setting from AC to PC (8.1). If the test is a glucose control solution test, press Set button again to change the setting from PC to QC (8.2). **NOTE: IF A TEST IS SET AS “QC”, THE RESULT WILL NOT BE CALCULATE INTO AVERAGES.**	8.1 8.2
9. After setting complete, remove the strip from meter and discard the used strip and lancet safely in a puncture resistant container.	
10. The meter has risk indicator function. If Keto is displayed, your blood glucose result may be higher than 17.7 mmol/L or 320 mg/dL. If Hypo is displayed, your blood glucose result may be lower than 3.9 mmol/L or 70 mg/dL.	
11. The testing range of the meter is from 10 to 600 mg/dL (0.6 to 33.3 mmol/L). If HI is displayed, your blood glucose result may be higher than 33.3 mmol/L or 600 mg/dL. If LO is displayed, your blood glucose result may be lower than 0.6 mmol/L or 10 mg/dL.	

UNDERSTANDING YOUR TEST RESULT

Expected values for people without diabetes:

Time of Day	Expected Range, Non-diabetes
Before Meal	Less than 100 mg/dL
After Meal	Less than 140 mg/dL

Source: American Diabetes, Association Position Statement, Diabetes Care Vol.37 (Suppl.1) P.S16 (2014).

For diabetes patients, please consult your healthcare professional to find out your target blood glucose value.
If your blood glucose result seems unusually high or low, or inconsistent with your previous results, check the following:

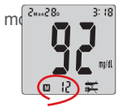
1. Does the code number on the test strip vial match the code number on the meter?
2. Was the blood sample applied to the test strip immediately after the strip was removed from the vial?
3. Was the size of the blood sample sufficient?
4. Was the test strip vial cap tightly sealed?
5. Was the test strip used before the expiration date?
6. Were the test strips stored away from extreme temperatures or from areas of high humidity?
7. Then run a quality control check with your GlucoLeader Glucose Control Solution and a new test strip. If the control test result is within the acceptable range, review testing procedure and repeat your blood glucose test with a new test strip. If your blood glucose value is still inconsistent with your previous results, contact your doctor immediately for help.

MEMORY RECALL

The GlucoLeader™ Enhance 2 Blood Glucose Meter can automatically store up to 800 results and auto-calculate your average results of 7-, 14-, 21-, 28- days on both AC and PC.
When recalling the results, each single result appears from the latest to the earliest with time and date.

To recall Results Stored in Memory

1. Turn meter on by pressing Mem button till you hear a beep sound. The first result displayed on the screen is your latest test result. M12 represents the 12th recorded of the overall results on this meter.
2. By pressing Mem button, you will see your test record from the m to the oldest.
3. Pressing the Set button to view the average results. “03” represents within the past 7 days there were 3 AC -test results. Press the Set button continuously to view the average results sequentially for 7, 14, 21 and 28 days.
4. Please press the Mem button for 2 seconds to EXIT or put it aside for 3 minutes for auto shutdown.



NOTE: ANYTIME IN MEMORY MODE, YOU CAN PRESS Mem B TIL YOU HEAR THE BEEP TO EXIT AND TURN OFF THE METER

DATA DOWNLOAD

You may download test results to your smartphone, you need to have smart cable and GlucoLeader Enhance 2 Health2Sync diabetes management App.
The smart cable should be purchased separately. The GlucoLeader Enhance 2 Health2Sync diabetes Management APP is a free iOS and Android apps listed on the Apple App Store and Google Play. Please search “Health2Sync“ to download the App:
Health2Sync provides innovative diabetes care & analytics service to help diabetics and care provider manage diabetes effectively. Through Smart Cable and Health2Sync App, diabetics can easily manage their blood sugar and relevant data, and obtain personalized reminders. Care provider can be connected to their patients through Health2Sync web platform. If you have inquiry, please contact with your local distributor for more information.

SPECIFICATIONS

1	Blood volume	0.8 micro liters
2	Sample type	capillary and venous
3	Test time	5 seconds
4	Measuring range	10~600 mg/dL (0.6~33.3 mmol/L)
5	Test strip storage conditions	35.6°F to 86°F (2°C to 30°C), 10%-90% humidity
6	Meter storage conditions	-13°F to 158°F (-25°C to 70°C), 10% -90% humidity
7	System operating conditions	46.4°F to 111.2°F (8°C to 44°C), 10% - 90% humidity
8	Transportation conditions	35.6°F to 86°F (2°C to 30°C), 10%-90% humidity
9	Memory capacity	800 blood glucose results
10	Automatic power off	3 minutes
11	Power supply	One 3-volt lithium battery (type CR 2032)
12	Display	LCD
13	Dimensions	97 × 60 × 16.5mm (LWH)
14	Weight	Approx.55.2g
15	Test Results Average	7,14,21,28-days AC / PC average
16	Construction	Hand-held
17	Meter type	The GlucoLeader Enhance 2 Meter is suitable for continuous
18	Control solution storage conditions	Refer to the control solution package insert

TAKING CARE OF YOUR METER

REPLACING THE BATTERY

The GlucoLeader™ Enhance 2 Blood Glucose Meter comes with a battery (not yet be installed when new purchasing). Please install your battery before starting.
Battery life will vary depending on usage, so always keep a spare on hand.
The battery should last about 12 months when testing 3 times a day.
When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace it as soon as possible. When battery symbol appears flashing on the display, the meter will no longer give results and you must replace the battery immediately.

TO REPLACE THE BATTERY

1. Make sure the meter is turned off.
2. Let the front of meter rest in the palm of your hand.
3. Slide battery compartment door open.
4. Remove the old battery and insert the new 3-volt Lithium battery into the battery compartment. Be sure to align the plus (+) and minus (-) signs correctly.
5. Slide battery compartment door closed. Check to see that your meter is working. If it fails to turn on, the battery may have been inserted incorrectly. Remove the battery and reinsert it correctly.

NOTE: EVERY TIME WHEN YOU REPLACE THE BATTERY, THE METER WILL TURN ON AUTOMATICALLY AND ENTER TO THE TIME/DATE SETTING. PLEASE SET CORRECT TIME AND DATE BEFORE TESTING.

CLEANING

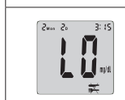
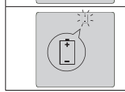
Clean the outside of the meter with a soft cloth, slightly dampened with water. Do not get moisture into the strip slot and data port.

STORAGE AND HANDLING

Keep your meter free of dust or water. Protect it from extreme temperature and humidity.

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

When any of the following messages appears, there is a problem with your GlucoLeader™ Enhance 2 Blood Glucose Meter or the way in which you are performing a test. These messages will help you to identify certain problems. If error messages appear that are not listed on the following pages, contact with your local distributor for help.

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check.	If some parts of the display are not working,contact your local distributor for help.
	Blood glucose result may be higher than 600 mg/dL or 33.3 mmol/L.	If you find the result is doubtful and hard to believe, review proper testing procedure and perform a quality check with glucose control solution. Repeat blood test, if “HI” still appears, call your doctor immediately.
	Blood glucose result may be lower than 10 mg/dL or 0.6 mmol/L.	If you find the result is doubtful and hard to believe, review proper testing procedure and perform a quality check with glucose control solution. Repeat test, if “LO” still appears, call your doctor immediately.
	Blood glucose result is higher than 320 mg/dL or 17.7 mmol/L.	If you find the result is doubtful and hard to believe, review proper testing procedure and perform a quality check with glucose control solution. Repeat blood test, if “Keto” still appears, call your doctor immediately.
	Blood glucose result is lower than 70 mg/dL or 3.9 mmol/L.	If you find the result is doubtful and hard to believe, review proper testing procedure and perform a quality check with glucose control solution. Repeat test, if “Hypo” still appears, please eat a candy and call your doctor immediately.
	Temperature is above or below the operating range of test strips.	The result you have obtained may not be accurate. Move to an area with temperature between 8ºC to 44ºC (46.4ºF - 111.2ºF). Do not artificially heat or cool the meter.
	Battery is low.	Change battery immediately.
	Test strip may be damaged.	Perform the test with new test strip.
	Test strip is used or test was not performed correctly.	Wait for the blood sign appear before applying blood.Perform the test with a new test strip and follow the test procedure correctly.If problem persists, contact Customer Care.
	Maybe: 1.The amount of blood applied was too small. Please repeat the test using a new test strip with a larger blood drop. 2.Defective test strip 3.Defective meter	Wait for the blood sign appear before applying blood.Perform the test with a new test strip and follow the test procedure correctly.If problem persists, contact Customer Care.
No responses when strip is inserted into the meter.	Maybe: 1. Battery is dead. 2. Wrong strip was inserted. 3. Meter is defective.	You have to: 1. Replace battery. 2. Insert the test strip correctly. 3. Contact us for help.
No responses when blood sample is applied to the strip.	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Perform Meter Check by inserting check strip.

NOTE : IF THERE IS ANY ERROR MESSAGE DISPLAYED BUT NOT LISTED HERE, OR YOUR METER SHUT DOWN FOR NO REASON, YOU CAN RESET THE METER BY REPLACE THE BATTERY.

PERFORMANCE EVALUATIONS

PRECISION

Tests were carried by trained technicians in the laboratory setting. The venous whole blood from one subject was adjusted to 6 different levels. Strips out of a single lot were tested. The results are shown in the following table.

Level	No. of tests	YSI Mean (mg/dL)	Strip Mean (mg/dL)	With Run SD(mg/dL) or CV.(%)
1	100	31.4	25.1	1.5(mg/dL)
2	100	87.4	80.4	2.8(mg/dL)
3	100	143.4	147.3	3.5%
4	100	225.1	221.9	2.6%
5	100	348.3	349.7	4.7%
6	100	481.6	478	3.6%

ACCURACY

600 samples at glucose concentration 46~576 mg/dL were tested at hospital by healthcare professionals. Fresh capillary finger whole blood samples were tested with the GlucoLeader™ Enhance 2 System; plasma samples from the subjects were tested with YSI Model 2300 Glucose Analyzer as reference. The results are shown in the following table.

Glucose concentration < 100 mg/dL(5.6mmol/L)		
Within ± 5mg/dL (0.28mmol/L)	Within ± 10mg/dL (0.56mmol/L)	Within ± 15mg/dL (0.84mmol/L)
85/172 (49.4%)	139/172 (80.8%)	171/172 (99.4%)
Glucose concentration ≧100 mg/dL(5.6mmol/L)		
Within ±5%	Within ±10%	Within ±15%
242/448(54%)	363/448 (81%)	437/448(97.5%)
Within ± 15mg/dL or ±15% (Within ±0.84mmol/L or ±15%)		
608/620 (98.1%)		

User performance

100 samples at glucose concentration 76~339 mg/dL were tested at hospital by lay user. 94.7% within ±0,83 mmol/L (±15 mg/dL) of the medical laboratory values at glucose concentrations below 5,55 mmol/L (100 mg/dL), and 100% within ±15% of the medical laboratory values at glucose concentrations at or above 5,55 mmol/L (100 mg/dL).

LOT	Batch code		Temperature limitation / Store at
	Caution		Do not reuse
	Keep away from sunlight		Biological risks
	Please consult instructions for use	IVD	In vitro diagnostic medical device.
	Use by /Expiry date	SN	Serial number
	Manufacturer	EC REP	Authorised representative in the European community

CE 0123 This product fulfills the requirement of directive 98/79/EC in vitro diagnostic medical device

The symbol indicating seperate collectionfor electrical and electronic equipment consists of the crossed-out wheeled bin. When the end-user wishes to discard this product, it must be sent to seperate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.

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