



Oracle[®]

Blood Glucose Monitoring System

GMH-B1; GMH-B2



Ver 1.3

311-4223500-005

Owner's Manual



Oracle[®]

Dear EZ Health[®] Oracle[®] GMH-B1/B2 System Owner:

This manual contains important information you must know about the system. Please read it thoroughly and carefully.

The greatest feature of this system is its **Bilingual Speaking Function** , which is an acoustic aid for users especially with visual disability. Please note that this function is optional. If the meter does not have , it will not provide speaking function.

Another unique feature is its Autocode[®] function which means there is no need to calibrate your meter, and allows you to easily monitor your blood glucose at home.

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

An audio version of the owner's manual is available on the enclosed CD or on our website at www.oraclediabetes.com or by calling one of our friendly representatives at 1(866) 829-7926.

IMPORTANT SAFETY INSTRUCTIONS

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 handicapped persons.
2. Use the device only for the intended use described in this manual.
3. Do not use 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.

KEEP THESE INSTRUCTIONS



TABLE OF CONTENTS

IMPORTANT SAFETY INSTRUCTIONS	03
IMPORTANT INFORMATION	06
ABOUT ALTERNATIVE SITE TESTING (AST)	07
INTRODUCTION OF THE SYSTEM	09
Intended Use	09
Principle of Measurement	09
Contents of the System	10
Appearance and Key Function of the Meter	11
Meter Display Segments	12
Speaking Function	13
Appearance of the Test Strip	14
PREPARATION BEFORE USE	15
Battery Replacement	16
Setting the Meter and Deleting the Memory	17
BEFORE TESTING	22
Checking with EZ Health® Oracle® Control Solutions	22
Important Control Solution Information	23
Performing a Control Solution Test	24
TESTING YOUR BLOOD	27
Testing Procedure	28
Expected Test Results	34
COMPARING METER AND LABORATORY RESULTS	35
USING THE METER MEMORY	37
Viewing Results on the Meter	37
Viewing Results on a Personal Computer	41

CARING FOR YOUR METER AND TEST STRIPS	43
Cleaning	43
Storage	43
PROBLEM-SOLVING GUIDE	46
Result Indicator	47
Error Message	48
Problem in Operation	49
SPECIFICATIONS	51
WARRANTY/CUSTOMER CARE	52



Oracle®

IMPORTANT INFORMATION

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- Test results below 3.3 mmol/L*¹ mean low blood glucose (hypoglycemia). Test results greater than 13.3 mmol/L*² mean high blood glucose (hyperglycemia). If you get results below 3.3 mmol/L or above 13.3 mmol/L, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results that fall below 3.3 mmol/L or above 13.3 mmol/L, follow the treatment advice of your healthcare professional.
- Apply only capillary whole blood sample to the absorbent hole. Applying other substances to the absorbent hole will cause inaccurate results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.
- 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.
- Please refer to the test strip package insert for additional important information.

*1: Kahn, R., and Weir, G.: Joslin's Diabetes Mellitus, 13th ed. Philadelphia: Lea and Febiger (1994), 489.

*2: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263.

ABOUT ALTERNATIVE SITE TESTING (AST)

Important: There are limitations for doing AST. Please consult your healthcare professional before you do AST.

What is AST?

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. This system allows you to test on the palm, the forearm, the upper arm, the calf, or the thigh with the equivalent results to fingertip testing.

What's the advantage?

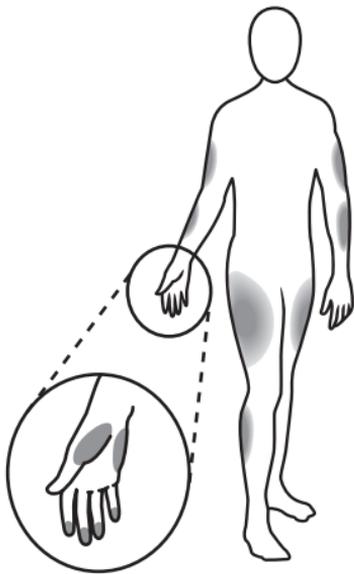
Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings are not so concentrated, you will not feel as much pain as at the fingertip.

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. Alternative site results may be different from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise). Therefore when testing blood glucose during or immediately after a meal, physical exercise, or after taking insulin, **take blood sample from your finger only.**

We strongly recommend you do **AST ONLY** in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.





Do **NOT** use AST if:

- You think your blood glucose is low.
- You are unable to notice symptoms of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are or may be pregnant.

How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

NOTE: We suggest that you rub the puncture site for about 20 seconds before taking your sample.

INTRODUCTION OF THE SYSTEM

Intended Use

The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples taken from the finger and the alternative sites including the palm, the forearm, the upper arm, the calf and the thigh. The system is intended for home use and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

Principle of Measurement

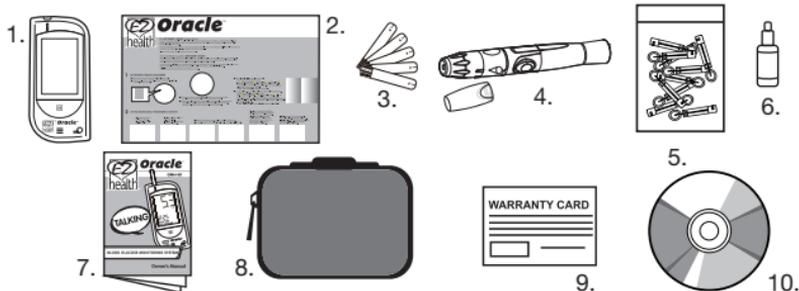
The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Contents of the System

The system should be used with three main products: the blood glucose meter, test strips, and a control solution. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only the EZ Health® Oracle® test strips and EZ Health® Oracle® or Autocode® control solution with your EZ Health® Oracle® meter.

Your system includes:

1. A meter
2. Your first time using guide
3. Test strips (sold separately)
4. Lancing Device with clear cap
5. 10 Sterile lancets
6. Control solution (Optional)
7. Owner's manual
8. Sporty carrying case
9. Warranty card
10. CD with Audio Guide and Software



PLEASE NOTE

- Check your system to be sure that it is unopened prior to use and that it contains all parts listed above. If either of these conditions occurred, please return your system to the place of purchase.
- Please note that strips and control solutions are optional. Those are not included in the standard kit. Please ask your local agent or call toll free 1(866) 829-7926 for help.

Appearance and Key Function of the Meter

TEST SLOT

The test slot is where you insert the test strip for testing. The meter will turn on automatically when you insert a test strip.

DISPLAY

Your test results are displayed here. The large, easy-to-read display guides you through the test using symbols and simple messages.

MAIN BUTTON

The main button in front of the meter is used to set up the meter, enter the memory mode, change the value of "date time", unit setting, memory deletion and turning the meter on and off.



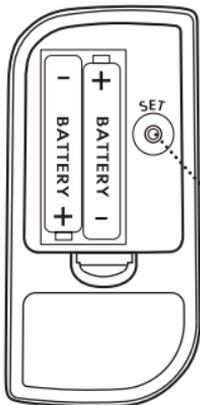
TALKING SYMBOL

Indicates that the meter contains speaking function.



DATA PORT

Located at the side, is for cable connection to the computer.



SET BUTTON

(in the back)
Set the date, time and unit, located in the battery compartment.

Meter Display Segments

Test Strip Symbol

Appears when the meter is on.

Blood Drop Symbol

This symbol tells you when to apply the sample.

Temperature Symbol

Appears with ambient temperature after inserting a test strip.

Face Symbol low/high

Both are result indicators. Face low symbol appears when test result is between 1.1 to 3.9 mmol/L.

Face high symbol appears when test result is greater than 10.0 mmol/L.

Date Time

CTL Symbol

Appears when performing a control solution test and indicates that the result will not be stored in the memory.

Day Average

Indicates that the displayed test result is an average.

Test Result Area

Test results are displayed here.

Voice Symbol

Indicates speaking function is on/off.

Battery Symbol

Appears when the battery is low.

Measurement unit

Appears with the test result in mmol/L.

Ketone Warning

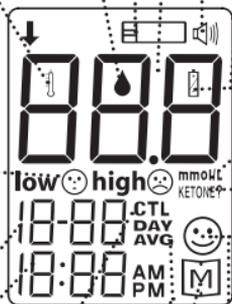
Appears when the test result is equal or higher than 13.3mmol/L.

Smile Symbol

Appears when the test result is within reference range.

Memory Symbol

Appears when you review the memory.



Speaking Function

When the talking symbol  is on the meter, it means that the meter provides speaking function. It “speaks” step by step and leads you through a blood glucose test. The following table tells you when and what the meter “speaks”.

WHEN does the meter say?	WHAT does the meter speak?
When meter is turned on.	Welcome music plays. “Thank you for using this product. Please relax during measurement.”
When room temperature is detected.	“The room temperature is (number) degree Celsius/ Fahrenheit.”
When room temperature is outside operating range.	“Room temperature is out of range, thus unable to measure.”
When the meter is ready to test. (“  ”symbol appears on display)	“Please apply blood into the strip.”
When the test is completed. (The result appears on display).	“Your blood glucose is (number) Millimole per Liter”
When the test result is outside measurement range, which is 1.1 to 33.3 mmol/L.	“The blood glucose is out of range, thus unable to measure.”

Appearance of the Test Strip

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:

Contact Bars

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

Test Strip Handle

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

Confirmation Window

This is where you confirm if enough blood has been applied to the absorbent hole of the strip.

Absorbent Hole

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



See pages 27~33, Testing Your Blood, for complete instructions.

PREPARATION BEFORE USE

Battery Replacement

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

The meter will alert you when the power is getting low by displaying two different messages:

1. The  symbol appears together with other display messages: the meter is functional and the result remains accurate, but it is time to change the batteries.



2. The  symbol appears with the flashing E-b symbol and "low": the batteries can not provide enough power to do a test. You must change the batteries immediately.

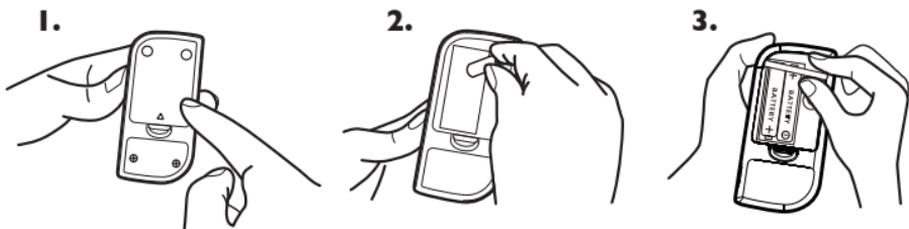


PLEASE NOTE

- Replacing the batteries does not affect the meter's memory (previous test results stored in memory). However, the time and date settings may need to be updated.
- Batteries might leak chemicals if not used 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).

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

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



WARNING

As with all small batteries, the batteries should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.

Setting the Meter and Deleting the Memory

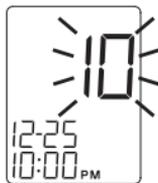
Year, month, date, time, unit of temperature, memory deletion, speaking volume and language selection preset. However if you replace the batteries, you may need to reset the settings of the meter.

Start with the meter off. Then press the Set button located in the battery compartment. The meter is now in the setting mode. You can start to set up the meter.



STEP 1 Set the Year.

The year will appear first, with the year segment flashing. Press and release the **M** button to advance one year. To move faster, keep pressing the **M** button until the desired number appears. With the correct year on the display, press the Set button and then the month segment flashes.



STEP 2 Set the Month

Press and release the **[M]** button until the correct month appears. To move faster, hold the **[M]** button down. With the correct month on the display, press the Set button and then the date segment flashes.

**STEP 3 Set the Date**

Press and release the **[M]** button until the correct day appears. To move faster, hold the **[M]** button down. With the correct day on the display, press the Set button and then the hour segment flashes.

**STEP 4 Set the Hour**

Press and release the **[M]** button to advance one hour. To move faster, hold the **[M]** button down. With the correct hour on the display, press the Set button and then the minute segment flashes.



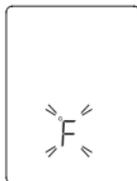
STEP 5 Set the Minutes.

Press and release the  button to advance one minute. To move faster, hold the  button down. With the correct minute on the display, press the Set button and then the current unit of temperature starts flashing.



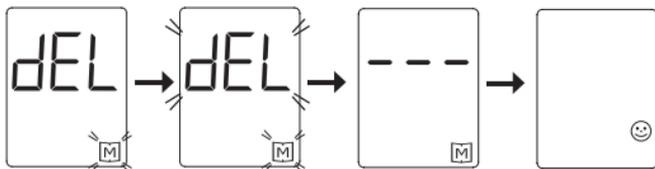
STEP 6 Select °F or °C

Press and release the  button to select the unit of temperature you want to use. Press the Set button and the meter will display "dEL" with flashing "" symbol.



STEP 7 Delete the Memory

When “dEL” and blinking “M” symbol is displayed, if you do not want to delete memory, press the Set button again to skip this step. If you would like to delete ALL memory, press M button, both “dEL” and “M” will flash. Press the M button again to delete ALL memory. “---” and “M” are displayed on the meter, following “☺” means that all data stored are deleted. The memory of this meter is empty now.



If your meter has a talking symbol (🗣️) on it, please press the Set button to proceed to the next step.

If not, you have completed the setting mode. Press the Set button to turn off the meter. “OFF” is displayed before shut down.

PLEASE NOTE

- The above settings can **ONLY** be changed in the setting mode. Therefore, when you perform a glucose testing, those parameters are not possible to be changed.
- Your meter displays 7-, 14-, 21-, 28-, 60- and 90-day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7-, 14-, 21-, 28-, 60- and 90-day preceding the current date and time settings. When the date and time are changed, the 7-, 14-, 21-, 28-, 60- and 90-day averages may change.
- While the meter is in the setting mode, if no button is pressed for 3 minutes, the meter will turn off automatically.

The memory of this meter is now empty.

STEP 8 Select Speaking Function

The meter displays “VOL”, “” and flashing number. Press the  button to select speaking volume from 0 to 7. Then press the Set button to proceed to the next step.

Number 0 indicates that the speaking function is turned off, where “” does not display on LCD during testing. Number 1 to 7 indicates speaking volume from low to high, where “” displays on LCD during testing.



STEP 9 Select Languages

L1/L2 and “” display on LCD. Your monitor can speak in one of two languages. Press the button to select. Select L1 for English, L2 for French. On some models, select L3 for Italian, L4 for Portuguese.



The setting model is all completed. Press the Set button to turn off the meter. “OFF” is displayed before shut down. The setting is completed.



Congratulations! You have finished setting your meter!

BEFORE TESTING

Checking with EZ Health[®] Oracle[®] or Autocode[®] Control Solutions

EZ Health[®] Oracle[®] and Autocode[®] control solutions contain a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, it is able to check that the meter and the test strips are working 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.

When should the control solution test be performed?

- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
- When your test strips are exposed to extreme environmental conditions (See **Storage** section of this manual).
- When you want to practice running the test.
- If you drop the meter.

Important Control Solution Information

- Use only EZ Health® Oracle® or Autocode® control solutions.
- Check the expiration date on the control solution vial. **Do not use if expired.**
- Control solution, meter, and test strips should come to room temperature (20-25°C/68-77°F) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Use only for 90 days after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.
- Store the control solution tightly closed at temperatures below 30°C (86°F). **Do not refrigerate.**

PLEASE NOTE

The control solution range printed on the test strip vial is for EZ Health® Oracle® or Autocode® control solution only. It is used to test meter and test strip performance. It is not recommended range for your blood glucose level. It is not the recommended range for your blood glucose level.

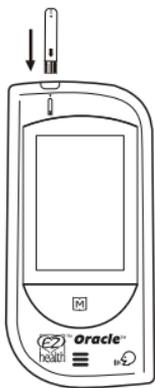
Performing a Control Solution Test

STEP I Insert the Test Strip

Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the followings in sequence:

“CH” and “” → ambient temperature

→ date, time and flashing “”

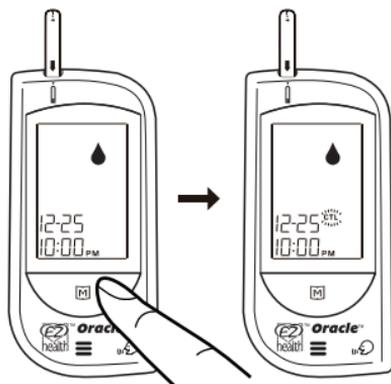


WARNING

- Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.
- Every time you perform a control solution test, you must enter into the “CTL” test mode so that the test result will not be stored in the meter memory. Failure to do so will confuse the blood glucose test result with the control solution test result in memory.

STEP 2 Press the **M** button

While the “**◆**” symbol appears on the display, press the **M** button and then “CTL” will appear on the display. With the “CTL” sign on the display, the meter will not store your test result in memory. If you decide not to perform a control solution test, press the **M** button again, and the “CTL” sign will disappear.



STEP 3 Obtain Control Solution.

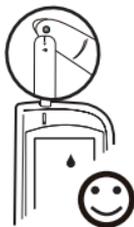
Shake the control solution vial well. Remove the cap. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to get another drop and place the drop on your fingertip first.



STEP 4 Apply Control Solution.

Move your finger (with control solution on it) to meet the absorbent hole of the test strip and the drop will be automatically drawn into the test strip. Remove your finger until the confirmation window is filled. The meter begins to count down.

To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface or on your finger tip first. Then touch the test strip to the drop.



STEP 5 Read and Compare the Result

After counting to 0, the test result of control solution is shown on the screen. Compare this result with the range printed on the test strip vial. It should fall within this range.



Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section of “**Problem in Operation**” in troubleshooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly. Do NOT test your blood. Contact your local Customer Care Line at 1(866) 829-7926 for help.

TESTING YOUR BLOOD

Be sure to read this section and the test strip package insert found in the test strip box carefully before testing. Make sure you have all items needed to test:

1. Blood Glucose Meter
2. Test Strip
3. Lancing Device
4. Sterile Lancet



WARNING

To reduce the chance of infection:

- Never share a lancet or the lancet device with anyone.
- 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 lancet device.

Testing Procedure

WASH AND DRY YOUR HANDS FIRST BEFORE STARTING.

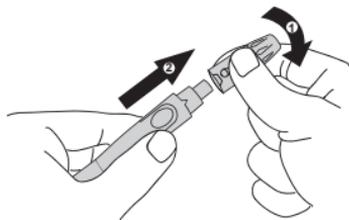
The EZ Health[®] Oracle[®] lancing device offers you 5 depths of skin penetration.



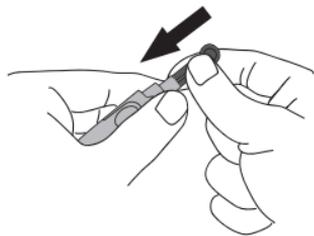
The longer the length of the indicator line, the greater the depth of penetration.

STEP I Setting up the EZ Health[®] Oracle[®] lancing device

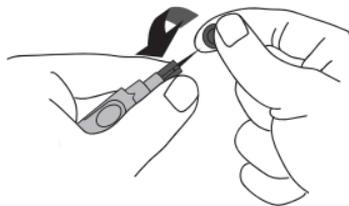
Twist and pull off the cap of the EZ Health[®] Oracle[®] lancing device.



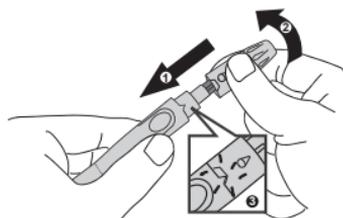
Insert a lancet into the lancet holder and push down firmly until it is fully secured.



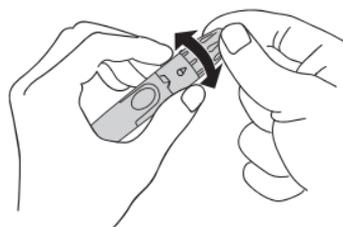
Twist the protective disk off the lancet.



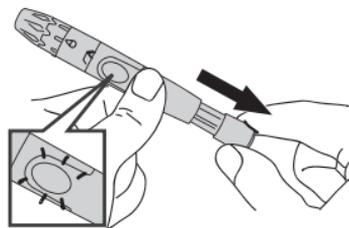
Replace the cap by aligning the arrow on the cap with the release button, and then push and turn the cap.



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.

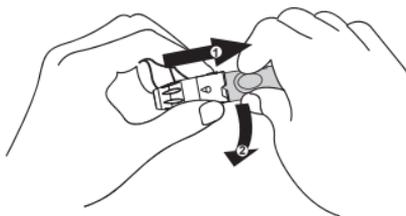


Pull the cocking control back until it clicks. You will see a color change inside the release button when it is ready. If it does not click the device may have been cocked when the lancet was inserted.



Blood from sites other than the fingertip

A clear cap, included with the kit, makes it easier to get a drop of blood for AST. When you want to obtain blood from sites other than the finger, **replace the lancing device cap with the clear cap.** Turn the clear cap until it is snug but not too tight, and then Slide the ejection/cocking control back until it clicks.



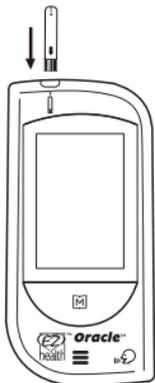
The lancing device is now ready for use. Set aside for later use.

STEP 2 Insert the Test Strip

Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the following in sequence:

“CH” and “” → ambient temperature

→ date, time and flashing “”



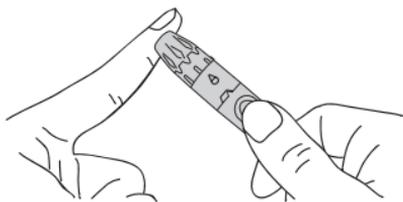
STEP 3 Get a Drop of Blood

Before collecting a drop of blood:

- Wash and dry your hands before you start.
- Select the puncture site either at the fingertip or another part of the body.
- Rub the puncture site for about 20 seconds before penetration.
- Clean the site using cotton swab moistened with 70% alcohol and let it air dry.
- For collecting blood samples from sites other than the fingertip, use the clear cap.

Lancing the finger

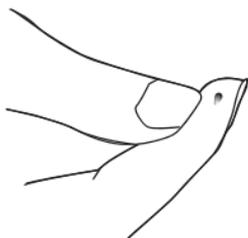
Press the EZ Health® Oracle® lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger. A click indicates that the puncture is complete.



• Sites other than fingertip

Please refer to the section of "**About AST**" for available puncture sites.

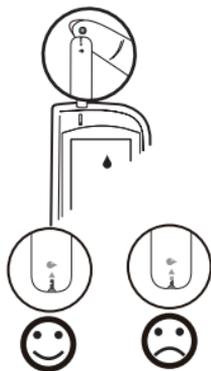
Remove the device from the puncture site. After penetration, remove the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample. Apply the blood to the test strip.



STEP 4

Apply blood into the test strip

When “” is flashing on the screen, apply your blood to the absorbent hole of the test strip until the confirmation window is **fully covered** with blood. The meter then begins to count down automatically.



STEP 5 Obtain an Accurate Result in 6 Seconds

The result of your blood glucose test is shown after the meter counts to 0. This reading is automatically stored in the meter.

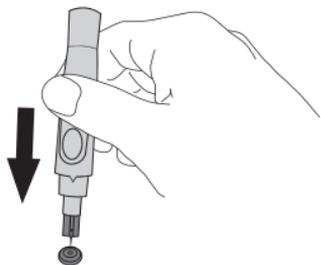


PLEASE NOTE

- Do not push your finger (with blood on it) against the test strip or try to apply a smeared sample on the test strip.
- 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 restart the test procedure.
- The blood should completely fill the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting, **NEVER** try to add more blood to the test strip. **Discard the test strip and retest with a new one.**
- If you have trouble filling the test strip, please contact customer service for help.

STEP 6 Remove the Lancet. Always use caution when removing the lancet.

To remove the lancet, pull the cap off. Place the protective disk on a hard surface, and push the exposed tip into the disk.



Slide the ejector forward to remove the used lancet. Dispose of the lancet according to your local regulations.



WARNING



The used lancet and the used test strip may potentially be a biohazard. Please discard it carefully according to your local regulations.

Expected Test Results

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that **keeping blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%*³. The results you get with the EZ Health[®] Oracle[®] system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Glucose range for people without diabetes	Your target range (mmol/L)
Fasting and before meal*	4.0 – 7.0 mmol/L	_____ (mmol/L)
2 hours after meals*	5.0 - 10.0 mmol/L (5.0 - 8.0 mmol/L if A1C targets not being met).	_____ (mmol/L)

* Source: CDA Clinical Practice Guidelines 2008

Treatment goals should be tailored to the individual. Glycemic targets for children less than or equal to 12 and pregnant women differ from these targets.

*³: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

Please work with your health care professional to determine a target range that works best for you.

COMPARING METER AND LABORATORY RESULTS

The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. (See test strip package insert for typical accuracy and precision data, and for important information on Limitations.) To make an accurate comparison between meter and laboratory results, follow the guide-lines below.

Before you go to the lab:

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

While at the lab:

Make sure that the samples for both tests (the meter test and the lab test 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 gray-top test tube.
- Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress*⁴. In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 3.9 mmol/L higher than blood drawn from a vein (venous sample) used for a lab test*⁵.

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 (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

*4: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

*5: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia:W.B. Saunders Company (1994), 959.

USING THE METER MEMORY

View Results on the Meter

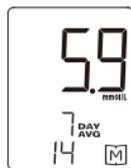
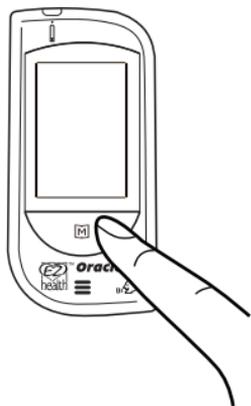
Your meter stores the 450 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14, 21, 28, 60 and 90-day averages of your blood glucose test results. You can review the test results in the memory with these easy steps.

STEP 1 Enter the Memory Mode

With the meter turned off, press the **M** button twice. The 7-day average will appear, indicating that you are in the memory mode. If you continue to press the **M** button, the 14, 21, 28, 60 and 90 day average will appear in order. You can then review the last 450 tests in the memory.

When using the meter for the first time, “---“ appears, showing that there are no 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., 14 (14 tests in the last 7 days).



The 14 day average is calculated from the blood glucose results obtained during the last 14 days. It also indicates how many blood glucose tests have been performed, e.g., 28 (28 tests in the last 14 days).



It is all the same for the 21, 28, 60 and 90 day average.

STEP 2 Recall Test Results

After the 90 day average, the most recent test result with date and time will be shown. Press the [M] button once and the next most recent test result will appear. Each time you press and release the [M] button, the meter will recall up to your last 450 test results in order. When the memory is full, the oldest result is dropped as the newest is added.



When reaching the last set of result, “End” and “M” will be shown on LCD display, and the meter will be turned off automatically.



STEP 3 Exit the Memory Mode

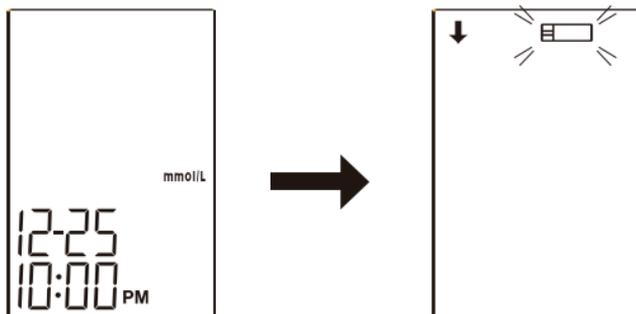
Keep pressing the M button for 5 seconds to turn off the meter.



PLEASE NOTE

The control solution results are **NOT** stored in the memory (please also go to page 24 **WARNING** for information). The list of past results and the result average are for blood glucose results only.

When pressing the  button to recall the test results, the meter will display date, time and the unit of measurement first. If you do not press the  button within 5 seconds, the blinking "" and "↓" will appear. In the meantime, you can choose to insert a test strip to start testing your blood or press the  button again to review the stored test results.



If no button is pressed for 2 minutes, the meter will show "OFF" and turn off automatically.

Viewing Results on a Personal Computer

Results in memory can be transmitted to a personal computer. An Interface Cable is required for data transmission, but is not included. Please ask your local agent or call toll free 1(866) 829-7926 for help. The software is available on the enclosed CD or can be downloaded from www.oraclediabetes.com.

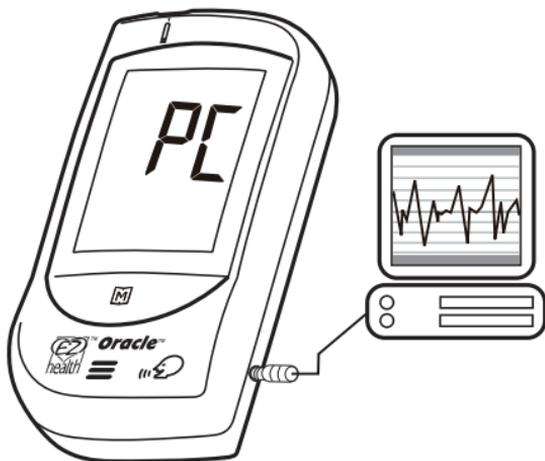
To learn more about EZ Health® Diabetes Management Software or to obtain an Interface Cable separately, please contact your local customer service.

Step 1 Installing Software

Install EZ Health® Diabetes Management Software on your computer by following the instructions provided in the user manual included on the CD or on EZ Health®'s website: www.oraclediabetes.com.

Step 2 Connect to Personal Computer

Connect the interface cable to the serial port in your computer. With the meter turned off, connect the Interface Cable to the Data Port of the meter. "PC" will appear on the display, indicating that the meter is ready to transmit data.





Step 3 Transmit Data

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

PLEASE NOTE

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

CARING FOR YOUR METER AND TEST STRIPS

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

Cleaning

Your meter does not require special maintenance. As no blood or control solution comes in contact with the meter, there is no special cleaning required.

1. 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.

2. Do not use organic solvents to clean the meter.

Storage

I. Meter Storage



- Storage condition: -20°C ~ 60°C below 95% relative humidity.
- Always store or transport the meter in its original storage case.

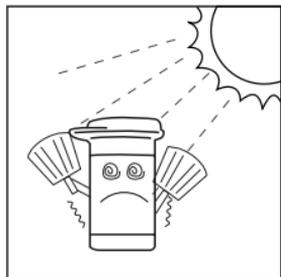


- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

2. Strip Storage



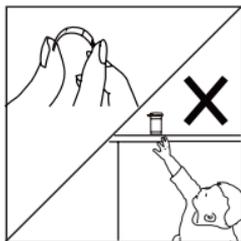
- Storage condition:
4°C ~ 40°C below 85% relative humidity.
Do not refrigerate.
- Store your test strips in their original vial only.
Do not transfer to other container.



- 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.
- Touch the test strip with clean and dry hands.

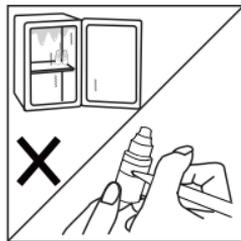


- Use each test strip immediately after removing it from the vial.
- Write the discard date (the date opened plus 90 days) on the vial label when you first open it. Discard remaining test strips 90 days after first opening date.



- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap may be a choking hazard. If swallowed, promptly see a doctor for help.

3. Control solution storage



- Storage condition: Store the control solution tightly closed at temperatures below 30°C (86°F). Do not refrigerate.
- Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.



PROBLEM-SOLVING GUIDE

Following is a summary of some display messages and symbols. These 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 message or a symbol. In the event of a problem, refer to the information under action.

Never try to disassemble the meter in any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended below but the problem remains unsolved, please call the customer service for support.

Result Indicator

Special symbols and messages appear together with your test result.

MESSAGE	WHAT IT MEANS
	😊 appears when your result is at reference range from 4.0 to 7.0 mmol/L
	low 😊 appears when your result is from 1.1 to 3.9 mmol/L. It indicates that the result is below reference range.
	Lo 😊 appears when your result is below measurement limit, which is less than 1.1 mmol/L.
Lo or low 😊 symbol indicates hypoglycemia (low blood glucose.) You should immediately treat hypoglycemia as recommended by your healthcare professional.	
	high 😊 appears when your result is greater than 10.0 mmol/L. It indicates that the result is higher than reference range.
	KETONE? appears together with high 😊 when your result is equal or higher than 13.3 mmol/L. This indicates there is a possibility of ketone accumulation if you are Type 1 diabetes. Please seek immediate medical assistance.
	H1 appears when your result is above measurement limit, which is higher than 33.3 mmol/L.

Error Message

MESSAGE	WHAT IT MEANS	ACTION
	Appears when the batteries can not provide enough power for a test.	Replace the batteries immediately.
	Appears when inserting a used test strip.	Test with a new test strip.
	Appears when ambient temperature is below system operation range.	System operation range is 10~40°C (50~104°F). Repeat the test after the meter and test strip have reached the above temperature.
	Appears when ambient temperature is above system operation range.	
	Remove the strip after applying blood to the absorbent hole.	Re-test with a new test strip.
	Problem with the meter.	Review the instructions and re-test with a new test strip. If the above steps do not work, please contact your local Customer Care Line at 1(866) 829-7926 for help.

Problem in Operation

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

PROBABLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Battery incorrectly installed or absent.	Check that the battery is correctly installed.
Test strip inserted upside down or incompletely.	Insert the test strip correctly with the contact bars end first and facing up.
Defective meter.	Please call your local Customer Care Line at 1(866) 829-7926 for help.

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

PROBABLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test with a new test strip and a larger sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic shutoff (3 minutes after last user action).	Repeat the test with a new test strip; apply sample only when “  <p>49</p>

3. If the control solution test result is out of range.

PROBABLE CAUSE	WHAT TO DO
Error in performing the test.	Read the instructions thoroughly and repeat the test again.
Did not shake the control solution vial very well.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date or the discard date of the control solution.
Control solution that is too warm or too cold.	Solution, meter, and test strips should come to room temperature (20-25°C/68-77°F) before testing.
Test strip deterioration.	Repeat the test with a new test strip.
Meter malfunction.	Contact your local Customer Care Line at 1(866) 829-7926 for help.

SPECIFICATIONS

Model No.: GMH-B1; GMH-B2

Dimension & Weight: 96mm(L) x 20mm(W) x 46mm(H), 69.87 g

Power Source: two 1.5V AAA alkaline batteries

Display: LCD

Memory: 450 measurement results with date and time averaging

Auto electrode inserting detection

Auto sample loading detection

Auto reaction time count-down

Sleeping Mode: Power consumption less than 80uA

Auto turn-off after 3 minutes without action

Temperature Warning

Operating Condition: 10°C~40°C, below 85% R.H. (noncondensing)

Storage/Transportation Condition: 4°C~40°C, below 85% R.H.

Measurement Unit: mmol/L

Measurement Range: 1.1~33.3mmol/L

Talking Function in both English and French

The device has been certified to meet the electrical and safety requirements of: IEC 60601-1, EN 60601-1, IEC 61010-1, EN 61010-1, EN 61010-2-101, EN 60601-1-2, EN 61326.

Warranty Registration Information

Customer Care

Call us with your Questions or Comments about your EZ Health[®] Oracle[®] Blood Glucose Meter. We are here to help. 9am-5pm EST., Mon-Fri.

Toll Free 1-866-829-7926 www.oraclediabetes.com or www.tremblayharrison.com

Important

Before using these products carefully read the owner's manual. For in vitro diagnostic use only. Store at room temperature below 86°F (30°C). Keep out of direct sunlight and humidity.

EZ PLUS[®] WARRANTY

Your EZ Health[®] Oracle[®] Blood Glucose monitor comes with the exclusive EZ PLUS[®] five year warranty. We warrant to the first retail purchaser that your EZ Health[®] Oracle[®] Blood Glucose monitor will be free from defects in material and workmanship for five years from the date of purchase.

The owner is required to submit a warranty card to Tremblay Harrison Inc. within sixty days of the original purchase. To obtain warranty service for such defects, return the Product, freight and insurance prepaid, together with satisfactory proof of date of purchase such as, a sales receipt or warranty card and shipping costs to:

Tremblay Harrison Inc., 1684 Dufferin Street, Toronto, ON, M6H 3M1.

Customers in Canada are asked to call Tremblay Harrison Inc. toll free at 1-866-829-7926. Customers may take the product to the retail location where the product was purchased.

Tremblay Harrison will repair or replace any Product found to be defective and return it to you. (Any replacement product may be new, refurbished or a different model.) This warranty will not apply if the defect or malfunction results from: subjecting the Product to any but the specified voltage; modification, alteration or repairs of the Product by persons not authorized by Tremblay Harrison Inc.; misuse, abuse, damage during transit or lack of reasonable care with respect to the Product; or failure to follow the written instructions enclosed with the Product. THE WARRANTY AND REMEDY PROVIDED ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN NO EVENT SHALL TREMBLAY HARRISON BE LIABLE FOR ANY LOSS, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, RESULTING FROM THE USE OR INABILITY TO USE THE PRODUCT, WHETHER RESULTING FROM BREACH OF WARRANTY OR ANY OTHER LEGAL THEORY, EVEN IF TREMBLAY HARRISON HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH INCONVENIENCE, DAMAGE OR LOSS.

Tremblay Harrison Inc. reserves the right to change the terms and conditions of this guarantee without informing the original purchaser.

The warranty is not transferable.

Manufactured by: Tremblay Harrison Inc. 1684 Dufferin Street, Toronto, ON. M6H 3M1
Toll free: 1-866-829-7926 www.tremblayharrison.com

Symbol	Referent
	In vitro diagnostic medical device
	Do not reuse
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by
	Date of manufacture
	Batch code
SN	Serial number
	Caution, consult accompanying documents
	Biological risks

