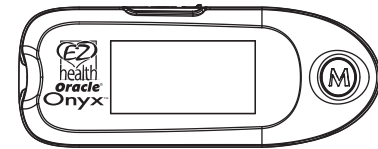Model GMH-B3   Version 1.1

EZ Health® Oracle® Onyx™

BLOOD GLUCOSE MONITORING SYSTEM

OWNER'S BOOKLET

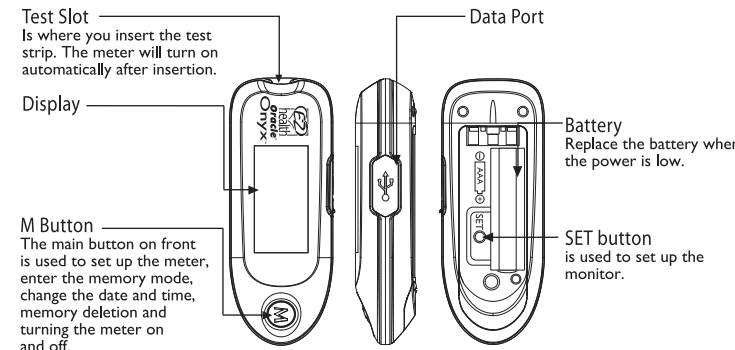## IMPORTANT SAFETY INSTRUCTIONS

READ BEFORE USE

Congratulations on purchasing the EZ Health® Oracle® Onyx™ Blood Glucose Monitoring System. The system consists of two main products: the meter and test strips. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Only use EZ Health® Oracle® (product code GMH-B1S550 or GMH-B1S100) test strips with your EZ Health® Oracle® Onyx™ Blood Glucose Meter.

IMPORTANT SAFETY PRECAUTIONS

*The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!

*All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

1."FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
2."CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Intended Use

This system is intended for external use (in vitro diagnostic use) by people with diabetes at home only. It is used for the quantitative measurement of glucose in samples of fresh capillary whole blood taken from the palm, forearm, upper arm, calf, thigh, or fingers. It is not intended to diagnose or screen for diabetes mellitus, or to be used on neonates. It is intended to be used by a single person and should not be shared.

This system provides you with whole blood equivalent results.
The standard kit for this system includes: ❶ EZ Health® Onyx™ Meter ❷ Owner's booklet ❸ Storage case
❹ Lancets ❺ Warranty card ❻ EZ Health® Oracle® Lancing device with a clear cap
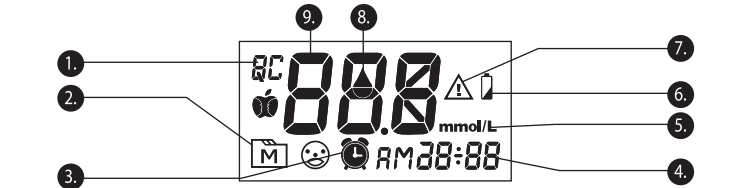
NOTE
Check your system to ensure that it is unopened prior to use and that it contains all parts listed above. If anything is missing or damaged, please return your system to the place of purchase.

APPEARANCE AND KEY FUNCTIONS OF THE METER

Test Slot
Is where you insert the test strip. The meter will turn on automatically after insertion.

Display

M Button
The main button on front is used to set up the meter, enter the memory mode, change the date and time, memory deletion and turning the meter on and off.

Data Port

Battery
Replace the battery when the power is low.

SET button
is used to set up the monitor.

METER DISPLAY

❶ Measuring Mode

❷ Memory
Indicates a test results stored in memory.

❸ Alarm

❹ Month/Day/Hour/Minute

❺ Measurement Unit
The measurement unit is fixed as mmol/L.

❻ Battery Symbol
Appears when the battery is low.

❼ Error Warning
Appears with error message.

❽ Blood Drop Symbol
Flashes when meter is ready for sample application.

❾ Test Result Area
Test results are displayed here.

GMH-B1S100 or GMH-B1S50 TEST STRIPS

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole on 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 in the strip.

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

CHECKING THE SYSTEM WITH CONTROL SOLUTIONS

Our control solutions contain a known amount of glucose that reacts with test strips. By comparing the result of your control solution test with the expected range printed on the test strip vial label, you can check that the meter and the test strips are working together as a system and that you are performing the test correctly. Use only EZ Health® Oracle® or EZ Health® Autocode® control solutions.

HOW TO PERFORM A CONTROL SOLUTION TEST

STEP1. Insert Test Strip

Insert a test strip into the test port with the contact bars end first and facing up. (Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.) The meter turns on automatically and displays the following in sequence:

LCD full display ⟶ CHK ⟶ flashing " 🩸 "
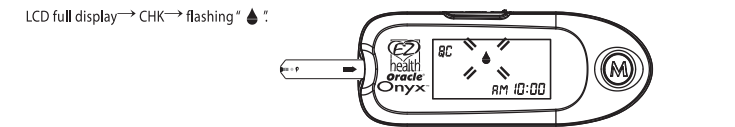
When the " 🩸 " symbol appears on the display, press ⓜ and "QC" will appear on the display. When the "QC" sign is displayed, the meter will store your test result in memory under "QC". If you decide not to perform a control solution test, press ⓜ again and the "QC" sign will disappear.
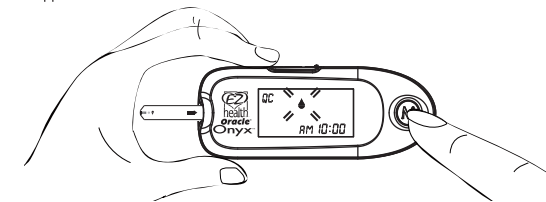
CAUTION
When doing a control solution test, you have to mark it so that the test result will NOT be included with the blood glucose TEST RESULTS stored in the memory. Failure to do so will mix the control solution test results with the blood glucose test results in memory.

STEP2. Apply Control Solution

Shake the control solution vial well. Remove the cap from the control solution bottle. Place the cap on a flat surface. Squeeze the bottle, discard the first drop, and wipe the dispenser tip clean to prevent contamination. Squeeze the bottle again to get another drop and place this drop on top of the cap.
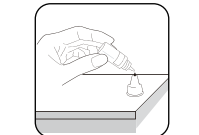
Hold the meter to touch the drop with the test strip's absorbent hole and the drop will automatically drawn into the test strip. Make sure the confirmation window is completely filled. The meter begins to count down.
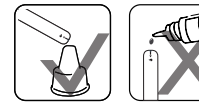
CAUTION
To avoid contaminating the control solution with the content of the test strip, it is recommended that you discard the first drop and place another drop of control solution on a clean surface first. Then touch the drop with the test strip.

STEP3. Check Results

After the meter counts to 0 the result of the control solution test will appear. Compare the result with the range printed on the test strip vial. The result should fall within this range.

THE FOUR MEASURING MODES

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

Modes	Use when
General (not display)	Any time of day without regard to time since last meal
AC	No food intake for at least 8 hours
PC	2 hours after a meal
QC	Testing with the control solution

You can switch between each mode by:
1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing blood drop.

2. Press ⓜ to switch between General, AC, PC and QC mode.
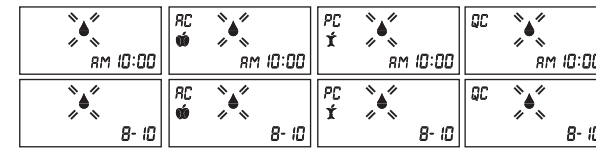
TESTING YOUR BLOOD

Before testing, be sure to read this section and the test strip insert found in the test strip box carefully. Make sure you have all the items needed for the test.

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** rely on test results at alternative sampling site, but use samples taken from the fingertip, if any of the following applies:
• You think your blood sugar is low.
• You are not aware of symptoms when you become hypoglycemic.
• The site results do not agree with the way you feel.
• After a meal.
• After exercise.
• During illness.
• During times of stress.
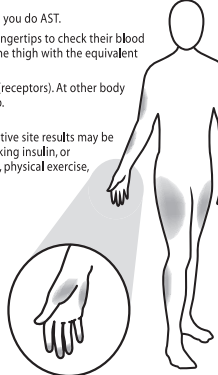
Warning:
To reduce the chance of infection:
*The meter and lancing device are for single use. Never share a lancet or the lancing device.
*Always use a new, sterile lancet. Lancets are for single use only.
*Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
*Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the "Cleaning and Disinfection" section.
*If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.
Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Lancing device must not be used for more than one person.

STEP1. Insert Test Strip
Insert the test strip into the test slot with the contact bars end first and facing up. The bars must be fully inserted into the port for an accurate result. The meter turns on automatically and displays the blood drop symbol.

LCD full display
⟶ CHK
⟶ flashing " 🩸 "
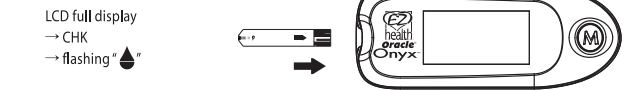
STEP2. Select the appropriate measurement mode by pressing ⓜ .
For selecting the measurement mode of AC, PC, or Gen, please refer to the "FOUR MEASURING MODES" section.

STEP3. Apply Blood Sample
Obtain a drop of blood of at least 0.7 μL using a lancing device. Use the clear cap for sites other than fingers and refer to the strip package insert for more details.

When the " 🩸 " symbol appears on the display, touch the drop of blood with the absorbent hole of the test strip. Do not rub the test strip with your finger or try to apply a smeared sample.
The blood should completely fill the confirmation window before the meter begins to count down. If the confirmation window is not filled completely before the meter begins to count down, do not add more blood to the test strip. Discard the test strip and start again. If you have trouble filling the test strip, please call your local customer service number for assistance.

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.
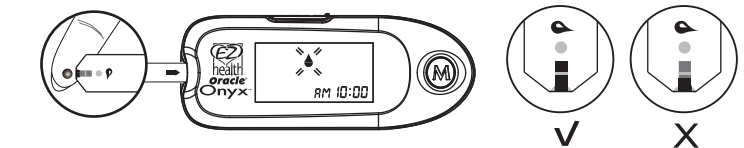
NOTE
If you do not apply a blood sample within 3 minutes, the meter will turn itself off. You must remove the test strip and insert it back into the meter to restart the test.

STEP4. Get Result
The result of your blood glucose test will appear after the meter counts to 0. Blood glucose test results are automatically stored in the meter's memory.

Warning:
Please do not change your treatment based on the result without first consulting your health care professional.

Turn the meter off by removing the test strip. Discard the used test strip and lancet carefully according to your local regulations.

NOTE
The meter will turn off automatically after 180 seconds without any action or you can press and hold the ⓜ button for 3 seconds to turn off the meter.
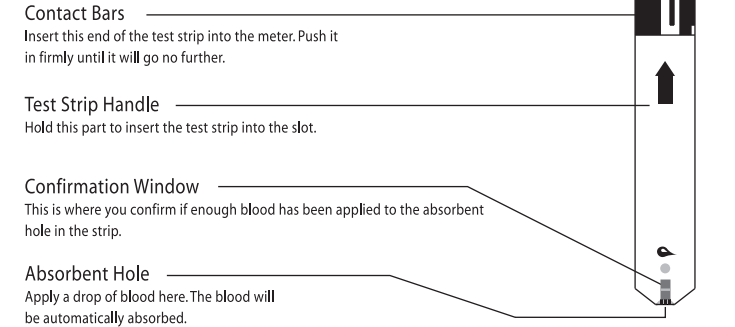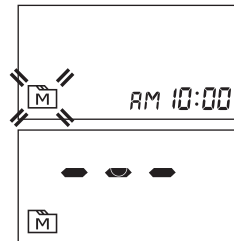
USING THE METER MEMORY

Viewing Results

Your Meter stores the 150 most recent blood glucose test results with date and time in its memory. You can review the test results with these easy steps.

STEP1. Enter the Memory Mode

With the meter turned off, press M twice. The first test result will appear, indicating that you are in the memory mode. If you continue to press M, you can then review the last 150 tests in the memory.

When using the meter for the first time or if the results have been deleted, "---" will appear, indicating that there are no test results in the memory.

STEP2. Recall Test Results

After the last test result, the most recent test result appears with the date and time. Press M to review your last 150 test results in order. When the memory is full, the oldest result will be deleted when the newest is added.

STEP3. Exit the Memory Mode

Press M for three seconds to turn off the meter.
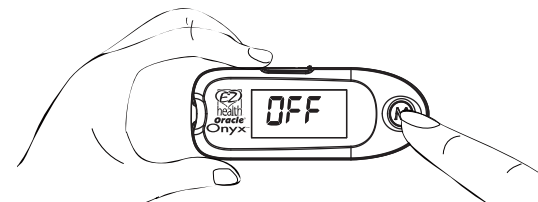
SETTING THE METER AND DELETING THE MEMORY

Start with the meter off. Then press the SET button located on the back. The meter is now in the setting mode.

STEP1. Set the Year

The year will appear first, with the year flashing. Press and release M to add one year. To go faster, press M down longer. Once the correct year is displayed, press the SET button and the date will appear on the display with the month segment flashing.
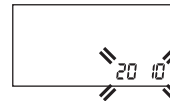
STEP2. Set the Month

Press and release M until the correct month appears. To go faster, press M down longer. Once the correct month is displayed, press the SET button and the day will flash.
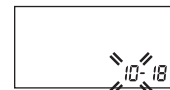
STEP3. Set the Day

Press and release M until the correct day appears. To go faster, press M down longer. Once the correct day is displayed, press the SET button and the time will appear on the display with the hour flashing.
*To set the time, you must first set the date.

STEP4. Select 12h or 24h clock

Press and release M to select the 12h or 24h clock. These are different time presentation formats. If you select 12h, AM and PM will be shown alongside the time. If you select 24h, the time format will be from 00:00 to 23:59 without showing AM or PM.
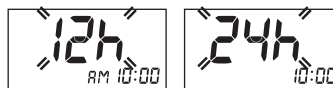
After you have finished selecting the 12h or 24h clock, press the SET button and then the hour will flash on the screen.

STEP5. Set the Hour

Press and release M to add one hour. To go faster, press M down longer. Once the correct hour is displayed, press the SET button and the minute will flash.
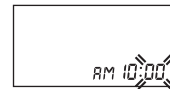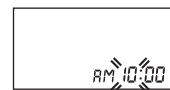
STEP6. Set the Minute

Press and release M to add one minute. To go faster, press M down longer. Once the correct minute is displayed, press the SET button to enter the memory deleting mode.

STEP7. Delete Results

With the "no" symbol flashing on the display, you can easily delete all the results stored in the memory by pressing M once. The meter will display "yes". Then press the SET button to delete all the results and "---" will be displayed.

If you do not want to delete the results, do not press M but press the SET button again to enter the alarm setting.

STEP8. Setting the Reminder Alarm

You may set up any or all of the reminder alarms (1-4). The meter displays "On" or "OFF" and, press M to turn on or off to set the first reminder alarm.

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

If you do not want to set an alarm, press SET to skip this step.
If you want to turn off an alarm, find the alarm number by pressing SET in the setting mode, press M to change from "ON" to "OFF".
At the time of your alarm, the meter will beep and automatically turn on. You can press M to silence the alarm and insert a test strip to begin testing. If you do not press M, the meter will beep for 2 minutes then switch off. If you do not want to test at this time, press M to switch off the meter.

DOWNLOADING RESULTS ONTO A COMPUTER

You can use the meter with a USB cable and the EZ Health® Diabetes Management Software System to view your test results on your personal computer. To obtain a USB cable, please contact us or the place of purchase for assistance.

1. Installing the software

To download the EZ Health® Diabetes Management Software, please visit our Control Your Health® Program on our website at http://www.oradediabetes.com

2. Connecting to a personal computer

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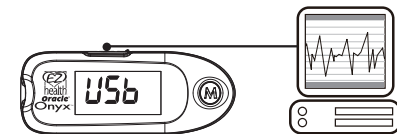
3. Data transmission

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

WARNING

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

CARING FOR YOUR METER

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

Cleaning

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

Meter Storage

• Always store or transport the meter in its original storage case.
• Avoid dropping and heavy impact.
• Avoid direct sunlight and high humidity.

CARING FOR YOUR TEST STRIPS

• Storage conditions: 4°C to 40°C (39.2°F to 104°F), below 85% relative humidity. Do not freeze.
• Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
• After removing a test strip from the vial, immediately close the vial cap tightly.
• Touch the test strip with clean and dry hands.
• Use each test strip immediately after removing it from the vial.
• Write the opening date on the vial label when you first opened it. Discard remaining test strips after 3 months.
• Do not use test strips beyond the expiry date. This may cause inaccurate results.
• Do not bend, cut, or alter a test strip in any way.
• Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

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

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

The following is a summary of display messages. If your meter displays an error message, please follow the actions for the error message as described in the table below. If the problem persists, please contact your local customer service agent for help.

Message	What it means	Action
E-b	The symbol appears with this message. This means that the battery does not have enough power for a test.	Replace the battery immediately.

Message	What it means	Action
E-U	A used test strip is inserted.	Repeat test with a new test strip. If the error message re-appears, please contact your local customer service agent for help.
E-t	The temperature of the environment, meter, or test strip is outside the system's operating range. You cannot perform a test until the meter and test strip are within the operating range of 10°C–40°C (50°F–104°F).	Repeat the test after the meter and test strip are within the operating temperatures.
E-E	Problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists, please contact your local customer service agent for help.
E-F	You may have removed the strip after applying blood to the absorbent hole.	Keep the test strip in the meter after it has absorbed the blood until the meter displays the test result.
E-A	System error.	Contact your local customer service agent for help.

MESSAGE	WHAT IT MEANS		
Lo	Appears when glucose < 1.1mmol/L		
☺	AC ⏰ Appears when glucose is 4.0-7.0 mmol/L	PC ⏱ Appears when glucose is 5.0-10.0 mmol/L	Gen Appears when glucose is 4.0-10.0 mmol/L
☹	AC ⏰ Appears when glucose is 1.1-3.9 and 7.1-33.3 mmol/L	PC ⏱ Appears when glucose is 1.1- 4.9 mmol/L and 10.1-33.3mmol/L	Gen Appears when glucose is 1.1- 3.9mmol/L and 10.1-33.3mmol/L
Hi	Appears when glucose > 33.3mmol/L		

For questionable results, please see test strip package insert for important information.

SPECIFICATIONS

Dimension: 93(L) x 36(W) x 21.3(H) (mm)
Weight: 45.4 g (including battery)
Power source: One AAA alkaline battery (for at least 500 measurements)
Display: LCD
Memory: 150 measurement results with date and time
Automatic detection of electrode insertion
Automatic reaction time count-down
Temperature warning
Operating conditions: 10°C–40°C (50°F–104°F), below 85% R.H.
Storage/transport conditions: -20°C– 60°C (-4°F–140°F), below 95% R.H.
Measurement units: mmol/L
Measurement range: 1.1–33.3 mmol/L

When the battery is low, you can still do up to 50 tests.

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

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
IVD	In vitro diagnostic medical device		Manufacturer
②	Do not reuse	SN	Serial number
🕮	Consult instructions for use		Do not use if package is damaged.
☀	Keep away from sunlight	⚠	Caution, consult accompanying documents
☂	Keep dry		Use within 3 months after opening
🌡	Temperature limitation	STERILE R	Sterilized using irradiation
⧖	Use by		
LOT	Batch code		

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M6H 3M1

Toll Free: 1-866-829-7926

For self-testing

311-4235300-001