



Use only with EZ Health® Oracle® GMH-B1, GMH-B2 and EZ Health® Oracle® Onyx™ GMH-B3 Blood Glucose Meter

### Patient Cautions:

- For in-vitro diagnostic use (external use only)
- Healthcare professionals and other users testing multiple patients with this system should handle everything that has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please review this instruction sheet and the Owner's Manual before you use EZ Health® Oracle® Test Strips. For reliable results and to maintain the manufacturer's complete service, support, and warranty, use EZ Health® Oracle® Test Strips only.
- 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.
- As with all small parts, the test strips and lancets should be kept away from small children who put things in their mouths. If they are swallowed, promptly see a doctor for help.

### For Home Use:

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

### Intended Use

EZ Health® Oracle® Test Strips and the EZ Health® Oracle® and EZ Health® Oracle® Onyx™ Blood Glucose Meters are used to measure the concentration of blood glucose by self testing for professional and home use. Routine blood glucose (sugar) testing with the EZ Health® Oracle® Blood Glucose Monitoring System or EZ Health® Oracle® Onyx™ Blood Glucose Monitoring System can provide you and your qualified healthcare professional with information on how your treatment program affects your blood glucose level. Testing blood glucose regularly can help keep your diabetes under control. Blood glucose management should be done in conjunction with advice from your qualified healthcare professional.

### Storage and Handling

In order to ensure that your test strips work properly, please use them according to the following recommendations. **IMPORTANT:** Do not use the test strips after expired or results will be inaccurate.

To keep your test strips in the best possible condition, please follow the recommendations below:

- Test strips expire 90 days after opening. Write the expiry date on the test strip vial when it is first opened.
- Store the test strips in a cool, dry place between 4°C and 40°C (39.2°F and 104°F) and below 85% relative humidity. **Do not freeze.**
- Use test strips at temperature between 10°C and 40°C (50°F and 104°F), and less than 85% humidity.
- Keep the test strips away from direct sunlight. Do not store the test strips in areas of high humidity.
- Test strips must be stored in their original vial ONLY. Do not transfer them to a new vial or other container.
- Do not touch the test strips when your hands are wet.
- Use each strip promptly after removing it from the vial. Close the vial lid quickly after removing a new strip.
- Keep the vial lid closed at all times.
- Do not bend, cut or alter the test strip. Doing so will lead to inaccurate results.

### How it Works

EZ Health® Oracle® Test Strips provide a quantitative measurement of glucose in whole blood. The absorbent hole fills automatically when contact is made with a drop of blood through simple capillary action. The blood is drawn into the absorbent hole and its glucose level is read by the meter. Results are displayed on the blood glucose meter. Only 0.7 µL of blood is required and the reaction time is 7 seconds. EZ Health® Oracle® Test Strips detect glucose levels from 1.1 to 33.3 mmol/L.

### Sample Collection

Test strips should be used with a fresh capillary whole blood sample. For best results it is recommended that you read the following procedure and the Owner's Manual before you obtain a blood sample. PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.

CAUTION: Lancing devices should never be used for more than one person. Only auto-disabling, single use lancing devices should be used for assisted blood glucose monitoring in multiple patients.

### Get a drop of blood from the finger

1. Wash your hands and the puncture site. Rinse and dry yourself thoroughly. If you use an alcohol swab, ensure that the puncture site is completely dry prior to obtaining a sample.
2. Lance the puncture site to obtain a drop of blood. You may massage or gently squeeze the area in order to obtain the required amount of blood. Do not squeeze the puncture site excessively.

### Alternative site testing (off-finger)

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. EZ Health® Oracle® Test Strips allow you to test on the palm, the forearm, the upper arm, the calf, and the thigh with the equivalent results to fingertip testing. Please read the Owner's Manual first before you do AST.

We strongly recommend that 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.

### Please rub the puncture site for about 20 seconds before getting a drop of blood.

**IMPORTANT: There are limitations for doing AST. Please read the Owner's Manual and consult your healthcare professional before you do AST.**

1. 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).
2. **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

### Blood Glucose Testing

1. Fully insert the test strip into the meter with the contact bars end first. The meter turns on automatically and then displays the blood drop symbol.
2. Get a drop of blood according to "sample collection" section. It requires at least 0.7 microliters (µL) blood for a correct reading.
3. Hold the blood drop to the absorbent hole of the test strip until blood has completely filled the confirmation window.
4. The meter counts down and then displays a result. The reading is automatically stored in the meter memory.
5. Shut down the meter by removing the strip. Discard the used strip.

Please also consult the Owner's Manual for detailed directions and illustrations.



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

### Quality Control (QC) Testing

QC Testing should 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 inaccurate.
- When your test strips are exposed to extreme environmental conditions (See Storage and Handling section of this package insert)
- When you want to practice running the test.
- If you drop the meter.

EZ Health® Oracle® or Autocode® CONTROL SOLUTION is used to check testing technique and system performance. Three levels of glucose control solution (low, normal, and high) can be used with the EZ Health® Oracle® Monitoring System or Oracle® Onyx™ Blood Glucose Monitoring System. By comparing your control solution test results with the expected range printed on the test strip vial label, you are able to check that the meter and the test strips are working together as a system and that you are performing the test correctly. The control range can be found on the test strip vial label. Read the Owner's Manual for complete testing details. **IMPORTANT:** The control range can change with each new vial of test strips. Always use the control range on the label of your current vial of test strips.

### Test Results

Your blood glucose test results are displayed in millimoles of glucose per liter of blood (mmol/L).

The meter is able to display test results between 1.1 to 33.3 mmol/L.

If your result is below 1.1 mmol/L, the meter will display "Lo". This indicates very low blood glucose levels or severe hypoglycemia. Repeat your test with a new strip and immediately seek help from your healthcare professional.

If your results are above 33.3 mmol/L, the meter will display "Hi". This indicates very high blood glucose levels, or severe hyperglycemia. Repeat your test with a new strip and immediately seek help from your healthcare professional.

### Reference values:

Time of day	Glucose range for most people with diabetes
Fasting and before meal*	4.0 - 7.0 mmol/L
2 hours after meals*	5.0 - 10.0 mmol/L (5.0 - 8.0 mmol/L if A1C targets not being met).

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

\* Source: CDA Clinical Practice Guidelines 2013  
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.

### Questionable or Inconsistent Results

If you are receiving test results that are unusual or inconsistent with how you are feeling:

- Make sure that the drop of blood completely fills the test area of the test strip.
- Confirm that the test strips are not past their expiration date.
- Check the performance of the meter and test strips using the control solution.

Please keep in mind that high or low blood glucose levels can indicate a possibly serious medical condition. If you continue to get results that are unusually high or low, consult your healthcare professional.

### Test principle

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.

### Chemical components of strip

Glucose oxidase (A. niger)..... 10%  
 Electron shuttle..... 50%  
 Enzyme protector.....8%  
 Non-reactive ingredients.....32%

### Limitations

**Hematocrit:** Below 20% or above 60% hematocrit levels can cause false results. Please consult your healthcare professional if you do not know your hematocrit level.

**Neonatal Use:** The test strips should not be used for the testing of newborns.

**Metabolites:** Ascorbic acid at normal blood concentration does not significantly affect glucose readings. High concentrations of acetaminophen, dopamine, L-Dopa, methyl dopa and uric acid may cause inaccurate test results. Blood glucose readings should be interpreted with caution.

**Lipemic Effects:** Elevated blood triglycerides up to 2000 mg/dL do not significantly affect the results. However, the glucose test may be affected beyond these levels.

**Do not use iodoacetic acid or fluoride as a preservative for blood specimens. Use only fresh capillary whole blood. Do not use serum or plasma.**

**Altitude Effects:** Test strips may be used at altitudes up to 10,742 feet (3,275m) without an effect on test results.

### Performance characteristics

#### Accuracy

Within ±0.83 mmol/L (15 mg/dL) at glucose concentration < 5.5 mmol/L (100 mg/dL) and within ±15% at glucose concentration > 5.5 mmol/L (100 mg/dL).

Studies were conducted using capillary blood and the regression analysis results are as below:

Comparison	N	Slope and y-intercept	r
Oracle® GMH vs. YSI-2300	960	y = 1.0063x - 3.5936	0.9764

### Precision

CVs (%) of intermediate precision and repeatability were less than 5%.

Within-day and day-to-day precision was evaluated and the results were as follows:

Within-day Precision					
Interval (mmol/L)	1.7-2.8	2.9-6.1	6.2-8.3	8.4-13.9	14.0-22.2
Mean	2.3	4.3	8.1	11.9	17.6
SD	0.11	0.18	0.25	0.36	0.60
CV	4.77%	4.24%	3.03%	3.03%	3.39%

Day-to-Day Precision			
Interval (mmol/L)	3.4-5.2	6-9	14.4-21.7
Mean	4.2	7.2	17.1
SD	0.17	0.20	0.50
CV	4.17%	2.81%	2.90%

### The product has been tested to meet the requirements of ISO 15197:2013.

For visually impaired persons assistance from sighted individuals will be required for meter set-up and training, control solution measurements, understanding some errors of the blood glucose meter, expiration date verification for test strips and control solutions, and alternate site testing (particularly the use of a clear cap on the lancing device).

### Symbol Information

Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Batch code
	Do not reuse		Manufacturer
	Consult instructions for use		Serial number
	Keep away from sunlight		Caution, consult accompanying documents
	Keep dry		Do not use if package damaged
	Temperature limitation		Use within three months after first opening
	Use by		

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For self-testing.



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