

Oracle[®] for Cats and Dogs

Blood Glucose And β -Ketone Monitoring System (Product code: GMP-A1)
For Veterinary Use Only.

Owner's Manual

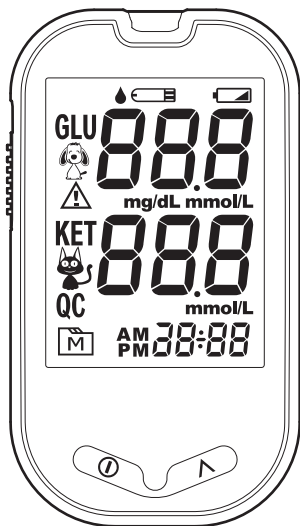


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Dear Oracle® for Cats and Dogs System Owner:

Thank you for choosing the **Oracle® for Cats and Dogs** Blood Glucose and β -Ketone Monitoring System. This manual provides important information to help you use the system properly. Before you begin, please read the following contents thoroughly and carefully. If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Purpose

This system is intended for the quantitative measurement of blood glucose and β -ketone in fresh capillary whole blood. It should not be used for the diagnosis or screening of diabetes mellitus. It allows cat and dog blood glucose and β -ketone levels to be measured by their owners for self-testing and by veterinary professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control in the animal.

The meter provides you with plasma equivalent results.

Professionals may test with capillary and venous blood sample from paw pad and marginal ear. Self-testing is limited to capillary whole blood testing.

Warnings and Precautions

Please read the following carefully before use:

1. For Veterinary use only.
2. For Cats and Dogs use only.
3. Use this device only for the intended use described in this manual.
4. Do not use accessories that are not specified by the manufacturer.
5. The **Oracle® for Cats and Dogs** Blood Glucose And β -Ketone Monitoring System (Product code: GMP-A1) should only be used with **Oracle® for Cats and Dogs** test strips. (Product code: GMP-A1S50 / KMP-A1S50) Using other test strips with this meter can produce inaccurate results.
6. Do not use the device if it is not working properly or is damaged.
7. This device does not serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult a veterinarian to have the results interpreted.
8. Keep the device and testing equipment away from children. Small

parts such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.

9. The presence of synthetic materials (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
10. Do not use this instrument in close proximity to sources of strong electromagnetic radiation as these may interfere with the accuracy of operation.
11. Remove the battery from the unused meter to avoid battery leakage.
12. Proper maintenance and control solution tests are essential to the longevity of your device. If you are concerned about the accuracy of measurement, please contact local customer service or place of purchase for assistance.
13. Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe your pet is suffering from severe dehydration, consult a veterinarian professional immediately.
14. If your pet's blood glucose results are lower or higher than usual, and they do not have any symptoms of illness, first repeat the test. If they have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of a veterinarian professional.
15. Use only fresh whole blood samples to test your pet's blood glucose. Using other substances will lead to incorrect results.
16. If your pet is experiencing symptoms that are inconsistent with their blood glucose test results and you have followed all the instructions given in this owner's manual, contact a veterinary professional.
17. We do not recommend using this product on severely hypotensive pets or those in shock. Please consult a veterinary professional before use.
18. Your meter can measure in either mg/dl or mmol/l. Ensure your meter is set to desired measurement unit before using.

Lancing Device and Lancet

1. Possible skin infection present at the sample site.
2. Never share a lancet and the lancing device.
3. Do not reuse lancets. Always use a new, sterile lancet for testing.

The used lancet may potentially be biohazardous. Discard it according to your local regulations.

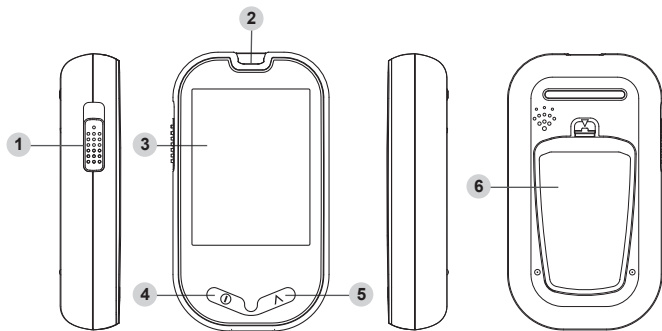
4. Always keep the lancing device and the lancet with all its components away from children.
5. Do not use if the sterile lancet package is damaged.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Product Overview

The contents included in the kit depend on the package. Check the components in the kit and quantity of each item. Test strips, control solution, sterile lancets and lancing device may be purchased separately. Please make sure you have all items needed for a test beforehand. If any item is missing or damaged, contact customer service for assistance.

Meter



1 Test Strip Ejector

Eject the used strip by pressing this button.

2 Test Strip Slot with Strip Indication Light and Data Port

Insert test strip here to turn the meter on for testing. Or insert the cable for data transmission.

3 Display Screen

4 Main Button (M)

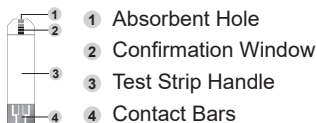
Enter the meter memory and adjust value.

5 Up Button (▲)

Enter the meter memory and choose Dog / Cat mode.

6 Battery Compartment

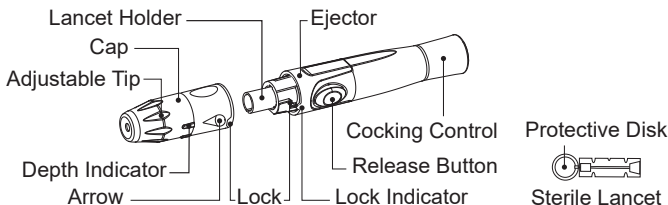
Test Strip



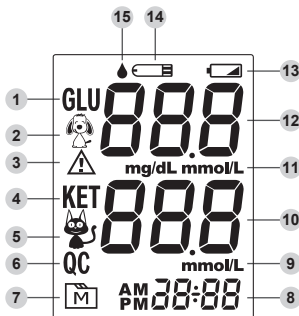
Control Solution



Lancing Device and Lancet (For self-testing)



Display Screen



- | | |
|------------------------------------|---|
| 1 Blood Glucose Symbol | 2 Dog Mode |
| 3 Error Message | 4 β -Ketone Symbol |
| 5 Cat Mode | 6 QC Mode
QC – control solution test |
| 7 Memory Mode | 8 Date / Time |
| 9 β -Ketone Measurement Unit | 10 β -Ketone Test Result |
| 11 Blood Glucose Measurement Unit | 12 Blood Glucose Test Result |
| 13 Low Battery Symbol | 14 Test Strip Symbol |
| 15 Blood Drop Symbol | |

Before Testing

Get all accessories ready and follow the preparation steps below before testing.

Setting the Meter

Before using this meter for the first time or if you change the meter batteries, you should check and update these settings.

Entering the Setting Mode

Start with the meter off (no test strip inserted). Press and hold **M** and **▲** at the same time for 3 seconds. The following settings are set up in sequence:

1. Date

With the YEAR / MONTH / DAY flashing in sequence, press **▲** to select the number. Press **M**.

2. Time format and time

Press **▲** to select the desired time format (12h or 24h). Press **M**.

With the HOUR / MINUTE flashing in sequence, press **▲** to select the number. Press **M**.

3. Measurement unit of blood glucose (GLU)

Press **▲** to select desired measuring unit. Press **M**.

4. Beep

With the beep displayed, press **▲** to switch between “On” and “OFF”. Press **M**.

5. Memory clearing

With “dEL” and “

Prepare the Lancing Device for Blood Tests

To set up the lancing device, you need: lancing device and lancet.

1. Twist and pull off the cap of the lancing device.
2. Insert a lancet into the lancet holder of lancing device and push down firmly until it is fully secured.
3. Twist off the protective disk of the lancet.
4. Replace the cap onto the lancing device.
5. Hold the cap and select the depth of penetration by turning the adjustable tip. The longer the length of indicator line, the greater the depth of penetration.
6. 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.

Perform Blood Tests

Before collecting a drop of blood

- ♦ Wash and dry your hands before you start.
 - ♦ Rub your pet's puncture site for about 20 seconds before penetration.
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To perform a blood glucose/ketone test on your pet, you need: meter, test strip, lancing device and lancet.

- 1. Turn on the meter by inserting a test strip:** Wait for the meter to display the flashing “

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5. Apply the sample: Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Make sure the absorbent hole of the test strip comes into contact with the blood sample but not the skin. Hold the meter still until the confirmation window of the test strip is completely filled. Confirmation window should be completely filled if enough blood has been applied.

NOTE

- ◆ Do not put blood on top of the test strip.
 - ◆ Always apply a blood sample after the test strip is inserted into the meter.
 - ◆ Do not hold the test strip parallel to the puncture site for absorption.
 - ◆ If you do not apply a blood sample to the test strip within 1 minute, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
 - ◆ The confirmation window should be filled with blood before the meter starts counting down. Never try to add more blood to the test strip. Discard the used test strip and retest with a new one.
-

6. Read your result: Place the meter flat on the table and wait for the test result display. Do not move the meter during the countdown.

7. Eject the used test strip: Eject the test strip by pushing the eject button on the side.

8. Remove the used lancet: Remove the sterile lancet by twisting the lancing device cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface and pushing the exposed tip into the protective disk. Slide the ejector forward to remove the used lancet and dispose of the lancet according to your local regulations.

Result Reading with Display Messages

Lo: test result is below the measurement range.

Hi: test result is above the measurement range.

A value display with  : test result in dog mode.

A value display with  : test result in cat mode.

Quality Control Tests

If you are concerned the meter or test strips are not working properly, you can check the performance of the meter, test strips and your technique by comparing the control solution results with the range printed on the test strip package.

Perform a Control Solution Test when:

- you suspect the meter or test strips are not working properly;
- your test results are not consistent with how your pet is acting, feeling, or if you think the results are not accurate;
- to practice the testing process; or
- you have dropped or think you may have damaged the meter.

To perform a control solution test, you will need: **meter, test strip and control solution.**

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display a flashing “”.

2. Apply the control solution

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the test strip absorbent hole to the droplet. Once the confirmation window fills completely, the meter will start counting down.

3. Read and compare the result

Compare the displayed number with the range printed on the test strip vial or foil packet and it should fall within range. If not, please read the instructions again and repeat the control solution test.

NOTE

- ♦ The control solution range printed on the test strip vial or foil packet is for control solution use only. It is not a recommended range for your blood glucose/ketone test levels.
 - ♦ For the blood glucose control solution test, your device will tag this measurement as QC test automatically.
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Out-of-range Result

Results that fall outside the expected range may indicate:

- An error in the way you are doing the test.
- Expired test strips and control solution.
- A problem with the meter.
- Control solution that is too warm or too cool.
- Failure to shake the control solution vial vigorously.

If you are still unsure of the problem, please contact customer service for assistance.

Review Test Results

To enter memory mode, start with the meter switched off.

1. Press and release **M**. “” will display with the latest result.
2. Press **M** or **▲** to scroll through all the test results stored in the meter.

Data Transmission

Data Transfer to a Computer

You can use the Oracle® for Cats and Dogs Care Management System to view test results on a **Windows 7 (or above)** computer. Connect to a computer via strip port cable and visit Oracle Diabetes website at <https://oraclediabetes.com> to find the appropriate Oracle® for Cats and Dogs Care Management System for this meter. Follow the instructions in the system for pairing.

NOTE

Strip portal cable sold separately.

Maintenance

Meter Storage and handling

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

- Store the meter at -20°C to 60°C (-4°F to 140°F), 10% to 93% R.H. (non-condensing).

Meter Cleaning and Disinfecting

Wipe the meter exterior with a soft damp cloth or mild cleaning agent, then dry the device with a soft dry cloth. Do not use organic solvents (except isopropanol and ethyl alcohol) to clean the meter. Do not rinse or immerse in water or other liquids. Always disinfect the surfaces of the meter with cotton moistened with 70% isopropanol or ethyl alcohol after taking a test. Avoid getting any moisture into any openings (e.g. test strip port, battery compartment).

Meter Disposal

The used meter should be treated as a contaminated item that may carry a risk of infection during measurement. This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.



Batteries

The meter will display the messages below to alert you when the meter power is getting low.

1. When the “” symbol appears along with display messages: The meter is functioning properly and the result remains accurate, but it is time to change the battery.
2. When E-b display: The power is too low to perform a test. Please change the battery immediately.

Properly dispose of the battery according to your local environmental regulations.

Lancing Device, Lancet Storage and Handling

- Avoid getting hand lotion, oils, dirt or debris in or on the lancets and the lancing device.
- Store the lancing device without a lancet inserted.
- Store the lancing device at -20°C to 60°C (-4°F to 140°F), 10% to 93% R.H.
- Store the sterile lancet at -10°C to 50°C (14°F to 122°F), 0% to 80% R.H.

Lancing Device and Cap Cleaning and Disinfecting

The disposable lancet is intended for single use only. The lancing device is reusable. To clean the lancing device and the cap, use mild soap and water to wipe and clean the lancing device. Do not rinse the device under water.

Disinfect the cap by placing it in 70% alcohol for 10 minutes and then allow it to air dry. Do not place the device in a dishwasher or use detergents.

Control Solution Storage and Handling

- Check the expiry date on the vial. Do not use if expired.
- Refer to the period after opening on the control solution vial. Record the first opening date on the vial.
- Tightly close the control solution and store at room temperature at 2°C to 30°C (36°F to 86°F), 10 to 90% R.H. Do not freeze.

System Troubleshooting

If you follow the recommended action but the problem persists, please call your local customer service.

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	The battery is too low.	Replace the battery immediately.
E-U	A used test strip is inserted.	Repeat with a new test strip.
E-t	Ambient temperature is above or below system operation range.	Repeat the test after the meter and test strip are within the operation temperature range.
E-0, E-A E-E	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact customer service for assistance.

E-F	Test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact customer service for assistance.
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Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer service.

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

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off.	Repeat the test with a new test strip. Apply sample only when flashing “  ” appears on the display.
Defective meter.	Please contact customer service.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test.
Control solution vial was poorly shaken.	Shake the control solution thoroughly and repeat the test.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Perform the test with a proper stored control solution.
Defective test strip.	Repeat the test with a new test strip.

Meter malfunction.	Please contact customer service.
Improper working of meter and test strip.	Please contact customer service.

Symbol Information

SYMBOL	REFERENT	SYMBOL	REFERENT
	Date of manufacture		Manufacturer
	Serial number		Do not reuse
	Temperature limit		Humidity limitation
	Caution		Use-by date
	Sterilized using irradiation		Batch code
	Consult instructions for use or consult electronic instructions for use.		
	Do not use if package is damaged and consult instructions for use.		
	This device does not belong to household waste and must be returned to a collection point for recycling electrical and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.		

Specifications

Dimension: 99.0 (L) x 55.4 (W) x 22.07 (H) mm

Weight: 68.6 g (without batteries)

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD with backlight

Memory: 400 measurement results

External Output: Strip Port

Operating Conditions:

Blood Glucose: 8°C to 45°C (46.4°F to 113°F), 10% to 90% R.H. (non-condensing)

β-Ketone: 10°C to 40°C (50°F to 104°F), 10% to 85% R.H. (non-condensing)

Sample Size and Reaction Time:

Blood Glucose Test: 0.5 µL, 5 seconds

β-Ketone Test: 0.8 µL, 10 seconds

Measurement Units:

Blood Glucose Test: mg/dL or mmol/L

β-Ketone Test: Fixed mmol/L

Measurement Range:

Blood Glucose Test: 10 to 800 mg/dL (0.56 to 44.4 mmol/L)

β-Ketone Test: 0.1 to 8.0 mmol/L

Control Solution Chemical Component:

Blood Glucose: Active ingredient (Glucose) 0.019% to 0.25% and inert ingredients > 99.75%.

β-Ketone: β-Hydroxybutyrate 0.012% to 0.08% and inert ingredients > 99.92%

*The control solution does not contain any human-derived or biological materials.

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6, EN 301 489-1, EN 301 489-17, EN 62479.



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