Alphatrak BLOOD GLUCOSE MONITORING SYSTEM SYSTÈME DE SURVEILLANCE DE LA GLYCÉMIE

User Guide

For *in vitro* Diagnostic Use in Animals Featuring the AlphaTRAK 2 Meter



Distributed by Zoetis Inc. Kalamazoo, MI 49007

www.AlphaTRAKmeter.com

Contact Customer Care at 1-888-963-8471

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The AlphaTRAK 2 Meter and How It Works



up (see image to the right).

This display always appears when the meter Downloads test results. is turned on. You should check that the meter Requires a compatible data matches the example exactly every time the management system. For meter turns on. Do not use the meter more information, please go to if the display check screen does www.AlphaTRAKmeter.com not exactly match the example. AlphaTRAK2 If the screen does not match, www.AlphaTRAKmeter.ca or the meter may show an incorrect result. Please www.AlphaTRAKmeter.co.uk contact Customer Care. c (Configure) Button Marks a control solution test **Display Screen** Scrolls forwards Displays test results and other important • Silences a reminder alarm information. Changes the test strip code C m (scrolls forwards) Changes date, time, alarm settings, sound options, and m (Mode) Button reviews stored readings Moves to different mode settings **Test Strip Port** · Changes the test strip code (scrolls backwards) Insert the Top end of a new Scrolls backwards AlphaTRAK 2 test strip here. Silences a reminder alarm Тор The meter powers on when you insert the test strip. Sample Areas (dark-coloured half-circles on test strip) AlphaTRAK 2 test strip Ŵ Apply blood or control solution to one sample area only. Insert strip into the meter printed side Bottom

English

i

Data Port

_Sample area

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Important Information About AlphaTRAK Blood Glucose **Monitoring System**

Important Health Related Information

The AlphaTRAK 2 meter is intended for use outside the body only (in vitro diagnostic use).

The AlphaTRAK Blood Glucose Monitoring System is intended for use in monitoring glucose samples taken from the dog or cat.

Glucose values are affected by stress, meals, exercise, health and medication intake. Severe dehydration and excessive water loss may cause false low results.

> Caution: The AlphaTRAK 2 test strips are not intended for human blood glucose testing and may give inaccurate results when used in humans.

Do use the AlphaTRAK 2 meter for:

- Testing blood glucose in dogs and cats
- Testing with fresh whole blood samples
- Testing with fresh whole capillary samples
- Testing with fresh whole venous samples
- Testing with whole blood collected in a syringe or tube with EDTA or heparin anticoagulant if testing within 10 minutes
- Testing with whole blood collected in a syringe or tube with no anticoagulant, if testing is performed immediately

Do not use the AlphaTRAK 2 meter for:

- Testing of arterial blood
- Testing with serum
- Testing with plasma
- Diagnosis of diabetes

Warning:

• This system contains small parts that may be dangerous if swallowed.

Caution: Please read all the instructions provided in this user guide and practice the testing procedures before using the AlphaTRAK 2 meter. Blood glucose monitoring should be done with the guidance of a veterinarian/veterinary surgeon.

English

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IMPORTANT: Use only AlphaTRAK 2 test strips and AlphaTRAK control solution with this meter. Using previous versions of the AlphaTRAK test strips or other brands of test strips and control solution with the AlphaTRAK 2 meter can produce inaccurate results.



Setting Up the AlphaTRAK 2 Meter

Purpose

The purpose of this section is to set the meter sound volume, time and date.



- **1.** With the meter off (no test strip inserted), press and **hold** (m) for **3** seconds until SE T appears.
- **2.** Press <u>m</u> to bypass setting the optional reminder alarms. You may choose to set these later (see Setting Reminder Alarms section).

Set Sound Volume



- With the sound volume on, the meter will beep when:
- The test strip is full of blood
 The test result appears on the display
 An error occurs

- You may also choose to silence the meter.
- **3.** Set sound volume

lf you prefer:	Press C until you see:	
No sound	Ð	
A low beep	\Diamond	• F
A louder beep	\bigcirc \mathbb{D}	

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Set Time



Contact Customer Care at 1-888-963-8471

Set Date

SET

so icejié: is Month

56了

Day

Note: The date format can display either:









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Obtaining a Blood Sample

Purpose

The purpose of this section is to obtain a capillary blood sample from the animal.

How to Lance

- Use the AlphaTrak lancet to obtain a blood sample from the animal.
- Consult a veterinarian/veterinary surgeon for a recommended sampling method and instructions.

1. Select the test site.

There are many sites to obtain capillary blood samples: the marginal ear vein in both cats and dogs; paw pad in cats and dogs; leg callus, usually dogs; inner or outer lip, dogs only.

Warming the area will help increase blood flow. This can be done by:

- Gently rubbing the test site or
- Applying a warm (not hot) cloth to the test site. If using a wet cloth, place the cloth inside a plastic bag to avoid diluting the blood sample.



- **2.** Wash your hands and the test site with warm water and soap to ensure accurate results.
 - Thoroughly dry your hands and test site.



	3. Remove the round cover from the lancet and prick the	test site.	AlphaTRAK Blood	Glucose Testing
_	Optional: a thin layer of petroleum jelly may be applied pr This can help the blood form into a droplet and avoid spil AlphaTRAK lancing device may be used to assist in obtain	ior to lancing the site. ing into the hair. The ng a blood sample.	Purpose The purpose of this section Performing a Bloo	n is to produce an accurate blood glucose test result. d Glucose Test
Englis	 Gently apply pressure to the test site with sterile gauze or the blood flow. If you accidentally prick yourself with a lancet, please follow norn If bleeding persists, please contact your local healthcare profession 	cotton wool to help stop nal first aid procedures. onal.	1. Selec 2. Wash accur • The	t the test site. your hands and the test site with warm water and so rate results. oroughly dry your hands and test site.



IMPORTANT: Use only AlphaTRAK 2 test strips. Other test strips can produce inaccurate results. The test strips are for single use only.

3. Check test strip expiry date.



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Important Test Strip Information

Please read the AlphaTRAK 2 test strip package insert for more information.

- Use the test strips within the meter's operating range: 40° 104° F (4° 40° C).
- Store test strips in a cool, dry place between 40° 86° F (4° 30° C).
- Store test strips away from direct sunlight and heat.
- Store test strips in their original vial only.
- Clean and dry your hands before removing a strip from the vial.
- Close the vial cap tightly immediately after removing a test strip.
- Do not transfer test strips to another container.
- Do not store test strips outside the vial.
- Do not bend, cut or alter test strips.
- Do not apply blood to both sides of the test strip.
- Do not press the test strip against the test site.
- Do not scrape the blood onto the test strip.
- Do not apply blood to the flat side of the test strip.
- Do not apply blood to the test strip when the test strip is out of the meter.
- Do not put blood or foreign objects into the meter.

Warning: Drying agents in the test strip vial may be harmful if inhaled or swallowed and may irritate skin and eyes.

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4. Remove test strip from vial.

5. Insert test strip to turn meter on.

Note: The meter turns off after 2 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.

If the meter does not turn on, go to Troubleshooting section.



6. Confirm System Check Screen.

- This display appears when you turn on the meter. Do not use the meter if the display check screen does not exactly match the example. Contact **Customer Care.**
- See The AlphaTRAK 2 Meter and How It Works section for more information.
- If the system check screen does not appear, go to Troubleshooting section.



7. Code the meter

When COCE and code number appear

- Press the **C** to scroll forwards or
- Press (\mathbf{m}) to scroll backwards until the number matches the \mathbb{CDE} on the test strip vial for dogs or cats. The AlphaTRAK 2 meter has a total of 99 codes.

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English







10. View result

The result appears on the display when the test is complete. The time that the meter takes to display a result depends on the animal's blood glucose level. Higher glucose levels require more time.

Note: If you see an "Er1, Er2, Er3, Er4 or Er6" on the display, it is an error code. Go to Error Codes section.

11. Remove test strip to turn meter off. Discard used lancet and test strip properly.

Understanding Blood Glucose Test Results

The meter displays results in mg/dL in the USA. Outside the USA the unit of measure will be in either mg/dL or mmol/L. The unit of measure is preset. You cannot change this setting.

> **IMPORTANT:** The meter displays results from 20 – 750 mg/dL or 1.1 – 41.7 mmol/L. Low or high blood glucose results can indicate a potentially serious medical condition.

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	Result	What It Means	What To Do
	Lower than 65 mg/dL	Low blood glucose (hypoglycaemia)	Repeat the test with a new test strip even if the result is <i>not</i> consistent with the symptoms.
English	(3.6 mmol/L) for adult cats & dogs		If the blood glucose result is <i>not</i> consistent with the symptoms, perform a control solution test with a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip.
			If the blood glucose result is still <i>not</i> consistent with the symptoms, contact a veterinarian/veterinary surgeon.
	Higher than 250 mg/dL	High blood glucose (hyperglycaemia)	Repeat the test with a new test strip even if the result is <i>not</i> consistent with the symptoms.
	(13.9 mmol/L) for adult cats & dogs ²		If the blood glucose result is <i>not</i> consistent with the symptoms, perform a control solution test with a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip.
			If the blood glucose result is still <i>not</i> consistent with the symptoms, contact a veterinarian/veterinary surgeon.

LO Result Display

Display	What It Means	Symptoms ¹	Wha
Appears when result is: lower than 20 mg/dL or 1.1 mmol/L	Severe low blood glucose (hypoglycaemia)	Dogs • Lethargy or abnormal drowsiness • Weakness • Shaky movements • Coma Cats • Weakness • Shaky movements • Disorientation • Convulsions	Follow a veterina surgeon's advice glucose. If the blood gluc match the symp control solution the meter and st properly.

IMPORTANT:

Low or high blood glucose readings can indicate a potentially serious medical condition.

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at To Do

narian/veterinary e to treat low blood

cose result does not ptoms, perform a n test to confirm that strips are working



HI Result Display

	Display	What It Means	Symptoms ¹	What To Do	
English	Appears when result is: higher than 750 mg/dL or 41.7 mmol/L	Severe high blood glucose (hyperglycaemia)	Dogs and Cats • Excessive thirst • Frequent urination • Weight loss • Excessive appetite	HI reading <i>with</i> symptoms, follow a veterinarian/veterinary surgeon's treatment advice. If the blood glucose result does not match the symptoms, perform a control solution test to confirm that the meter and strips are working properly.	

Error Codes					
Message	What It Means	What To Do			
Er I	 The sample is too small There may be a problem with the test strip Meter error Blood glucose lower than 20 mg/dL or 1.1 mmol/L 	 Follow a veterinarian/veterinari treatment advice to treat low b animal has symptoms such as: Dogs Abnormal drowsiness Weakness Shaky movements Seizure Coma Cats Weakness Shaky movements Seizure Coma Cats Weakness Shaky movements Disorientation Convulsions If no symptoms are present, per solution test using a new test s results are within the range pri strip vial, retest using blood an 			

3. If the control solution result is out of range or the error reappears, contact Customer Care.

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ary surgeon's blood glucose if the s:



erform a control strip. If the test rinted on the test nd a new test strip. out of range or the omer Care.

Message	What It Means	What To Do	Message	What It Means	What To Do
 There may be a problem with the test strip Meter error Very high blood glucose higher than 750 mg/dL or 41.7 mmol/L I. Follow a veterinarian/veterinary surgeon's advice to treat high blood glucose if the animal has symptoms such as: Frequent urination Excessive thirst Excessive appetite Weight loss 2. If no symptoms are present, perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip. 3. If the control solution result is out of range or the error reappears, contact Customer Care.		8-3	 Incorrect test procedure. For example, putting blood on the test strip before inserting it into the meter or applying blood before and appear There may be a problem with the test strip Meter error 	 Wait for A and A to appear h blood or control solution. Perform a control solution test test strip. If the test results are printed on the test strip vial, re and a new test strip. If the control solution result is error reappears, contact Custo 	
			8-4	 There may be a problem with the test strip Meter error 	 Perform a control solution test test strip. If the test results are printed on the test strip vial, re and a new test strip. If the control solution result is error reappears, contact Custo
	Message Er 2	Message What It Means There may be a problem with the test strip Meter error Very high blood glucose higher than 750 mg/dL or 41.7 mmol/L	Message What If Means What To Do E C 2 • There may be a problem with the test strip • Follow a veterinarian/veterinary surgeon's advice to treat high blood glucose if the animal has symptoms such as: • Very high blood glucose higher than 750 mg/dL or 41.7 mmol/L • Frequent urination • Excessive appetite • Weight loss 2. If no symptoms are present, perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip. 3. If the control solution result is out of range or the error reappears, contact Customer Care.	Message What It Means What To Do Message E C C • There may be a problem with the test strip • Follow a veterinarian/veterinary surgeon's advice to treat high blood glucose if the animal has symptoms such as: • Frequent urination • Excessive thirst • Excessive thirst • Excessive appetite • Weight loss 2. If no symptoms are present, perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip. 3. If the control solution result is out of range or the error reappears, contact Customer Care. E C Ч	Message What It Means What To Do Message What It Means ECC • There may be a problem with the test strip • Frequent urination • Frequent urination • Excessive appetite • User yhigh blood glucose if the animal has symptoms such as: • Frequent urination • Excessive thirst • Excessive thirst • Excessive appetite • What It Means 2. If no symptoms are present, perform a control solution result is out of range or the error reappears, contact Customer Care. 2. If no symptoms contact Customer Care. • Meter error • Incorrect test procedure. For example, putting blood before for einserting it into the meter or applying blood before for einserting it into the meter or applying. 3. If the control solution result is out of range or the error reappears, contact Customer Care. • Incorrect test procedure. For example, putting blood before for einserting it into the test strip. 4. If the control solution result is out of range or the error reappears, contact Customer Care. • Incorrect test procedure. For example, putting blood before for einserting it into the test strip. • Meter error • If the control solution result is out of range or the error reappears, contact Customer Care. • There may be a problem with the test strip. • Meter error • If the control solution result is out of range or the error reappears. • Meter error • Meter error

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before applying

st using a new e within the range retest using blood

s out of range or the omer Care.



t using a new within the range etest using blood

s out of range or the omer Care.

	Message	What It Means	What To Do
English	8-8	• m or c was pushed when applying blood sample or control solution.	 Retest using a new test strip. Do not touch the (m) or the C button while applying blood or control solution to the test strip. If the error reappears, contact Customer Care.

Troubleshooting

	What It Means	What To
1. The meter does not enter test mode after inserting a test strip.	• Test strip is inserted upside down, or bottom end in, or not fully inserted into the meter	1. Insert test strip print side
	 No battery is installed Battery is installed incorrectly 	1. Install battery with (+) fa
	Dead battery	 Replace battery. Reset danecessary. If meter still does <i>not</i> entropy contact Customer Care.
	 Defective test strip or meter Blood or foreign objects put in the test strip port 	1. Contact Customer Care.



		What It Means	What To Do
English	2. The test does not start after applying the blood drop.	Blood drop is too small	1. Add blood to the same sample area within 60 seconds, or repeat the test using a new test strip and a larger blood drop.
		 Defective test strip Sample applied after meter turns off 	 Repeat the test using a new test strip. Wait for And A to appear before applying blood or control solution. If problem persists, contact Customer Care.
		Defective meter	1. Contact Customer Care.

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AlphaTRAK Control Solution

Purpose

AlphaTRAK control solution is a red liquid that contains a fixed amount of glucose.

The purpose of doing a control solution test is:

- To practice testing *without* using animal blood
- To confirm that the meter and test strips work together properly
- When you are unsure of the blood glucose test results

Contact Customer Care for information on how to obtain control solution.

Control Solution Information

- Use only AlphaTRAK control solution with the AlphaTRAK 2 meter.
- Replace the cap securely on the bottle immediately after use.
- Control solution results are accurate only between 59° 104° F (15° 40° C).
- Do not add water or other liquid to control solution.

For information on how to obtain control solution, contact Customer Care.



IMPORTANT: Control solution results should fall within the control solution range printed on the test strip vial or package insert. Do not use this range when testing blood glucose.

CAUTION: It is not a range for the animal's blood glucose level.



Out of Range Control Solution Results

- Repeat the test if control solution results are outside the range printed on the test strip vial.
- Repeat the test to confirm the results.
- The correct test procedures may not have been followed.
- Stop using the meter if control solution results are consistently outside the range printed on the test strip vial. Contact Customer Care.

Causes of out-of-range results include:

- Expired or bad control solution
- Expired or bad test strip
- Testing error
- Watered-down control solution
- Meter malfunction
- Test strip deterioration
- Control solution test done outside 59° 104° F (15° 40° C)
- Correct code is not set in the meter

Performing an AlphaTRAK Control Solution Test



1. Check control solution expiry date.

IMPORTANT: Do *not* use control solution past expiry date. Discard control solution 3 months after opening or on the expiry date printed on the bottle whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.)



2. Remove test strip from vial.

3. Insert test strip to turn meter on.

Note: The meter turns off after 2 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.

If the meter does not turn on go to Troubleshooting section.

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English



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4. Confirm System Check Screen.

- This display appears when you turn on the meter. Do not use the meter if the display check screen does not exactly match the example. Contact **Customer Care.**
- See The AlphaTRAK 2 Meter and How It Works section for more information.
- If the system check screen does not appear, go to Troubleshooting section.



5. Code the meter

When **COdE** and code number appear

- Press the **C** to scroll forwards or
- Press ${f (m)}$ to scroll backwards until the number matches the CDdE on the test strip vial for dogs or cats. The AlphaTRAK 2 meter has a total of 99 codes.

Note: To ensure accurate test results, make sure the code number on the meter always matches the number in the outlined box on the test strip vial for either dog or cat.

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- **6.** Gently invert the control solution bottle. Wipe tip with tissue and discard the first two drops. Apply and **hold** control solution to 1 sample area of the test strip until:
 - You see short lines moving clockwise on the display or
 - You hear a beep

This indicates the test strip obtained enough control solution and the meter is processing. If the test does not start after applying the control solution, go to Troubleshooting section.

> **IMPORTANT:** If a short line does *not* appear after 5 seconds, the sample may be too small. Do not add control solution to both sides of the strip. The test strips are for single use only. Do not reuse test strips. Discard used test strips.



7. View result.

The result appears on the display when the test is complete.

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English





15/1-20423

 \approx 7.7 mmol/L (Example only) **8.** Compare the control solution result to the range printed on the test strip vial or package insert. The result should fall within the range.

Note: If you see an "Er1, Er2, Er3, Er4 or Er6" on the display, it is an error code. Go to Error Codes section.

9. Press and *hold* **C** for **2** seconds until **a** appears on the display to mark the result as a control solution result. To unmark a control solution test result, press and **hold (C)** for **2** seconds. A value with the *a* indicates you have marked this reading as a control solution test.

10. Remove the test strip to turn meter off.

Using Meter Memory

Purpose

The purpose of this section is to review your stored test results and 7-, 14- and 30-day averages.

Viewing Blood Glucose Averages in Memory

Start with the meter off (no test strip inserted). Press (**m**). The 7-day average appears (control solution, LO and HI readings not included).

Note: To exit meter memory at any time, press and hold (m).

Example:



the average

- n= number of results included in average

- Press **C** to scroll through 14- and 30-day averages and all stored test results. The most recent result appears first.
- Press (**m**) to scroll backwards.

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English

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Viewing Test Results in Memory

The meter memory stores the last 250 test results with time and date. Press **C** to scroll through the results. The most recent result appears first.

English	mem	on the display indicates that you are viewing stored test results.
	davg	shows the average value of glucose readings from the last 7-, 14- or 30-days.
	ŀ	on the display indicates that the test result occurred when it was too hot or too cold to use the meter and may <i>not</i> be accurate. This result is included in 7-, 14- and 30-day averages.
	LO	a test result of under 20 mg/dL or 1.1 mmol/L is included in memory as LO.
	X I	a test result of over 750 mg/dL or 41.7 mmol/L is included in memory as HI.
	mem 🔍	indicates a control solution test result.

Setting Reminder Alarms (optional)

Purpose

The purpose of this section is to set up to four reminder alarms to prompt you to test throughout the day.



1. With the meter off, press and **hold** (m) for **3** seconds until $\{ \xi \}$ appears and **0** is flashing.

2. Press **C**. Reminder alarm **1** flashes.



Note: You are setting time for Reminder Alarm not clock time.

- **3.** Set hour
 Press **m** to set hour
 - Press **C** to display correct hour
 - Press (m) to save



- **4.** Set minutes
 - Press **C** to display correct minutes
 - Press **m** to save

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	5. Set alarm sound volume			
_	lf you prefer:	Press C until you see:	Then	
	No sound	Ð		
lish	A low beep	D	• Press (m) to save	
Eng	A louder beep	\bigcirc \mathbb{D}		
	6. Press C and repeat 2, 3, 4 and 5 to set remaining reminder alarms or			
	7. Press and <i>hold</i> (m) for 3 seconds until meter turns off.			

Go to www.AlphaTRAKmeter.com, www.AlphaTRAKmeter.ca or www.AlphaTRAKmeter.co.uk to download the PetDialog Diabetes management application.

Maintaining the AlphaTRAK 2 Meter

Replacing the Battery

The meter comes with one CR 2032 3V lithium battery installed.
When ^[1] appears on the display, the battery is low.
When ^[2] appears, the meter may fail to turn on.
IMPORTANT: When ^[2] appears, replace the battery immediately.
When you are ready to install a new battery, remove the old battery and install the new battery within 60 seconds to avoid losing time and date settings.

- If time and date settings are lost, both time 12:00 and date 00-00 will flash until reset. Reset time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, you may still perform an accurate blood glucose test.
- Memory log and previously stored user settings, such as date and time format, are not affected by removing the battery.

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1. Slide the battery door to the right to open.

2. To remove the battery, pull the plastic tab up to release the battery.

3. Insert a new battery: (+) facing up.



4. To close, slide the battery door in until it snaps into place.



Note: The battery in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

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Cleaning the AlphaTRAK 2 Meter

Avoid getting dirt, dust, blood, control solution or liquid in the meter test strip and data ports. Clean the outside of the meter using a damp cloth and:

- Mild detergent/soap and water, or
- 70% isopropyl alcohol (available in the USA)
- A mixture of 1 part household bleach, 9 parts water

IMPORTANT:

Do not immerse the meter in water or other liquid.



	Specifications		
English	Assay method	Coulometric electrochemical sensor	
	Automatic shutoff	2 minutes of inactivity	
	Calibration	Plasma equivalent	
	Haematocrit	15% to 65%	
	Measurement units	mg/dL or mmol/L	
	Meter storage temperature	– 4° to 140° F (– 20° to 60° C)	
	Memory	250 blood glucose and control solution tests with date and time	
	Operating relative humidity	5% to 90% (non-condensing)	
	Operating temperature	40° to 104° F (4° to 40° C)	

Power source	One CR 2032, 3V lithium battery, replaceable
Result range	20 to 750 mg/dL or 1.1 to 41.7 mmol/L
Sample	whole blood, capillary or venous
Sample size	0.3 microlitre (300 nanolitres)
Size	2.0 in (w) x 3.3 in (l) x 0.63 in (d) 5.1 cm (w) x 8.
Weight	1.4 to 1.6 oz. (39.7 to 45.4 g) including battery

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Definition of Symbols i Consult instructions for use IVD For in vitro diagnostic medical device English REF Temperature limitation Catalogue number 1 × Manufacturer Recycle LOT Batch code SN Serial number Ω 8 Use by Do not reuse The battery in this product X should be removed and CE CE Mark disposed in accordance with local regulations for separate collection of spent batteries.

Contact Customer Care at 1-888-963-8471

References

- 1. BSAVA Manual of Canine and Feline Endocrinology, Third Edition, British Small Animal Veterinary Association. Edited by Carmel Mooney and Mark E Peterson. 2004
- 2. Ettinger SJ, Feldman EC. Textbook of Veterinary Internal Medicine. Vol 2. WB Saunders Company. pp 1529 - 1534. 1995

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