

Continuous Glucose Monitoring System for Cats and Dogs

User Manual

Application, Activation, Pet Owner App, and Veterinarian Web Portal



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Before you use the GluCurve Pet CGM System ("System"), review the user manual in its entirety. The user manual includes all safety information and instructions for use.

Failure to use the System according to the instructions may result in you missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If the glucose readings from the GluCurve do not match symptoms or expected readings, use a blood glucose value from a blood glucose meter or chemistry analyzer to make diabetes treatment decisions. Seek medical attention when appropriate.

While rare, the product's adhesive patch may irritate the skin of some pets with sensitive skin. A No-Sting Skin-Prep Wipe is included in the box for use to reduce the chance of any adverse skin reactions while increasing the adhesion to skin.

USE AT YOUR OWN RISK. A veterinary must weigh the risks and benefits before using the GluCurve Pet CGM on an animal. ALR Technologies SG Ltd. will not accept any liability for adverse skin reactions from use of the product.

Accuracy may vary in the hypoglycemic range due to the limitations of CGM technology.

Do not use if the applicator is damaged or broken. Do not use past expiration date.

Protective measures (e.g. clothing, harnesses, vests, e-collars, cones, etc.) should be used to ensure the GluCurve stays on for 14 days. While well tolerated by most pets, duration of use cannot be guaranteed and biting or scratching the device off is possible.

14 days of use may not be reached due to muscle/joint activity that can cause the sensor probe to deviate from its optimal position or become damaged. Ensure the GluCurve is applied to a flat area with minimal bending of the skin to maximize length of use.

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Chapter 1: Important Safety Information

General Description

The GluCurve Pet CGM is a Continuous Glucose Monitoring (CGM) System and is indicated for the continuous monitoring of interstitial fluid glucose levels in cats and dogs. Glucose levels are monitored by an electrochemical sensor which is factory calibrated, not requiring blood glucose value calibration. It is a single-use device that can be worn for up to 14 days by a single user. The GluCurve provides glucose levels every 1 minutes, displays glucose trends, fluctuations, and TIR (time in range). Unexpected or unusual readings should not be relied on for treatment decision or therapy adjustments without the verification of a Blood Glucose Meter or chemistry analyzer.

Benefits

The expected benefits of using the GluCurve Pet CGM System include:

- Improved quality of life by increasing glycemic awareness
- Serial glucose readings obtained in the pet's home environment
- Avoidance of stress induced elevated glucose levels in-clinic
- Glucose readings every 1 minutes for up to 14 days to display trends
- Customized diabetes management software for cats and dogs to better analyze glucose readings

Contraindications

- The GluCurve must be removed prior to Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan.
- The GluCurve should not be applied at a site where severe skin scald, burns, sunburns, wounds, ulcers, surgical scars, or other abnormalities are present.

System Safety Statements

A CAUTIONS AND LIMITATIONS

- Do not use the GluCurve if the applicator is damaged. Contact Customer Service at <u>GluCurveSupport@alrt.com</u>.
- Transport and store the sensor pack and applicator at temperatures ranging between 41°F and 104°F. Do not store in freezer. If transported and stored out of this temperature range, the performance may be affected.
- Do not use if expired.
- Intense exercise and/or movement may cause the sensor to loosen due to sweat

or movement of the sensor. If the sensor comes loose or the sensor tip is coming out of the skin, no readings or unreliable low readings may be obtained. Do not attempt to reinsert the sensor. In case of doubt of the accuracy of the sensor readings as it came loose, verify glucose levels by using a blood glucose meter.

- The system contains small parts that may be dangerous if swallowed. Keep it out of reach of children.
- The sensor automatically stops working after the 14-day wear period and must be removed.
- Inaccurate glucose readings may occur. When symptoms do not match readings, or readings are suspected to be inaccurate, use blood glucose values obtained from a blood glucose meter or chemistry analyzer to make diabetes treatmentrelated decisions. Seek medical attention when appropriate.
- The performance of the GluCurve when used with other implanted medical devices has not been evaluated.
- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the GluCurve and results from a blood glucose meter.
- Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.
- Severe dehydration (excessive water loss) may cause false low sensor results. In the presence of symptoms that may lead to suspicion of dehydration consult a veterinarian.
- The system must be removed prior to Magnetic Resonance Imaging (MRI), X-ray examination, Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, X-ray, CT scans, or diathermy on the performance of the system has not been evaluated.
- It is not known how different conditions or medications common to pregnancy, dialysis, or critical illnesses may affect performance of the GluCurve.
- Interfering Substances: Taking high amounts of ascorbic acid (vitamin C) or acetylsalicylic acid while wearing the sensor may falsely raise sensor glucose readings. Ascorbic acid or acetylsalicylic acid are oxidized on the surface of the sensing electrode and generate a certain interference current, potentially causing inaccurate sensor readings. The level of inaccuracy depends on the amount of substances present in the body. If symptoms do not match the sensor glucose readings after taking ascorbic acid or acetylsalicylic acid, do a blood glucose test.
- Magnetic fields could cause the sensor to power off and stop working.
- The GluCurve has not been tested following anti-coagulant therapy, glucose readings may be inaccurate.
- Seek help from a veterinarian if the sensor tip breaks.

Risks

The risks with using the GluCurve Pet CGM System are:

1. Inaccurate or Missing Glucose Reading Risks

Due to mobile device issues:

- Battery: If the mobile device battery is dead, live readings will not be obtained.
- App on: Keep the GluCurve Pet CGM app on to receive live readings.
- In range: Mobile device must be within 16 feet from the sensor, with no obstacles between them, to ensure proper communication. If both devices are not in range, no readings will be obtained.
- No System errors: in the event of a system error such as no readings, sensor error, or signal loss, no readings will be obtained.

Due to GluCurve Pet CGM hardware issues:

- Sensor electrode: If the Sensor electrode becomes loose or dislodged inaccurate or invalid glucose readings may be displayed.
- Electronical: if there is an electronical issue such as a short, overload, or any type of malfunction glucose readings may be inaccurate or not displayed at all.
- Enzymes: any inconsistency or damage to the GOx enzymes on the sensor electrode may cause varying degrees of inaccuracy at times or for the duration of the sensor life.

2. Interfering Substance Risks

For the GluCurve Pet CGM system, acetaminophen, ascorbic acid and acetylsalicylic acid may affect the accuracy of glucose readings.

3. Sensor Insertion Risks

Despite being uncommon, insertion of the sensor can cause:

- Insertion site pain
- Bleeding
- Sensor probe breakage

Despite being uncommon, wearing the adhesive patch can cause:

- Inflammation
- Skin irritation
- Skin allergy

A No-Sting Skin-Prep Wipe is included in the box for use to reduce the chance of any adverse skin reactions while also increasing the adhesion to skin.

USE AT YOUR OWN RISK. A veterinary must weigh the risks and benefits before using the GluCurve Pet CGM on an animal. ALR Technologies SG Ltd. will not accept any liability for adverse skin reactions from use of the GluCurve.

Chapter 2: The GluCurve Pet CGM Overview

The GluCurve Pet CGM System comprises of three main parts: a Sensor Kit, the GluCurve Pet CGM App, and the Veterinary Web Portal.

When opening, check that all the contents are present and undamaged. If any parts are missing or damaged, contact the Customer Service at <u>GluCurveSupport@alrt.com</u>.

Sensor Kit

The Sensor Kit includes:

- Sensor Applicator (containing sensor)
- No-Sting Skin-Prep Wipe
- Quick Start Guide

Applicator:

Sensor:

Applies the sensor onto the pet.

Inserts into the sensor to communicate with smart device

No-Sting Skin-Prep wipe: Creates a film barrier between skin and adhesive







GluCurve Pet CGM App

The GluCurve Pet CGM App is available for iOS and Android, the pet parent will install it onto their smart device. The app receives the glucose readings from the sensor via Bluetooth communication and sends the information to the veterinary web portal.

Veterinary Web Portal

The Veterinary Web Portal is a free diabetic patient management platform used by veterinarians to view the glucose readings from the GluCurve and access various features and reporting, it is accessible at <u>www.GluCurve.ca</u>.

Chapter 3: Application and Removal

The Quick Start Guide below is included in the GluCurve box and should be read in entirety before use.



2 Application

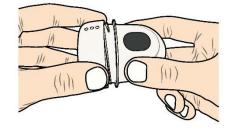


CAUTION: Read the Warnings and Information sections before use.

Step 1: Choose an application site that generally stays flat with minimal bending or folding of the skin.

Step 2: Using 40 blade clippers or higher, shave a 2-inch by 1.5-inch patch of fur as close to the skin as possible.

Step 3: Wipe application site with No-Sting Skin-Prep Wipe included in box. Allow site to dry for 30 seconds before proceeding.

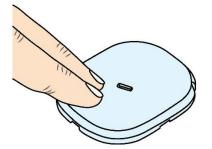


Step 1: Unscrew and remove the bottom cap from the applicator.

Note: The pet parent will need to scan the QR code on the cap to pair their smart device with the sensor. DO NOT DISCARD.



Step 2: Hold applicator against skin and press the circular button. Hold for 10 seconds and quickly pull applicator away from skin.



Step 3: Press the sensor and the protruding adhesive pad firmly into the skin.

(3) Registration

Note: Returning GluCurve patients can skip Registration and go to Activation Step 3.

Step 1: Using a computer, laptop, or tablet, navigate to www.GluCurve.ca and click the veterinary portal button.

Step 2: Click the sign up button to create a new veterinarian clinic account or enter your credentials and log in for existing veterinary accounts.

Step 3: Click the Add New Patient button in the top right-hand corner.

Step 4: Choose registration method in the Add New Patient form:

Direct (recommended) will ask you to create a username and password for the patient that the pet parent will use to access the GluCurve app and complete activation. WARNING: The username and password should NOT be personal and may need to be shared with others. Invite will send the pet parent a link via email or text asking them to create a username and password for the patient that they will use to access the GluCurve app and complete activation.

4 Activation

WARNING: The username and password should NOT be personal and may need to be shared with others.

Step 1: If direct registration was completed, instruct pet parent to download the GluCurve app for iOS or Android (QR codes below) and log in using the

If **invite** registration was selected, the pet parent will receive a text/email with links to download the GluCurve app for iOS or Android (or scan QR codes below). Once downloaded, return to invite text/email and click the activation link. The pet parent will be asked to choose a username and password that will be used to log into the GluCurve app for this specific pet.

Step 2: The pet parent will be asked to accept the terms and conditions of use and the privacy policy.

Step 3: The pet parent will be asked to pair the sensor with their smart device via Bluetooth by scanning the QR code on the applicator / GluCurve box or manually enter the 8 character code. This will complete Activation, there is now a 1-hour warm-up period before glucose levels will be displayed. Note: Accuracy may vary more widely during initial few hours of use.









GluCurve Pet CGM Help

GluCurve App for iOS

GluCurve App for Android



WARNING: Protective measures (e.g. clothing, harnesses, vests, e-collars, cones, etc.) should be used to ensure the GluCurve stays on for 14 days. While well tolerated by most pets, duration of use cannot be guaranteed and biting or scratching the device off is possible.

WARNING: Insulin therapy should NOT be changed in the event of unexpected or unusual glucose readings without confirming glucose read-ings using a Blood Glucose Meter.

WARNING: While rare, skin irritation may occur from a reaction to the adhesive pad. Use at your own risk,

WARNING: Accuracy may vary in the hypoglycemic range due to limitation of CGM technology.

WARNING: Do no use past expiration date.

WARRANTY: The warranty for the GluCurve Pet CGM covers factory defects only, human error and pet error are not covered.

RECYCLING: Check with local laws and regulations before recycling any part of the GluCurve Pet CGM. The applicator and sensor are made from various plastics and metals. The sensor contains electronic circuitry.

HOW IT WORKS: When applied, a guide needle in the applicator deploys a 7-8mm electrode into the interstitial fluid of the animal where glucose oxidase enzymes on the electrode interact with glucose in the interstitial fluid to create minute amounts of current. The current is translated into blood glucose levels using an advanced algorithm and displayed in the veterinary web portal and the pet owner app.

Sensor Life	Up to 14 days
Reading Intervals	Every 1 minutes
Glucose Range	40-540 mg/dL
Bluetooth Range	16+ feet
Water Resistance	IP28
Operating Temperature	41F to 104F
Sensor Size	30 x 25 x 3.5 (mm)
Sensor Weight	3.6g
Shelf Life	12 months
Power Source	3V lithium battery
Atmospheric Pressure	70 kPa to 104 kPa

Support

A help section can be found in the GluCurve app, in the veterinary web portal, and on www.GluCurve.ca.

For further support email GluCurveSupport@alrt.com or call 1-833-925-0138 between the hours of 9am and 8pm EST

Created By

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General Inquiries: Contact@alrt.com

Removing the GluCurve Pet CGM

To remove the sensor, pull up the edge of the adhesive that keeps the Sensor attached to the skin and peel away from the skin in one motion. **Note**: Any remaining adhesive residue on the skin can be removed with warm, soapy water or isopropyl alcohol. Discard the used sensor.

Chapter 4: The GluCurve App

The glucose data from the sensor is retrieved by a phone or tablet via Bluetooth using the GluCurve app, the app also simultaneously sends the data to the Veterinary Web Portal.

The blood glucose reading is updated every 1 minutes during real-time monitoring.

\triangle CAUTIONS AND LIMITATIONS

- The GluCurve App provides interstitial glucose levels from the CGM sensor used for glycemic management but should not be taken solely as the basis of treatment decision or therapy adjustment.
- If the sensor glucose readings do not match the symptoms or expected results, verify readings using a Blood Glucose Meter or chemistry analyzer.
- If the App itself closes unexpectedly, relaunch the App. No data will be lost.
- For the GluCurve app to function properly, the user must enable Bluetooth, and give the GluCurve app permission to access Bluetooth and the Camera.

Downloading the App

Scan the app QR code below or search "GluCurve" in the app store, follow the onscreen instructions to install the GluCurve app.





iOS

Android

Activating a Sensor

- Bluetooth must be enabled on the smart device so that the GluCurve app can pair and communicate with the sensor.
- Accuracy may vary more widely during initial few hours of use due to the immune system response to inserting the sensor electrode.
- Only one sensor can be paired to a pet/username at a time. If a new sensor is paired, it will automatically unpair the current one.

First Time Users:

Follow the Quick Start Guide instructions in Chapter 3 or included in the box.

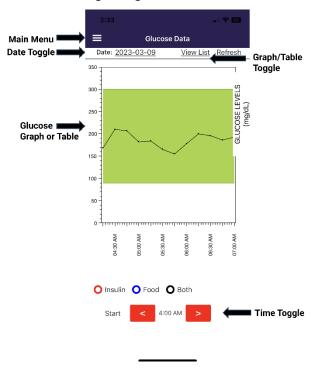
Existing Users

Follow the Quick Start Guide instructions in Chapter 3 or included in the box.

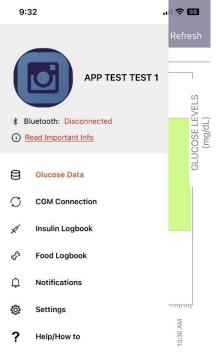
Using the GluCurve App

- Bluetooth must be enabled on the smart device with the GluCurve app running in the background to receive glucose readings from the sensor.
- The GluCurve app must be within 16 feet of the sensor (without obstacles) to communicate via Bluetooth.
- Accuracy may vary more widely during initial few hours of use due to the immune system response to inserting the sensor electrode.
- The glucose range is between 40-540 mg/dL, anything below or above will be displayed as low/high.
- Glucose readings are captured by the sensor every 1 minutes for up to 14 days.

The following image shows the home screen of the GluCurve app.



The following image shows the main menu of the GluCurve app.



Glucose Data – Tap to view the graph/table home screen.

CGM Connection – Tap to activate new sensor or see current sensor status.

Insulin Logbook – Tap to log what time insulin is given, it will transfer to the veterinary chart.

Food Logbook– Tap to log what time food is given, it will transfer to the veterinary chart.

Notifications – Reserved for future use.

Settings – Tap to view app settings and information.

Help/How to – Tap to view how to guides, videos, and other help related content.

Chapter 5: The Veterinary Web Portal

A CAUTIONS AND LIMITATIONS

- The GluCurve App provides interstitial glucose levels from the CGM sensor used for glycemic management but should not be taken solely as the basis of treatment decision or therapy adjustment.
- If the sensor glucose readings do not match the symptoms or expected results, verify readings using a Blood Glucose Meter or chemistry analyzer.

Accessing the Veterinary Web Portal

- The Veterinary Web Portal can be accessed at <u>www.GluCurve.ca</u>.
- If your clinic already has an account but you do not have a username and password, a fellow veterinarian at your clinic with a username and password will need to log in and click their account in the top right hand corner of the screen to send you an invite.
- To register a patient or sign up as a first time user Follow the Quick Start Guide instructions in Chapter 3 or included in the box.

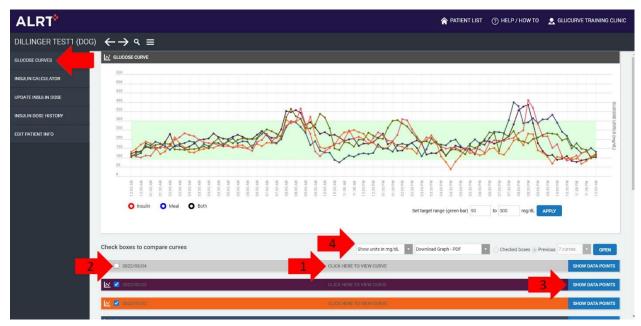
After signing in you will be taken to your clinic's list of patients.

- 1. Patient List Click to return to this list at any time.
- 2. Account Name Click to access your account or log out.
- 3. Add New Patient Click to add a new GluCurve Pet CGM patient.
- 4. Sort Click sort arrow to sort the list by that column.
- 5. **Patient Name -** Click patient's name or owner's last name to view patient records.

IST OF PATIENT	S		1	2 2+ Add new patient
HOW 50 • ENTRIES				
PET'S NAME	PET OWNER'S LAST NAME	LAST GLUCOSE CURVE	Туре	- action 3 -
app test	test 1	3/9/2023 6:56:37 AM	og	Ô.
15	test	2/10/2023 4:10:32 PM	4 Cat	1
dillnger2	test	2/5/2023 7:39:59 PM	bog	Ū
abigail	Test 11	9/27/2022 10:03:25 AM	Cat	Ĩ
lack	test10	6/23/2022 12:29:36 AM	Dog	Û
nacho	test 8	3/8/2022 5:43:48 PM	Cat	節
diamond	test 9	3/6/2022 5:32:24 PM	Dog	Û
dillinger 5	test1 5	3/4/2022 10:03:13 AM	Dog	⑪
kenwood	test6	3/3/2022 10:33:05 AM	Cat	Î
sadie	test6	3/2/2022 12:33:37 PM	Cat	Û
herman	test4	2/25/2022 12.02.28 AM	Cat	Û
rudolf	test3	2/23/2022 5:30:37 PM	Dog	Û
skeletor	test2	2/23/2022 2:01:26 PM	Dog	Û
goose	test7	2/22/2022 2:58:20 PM	Cat	Î
rudolf	test3		Dog (Pending registration)	i 12

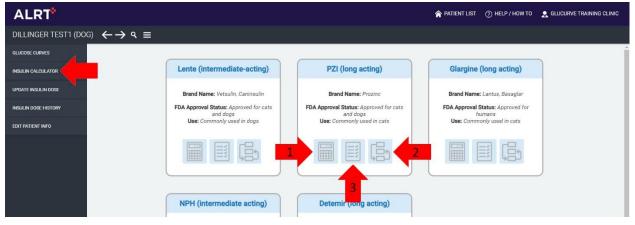
After clicking a patient's name you'll be taken to the glucose curve tab for that patient.

- 1. Click each individual date's bar to see the individual date's glucose curve.
- 2. Check the box on each date's glucose curve you want to compare and overlay in the top graph.
- 3. Click show data points to see each individual 1 minute glucose reading for the date.
- 4. Set the target range (green bar) for this individual patient.
- 5. Choose:
 - a. mg/dL or mmol/L.
 - b. Download graph or data.
 - c. View time in range report or average glucose reports.
 - d. View reports by checking the date boxes you wish to include or by default values.



Click the Insulin Calculator tab for a list of insulins, calculators, guidelines, and flowcharts.

- 1. Click the calculator icon to pull up an insulin dose calculator.
- 2. Click the document icon to pull up suggested dosing guidelines.
- 3. Click flow chart icon to pull up the Manufacturer or AAHA dosing flow chart.



Click the update insulin dose tab and fill out the information whenever insulin dose or type is switched for easy tracking.

ALRT							A PATIENT LIST	HELP / HOW TO	GLUCURVE TRAINING CLINIC
DILLINGER TEST1 (DO	G) $\leftarrow \rightarrow \circ$	ג ≡							
GLUCOSE CURVES	UPDA	TE INSUL	LIN DOS	SE					
INSULIN CALCULATOR									
UPDATE INSULIN DOSE	Insulin Frequency	Vetsulin							
INSULIN DOSE HISTORY	Dose		Units (U)						
EDIT PATIENT INFO	Weight		kg(s)						
	Start Date	09-21-2023	111						
		SAVE							

Click the Insulin Dose History tab to display the insulin dose history for this patient.

ALRT				A PATIENT LIST	⑦ HELP / HOW TO	👷 GLUC	URVE TRAINING CLINIC
DILLINGER TEST1 (DO)G) ←→ ٩ ≡						
GLUCOSE CURVES	INSULIN DOSE	HISTORY					
INSULIN CALCULATOR							EXPORT TO EXCEL
UPDATE INSULIN DOSE	DATE PRESCRIBED	PET WEIGHT	INSULIN	UNITS	FRE	QUENCY	ACTION
	2022/11/21	7 kg	Vetsulin	0.4 Units		BID	2 🗊
INSULIN DOSE HISTORY	SHOWING 1 TO 1 OF 1 ENTRIES						
EDIT PATIENT INFO							

Click the Edit Patient Info to:

- Verify pet owner's username used to log into the GluCurve app and/or reset their password if needed.
- Edit pet owner email or phone number.
- Edit patient name.
- Click Devices to see a list of CGMs used for this patient.

ALRT	🏫 PATIENT LIST 🔿 HELP / HOW TO 🙎 GLUCURVE TRAINING CLINIC
DILLINGER TEST1 (DOG) $\leftarrow \rightarrow \diamond \equiv$	
GLUCOSE CURVES	
INSULIN CALCULATOR	
LIPDATE INSULIN DOSE	
INSULIN DOSE HISTORY Pet owner's username Dillinger_jmva	
EDIT PATIENT INFO	
ACCOUNT SECTINGS Species Dog Pet's name dilinger Pet owner's last name test Moble +1 4436037050 E-Mail Address Dilinger_grwa@aintest.com * Local time-zone (GMT -0500) Eastern Time (US + Canada)	
SAVE CHANGES	

Chapter 6: Troubleshooting

Stage	Problem	Solutions
Application	Sensor won't stick to skin	• Verify 40+ blade clipper was used and fur was shaved as clean as possible.
		 Verify No-Sting Skin-Prep wipe included in box was used and dried before application.
		 Verify applicator was pressed firmly into skin for 10 seconds.
		• Verify applicator was pulled away from skin quickly in one smooth motion.
Registration	Username / Password	• If you don't have a veterinary username or password see Chapter 5: The Veterinary Web Portal.
		 Forgotten usernames and passwords can be retrieved at <u>www.GluCurve.ca.</u>
Activation	Pet owner didn't get invite email / text	• In the veterinary web portal, click the edit icon for the corresponding name, verify information is right and resend link.
		 If that doesn't work switch to direct registration and provide them with a username/password. Some devices will block texts/emails as spam.
Activation	Can't pair smart	Verify smart device has Bluetooth enabled.
	device with sensor	 Verify GluCurve app has permission to use both Bluetooth and Camera.
		 Verify smart device is within 16 feet of GluCurve sensor.
		 Select to manually pair device if camera or QR code does not work.
		 If problem persists, try a different smart phone or tablet.
GluCurve App	Don't see new glucose readings	• Verify Bluetooth is enabled on smart device and within range of GluCurve sensor.
		• Tap CGM Connection in the main menu of app, verify Bluetooth and internet are connected.
		 If problem persists email customer support at <u>GluCurveSupport@alrt.com</u>, DO NOT REMOVE SENSOR unless instructed by ALR Technologies or 14 day use is up.
Veterinary Portal	How to / Navigation	See Chapter 5: The Veterinary Web Portal, click Help/How to at the top of the veterinary portal, or go to
		https://www.glucurve.com/productresources for help and how to guides/videos.
Miscellaneous	Accuracy	Accuracy may vary during first few hours of wear.
		 Accuracy may lag behind during fast rises or drops in glucose levels such as after eating or insulin injections.
		• Verify unusual or unexpected results with a Blood Glucose Meter or chemistry analyzer.
		• Verify the sensor is properly attached and has not been tampered with by the pet.
		CGMs are intended to help better identify trends to obtain better glycemic control, any single reading may vary.

	 If inaccuracy persists of 20% or more, email customer support at <u>GluCurveSupport@alrt.com</u>, DO NOT REMOVE SENSOR unless instructed by ALR Technologies or 14 day use is up.
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Chapter 7: Labelling Symbols

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i	Consult instructions for use		Manufacturer
X	Temperature limit	SN	Serial number
$[\begin{tabular}{c} \end{tabular} \end{tabular} \end{tabular} \end{tabular}$	Date of manufacture	Ť	Keep dry
MR	MR unsafe	(((•)))	Non-ionizing electromagnetic radiation
†	Type BF Applied Part		Caution
	Environmentally Safe Period	STERILE R	Sterilized using irradiation
\otimes	Do not re-use	E.S.	General symbol for recovery/recyclable
\leq	Use-by date	<u>%</u>	Humidity limitation
	Do not use if package is damaged and consult instructions for use	X	This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations.
MD	Medical device		Refer to instruction manual/booklet
UDI	Unique device identifier	CE	CE mark
EC REP	Authorized representative in the European Community	IP28	Indicates the degree of protection provided by enclosure according to IEC 60601-1
	Direct current		

Chapter 8: Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The System is suitable for use in all establishments other than
Harmonic emissions IEC 61000-3-2	Not applicable	domestic and those directly connected to the public low voltage power supply network
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

IMMUNITY test	IEC/EN 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV; ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV; ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors
			are covered with

IMMUNITY test	IEC/EN 60601 test level	Compliance Level	Electromagnetic environment – guidance
			synthetic material, the relative humidity should be of at least 30 %.
Electrical fast transient IEC 61000-4-4	 ±2 kV for power supply lines ±1 kV for input/ output lines 	Not applicable	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	Not applicable	Not applicable
Voltage dips and interruptions IEC 61000-4-11	0%, 70%, 0% of U⊤	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

NOTE: U_T is the AC Mains voltage prior to application of the test level.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3V ISM and amateur radio bands between 150 kHz to 80 MHz 6V	Not applicable	Not applicable

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	80MHz to 2700MHz 10V/m 385MHz 27V/m 450MHz 28V/m 710MHz, 745MHz, 780MHz 9V/m 810MHz, 870MHz, 910MHz 28V/m 1720MHz, 1970MHz 28V/m 2450MHz 28V/m 5240MHz, 5500MHz, 5785MHz 9V/m	10V/m, 80% Am at 1kHz 27V/m PM at 18Hz 28V/m FM ± 5 kHz deviation at 1kHz sine 9V/m PM at 217Hz 28V/m PM at 28V/m PM at 217Hz 28V/m PM at 217Hz 9V/m PM at 217Hz 9V/m PM at 217Hz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 80 MHz to 2.5 GHz

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

(((•)))

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF

communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80	80 MHz to 800	800 MHz to 2.7
	MHz	MHz	GHz
	Not Applicable	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	Not Applicable	0.12	0.23
0.1	Not Applicable	0.38	0.73
1	Not Applicable	1.2	2.3
10	Not Applicable	3.8	7.3
100	Not Applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 9: Technical Specification

Classification

As defined by IEC 60601-1, the device is classified as follows:

- Internally powered.
- Type BF applied parts.
- Ordinary equipment.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture.
- Continuous operation.
- IP28.

Sensor Specifications

Sensor Specifications		
Sensor Useful Life	14 days	
Sensor glucose assay method	Amperometric electrochemical sensor	
Sensor glucose reading range	40 to 540 mg/dL (2.2 mmol/L to 30.0 mmol/L)	
Sensor size	30 x 25 x 4 (mm)	
Sensor weight	4g	
Sensor power source	3V DC lithium battery	
Sensor memory	Up to 14 days	
Operating temperature	41°F to 104	
Sensor pack and applicator shelf life	12 months	
Sensor pack and applicator storage, transport temperature	39°F to 77°F	
Operating and storage relative humidity	10% to 90%, non-condensing	
Operating and storage atmospheric pressure	70 kPa to 106 kPa	
Sensor water resistance and ingress protection	IP28: Protected against insertion of large objects in not less than 12.5 mm diameter and the effects of continuous immersion in water over an hour	
Sensor pack and applicator transport relative humidity	10% to 90%, non-condensing	
Sensor pack sterilization	Sterile by radiation	
Frequency band	2.402 – 2.480 GHz BLE	
Bandwidth	1 MHz	
Maximum output power	3.7 dBm (2.34 mW)	
Modulation	GFSK	
Data communication range	16 feet	

Quality of service (QoS)

Sensor wireless communication

The sensor and App connect via a BLE network. The sensor sends glucose data and system related alerts to the App. The sensor and the App verify the integrity of received data after wireless transmission. Quality of the connection is in accordance with the Bluetooth Specification v5.0. The App is designed to only accept radio frequency (RF) communications from recognized and paired sensors.

ALR Technologies SG Ltd is a publicly traded company under the stock symbol ALRTF.

ALRT is a data management company that originally developed the ALRT Diabetes Solution, a comprehensive approach to diabetes care that includes an FDA-cleared and HIPAA compliant diabetes management system that collects data directly from blood glucose meters and continuous glucose monitoring devices, and a patent pending Predictive A1C algorithm to track treatment success between lab reports and an FDA-cleared Insulin Dosing Adjustment program. The overall goal is to optimize diabetes drug therapies to drive improved patient outcomes.

In addition, the animal health division of ALRT has developed the GluCurve Pet CGM; a solution to assist veterinarians better determine the efficacy of insulin treatments and to help to identify the appropriate dose and frequency of administration for companion animals, thereby delivering the same optimization of diabetic drug therapies to pets as to humans.

More information about ALRT can be found at www.alrt.com and https://sg.alrt.com.