POWERED BY ALRT

GluCurve® Pet CGM

Continuous Glucose Monitoring System
for Cats and Dogs

User Manual



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⚠ **WARNING**:

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 more widely in the hypoglycemic and hyperglycemic 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 decisions 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

⚠ **CAUTIONS AND LIMITATIONS**

- Do not use the GluCurve if the applicator is damaged. Contact Customer Service at GluCurveSupport@alrt.com.
- 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 treatment-related 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 GluCurveSupport@alrt.com.

Sensor Kit

The Sensor Kit includes:

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

Applicator:
Applies the sensor onto the pet.



Sensor:
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 www.GluCurve.com.

Chapter 3: Application and Removal

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

GluCurve® Pet CGM



QuickStart Guide

Information to discuss with the client:

The goal: At-home monitoring is a great benefit of using a Continuous Glucose Monitor (CGM), but it's important for the client to understand the primary goal is to collect enough glucose readings to identify the trend and either confirm the current treatment plan or make an adjustment to better regulate the pet.

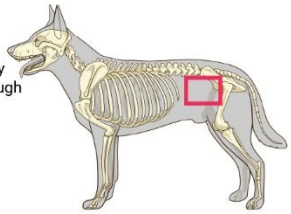
The expectations: It's possible the pet will remove or damage the CGM before the full 14 days of use. While 14 days of use is ideal, it is not necessary. This is a key point to discuss with the client, the focus should be on obtaining enough readings to identify the trend and make a treatment decision, not duration of use for at home monitoring. **See Scenario 2 on the back for more information.**

The value of a CGM: It's helpful for the client to understand the alternative to using a CGM to put its value in perspective. In-clinic glucose curves can be unreliable due to stress, at-home spot checks can be difficult to perform, and both methods only provide a handful of readings that miss the highs and lows. When compared to the alternative options, CGMs stand out for the unique amount of data they provide at a relatively low price point.

See scenarios 1-3 on the back for more helpful information.

Step 1: Create free Veterinary Portal account (first-time users only)
If this is the first time your clinic has used a GluCurve Pet CGM, go to www.GluCurve.com, click Veterinary Portal, click the Sign Up button, fill out the form, and activate your account before proceeding.

Step 2: Choose application site
We recommend the upper flank (cats and dogs), past the ribs, but out of reach of the hind leg, in a location minimally impacted by movement that generally stays flat. **NOTE:** Use your discretion while ensuring the location is fatty enough to support the CGM, location tolerance may vary by pet.

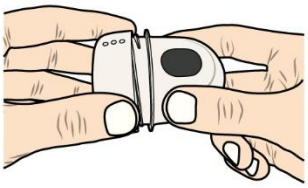


Step 3: Shave
Using 40 blade clippers or higher, shave a small 2-inch by 1.5-inch patch of fur as close to the skin as possible.

Step 4: Skin Prep Wipe
Wipe the application site with the No-Sting Skin-Prep Wipe included in the box. Allow site to dry for 30-60 seconds before proceeding.

DO NOT USE GLUE ON THE APPLICATION SITE OR SENSOR

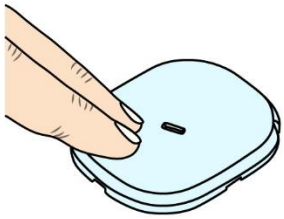
Step 5: Apply the GluCurve Pet CGM



Unscrew and remove the bottom cap from the applicator. **Note: Do not discard.** The pet parent needs to scan the QR code on the cap to activate the sensor and pair their phone. **Do not use glue.**



Press the applicator firmly against the skin and push the oval button to apply the sensor. Hold for 10 seconds, then pull the applicator away from the skin.



Press the sensor and the protruding adhesive pad firmly into the skin.

Step 6: Add patient in Veterinary Portal (first-time patients only)
If this is the first time the patient is using a GluCurve Pet CGM, go to www.GluCurve.com, click Veterinary Portal, log in, and click the Add New Patient button.

The GluCurve Pet CGM utilizes a username/password system for each patient, this allows any user with the credentials to log into the GluCurve app on any device to view or upload live readings. When adding a new patient, choose "**direct**" to create a generic username/password yourself to give to the pet parent or choose "**invite**" to email/text the pet parent a link to create the username/password themselves. **Note**: Ensure the password chosen is not sensitive and can be shared with other users.

Step 7: Activate sensor on GluCurve app
Clients using the GluCurve Pet CGM for the **first time** will need to download and log into the GluCurve app for iOS or Android with the username/password you or they created, and accept the terms and conditions of use and the privacy policy. **Repeat users** will need to log into the GluCurve app using their username/password, select the menu icon in the top left corner, select "CGM Connection", and select Start New Sensor.

Ensure Bluetooth is turned on. The client will be asked if the sensor was applied, click yes, click "use camera to scan code" and scan the QR code on the applicator cap. If you do not have the cap or are having trouble, click "Can't scan" and the app will search for the sensor and let you select it from a list.

Note: Veterinary clinics can log into the GluCurve app using their veterinary portal credentials to activate sensors and view/upload live readings too.

Warnings and Important information

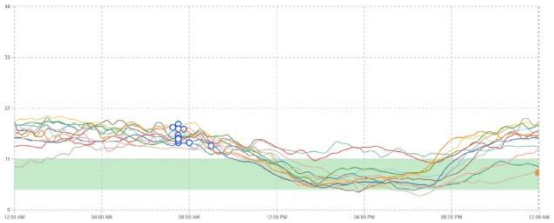
- Insulin therapy should NOT be changed in the event of unexpected or unusual glucose readings without confirming glucose readings.
- Clinical signs and Blood Glucose Meter (BGM) should be the primary sources of detection for hypoglycemia or hyperglycemia.
- While rare, skin irritation may occur from a reaction to the adhesive pad. **Use at your own risk**.
- Accuracy in the hypoglycemia and hyperglycemia range may vary more widely due to the limitations of CGM technology.
- Accuracy during the first few hours may vary.
- Do not use past expiration date.
- While well tolerated by most pets, duration of use cannot be guaranteed and damaging, biting, or scratching the sensor off is possible. Protective measures such as a surgical suit, harness, clothing, or soft cone may be needed for some pets.
- **WARRANTY:** The warranty for the GluCurve Pet CGM covers factory defects only, human error and pet error are not covered.
- **RECYCLING:** Check local laws and regulations before recycling any part of the GluCurve Pet CGM.

Flip Page

Three scenarios to understand and discuss with the client:

Scenario 1: 14 days of continuous glucose readings

Ideally, the sensor will provide 14 days of continuous glucose readings that are overlayed on a chart in the veterinary portal as 24-hour curves. This gives the veterinarian the ability to pick and choose which days to overlay and compare to best detect the overall trend to assist in making treatment decisions.

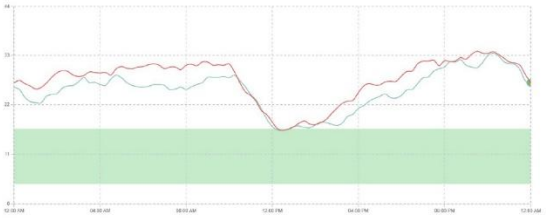


Each line represents a 24-hour daily curve

Scenario 2: CGM is removed/damaged before 14 days

While 14 days of use is ideal, it is not necessary. The patient's chart to the right demonstrates how 1 or 2 days of continuous readings can clearly show the glucose trend and be used to assist in making a treatment adjustment to better regulate the glucose levels of the patient.

Typically, only a few days of readings are needed to show the highs, lows, reaction to food/insulin, activity, and the overall trend. Therefore, if the pet removes or damages (see Scenario 3 below) the CGM before the full 14 days of use, it is not a waste of time or money and will typically still provide enough data to either confirm the treatment plan is optimal or to make an adjustment to better regulate the pet (which is the goal).



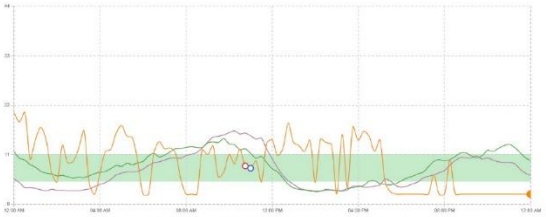
Each line represents a 24-hour daily curve

Scenario 3: The sensor inside the skin gets damaged

A membrane protects the glucose oxidase (GOx) enzymes on the 5mm electrode (tiny sensor) deployed into the skin to the interstitial fluid. This membrane can be damaged by internal tissue pressing into it over time, or by biting, scratching, or skin twitching that causes the electrode to shake violently. If this occurs, the sensor may stop reporting accurate readings before only displaying readings of 40 mg/dL / 2.2 mmol/L.

The patient's chart to the right demonstrates how it can be identified by unnatural waves (spikes and drops) as seen in the orange curve, compared to the green and purple natural curves before the electrode was damaged.

This is not due to any defect in the CGM, it is a challenge to overcome with the anatomy of cats and dogs and can typically be solved by changing the placement location. **Note:** See **Scenario 2** for details, typically, enough accurate data will be captured before the damage occurs to assist in making a treatment decision to provide value to the patient, client, and veterinarian.



Each line represents a 24-hour daily curve

GluCurve App for iOS

GluCurve App for Android

GluCurve Pet CGM User Manual

GluCurve Pet CGM Help

Specifications

Sensor Life	**Up to 14 days**
Reading Intervals	**Every 1 minute**
Glucose Range	**40-800 mg/dL**
Bluetooth Range	**15+ feet**
Water Resistance	**IP28**
Operating Temperature	**41F to 104F**
Sensor Size	**30 x 25 x 4 (mm)**
Sensor Weight	**4g**
Shelf Life	**1 year**
Power Source	**3V lithium battery**
Atmospheric Pressure	**70 kPa to 106 kPa**

Contact

Email Support: GluCurveSupport@alrt.com
Phone Support: (833) 925-0138 Mon-Fri 9am-6pm EST

Global Headquarters:
ALR Technologies SG Ltd
9 Raffles Place, #26-01 Republic Plaza
Singapore 048619

QuickStart Guide version: B51026

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.

⚠ **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 on-screen instructions to install the GluCurve app.

iOS

Android

Activating a Sensor

⚠ **WARNINGS:**

- 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

⚠ **WARNINGS:**

- 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 40-800 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.

Chapter 5: The Veterinary Web Portal

⚠ **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 www.GluCurve.com.
- To sign up or register a patient for the first time, follow the QuickStart Guide instructions in Chapter 3 or included in the box.

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 www.GluCurve.com.
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 device with sensor	• Verify smart device has Bluetooth enabled. • 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 GluCurveSupport@alrt.com, DO NOT REMOVE SENSOR unless instructed by ALR Technologies or 14 day use is up.
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 GluCurveSupport@alrt.com, DO NOT REMOVE SENSOR unless instructed by ALR Technologies or 14 day use is up.
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Chapter 7: Labelling Symbols

	Consult instructions for use		Manufacturer
	Temperature limit		Serial number
	Date of manufacture		Keep dry
	MR unsafe		Non-ionizing electromagnetic radiation
	Type BF Applied Part		Caution
	Environmentally Safe Period		Sterilized using irradiation
	Do not re-use		General symbol for recovery/recyclable
	Use-by date		Humidity limitation
	Do not use if package is damaged and consult instructions for use		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.
	Medical device		Refer to instruction manual/booklet
	Unique device identifier		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 domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

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 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_T	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
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, 1845MHz, 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 18Hz 28V/m PM at 217Hz 28V/m PM at 217Hz 9V/m PM at 217Hz	$\mathrm{d} = 1.2\sqrt{P}$ 80 MHz to 800 MHz $\mathrm{d} = 2.3\sqrt{P}$ 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 MHz Not Applicable	80 MHz to 800 MHz $\mathrm{d} = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $\mathrm{d} = 2.3\sqrt{P}$
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 Useful Life	14 days
Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	40 to 800 mg/dL (2.2 mmol/L to 44.4 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 www.GluCurve.com.

The Continuous Glucose Monitor hardware for the GluCurve Pet CGM System is manufactured in China.