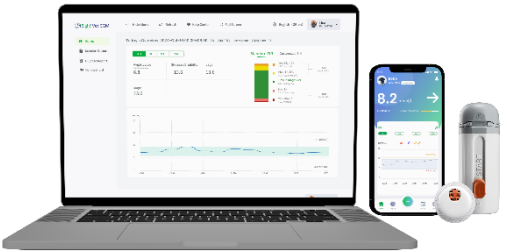
WOODLEY
EQUIPMENT COMPANY LTD.

InSight® Vet CGM

Continuous Glucose Monitoring System

User Guide



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Basic Information

Product Name:

InSight Vet CGM Continuous Glucose Monitoring System

Working Principle

This product is a real-time, calibration-free continuous glucose monitoring system. Its working principle involves a flexible sensor implanted under the animal's skin, where glucose oxidase on the sensor reacts electrochemically with the glucose in the interstitial fluid, generating a measurable electrical signal. This signal is transmitted to the app via a transmitter, where the data is processed and the glucose concentration in the interstitial fluid is displayed.

Structure and Composition

This product consists of four parts: the sensor assembly, the transmitter assembly, the inserter assembly and the glucose management software. This product is designed for single use. The sensor assembly and the needle are sterile (sterilised by irradiation), while the other parts of the applicator assembly and the transmitter assembly are non-sterile.

Product Accessories List

- x1 InSight Vet CGM Continuous Glucose Monitoring System (disposable)
- x1 Quick User Guide
- x1 Service Kit (including an overpatch)

Safety Information

Scope of Application

This product is intended for continuous or periodic monitoring of glucose levels in the interstitial fluid of adult cats and dogs with diabetes. The product can provide and store real-time glucose values, allowing users to track trends in glucose concentration changes. It can also issue alerts when glucose levels fall below or rise above preset values. This product is for single use only, designed for a single user and does not require user calibration. The measurement results from this product should not be used as the basis for deciding or adjusting the treatment plan for diabetic patients. The product is not intended for use on humans.

Contradictions

This product must be removed before undergoing Magnetic Resonance Imaging (MRI).

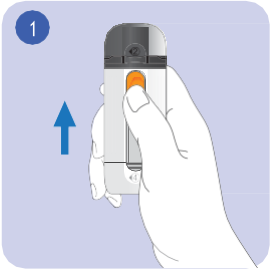
Precautions

- The use of the continuous glucose monitoring system has not been evaluated in pregnant animals, animals undergoing dialysis or animal patients under 1 year of age.
- The monitoring results of this product are intended as a reference for the auxiliary diagnosis of diabetes. If the system is used while undergoing medical examinations involving strong magnetic fields or electromagnetic radiation, including X-ray examinations, MRI (magnetic resonance imaging) or CT (computed tomography) scans, the sensor in use must be removed and replaced with a new one after the examination. The impact of these medical procedures on the system's performance has not been evaluated.
- If significant skin irritation is observed around or under the sensor during wear, observe the condition and manage it accordingly. If the irritation subsides, continued use is possible. However, if the irritation persists or the animal experiences significant discomfort, consult a professional veterinary healthcare provider and consider removing the product.
- This product is a one-piece design. The sensor, transmitter and introducer are for single-use only. Do not reuse them.
- Modification is prohibited. Do not modify any components of the continuous glucose monitoring system.
- After wearing the product, ensure that the application site on the animal is protected from external impacts. Avoid snagging the product while putting on or taking off pet clothing. Be cautious of bumps when entering and exiting doors or elevators, and prevent the pet from engaging in actions such as rolling on the ground, which could dislodge the product.
- Vigorous exercise may cause the sensor to shift or loosen. If the sensor becomes loose or dislodged from the implantation site, it may not provide accurate readings. Remove it if necessary. If the sensor probe is found or suspected to be broken, do not attempt to handle it yourself. Seek assistance from professional healthcare providers or contact Woodley Equipment Company.

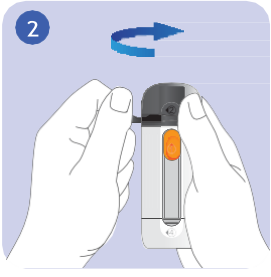
- The continuous glucose monitoring system contains small parts that could pose a choking hazard if swallowed. Ensure that the product is kept out of reach of children and pets both during use and before or after use.
- Accidental pressing of buttons could cause the introducer needle to extend, posing a risk of injury to people and pets. After application, promptly cover the device with the protective cap and dispose of the introducer needle according to local regulations. Keep the introducer needle out of reach of pets and children.
- The sensor and transmitter are designed to be waterproof, allowing the pet to wear them during regular bathing, showering and swimming. However, avoid exposing the product to seawater, immersing it in water deeper than 1 meter or keeping it submerged for more than 30 minutes.
- During periods of rapid glucose changes (exceeding 0.1 mmol/L per minute), the interstitial glucose levels detected by the continuous glucose monitoring system's sensor may not accurately reflect blood glucose levels. In such cases, use a pet glucose meter to perform a blood test to verify the sensor's glucose readings.
- To confirm hypoglycaemia or near-hypoglycaemia detected by the continuous glucose monitoring system's sensor, a blood test with a glucose meter can be performed.
- Do not ignore symptoms in pets that may be caused by hypoglycaemia or hyperglycaemia. If symptoms do not match the continuous glucose monitoring system readings or if the readings are suspected to be inaccurate, check the sensor's glucose readings with a glucose meter or other methods.
- Severe dehydration or excessive fluid loss in animals may lead to inaccurate results. Rehydrating the pet promptly may restore accuracy. If you believe your pet is dehydrated and requires treatment, consult a professional veterinary healthcare provider immediately.
- The performance of this system has not been evaluated when used in conjunction with other implanted medical devices.

Sensor Wearing

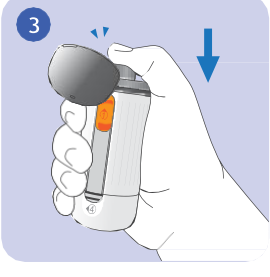
The intended operators of this product are pet owners or professional healthcare providers. Please carefully read the user manual, quick user guide or receive training from a professional before use. The product can be used in a home environment.



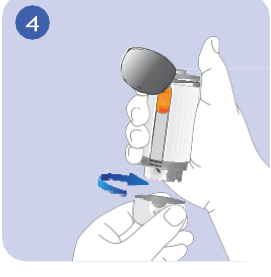
Push the button upwards until it can no longer be pushed.



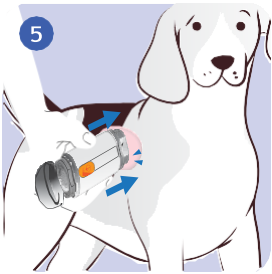
Tear off the pull tab on the top cap and open the cover.



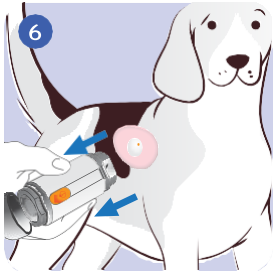
Press the button until you hear a click.



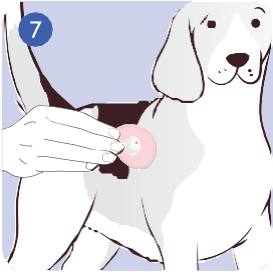
Twist off the device's lower cover counterclockwise to prepare for sensor insertion.



Place the bottom of the device on the insertion site and press down firmly to insert the sensor.



Gently remove the device and check if the sensor is properly adhered. If necessary, use tweezers to assist in peeling the sensor from the applicator.



Press down on the adhesive around the sensor to secure it and reinforce it with protective tape. Make sure the tape adheres well to the skin and is firmly attached.

Precautions

- After insertion, dispose of the used insertion device according to regulatory requirements. Be aware that it contains a sharp needle tip and disassembly is prohibited.
- Do not press down on the insertion device before placing it on the prepared area to avoid damaging the product or causing injury.
- Improper positioning during insertion may cause minor bleeding. If bleeding persists, remove the sensor and insert a new one in a different location.

Sensor Connection and Protection

- After successfully logging into the app, use the scanning frame to scan the QR code on the outer packaging or the insertion device to connect to the sensor.
- Once the sensor is connected, it is important to protect it properly. Most animals can tolerate the product well but inadequate protection can reduce the duration of its use. Pets might scratch, bite, rub, shake or, in multi-pet households, play with other pets, which can lead to the sensor becoming dislodged. Therefore, taking appropriate protective measures is crucial.

  Depending on the pet's condition, you can use:
  - Pet clothing
  - Bandages
  - A Cone
  - If the pet's skin can tolerate it, bio-organic glue can also be applied to the product before use to enhance adhesion.

Due to the differences in pet types, activity levels and personalities, specific protective measures should be tailored to the individual pet's needs. It is recommended to discuss protective measures with your veterinarian.

Product failures caused by dislodgement are not covered under the warranty.

About the App

This chapter will explain the relevant information regarding the blood glucose management software, as well as how to use a smart device with the installed blood glucose management software to connect to the sensor via Bluetooth wireless communication and retrieve data from the sensor.

Note:
The software interface screenshots provided in this section are for reference only; the display on the smart device may vary based on the actual situation.

App Overview
The pet-specific blood glucose management software is a part of the continuous glucose monitoring system (CGM) designed for pets. It retrieves glucose-related data from the sensor, helping users to achieve continuous monitoring and alerts for their pet's blood glucose levels.

The continuous glucose monitoring system provides continuous, comprehensive and reliable 24/7 blood glucose information. The blood glucose management software features a graphical user interface, composed of windows and function keys, with four main menus: Real-Time Blood Glucose, Daily Data, Multi-Day Comparison and Personal Centre.

The key functions include:

- Real-Time Blood Glucose
- Add sensor devices
- Display current blood glucose values, blood glucose trends and data trajectory
- View continuous glucose monitoring curves and key blood glucose indicators for the past 4 hours, 8 hours, 12 hours and 24 hours
- Log continuous glucose monitoring-related events
- View blood glucose alert history

Daily Data
- View daily blood glucose analysis data
- View the continuous glucose monitoring curve for each day and the recorded events for that day

Multi-Day Comparison
- View recorded multi-day continuous glucose monitoring curves
- Compare continuous blood glucose curves and data over multiple days

Personal Centre

- Alarm settings function
- Modify system default blood glucose safety ranges and set alarm options
- Edit pet and personal information
- Access usage help
- View software version information

Expected Performance

Blood Glucose Update Frequency: In the 'Real-Time Blood Glucose' feature page of the blood glucose management software, new blood glucose data is displayed every 3 minutes.

Compatible Hardware

The blood glucose management software is only compatible with sensors in the continuous glucose monitoring system. Smart devices with the installed blood glucose management software can connect to the sensors via Bluetooth wireless communication to obtain blood glucose data and related information.

Software Precautions

The blood glucose management software is only intended for use with sensors in the continuous glucose monitoring system to obtain interstitial glucose concentration levels in adult pets (≥1 year). The test results provided by the product are not to be used as the basis for determining or adjusting the treatment plan for diabetic pets.

The accuracy of reports generated by the blood glucose management software cannot reach 100% and is intended only to improve the management and prevention of pet diabetes. It should not be used as a basis for adjusting treatment medications.

Note:
If the blood glucose readings obtained through the blood glucose management software do not match the pet's current physical condition, consult a professional healthcare provider and follow their advice for appropriate actions.

Note:
If the smart device has insufficient storage space, the blood glucose management software may experience operational issues. In such cases, users should clear the device's storage space and restart the application to continue normal use. It is recommended that users regularly clean their smart device's storage space.

Note:
The blood glucose management software occupies about 200 MB of memory during operation. To ensure the software runs smoothly, allocate sufficient operating resources for it.

Note:
Users should regularly ensure that the blood glucose management software runs on smart devices that are free of viruses or malware and use the latest security patches for updates.

Note:
Before officially using the blood glucose management software, users should set the system time on the smart device correctly. Changing the system time during use may lead to anomalies in the stored data.

Note:
The operating environment for the blood glucose management software must meet certain conditions; otherwise, software performance may be affected.

Note:
If the application unexpectedly closes during use, try restarting the software to resolve the issue.

If users click on unauthorised functions or interfaces, pop-up warnings will block the action.

Please use smart mobile terminals (e.g., smartphones) that meet national standards and are certified for installing the app.

During app operation, follow the safety usage tips provided by the smart mobile terminal. For cleaning the smart mobile terminal, refer to its user manual.

After sensor implantation, monitoring data will be transmitted to the transmitter component, which handles data transmission between the transmitter component and the app. No other non-system components should be connected.

Installation and Maintenance

Table 1: Software Operating Environment

	Android	IOS
System	Android 5.0 or higher Harmony 1.0 or higher	iOS13 or higher
CPU	2.0 GHz 64-bit dual-core or higher	1.4 GHz 64-bit dual-core or higher
RAM	4GB or higher	2GBor higher
Network Bandwidth	5Mbps or higher	

Installing the Software
Download the installation package for the blood glucose management software from the specified website for this product. Once the download is complete, click on the installation package to open the installation page, then click 'Install'. After the installation is complete, select 'Open' to launch the blood glucose management software and proceed with further operations

Maintenance and Support
Woodley Equipment Company provides technical support and maintenance for the blood glucose management software through software updates. For software upgrade and maintenance, please contact us using the provided contact information.

Uninstalling the Software
To uninstall the blood glucose management software from a smart device, press and hold the icon for the continuous glucose monitoring system software on the device's desktop. An 'Uninstall' option will appear next to the icon. Click 'Un- install' to remove the software.

Alternatively, you can uninstall the software through the 'Settings' – 'App Management' section of the smart device.

Note:
The process for uninstalling software may vary between different manufacturers' smart devices; please refer to the manufacturer's actual uninstallation instructions.

Known Limitations

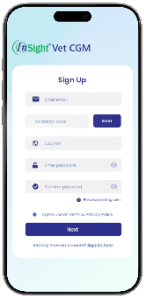
Users must enter the correct mobile verification code to complete the login and proceed with further operations. The account must be an email account only.

App Operation Guide

Download App

Scan the QR code to download and install the app.

Register Account



After installing the software, please follow the system prompts to:

1. Open the Blood Glucose Management Software.
2. Agree to permissions for [Bluetooth], [Background App Activity], [Location], etc.
3. Register using your email.
4. Complete the basic information setup.

Sensor Pairing

Scan the QR code on the product packaging or the device to connect to the sensor. Once connected successfully, the system will enter a 30 minute initialisation phase.

(e.g. UDI Code)

Start Initialisation:
During the 30 minutes after the sensor is applied, it will be in the initialisation phase.

During this period, the main screen of the software will display the remaining time of the initialisation phase (e.g., 29 minutes, 28 minutes, etc.).
Users will not be able to obtain glucose readings during this time.

Start Monitoring and Enter the 'Home Screen':
After 30 minutes, the sensor's initialisation phase will end.
At this point, you can obtain glucose readings detected by the sensor through the blood glucose management software, which will update every 3 minutes.

Handling Device Disconnection from the Sensor:
If the smart device disconnects from the sensor, the real-time monitoring page will display "Device Connection Failed".

1. Check if Bluetooth is enabled on your smart device. Follow system prompts to enable Bluetooth and reconnect to the sensor.

2. Ensure that the distance between the smart device and the sensor is within the transmitter's range. If not, move the smart device closer to the sensor.

3. Refer to the [Software Precautions] section in this manual for further details.

If your smart device reconnects to a sensor that has been operating for more than 30 minutes, the sensor will quickly upload all recorded data to the software.

Once all recorded data has been uploaded, glucose readings will continue to update every 3 minutes until the sensor expires after 10 or 14 days of use.

Real-time Data

Note:
The software interface images provided in this manual are for reference only. Please refer to the actual app for the accurate display.

Trend Arrows

↑↑	Glucose is rapidly rising
↑	Glucose is rising
↗	Glucose is slowly rising
→	Glucose is steady
↘	Glucose is slowly falling
↓	Glucose is falling
↓↓	Glucose is rapidly falling

Add Event

Users can click 'Add Event' on the Tab Menu to record activities such as your pet's meals, exercise, injections, blood samples, weight and other activities.

After completing the check-in, the real-time glucose curve will display the corresponding icon from the check-in options.

Table 2 Icon definition

	Meal Icon Add a record of your pet's meals, detailing the food consumed at each meal.
	Exercise Icon Add a record of your pet's exercise, including the type of activity.
	Insulin Icon Add Insulin dosing record.
	BG Icon Add a record of your pet's blood glucose test.
	Weight Icon Add a record of your pet's weight.

View Blood Glucose Alerts Records
View historical alert records for low and high blood glucose levels. Click the icon in the top right corner to access the alert records page.

Blood Glucose Report Daily Data
View detailed daily blood glucose data by clicking 'Daily Data' at the bottom. This section provides glucose indicators, blood glucose analysis and daily event records to help you understand daily glucose levels comprehensively. You can also review blood glucose data from other dates by clicking 'Previous Day', 'Next Day' or 'Calendar' at the top of the page.

Multiple Day Comparison:
Single Day Observation – View glucose data curve charts for all recorded times.
Multiple Day Comparison – Compare glucose curves and data across multiple days.

Personal Centre
Edit Profile:
Click to edit personal information and blood glucose data, then click 'Save'. To discard changes, click the 'x' button in the top left corner.

Device Data:
Click to view information about the sensors currently in use and those previously used.

Alarm Settings:
Click to set glucose alert intervals, frequencies, alert methods, thresholds and 'Do Not Disturb' settings.

My Reports:
Click to view generated blood glucose analysis reports.

User Manual:
Click to view the sensor installation process. If you are familiar with it, you can click 'Skip' in the top right corner or the 'x' button in the top left corner to exit.

My Settings:
Click the settings icon to access the settings page, which includes software name, version information, privacy policy, user agreement and account logout. To log out, click 'Profile'>'Logout' to exit the current account; log in with a new account after logging out.

View Blood Glucose Alert Records:
Click the bell icon in the top right corner to access the alert records page for low and high glucose levels.

Blood Glucose Calibration:
Due to variations in pet sizes and factors affecting blood glucose values, a calibration feature is provided. If you feel that the app's glucose data is inaccurate while your pet's glucose levels are stable, use the calibration function to adjust the data.

Performance Efficiency
Under the software operating environment described in this manual, the blood glucose management software's 'Real-Time Blood Glucose' page can display a new glucose reading every 3 minutes.

Compatibility
If an update is required for the blood glucose management software installed on a smart device, the new version will overwrite the old version. Only one version of the software can be installed on a smart device; the functionality will be based on the latest installed version. Running the software alongside other applications will not affect their functionality or cause errors. The software communicates with the sensor's transmitter via Bluetooth protocol. No prior environment or parameter configuration is needed for using the software.

Ease of Use
Basic knowledge required to use the blood glucose management software includes:

- Understanding of smart device usage.
- Ability to use Android, Harmony OS or iOS operating systems.

Prompt Information
- If the user enters an incorrect verification code, a pop-up will indicate "Incorrect Verification Code".
- Before clicking the input field, it will show a grey placeholder text e.g. "Please enter...".
- For errors in scanning the QR code or entering the connection code, a pop-up will display "This device is already bound to another account" or "Device not found".
- When logging out, a pop-up will prompt "You will not receive glucose information after logging out".
- For device connection failures or no device connection, the interface will display messages like "Device Connection Failed" or "Connect Device".

Reliability
The blood glucose management software can be managed and backed up using the 'Data Export' feature.

Information Security
The software protects information security using phone numbers and access is restricted to the user or authorised followers only.

Maintainability
To maintain the blood glucose management software, go to the bottom of the software home page, click 'Personal Centre', then select 'My Settings' to perform maintenance.

Portability
The blood glucose management software is designed to operate at least within the environment described under 'Software Operating Environment' in

this manual.

Glossary

- TIR (Time in Range): The proportion of time with normal blood glucose levels relative to the total time.
- TAR (Time Above Range): The proportion of time with blood glucose levels above the normal range relative to the total time.
- TBR (Time Below Range): The proportion of time with blood glucose levels below the normal range relative to the total time.
- AGP (Ambulatory Glucose Profile): A method used to describe blood glucose data, primarily for diabetes management. AGP organises and visualises data collected from continuous glucose monitors (CGM) or other glucose monitoring devices to provide a comprehensive understanding of a patient's glucose control. AGP is typically presented in chart form, showing glucose levels over a period, including average glucose, glucose fluctuation range and high/low glucose points. This helps healthcare professionals assess glucose control, identify potential issues and support more effective treatment planning.
- Average Glucose: The mean glucose level over a specified period.
- LAGE (Largest Amplitude of Glucose Excursion):** The maximum glucose fluctuation during the day.
- GV (Glucose Variability): Refers to the degree of frequent and significant fluctuations in glucose levels over a period. It is an important measure of glucose control stability, usually assessed using data from continuous glucose monitoring (CGM) or other glucose monitoring devices.
- MAGE (Mean Amplitude of Glucose Excursions):** The average amplitude of glucose fluctuations.
- MODD (Mean of Daily Differences): The average absolute daily glucose difference.

Maintenance and Disposal

Maintenance
The InSight Vet CGM Continuous Glucose Monitoring System is for single-use only and contains no repairable parts.

If necessary during use, you can gently wipe the surface of the transmitter with a medical alcohol wipe and let it air dry.

The transmitter and sensor are precision instruments. In case of malfunction, please contact Woodley Equipment Company. Repairs by third-party individuals or institutions are not allowed. The manual does not provide circuit diagrams or component lists. If you encounter issues during use, please refer to the manual or contact Woodley Equipment Company.

Disposal
Disposal of this product should comply with local regulations regarding electronic devices, batteries, sharp objects and materials potentially exposed to liquids. For more information on how to properly dispose of the system components, please contact Woodley Equipment Company.

Potential Interfering Substances Information
It has been verified that 4 mg/L of ascorbic acid does not interfere with sensor performance.

Clinical Information
The effectiveness and safety of the product were evaluated in a multi-centre, paired clinical trial, using the EKF analyser as the gold standard.

Fifty diabetic outpatient and inpatient subjects were enrolled across multiple clinical trial centres. The clinical trial results demonstrated that the product's effectiveness and safety meet the needs of veterinary clinical applications, with the primary accuracy results as follows:

Effectiveness Evaluation Indicators	**Outpatient**	**Inpatient**
EKF analyser measured venous blood glucose >4.4 mmol/L (80 mg/dL)	Deviation within ±20%	Deviation within ±20%
	1728/1801 (95.95%)	1673/1721 (97.21%)
EKF analyser measured venous blood glucose <4.4 mmol/L (80 mg/dL)	Deviation within ±1.1 mmol/L (20 mg/dL)	Deviation within ±1.1 mmol/L (20 mg/dL)
	73/74 (98.65%)	99/101 (98.02%)
20/20% concordance rate with EKF analyser measured venous blood glucose	1801/1875 (96.05%)	1772/1822 (97.26%)
Mean Absolute Relative Difference (MARD)	7.43%	7.15%
High blood glucose alert success rate/failure rate	99.86%/2.37%	99.34%/1.32%
Low blood glucose alert success rate/failure rate	100%/0.28%	100%/0.35%
High blood glucose detection success rate/ failure rate	96.92%/3.08%	94.55%/5.45%
Low blood glucose detection success rate/ failure rate	87.05%/12.05%	100%/0%
Sensor repeatability	0.06	0.06
Sensor lifespan	95.20%	99.18%

Troubleshooting

Problem	Cause	Solution
The sensor is not attached to the pet's skin.	The area has remaining dust, oil or hair.	Remove the transmitter and sensor components. Consider shaving the fur and/or cleaning the area with soapy water. Ensure that a 40+ blade clipper was used and the fur is shaved as cleanly as possible. Follow the instructions for applying the sensor component. Ensure that the skin preparation wipe provided in the packaging was used and allowed to dry before use. Confirm that the inserter was firmly pressed into the skin for 10 seconds. Check if the separation of the inserter from the sensor was appropriate.
Skin irritation at the application site.	Friction at the site due to clothing seams, tight areas or accessories.	Ensure that there is no friction at the site from clothing edges or the pet's chest or back.
	Possible allergy to adhesive materials.	Use the skin-tac skin prep wipe before applying the product. If irritation occurs, please consult a professional veterinarian to determine the best solution.
Running the App: Unable to read blood glucose data.	Bluetooth disconnected, GPS not enabled or weak signal.	Please connect Bluetooth, enable GPS access or move to an area with a strong signal.

Technical Information

Basic Parameters

Performance Indicators	
Measurement Range	2 mmol/L to 42 mmol/L
Measurement Accuracy	When glucose concentration ≤ 7.5 mmol/L, deviation ≤ ±1.0 mmol/L
	When glucose concentration >7.5 mmol/L, deviation ≤ ±7.5%
Operating Conditions	Temperature: +5°C to +40°C Relative Humidity: 10% to 90% Atmospheric Pressure: 700 to 1060 hPa
Storage and Transport Conditions	Temperature: +2°C to +30°C Relative Humidity: 10% to 90% Atmospheric Pressure: 700 to 1060 hPa
Water Resistance	Level 7 when sensor component and transmitter component are connected
Shelf Life	12 months (refer to product label for production and expiration dates)

Usage Life	10 days or 14 days
Network Security Requirements	
Interface Type: Low-energy Bluetooth wireless transmission Communication Protocol: Bluetooth BLE	
Wireless Transmission and Reception Band and Bandwidth	Band: 2.402 GHz to 2.480 GHz Bandwidth: 2 MHz
Wireless Transmission and Reception Modulation Type	GFSK
Effective Radiated Power for Wireless Transmission	-2 dBm
User Access Control	Email + Verification Code
Application Parts	Parts in contact with the patient include adhesive tape, PCB housing and flexible sensor

Electromagnetic Compatibility

⚠ The system can monitor a minimum glucose concentration of 2.0 mmol/L and a maximum of 42.0 mmol/L.

⚠ Active medical devices are subject to specific EMC (Electromagnetic Compatibility) precautions and must be installed and used according to these guidelines.

⚠ Portable and mobile communication RF devices may affect the use of electrical equipment.

⚠ The continuous glucose monitoring system should not be used close to or stacked with other devices. If proximity or stacking is necessary, ensure that it operates correctly in its configured setup.

Guidelines and Manufacturer's Statement – Electromagnetic Emission		
The continuous glucose monitoring system is intended for use in the specified environment. The purchaser or user should ensure its operation in such an environment.		
Emission Tests	**Class**	**Electromagnetic Environment – Guidelines**
Radio Frequency Emission: GB 4824	Group 1	The continuous glucose monitoring system uses radio frequency energy solely for its internal functions. Therefore, its RF emissions are very low and the likelihood of causing interference with nearby electronic devices is minimal.
Radio Frequency Emission: GB 4824	Class B	The system is designed for use in various environments, including residential settings and can be connected directly to the public low-voltage power supply network for residential use.
Harmonic Emissions: GB 17625.1	Not applicable	
Harmonic Emissions: GB 17625.1	Not applicable	

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
The continuous glucose monitoring system is intended for use in the specified environment. The purchaser or user should ensure its operation in such an environment.			
Immunity Test	**IEC 60601 Test Levels**	**Compliance Level**	**Electromagnetic Environment - Guidelines**
Electrostatic Discharge (ESD): GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±8kV air discharge	The floor should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst: GB/T 17626.4	±2 kV for power supply lines, ±1 kV for input/output lines	Not applicable	/
Surge: GB/T 17626.5	±1 kV line-to-line, ±2 kV line-to-ground	Not applicable	/

Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines: GB/T 17626.11	<5% UT for 0.5 cycle (at UT, >95% voltage dip) 40% UT for 5 cycles (at UT, 60% voltage dip) 70% UT for 25 cycles (at UT, 30% voltage dip) <5% UT for 5 seconds (at UT, >95% voltage dip)	Not applicable	/
Power Frequency Magnetic Field (50/60Hz): GB/T 17626.8	3 A/m	3 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT refers to the AC mains voltage prior to the application of the test level.			

Suggested Safe Distance

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Continuous Glucose Monitoring System

InSight Vet CGM is intended to be used in an electromagnetic environment where radiated RF disturbances are controlled. The purchaser or user of InSight Vet CGM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and InSight Vet CGM as recommended below, according to the maximum output power of the communication equipment.

Rated Power of Transmitter (W)	0.01	0.1	1	10	100
Safe Distance (m) Based on Transmitter Power					
150 kHz - 80 MHz d = 1.2√P	0.12	0.38	1.2	3.8	12
80 MHz - 800 MHz d = 1.2√P	0.12	0.38	1.2	3.8	12
800 MHz - 2.5 GHz d = 2.3√P	0.23	0.73	2.3	7.3	23

For transmitters with a maximum rated output power not listed in the table above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter. Here P is the maximum rated output power of the transmitter in watts (W) as provided by the transmitter manufacturer.

Note:
At 80 MHz and 800 MHz, the higher frequency range should be used.

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

Electromagnetic Compatibility Basic Performance

The system operates normally, maintains normal communication with the application and does not experience crashes or errors.

The measurement accuracy meets the following standards:

When glucose concentration is ≤ 7.5 mmol/L, the deviation is not greater than ±1.0 mmol/L.

When glucose concentration is > 7.5 mmol/L, the deviation is not greater than ±7.5%.

Symbols

	Manufacturer		Mandatory to Read Instructions
	Date of Manufacture		Warning
	Expiry Date		Humidity Limit
	Lot Number		Temperature Limit
	Product Code		Keep Dry
	Serial Number		BF Type Applied Part
	Sterilised by Radiation		Non-ionising Radiation
	Do Not Reuse		Magnetic Resonance Unsafe
	Do Not Use if Packaging is Damaged		IP27 Rating: Solid objects greater than or equal to 12.5 mm in diameter, water protection level 7
	Packaging is Recyclable		Dispose in Accordance with Local Regulations
	Stacking Layer Limit n ≤ 5		Stacking Mass Limit
	Keep Upright		Fragile
	Avoid Heat and Radiation Sources		

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