Continuous Glucose Monitoring Systems

Transmitter, Sensor, App

USER MANUAL

Model： i3

INFINOVO MEDICAL CO.,LTD.

JN-STP-I3-SMS-001
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Table of Contents

Terminology

Sensor	Component of the monitoring system, containing the applicator, sensor electrode and sensor base. The applicator inserts the sensor electrode under the skin to measure glucose level in interstitial fluids.
CGM	Abbreviation for Continuous Glucose Monitoring
CGMS	Abbreviation for Continuous Glucose Monitoring Systems
Applicator	A disposable component that inserts the sensor electrode under the skin and will be removed after the sensor electrode is inserted.
Sensor electrode	A device inserted under the skin that reacts with the interstitial fluid and converts biological signals into electrical signals.
Sensor base	A small plastic base attached to the abdomen skin to hold the transmitter.
Releaser	A plastic part, used for removing the transmitter from the sensor base.
Transmitter	The transmitter is a component of the Continuous Glucose Monitoring system, which is embedded in the sensor base and sends the blood glucose information to the Mobile Application wirelessly via Bluetooth Low Energy.
Transmitter serial number	Consisting of numbers and letters, it is unique for each transmitter and can be found on the back of the transmitter and on the transmitter package.
App	The mobile software that receives blood glucose information, displays blood glucose readings, trend curves, trend arrows and transmitter status.
Default value	The values that come with the system.
Calibration	Blood glucose value measured by a blood glucose meter and entered into the App for calibration to ensure the accuracy of the CGMS reading.
Blood Glucose value	Values measured by blood glucose meter.
Sensor Glucose readings	Values measured by Continuous Glucose Monitoring Systems
Trend curve	Displays changes and tendencies of glucose readings over a period of time and current blood glucose status.
Trend arrow	Indicate the speed and tendency of changes of glucose readings.
Data receiving range	The communication distance between the App and the transmitter, which shall be within 2 m without obstacle.
Repeat prompt	When the first notification is not confirmed, the prompt information will be repeated.

1 Product overview

The Continuous Glucose Monitoring Systems consists of a disposable Sensor, a Transmitter, the Mobile Application, and Analysis Software. It is recommended to wear the sensor on the abdomen and avoid movements where the sensor is applied. The sensor electrode chemically reacts with glucose in the hypodermic interstitial fluid to generate an electrical signal. Transmitter analyzes and calculates the electrical signal, and generates the blood glucose values, which is sent to the mobile App. The user analysis software downloads and collects data from the mobile App for processing and analysis, then gives reports.

During the monitoring period, at least two blood glucose values (from fingerstick testing with BG meter) need to be entered into the CGM App every day (every 12 hours) for calibration. The CGMS measures a glucose reading every three minutes, totaling 480 readings each day. The system is indicated for continuous monitoring of the blood glucose data for 14 days and form a continuous blood glucose curve. In addition, dining, sport, medication and other activities can be recorded as an event.

Glunovo i3 CGM

Analysis Software

1.1 Sensor overview

Sensor

The continuous glucose monitoring sensor is a product in a sterile sealed pouch. The sensor is mainly made up of an applicator, a sensor base and a sensor electrode. An adhesive pad is attached to the sensor base. Insert the sensor electrode into the subcutaneous tissue of the abdomen and remove the applicator. The sensor base is attached to the skin for up to 14 days of monitoring. Please dispose of the sensor according to your local regulations for medical waste, after the sensor session is finished,

The performance parameters of sensor

Model No.	SI3-WL-03
Measurement range	2.2-22.2 mmol/L
Effective working time	14 days
Calibration method	Glucose Meter
Calibration range	2.2-22.2 mmol/L
Storage conditions	Temperature:2°C-25 °C; Relative humidity:15%-85%
Transport conditions	Room temperature for transportation
Rated voltage	d.c. 3V
Working conditions （After the transmitter placed in the sensor base）	Temperature： 10 °C-40 °C； Relative humidity： 10%-95%
Battery lifetime	No less than 14 days
Sterilization method	Irradiation sterilization
Validity period	Details see the product label
Power support	Internal power supply

1.2 Transmitter overview

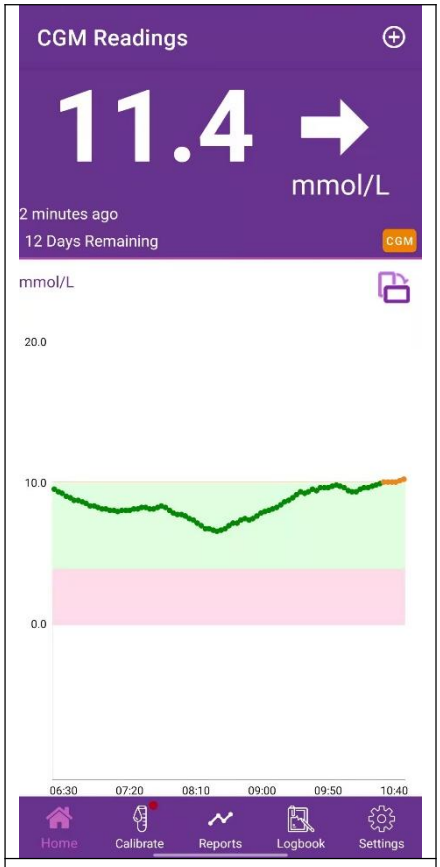
The continuous glucose monitoring transmitter is a component connected to the sensor base. Once the transmitter is embedded in the sensor base and the sensor electrode is activated through the App, the transmitter sends the sensor glucose value to the App. When properly worn, the transmitter and App have a transmission range of 2 meters without obstruction. Wireless connection might be disrupted in swimming pools, bathtubs and waterbed.

The performance parameters of transmitter

Model No.	TI3-WL -03
Size	length33.1 mm *width19.35 mm *height 8.3mm
Weight	3.7 g
Display interval	3 mins
Calibration method	Blood Glucose meter
Calibration frequency	twice per day（24h）
Data receiving range	2 m（without obstruction）
Expect product service life	Reused up to 8 times
Validity period	36 months
Operation mode	Continuous performance
Protection grade	IP27
Working conditions（After the transmitter placed in the sensor base）	Temperature：10 ºC-40 ºC； Relative humidity：10%-95%
Atmospheric pressure	70kPa-106 kPa
Transport and Storage conditions	Temperature：0 ºC-45 ºC； Relative humidity：10%-95%
Wireless	Bluetooth 5.0, 2402-2480 MHz, GFSK, 0 dBm

1.3 App overview

The App is a mobile medical application for its continuous glucose monitoring system to receive and process glucose readings. The software displays real-time blood glucose readings, trend curves, trend arrows, and transmitter status. It has functions such as adding Notes, Alarms/Alerts, Logbook Entries, Reports, Data Export feature and so on.



Main interface of App

The main interface of App displays blood glucose readings, trend curves and trend arrows. App and transmitter can be connected through Bluetooth, pairing for data communication. A blood glucose meter is also needed to use the Continuous Glucose Monitoring System.

The performance parameters of App

Item	Detail
Operating system	Android 6.0 and above/IOS 13.2 and above
Connection	One App can only connect to one transmitter at the same time
Data transmission	Transmitter and App (phone) transmit data via Bluetooth protocol The file exported by the app is transferred to the analysis software.
Storage Format	App export data storage format is Excel file

1.4 Analysis overview

Analysis software downloads and collects data from the Mobile App for processing and analysis, then produces reports.

Warning

The software does not provide any medical advice and cannot be used for such purpose. Do not adjust your treatment plan without consulting your medical diabetes team.

2 Safety Information

2.1 Application definition

The device is intended for continuous or periodic recording of glucose levels in interstitial fluid for adult patients with diabetes aged 18 or older. The information is intended to support, rather than to replace standard glucose meter and is intended for detecting trends and track pattern to provide reference information for patients to better manage diabetes. The system provides real-time blood glucose value, which is received and displayed by the App. The blood glucose value data can be further imported into the software for analyzing historical blood glucose values.

Apply site:

- Abdomen

Frequency of data interaction:

- Once every 3mins

Reuse:

- Sensor is disposable； The transmitter can be reused up to 8 times.

Warning
CGMS(i3) does not provide any medical advice and cannot be used for such purpose. Do not adjust your treatment plan without discussing it with your medical diabetes team.

2.2 Important user information

In order to use this product safely, please review your product instructions before using your Continuous Glucose Monitoring System. The instructions include contraindications, warnings, cautions, and other important user information. Discuss with your doctor how to use the information to help you control your blood glucose. The instruction manual contains important information about system troubleshooting and equipment performance characteristics.

2.3 Contraindications

Part of the sensor shall pierce the skin, so it is recommended that people with delicate skin use the device cautiously. The product must be removed before you undergo magnetic resonance imaging (MRI).

Intake of acetaminophen while wearing the sensor may falsely raise your sensor glucose readings.

2.4 Warning

- Read the instructions thoroughly. incorrect use of the continuous blood glucose monitoring system may lead to misunderstanding of the information provided by the system or affect the performance of the system and miss low/high blood glucose incidents.
- Continuous glucose monitoring cannot be used as a basis for diabetes diagnosis, such as for insulin injection treatment. It cannot replace blood glucose meter. The value of blood glucose may differ from the reading of blood glucose. Using glycemic readings as a diagnostic basis for diabetes may result in low/high blood glucose.
- Do not ignore the symptoms of high / low blood glucose levels. If the sensor glucose reading does not match the symptoms, a blood glucose meter should be used to measure the blood glucose even if the CGM reading is within the normal range.
- Calibrate at least twice a day, or the sensor glucose readings might be inaccurate and you might miss a low or high blood glucose value.
- In rare cases, the sensor electrode may be fractured. If the sensor electrode breaks and there is no visible sensor electrode on the skin, do not attempt to remove it yourself. Seek professional medical help in the condition of infection or inflammation - redness, swelling or pain. If the sensor electrode ruptures, please report to our technical support.
- Do not use sensors when its sterile packaging is damaged. Using unsterilized sensors may lead to infection.
- The storage temperature of the sensor is 2^{o}C-25^{o}C. The sensor can be transported at room temperature. The storage time is the shelf life of the sensor. If the temperature range of the refrigerator is 2^{o}C-25^{o}C, the sensor can be stored in the refrigerator. Improper storage results in inaccurate blood glucose readings and missing low/high blood glucose levels. If the sensor is stored in the refrigerator, please take it out half an hour before use. The sensor can be used at room temperature.
- The device is not designed to remain in the body long-term, or to be replaced ‘immediately’ with a similar or identical device.
- Your transmitter communicates with your App via Bluetooth. The communication might be affected by strong electro-magnetic field, keep your CGMS away from any strong electro-magnetic field. Otherwise, degradation of the performance of this equipment could result in malfunctioning of the system.
- With the prompt function turned off, the App cannot give a prompt (notification) even if the Transmitter and the App are within communication range.
- Symptoms that may be caused by high/low blood glucose should not be ignored. If the symptoms you are experiencing do not match the CGMS readings, or you suspect that the CGMS readings may be inaccurate, check the glucose by performing a fingerstick blood test using a blood glucose meter.
- When CGMS shows that your glucose level is low or near the low limit,

perform a fingerstick blood test using a blood glucose meter.

- The CGMS contains small parts that may cause choking once swallowed, keep them off the reach of children.

2.5 Precautions

- The sensors and transmitters of the CGMS should be matched. The products of different generations cannot be connected and cannot work. Make sure that the system uses the correct software version.
- Before opening the sensor package, wash your hands with soap and water and dry them.
- Before inserting the sensor, clean the skin with alcohol wipes and let it dry up. This helps prevent infection. Do not insert the sensor until the skin is dry so that the tape on the sensor base can be better attached to the skin.
- Change the insertion site each time. Using the same insertion site too often may not allow the skin to heal, and may cause scars or skin allergies.
- Do not insert sensors in areas that may be bent, squeezed, tattooed, hairy or allergic. These sites are not ideal for measuring blood glucose. Inserting sensors in these places may affect the performance, missing low/high blood glucose values.
- Do not insert sensors within 5 cm of insulin injection and placement of insulin pump. Insulin may affect the performance of the sensor, missing low/high blood glucose levels.
- To make calibration, enter the exact blood glucose value measured by the glucometer within 3minutes. Inaccurate input or input exceeding 3minutes may affect the performance of the sensor and result in missing low/high blood glucose values.
- Rapid changes in blood glucose level might not be displayed in time, such as during exercise or after meals. There is always a time lag between glucose level in the blood and glucose level in the interstitial fluid, the lag time is different from person to person.
- When properly worn, the transmitter and App have a transmission range of 2 m without obstruction. Wireless connection in the water is not very well, so the range of connections in places like swimming pools, bathtubs and waterbeds will be reduced. If the distance between the transmitter and App is more than 2 m or if the distance between them is blocked, they may not be connected or the connection distance may be shorter. You may miss the low/high blood glucose level. Yet all the data will still be stored in your transmitter, so your App is able to display all the data when there is good communication again.
- The transmitter can be reused up to 8 times in its lifetime, so do not discard it.
- In rare cases, the sensor may give inaccurate glucose readings. If the glucose reading is believed to be incorrect or inconsistent with your symptoms, perform a fingerstick glucose test and check to ensure that the sensor is not loose.

- Intense exercise may cause the sensor to be detached or loosened. If the Sensor is loose, you may not get a reading or the reading may not be reliable and may not match how you feel. Follow instructions on selecting the appropriate site for wearing the sensor.
- Severe dehydration or excessive water loss may result in inaccurate CGMS readings.
- On rare occasions, patients may experience mild skin redness and swelling on the insertion site.

3 Risk and Efficacy

3.1 Risk

Inserting sensors and wearing adhesive tapes are less likely to cause infection, bleeding, pain or skin irritation (redness, swelling, bruising, itching, scarring or discoloration). If these symptoms occur, the patient may feel uncomfortable at the location where the sensor is inserted.

In rare cases, the sensor electrode may break and remain in the body. This phenomenon did not appear in the clinical study. If you feel the sensor is broken inside your skin, contact your medical diabetes team and technical support.

When the prompt function is turned off or the transmitter and App are not within the communication range, the prompt cannot be obtained.

When you cannot hear the tone or feel the vibration, you may not notice the prompt.

Sometimes the sensor glucose readings may be slightly different from the values measured by blood glucose meter. In most cases, the sensor glucose reading moves with the blood glucose level and will remind you when the glucose level exceeds the target range.

If you are at high/low blood glucose levels and you miss the reminding and warning message, you might not test your blood glucose with blood glucose meter and miss high/low blood glucose values.

3.2 Efficacy

The Continuous Glucose Monitoring Systems provides more effective and comprehensive information than the blood glucose meter. In 14-day monitoring, the continuous blood glucose monitoring system provides a blood glucose reading every three minutes to help you observe the trend of blood glucose changes. Dynamic information can help you check the current blood glucose status, as well as the direction and speed of changes in blood glucose. Recognizing trends in blood glucose can help you take steps to avoid high/low blood glucose levels.

App alerts when blood glucose levels exceed your target blood glucose range or when blood glucose drops or rises rapidly. The alerts can remind you to take measures to avoid low/high blood glucose.

4 Installation and Use

This chapter describes how to use your i3 systems, please read carefully before use, and follow the indication step-by-step.

4.1 Installation

4.1.1 App installation and setting

a) Download App from Google Play / App Store;

b) After installed, please complete personal information.

c) Setting your target and Alarm/Alert Sound type.

4.1.2 Prerequisites

Turn on the Bluetooth of the mobile phone and keep the phone within 2 meters of the Transmitter in an accessible state. Allow the App to access your smart device location for Android system.

4.1.3 Sensor Insertion

1）Prepping

a) Do NOT use if the sensor package seems to be damaged or is already opened.

b) Do NOT use after the sensor expiry date.

c) Wash your hands

d) Clean bottom of transmitter with alcohol wipe;

e) Let the transmitter dry.

***Note*:** *Be careful, don't touch its metal dots on the back of the transmitter and scratch it (that may damage the water-resistant seal).*

2）Insertion site

a) Only on the Abdomen;

b) 5 cm away from the belly button;

c) 5 cm away from the insulin Injection site;

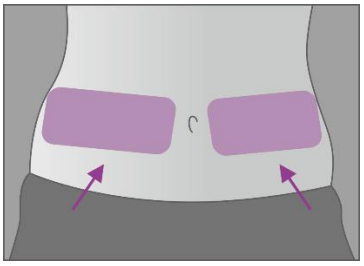
d) Avoid position where it can be pressed when you are wearing a belt;

e) Avoid fatty clotting site

f) Avoid tattoos, excessive hair, scars, inflammation etc.

***Note*:**

- *Change insertion site after previous use*
- *Clean the skin condition before insertion*
- *Check whether package is broken*
- *Check expiration date before insertion*



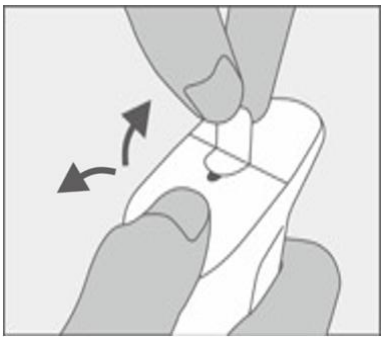
Insertion site

3）Clean insertion site

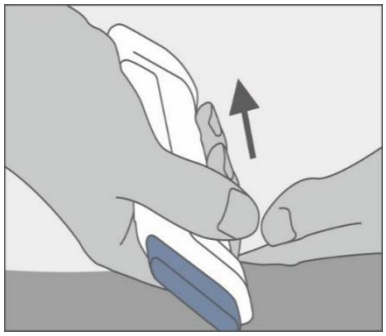
a) Clean the insertion site with an alcohol wipe and allow it to dry before proceeding.

b) Make sure area is clean and free of lotions, perfumes, and medications.

4）Apply Sensor

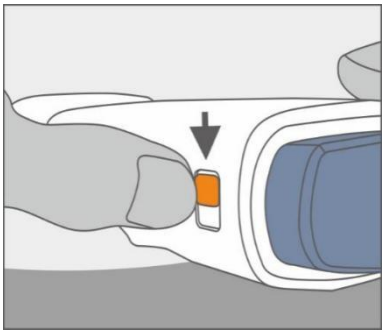


Remove the protective liners from the bottom of the sensor base, and don't touch the adhesive tape.

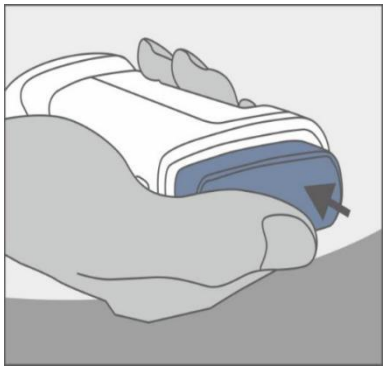


Place sensor horizontally on the abdomen;

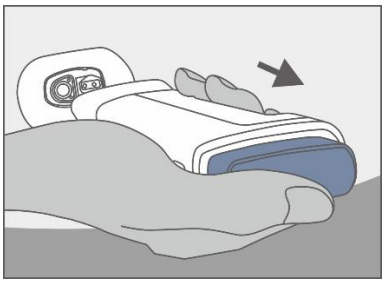
Press the applicator to ensure that the tape is firmly attached on the skin.



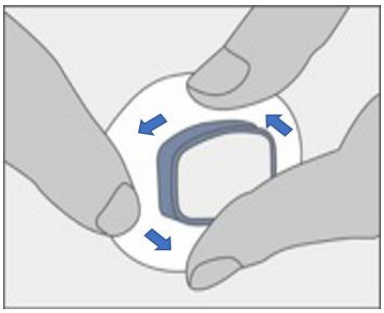
Hold the applicator and pull the Safety Lock to unlock mode.



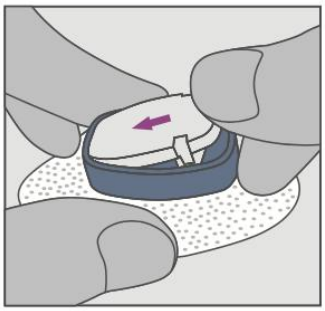
Press the top button of the applicator, and the sensor electrode will be inserted automatically;

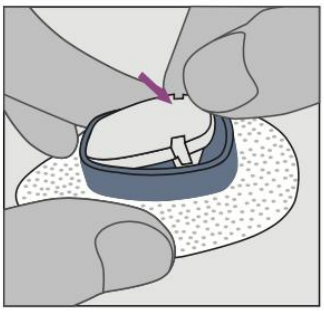


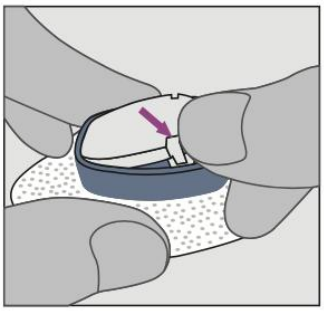
Gently pull applicator up until you see adhesive patch.



Ensure the tape firmly bonded.
Run your fingers around the adhesive.







Slide transmitter (pointy side) into the slot against one end of the sensor base.

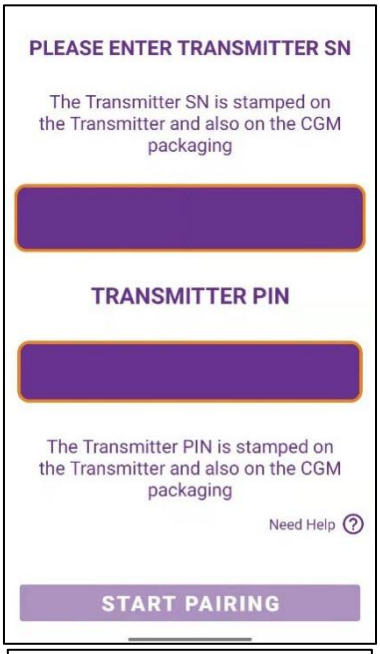
Press the other end of the transmitter until it clicks into the holder, you will hear 2-clicks sound.

If the transmitter is not embedded properly， it may cause the transmitter to break away.

Warning
The sensors （Model No. SI3-WL-03） and transmitters （Model No. TI3-WL-03） of the Continuous Glucose Monitoring Systems （i3） should be suitable for each other. The products of different generations cannot be connected to each other and thus cannot work. Make sure that the system uses the correct Glunovo software version.

4.2 Use

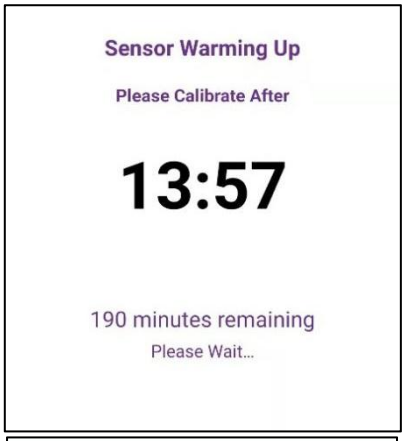
4.2.1 Pairing Transmitter



Enter Transmitter SN and PIN Code to start pairing.

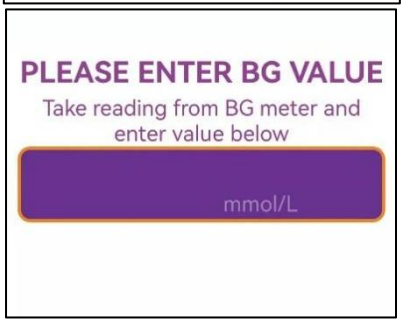
Note: *For problems in pairing, check <Troubleshooting>.*

Enter sensor LOT number to “Start CGM”.



Warm up time: 190 Mins.

Note: *No High/Low Alarm during warming up; Keep the connection between transmitter and smart phone during warming up.*

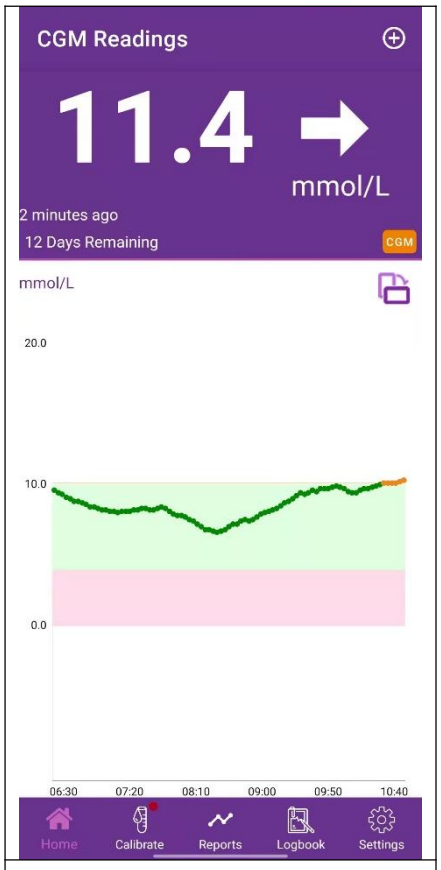


Initial calibration after warm-up;

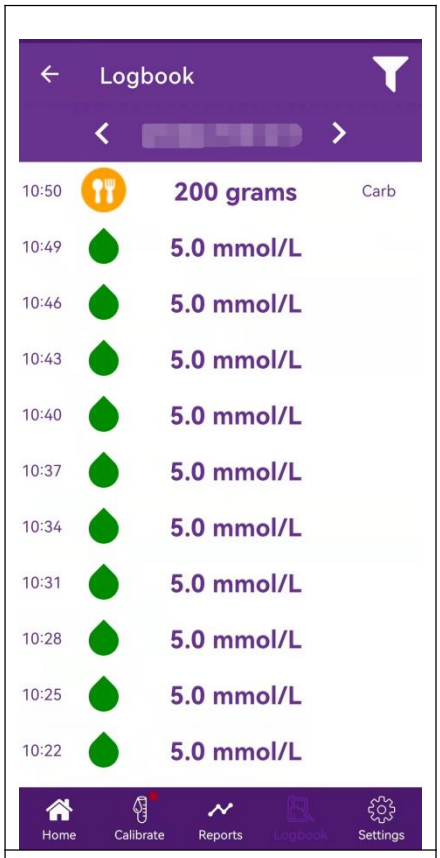
Note*: Do the calibration before meal.*

4.2.2 Sensor glucose readings and curve

Blood glucose readings and trend curve are shown in App's Home Screen.



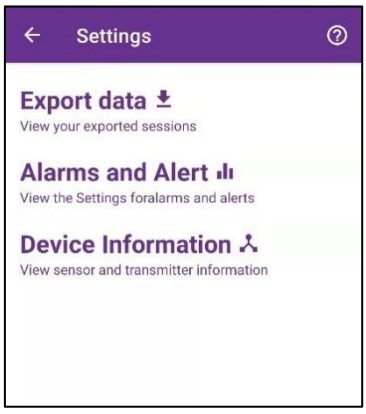
Home Screen



Logbook

Caution
Continuous glucose monitoring cannot be used as a basis for diabetes diagnosis, such as insulin injection. It cannot replace the blood glucose meter. The value of blood glucose may not be consistent with the reading of blood glucose. Using glycemic readings as a diagnostic basis for diabetes may result in low/high blood glucose.

4.3 End session and remove sensor



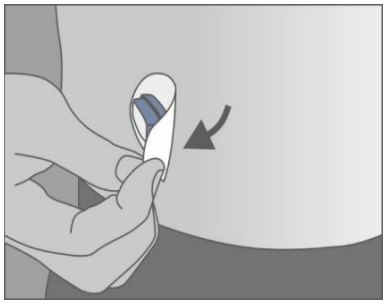
Settings→EXPORT NOW

Note: *After 14 days' monitoring, CGMS will be stopped automatically, also can be removed manually.*

Settings→Device Information→Remove Current Device

Note: *After the sensor is ended, the App will not receive BG readings and Alarm/Alert.*

Note:*Data for this session will be reserved for future export*



Take off adhesive pad.

Note: *Remove sensor and transmitter together.*

Take out transmitter with the releaser.

Put the transmitter back to package, if not using.

Note:

Transmitter can store data up to 14 days, and it will erase all data once it is removed from the sensor.

Take out the transmitter, after you remove transmitter and sensor together from your body.

Warning

In rare cases, the sensor electrode may fracture. Don't ignore it. If the sensor electrode breaks and there is no visible sensor electrode on the skin, do not attempt to remove it yourself. Seek professional medical help in case of infection symptoms or inflammation - redness, swelling or pain. If the sensor electrode ruptures, please report to our technical support.

No safety hazard was found in the patient's residual rupture sensor electrode during in vitro NMR test. There was no obvious migration or heating of the sensor electrode, and the imaging was limited to the area around the sensor electrode.

4.4 Calibration

The glucose readings need to be calibrated for the display of the readings and trend curves, and to maintain the accuracy throughout the monitoring process. The time points for calibration are:

- **Initial calibration:**

After the sensor is activated and the sensor warm-up is complete, App will send a notification for the first calibration. The App will not display the blood glucose readings and trend curves until the first reference blood glucose is entered for calibration.

- **Calibrate twice per day:**

Calibration shall be done twice a day (ideally every 12 hours). The purpose of calibration is to keep the sensor glucose readings more accurate.

- **Calibrate to check blood glucose and CGMS**

> **Caution**
> Blood glucose must be entered manually during calibration. It must be calibrated by accurate blood glucose values in order to obtain accurate sensor glucose readings.

4.4.1 How to calibrate

Accurate blood glucose values need to be entered for each calibration. Blood glucose for calibration must be between 2.2 and 22.2 mmol/L (40 mg/dL and 400 mg/dL) and shall be within 3 minutes after testing.

a) If the blood glucose measured by the glucose meter is outside the range of 2.2-22.2 mmol/L (40 mg/dL - 400 mg/dL), it cannot be used for calibration.

b) Before calibration, make sure the transmitter and mobile App are connected.

c) Use a blood glucose meter to routinely test blood glucose for calibration. Do not replace the glucometer during the monitoring process. The accuracy of different brands of blood glucose meters and test strips will vary.

d) The accuracy of blood glucose readings used for calibration may affect the accuracy of sensor glucose readings.

> **Caution**
> Blood glucose should not be calibrated during rapid change of glucose levels and the general rate of change is 0.11 mmol/L (1.98 mg/dL) per minute. Do not calibrate when the single arrow or double arrow is displayed on the App interface which indicates that your blood glucose level increases/decreases by 0.11-0.17 mmol/L (1.98 mg/dL - 3.06 mg/dL) or over 0.17 mmol/L (3.06 mg/dL) per minute. Calibration can significantly affect the accuracy of sensor glucose readings when glucose value rises or falls.
>
> In order to obtain more accurate data, it is recommended to test and calibrate the blood glucose before going to bed at night and during fasting the next morning.

> **Warning**
> Calibrate at least twice per day. Calibrating less often than twice per day might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

The steps to enter the blood glucose value during calibration are as follows:

a) Wash hands and dry, make sure the blood glucose test strips are stored properly during the shelf life, and make sure the blood glucose meter can work normally;

b) Follow the instructions and use the blood glucose meter to test the blood glucose;

c) Enter the Calibration screen from Home Screen;

d) Using a BG meter, do a fingerstick test and enter the value in the calibration entry box. Press “Calibrate” button.

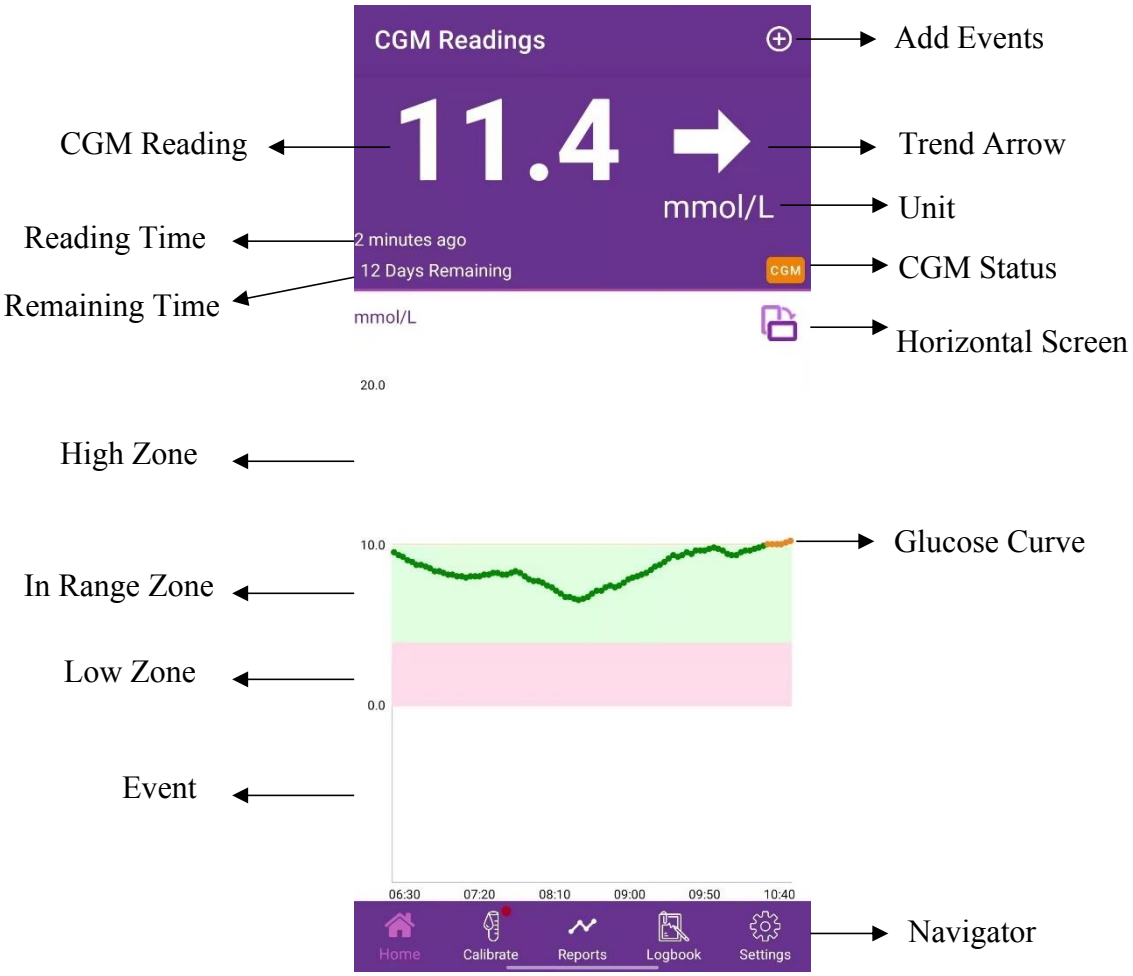
4.4.2 How to do a good calibration

No.	Do	Not to do
1	Calibrate when CGM reading is within your target range, if possible close to your BG target. And so is your goal to keep your sensor glucose in the target range as much as possible.	Do not over-calibrate: calibrate two or three times per day, no more – unless, in the event of such: CGMS readings are more than 20% off the BG test value. CGMS algorithms may become unstable when calibrated too often in a day.
2	Only calibrate when your CGMS arrow is stable '→'.	Do not always assume that glucose meter is right and CGMS is wrong. When in doubt, test two or three times. CGMS has been averaging glucose meter errors (only guaranteed to +/- 20%) for several days – it could well be closer to the true value overtime than glucose meter.
3	You should be ready to calibrate more frequently than usual, if need be, during the first 3 days.	Avoid calibration when CGMS value arrow shows rise '↑', rapid rise '↑↑', decrease "↓', rapid decrease '↓↓'.
4	It's better to validate that your true BG is stable. When you are not sure if your BG is stable, do fingerstick twice within an interval of 5 minutes. If the second reading is similar to the first one, then do a calibration using the latest BG test.	N/A

5 App interface introduction and function application

5.1 Main interface

The main interface contains glucose readings, glucose curve, trend arrows, CGM status.



5.1.1 Trend arrows:

Arrows	Definition
	Stable: Blood glucose is stable (no more than 0.06 mmol/L (1.08 mg/dL) rise or fall per minute).
	Slow increase: blood glucose increases by 0.06 to 0.11 mmol/L (1.08-1.98 mg/dL) per minute.
	Increase: blood glucose increased by 0.11-0.17 mmol/L (1.98 mg/dL - 3.06mg/dL) per minute.
	Rapid increase: blood glucose increased by more than 0.17 mmol/L (3.06 mg/dL) per minute.

	Slow decrease: blood glucose decreased by 0.06 to 0.11 mmol/L (1.08- 1.98 mg/dL) per minute.
	Decrease: blood glucose decreased by 0.11-0.17 mmol/L (1.98 mg/dL - 3.06mg/dL) per minute.
	Rapid decrease: blood glucose decreased by more than 0.17 mmol/L (3.06 mg/dL) per minute.
No arrow	App cannot, for the moment, calculate the rate of increase or decrease in blood glucose (data synchronization or disconnection).

5.1.2 Glucose Curve

Glucose curve shows: sensor glucose readings and trends.

Swiping from left to right on the glucose curve, you can review the recent sensor glucose readings. Sensor glucose reading shows between 2.2-22.2mmol/L (40mg/dL - 400mg/dL). During Sensor Glucose below 2.2mmol/L or above 22.2mmol/L, there will not be recorded in glucose curve, but sensor glucose readings are still recorded once every 3 minutes in Logbook.

At the top of the glucose curve, you can tap on the trend view you want to see glucose levels of the last 4-, 8-, 12-, or 24-hours.

5.1.3 CGM Status

CGM Status

Click “CGM” icon in homepage to enter CGM status, which is showing:

CGM Status:	RUNNING, STOPPED, SESSION END, LINK LOST
Transmitter SN	Transmitter SN
Sensor LOT	Sensor LOT number

Sensor Current	latest current from sensor
Last Calibration	The latest calibration time
App Version	The full version of App

5.1.4 Events

You can add Events (carbs, insulin, Medication, sport, and BG) by clicking

.

5.2 Function Bar

Function bar contains: Home, Calibration, Reports, Logbook and Settings.

5.2.1 Calibration

To add calibrations via meter.

Range: 2.2-22.2mmol/L (40mg/dL- 400mg/dL)

5.2.2 Report

Time In Range	TIR (time in range) indicates the percentage of how long your glucose value was within the target range during a defined period.
Glucose Profile	A profile displaying glucose fluctuation. The chart needs at least 24 hours valid data.

5.2.3 Logbook

All calibrations, alarm/alert and sensor readings are recorded in Logbook and marked with different icons.

5.2.4 Settings

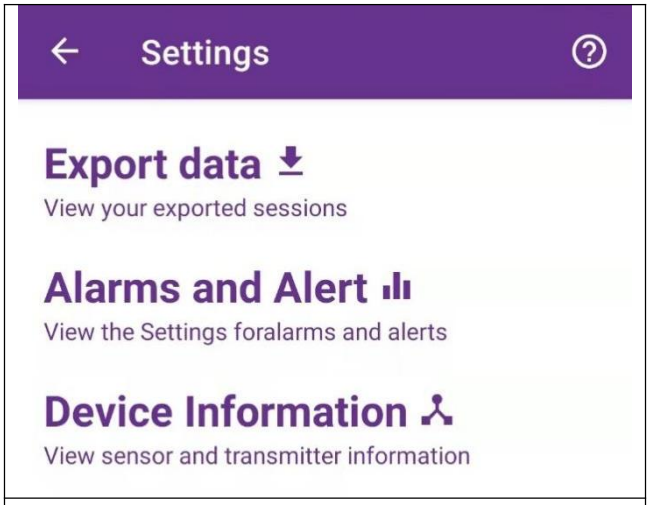
The screen of Settings has three main sections：

a) Export data： CGMS monitoring information can be export as an Excel file in phone's storage. Uninstall App may cause data lost.

b) Alarms and Alert： Change alarm and alerts threshold and customize alarm.

c) Device Information： View sensor and transmitter information

Note: *Data can be analyzed by Analysis Software.*



Settings

5.3 Alarm/Alert

App provides Urgent Low Alarm, High/Low Alarm with sounds, vibrations, view, and notifications. Alarm/Alert can be snoozed.

Glucose Alarm will still sound, even in phone's vibration or mute mode for Android.

Note: *If the Android Phone is in "Do Not Disturb Mode", the urgent low alarm may not be triggered. Remember to turn off "Do Not Disturb" or "Battery Saving" mode.*

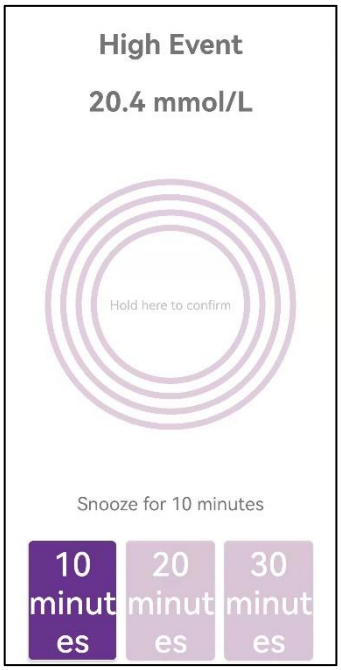
5.3.1 Thresholds

Alarm	Introduction	Threshold setting	Default
Low Limit	If the blood glucose is lower than this value, app will give an alarm of hypoglycemia.	3.3- 5.6 mmol/L (60-100 mg/dL)	3.9mmol/L (70 mg/dL)
Urgent Low	If the blood glucose is less than 3.1 mmol/l, app will give an urgent hypoglycemia alarm	3.1mmol/L (56 mg/dL)	3.1mmol/L (56 mg/dL)
High Limit (Hyperglycemia display limit)	If the blood glucose is higher than this value, it will be displayed in the white area of the trend chart, but the app will not generate an alarm.	6.7 mmol/L (120 mg/dL) -High Limit	10.0 mmol/L 180 mg/dL
High Alarm	If the blood glucose is higher	High Alarm-	13.0mmol/L

Limit	than this value, app will generate hyperglycemia alarm.	22.2 mmol/L (400 mg/dL)	(234 mg/dL)

Warning
Don’t make medical decision based on sensor glucose levels.

5.3.2 Snooze Alarm



You can press-hold circles for 4 seconds during an Alarm to snooze Alarm for 10 mins, 20 mins or 30 mins.

5.3.3 System Recovering

System recovering, means CGMS is not in normal operation. CGM readings will not be displayed during this period. Please use glucose meter to check blood glucose; Please press “Help” for help when you see this notification.

5.3.4 Connecting

When the phone's Bluetooth is off or the app's Bluetooth is disconnected, the app will indicate that the CGMS is disconnected. No data or alarms will be received when disconnected. When the disconnect prompt appears, keep the phone at a working distance from the transmitter and remove any obstructions or check whether the phone's Bluetooth is turned on. The connection will automatically recover when Bluetooth signal recovers.

6 Problems and Troubleshooting

Failure to press the top button of the applicator

- Slide the safety lock to the unlock position， then press the top button of the applicator.

The Sensor pad is not sticky enough

- Before inserting the sensor, clean the skin with alcohol wipes and let it dry.
- The position of the sensor needs to be shaved and cleaned so that the adhesive tape can be attached firmly. Use medical adhesive tape to reinforce sensor base, the medical adhesive tape should be pasted around the white adhesive tape.

Calibration troubleshooting

- Calibration tips will appear during monitoring. The suggestions for troubleshooting are as follows:

Do not calibrate when the main interface shows that the device is not connected.

Do not calibrate if the blood glucose level is lower than 2.2 mmol/L or higher than 22.2 mmol/L (lower than 40mg/dL or higher than 400mg/dL).

Wash your hands and let it dry, make sure the blood glucose test strips are stored properly during its shelf life, and make sure the blood glucose meter can work normally. Test the blood glucose according to the instructions of the blood glucose meter.

Avoid taking drugs that contain acetaminophen/paracetamol.

Sensor low power

- Export data in time and stop monitoring when the sensor battery is exhausted.

Notification failure

- View the sound or vibration mode of the notification.

7 Maintenance

Sensor

- Continuous glucose monitoring sensors are not repairable. If you have a problem, please contact technical support.

Transmitter

- Wipe the bottom of the transmitter with a wet cloth or alcohol wipe before/after using each time.
- Continuous glucose monitoring transmitters are not repairable. If you have a problem, please contact technical support.

Note: *Keep the bottom of the transmitter clean to avoid short circuit.*

Discarded treatment of products

- Consult the local Medical Waste Administration for treatment.

8 Travel information

Wearing sensors and transmitters is safe when passing through metal detectors. If you have concerns or discomfort with crossing security doors, follow the regulations of the Transportation Security Administration: You should inform the security inspection agency that you are wearing a continuous blood glucose monitoring system. You can request a full-body search and visual inspection instead of security door scanning. Inform the security agency that the sensor cannot be removed because it is inserted in the skin.

If you have any questions or concerns, please visit the website of the travel safety administration.

9 EMC Statement

Guidance and Manufacture's declaration – electromagnetic emissions

The Continuous Glucose Monitoring Systems is suitable for use in the specified electromagnetic environment (s) and it has met the following standard's emission requirements.

Phenomenon	Home healthcare environment
Conducted and radiated RF emissions	CISPR 11, Group 1, Class B
Harmonic distortion	N/A
Voltage fluctuations and flicker	N/A

Guidance and manufacture's declaration – electromagnetic immunity

The Continuous Glucose Monitoring Systems is suitable for use in the specified electromagnetic environment (s) and it has met the following immunity test levels. Higher immunity levels may cause the Continuous Glucose Monitoring Systems essential performance lost or degraded.

Phenomenon	Basic EMC standard or test method	Home healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80%AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances".
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50 Hz or 60Hz
Electric fast transient bursts	IEC 61000-4-4	N/A
Surges	IEC 61000-4-5	N/A
Conducted disturbances induced by RF fields	IEC 61000-4-6	N/A
Voltage dips	IEC 61000-4-11	N/A
		N/A
Voltage interruptions	IEC 61000-4-11	N/A

Recommended minimum separation distances

RF wireless equipment is used in various healthcare locations therefore when the CGMS is used in close proximity to other medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. Continuous Glucose Monitoring Systems has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and Continuous Glucose Monitoring Systems as recommended below.

EMC Statement

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID	Pulse modulation 217Hz	2	0.3	28

		2450, LTE Band 7				
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Continuous Glucose Monitoring Systems including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

10 User help

Technical support

Technical support: INFINOVO MEDICAL CO.,LTD.

Registration and Operation Address: 3rd Floor, 6th Building, No.888 Zhujiang Road, Rudong, Jiangsu, China

Tel. +86.0513.68928098

Fax. +86.0513.68928019

ZIP-Code. 226400

Sales support

Sales support: INFINOVO MEDICAL CO.,LTD.

Registration and Operation Address: 3rd Floor, 6th Building, No.888 Zhujiang Road, Rudong, Jiangsu, China

Tel. +86.0513.68928098

Fax. +86.0513.68928019

ZIP-Code. 226400

Website：www.infinovo.com

11 The warranty

11.1 The scope and duration of warranty

Under normal use conditions, the original purchaser is provided with a limited warranty when there are quality problems with raw materials and processes.

Note: *if a warranty replacement is received, all remaining warranty rights of the original purchaser are transferred to the replacement and the warranty page is invalid.*

11.2 The following conditions are not in the scope of warranty

Limited warranty is based on the normal use. Limited warranty does not include :(a) Accidents, improper use, abuse, neglect, fault caused by abnormal electromechanical pressure, man-made failures, etc.;(b) marks on the device are removed or blurred; (c)Surface or other exposed parts are scratched or damaged; (d) Failure or damage caused by the connection of accessories, products, or other external devices not manufactured or approved by the company; (e) Failure or damage caused by improper testing, operation, maintenance, installation or adjustment; (f) Self-disassembling equipment.

11.3 Warranty liability

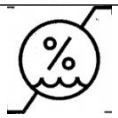
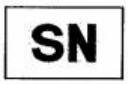
During the warranty period, the company chooses to replace any product with quality problems for the purchaser for free. The purchaser must return the product to the sales support department in proper packaging. Purchase receipt or similar sales certificate with date of purchase and seller's name and address should be send back together with the product. Contact the sales support department to get the address. Once the product is received, the company will replace it immediately. If the company determines that the product is not covered by the warranty, the purchaser must pay for all shipping charges for the returned product.

11.4 Warranty Statement

The above limited description of the company's limited warranty is unique, replacing all other warranties, express or implied, regardless of the facts or the implementation of laws and regulations. Except for the scope prohibited by laws and regulations, the company does not bear any special incidental, indirect or indirect damages. This rule applies even if the company or the agent has recommended and is liable for any failure to remedy the remedy. The limited warranty should not extend to anyone other than the original purchaser and stipulates the purchaser’s exclusive compensation. If any portion of the Limited Warranty is illegal or legally unenforceable, and it is partly illegal or mandatory, it shall not affect the enforceability of other parts of the Limited Warranty. The other parts are recognized by the purchaser and will always be interpreted as limited or as a limited legal license.

12 Label symbol and graphic description

Label symbol and graphic description

Symbol	Description
	Please Read the Instructions before Use
	No Secondary Use
	Do not Use if Package is Damaged
	Type BF Applied Part
	Temperature Limitation
	Humidity Limitation
	Sterilized Using Irradiation
	Keep Dry
	Keep away from sunlight
	Caution
	Dustproof and Waterproof class
	Product Number
	Serial Number
	Environmental Protection
	Non-ionizing Radiation

	Date of Manufacture
CE 0197	After passed CE certification, mark the CE-marking on package;
	INFINOVO MEDICAL Co., LTD. 3rd Floor, 6th Building, No.888 Zhujiang Road, Rudong, Jiangsu, China
EC REP	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124, Heidelberg, Germany Tel: +49 1754870819

13 Date of manufacture

The production date and expiry date are shown on the package.

Appendix

Appendix 1 Warranty Card

If there is a problem of non-human damage to the product you purchased, please return it to us for warranty.

Customer service information

Customer name	
Contact number	
Contact address	
Product name	
Product model	
Date of purchase	
Maintenance date	
Fault description	
Maintenance state	