Continuous Glucose Monitoring System

Sensor, Transmitter, App

USER MANUAL

Model：D3

Infinovo Medical Co., Ltd.

IFU-D3-001

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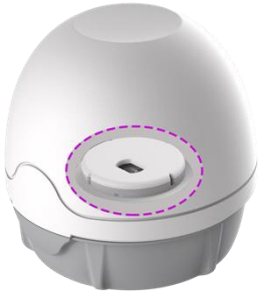
Terminology

CGMS	Abbreviation for Continuous Glucose Monitoring System, consist of applicator, (include sensor and transmitter) and App.
Applicator	A disposable component that applies the sensor onto skin.
Sensor	Core component of the Continuous Glucose Monitoring System, built a transmitter inside, is intended to measure blood glucose level in interstitial fluids and transmit glucose data to App.
Sensor electrode	A component attached with sensor, is intended to apply under the skin that reacts with the interstitial fluid and converts biological signals into electrical signals.
Transmitter	The transmitter is built into sensor, used to convert electrical signal into glucose reading and send the glucose reading wirelessly to the App.
Mobile Application（App）	The mobile software that receives blood glucose information, displays glucose condition.
Default value	The values that come with the system.
Calibration	Blood glucose value measured by the blood glucose meter and entered into the App for calibration to ensure the accuracy of the blood glucose reading.
Blood Glucose (BG) Meter	A medical device used to measure how much glucose is in blood
Blood Glucose (BG) value	Blood Glucose value is the amount of glucose in blood measured by blood glucose meter.
Sensor Reading	The glucose value measured by Continuous Glucose Monitoring System
Data receiving range	The communication distance between the App and the sensor, which shall be within 6 m without obstacle.
Repeat prompt	When the first notification is not confirmed, the prompt will be repeated.

1. Product Overview



1）Applicator App
2）Sensor(inside)

The D3 Continuous Glucose Monitoring System consists of a fully disposable Applicator (include sensor and transmitter) and Mobile Application, in which the core component is the Sensor.

Continuous Glucose Monitoring System (D3) can display glucose readings automatically after when activating the sensor. The CGMS measures a glucose reading every three minutes, making 480 readings in total each day. The system can continuously monitor 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.

1.1. Working Principle

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.

1.2. Component Structure

Applicator（disposable）	Intact state 	Open state 	Applicator, intends to apply the sensor onto abdomen or onto back of upper arm. When rotated, applicator will come to open state.
Sensor (14-day)	Front side 	Reverse side 	Sensor is a all-in one component, attached with a sensor electrode on the reverse side. The transmitter is built into sensor.

1.3. App Overview

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

The main interface of App mainly displays blood glucose readings, trend curves and trend arrows. App and transmitter can be connected through Bluetooth, pairing for data communication.

Operational Requirement

Item	**Detail**
Operating system	Android 9.0 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
Storage Format	App export data storage format is Excel file

2. Safety Information

2.1. Application definition

2.1.1. Intended Use

The D3 Continuous Glucose Monitoring System is intended for continuous or periodic recording of glucose levels in interstitial fluid for patients with diabetes aged 18 or older. The information is intended to detect trends and track patterns to provide reference information to patients for better diabetes management. The system provides real-time blood glucose value, which is received and read by the App.

2.1.2. Intended user:

The users are medical staff, patients, and family members of patients who should be aged 18 and above with no restrictions on gender, weight, education, professional competence, health condition, linguistic and cultural background; however, the patients should have minimum knowledge to understand the content of the IFU, hygiene, and distinguish body parts. Also, patients with disabilities might need assistance in the process of operating the device.

2.1.3. Intended environment:

Home Healthcare Environment and Professional Healthcare Facility Environment.

2.1.4. Indications

1) Type 1& 2 diabetes mellitus.
2) Special types of diabetes (excluding monogenic diabetes syndromes, diseases of the exocrine pancreas, and drug or chemical induced diabetes).
3) Abnormal blood glucose levels.
4) Patients requiring improved glycemic control.
5) People requiring frequent or continuous monitoring of blood glucose.

2.1.5. Apply site

Abdomen, back of the upper arm.

2.1.6. Reuse

D3 CGMS is a single-use product, not reusable.

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 instruction for use. 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.

Any serious incident that has occurred in relation to the CGMS (Glunovo) should be reported to Infinovo and the competent authority of the Member State in which you are established.

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, computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

Taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the CGMS readings and make them look higher than they really are.

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

The CGM System was not evaluated for the following persons:

- Pregnant women
- Peritoneal dialysis patients
- Patients with implanted pacemakers
- Patients with coagulation disorders or those taking anticoagulant drugs

2.4. Warning

- The CGMS should not be used by patients who have diffuse subcutaneous nodules.
- Read the instructions thoroughly before using. 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 the low/high blood glucose incidents.
- Talk to your health care professional about how you should use your CGMS glucose information to help your diabete management.
- Failure to use CGMS may result in your missing severe hypoglycemia (low blood glucose) or

hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts does not match your symptom or expectation, use a fingerstick blood glucose (BG) value from your blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

- After restarting your phone, please check again if bluetooth is turned on. If it's turned off, please enable bluetooth again to ensure real-time data transmission and notifications. Android users, after enabling airplane mode, please double-check if Bluetooth is turned on. If it's turned off, please enable Bluetooth again to ensure real-time data transmission and notifications. iOS users don't need to consider this for the time being.
- Avoid areas:

  1. With loose skin or without enough fat to avoid muscles and bones.
  2. That get bumped, pushed, or you lie on while sleeping.
  3. Within 5 cm of infusion or injection site.
  4. Near waistband or with irritations, scarring, tattoos, or lots of hair.
  5. With moles or scars.
- In rare cases, the sensor electrode may fracture. 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.
- Do not use sensors when its sterile packaging is damaged. Using unsterilized sensors may lead to infection.
- The storage temperature of the sensor is 2oC-30oC. 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.
- 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 off, the App cannot give a prompt (notification) even if the Transmitter and the App are within communication range.
- The CGMS contains small parts that may cause choking if swallowed, keep them away from the reach of children.
- Do not use if expiry date has passed.

2.5. Precautions

- No modifications to the CGMS are allowed. Unauthorized modification of the CGMS may cause the product to malfunction and become unusable.
- Before using this product, you need to read the Instruction Manual or be trained by a professional. No doctor's prescription is required for use at home.
- The CGMS contains small parts that can be dangerous if swallowed.
- During rapid changes in blood glucose (more than 0.1 mmol/L per minute), glucose levels measured in interstitial fluid by the CGMS may not be the same as blood glucose levels. When blood glucose levels drop rapidly, the CGMS may produce a higher reading than the blood

glucose level; Conversely, when blood glucose levels rise rapidly, may produce a lower reading than the blood glucose level. In these cases, the reading should be checked by a fingertip blood test using a glucose meter.

- Severe dehydration or excessive loss of water may result in inaccurate results. When you suspect you are dehydrated, consult a health care professional immediately.
- If you think the CGMS sensor reading is inaccurate or inconsistent with the symptoms, use a blood glucose meter to test your blood glucose level or calibrate the glucose sensor.
- The sensor loosens or takes off may cause the APP to have no readings.
- This product is waterproof and can be worn during showers and swimming, but do not bring it into water more than 1 meters deep for longer than 120 minutes.
- Before opening the sensor package, wash your hands with soap and water and dry them.
- Before inserting the sensor, clean the skin with alcohol tablets 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.
- To calibrate the system, enter the exact blood glucose value measured by the glucometer within 3 minutes. Inaccurate input or input exceeding 3 minutes may affect the performance of the sensor and result in missing low/high blood glucose values.
- Rapid changes in blood sugar can affect the accuracy of the system, such as during exercise or after meals.
- When properly worn, the transmitter and App have a transmission range of 6 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. There are no tests for different types of obstruction. If the distance between the transmitter and App is more than 6 m or if the distance between them is blocked by an obstruction, 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.
- 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 application.
- On rare occasions, patients may experience mild skin redness and swelling on the insertion site.
- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the app, contact Customer Service.
- Make sure that your phone and Sensor kit are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.

3. Risk and Efficacy

3.1. Risk

• Inaccurate glucose values

Exposure to heat for longtime may cause inaccurate results.

• Mild to severe to sensor related -wear reactions

E.g. allergic reaction, moderate to severe itching, rash, erythema, bleeding, minor infection at the insertion site, discomfort during insertion.

• Hypo and Hyperglycemia events

Hypo and Hyperglycemia events stemming from missed alerts or sensor inaccuracies.

• Sensor tip broken

In rare cases, the sensor tip 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.

3.2. Efficacy

The potential clinical benefits of CGMS are:

• Improved management of A1C and TIR for tighter glycemic control

• Shortened time spent in hypoglycemia and hyperglycemia

• Reduction in hypo and hyperglycemia events in diabetes patients

4. Installation and Use

This chapter describes how to use your D3 systems, please read carefully before use, and follow the indication step-by-step.

4.1. Installation

4.1.1. App installation and setting

1) Download App from Google Play / App Store.
2) After installed, please complete personal information.
3) Setting your target and Alarm/Alert Sound type.
4) Units of measurement：Select Glucose unit mmol/L or mg/dL.

4.1.2. Prerequisites

To optimize your smartphone user experience and ensure real-time access to blood glucose readings and status in the background, please note the following:

1) Ensure your phone has sufficient battery power: Keep your phone's battery fully charged during use to avoid disconnection or the inability to receive timely alerts due to low battery.
2) Maintain the distance between your phone and the sensor within a range of 6 meters: To ensure a stable Bluetooth connection, keep the distance between your phone and the sensor within 6 meters. If the distance is too far, it may lead to disconnection and hinder data transmission.
3) Allow the app to run in the background: Ensure that your phone doesn't forcefully close the app or put it into power-saving mode. The app can only receive blood glucose readings and sensor status when it runs in the background.
4) Optimize settings for alert messages:
    a) Ensure your phone is not in silent mode.
    b) Disable the "Do Not Disturb" mode to receive alert messages promptly.
    c) Grant notification permissions for the app in the settings.
    d) Enable background refresh for the app to receive the latest data in a timely manner.
    e) Disable battery optimization for the app to prevent excessive restrictions on background operation.
5) Avoid adding the app to the deep sleep app list to ensure it continues running in the background.
6) Exercise caution when setting automatic updates for your phone's operating system: When configuring automatic updates, pay attention to the compatibility of the updated operating system to ensure the app functions properly.

Warning:
If you don't set up your phone according to the instructions above, you may miss alerts for high or low blood glucose.

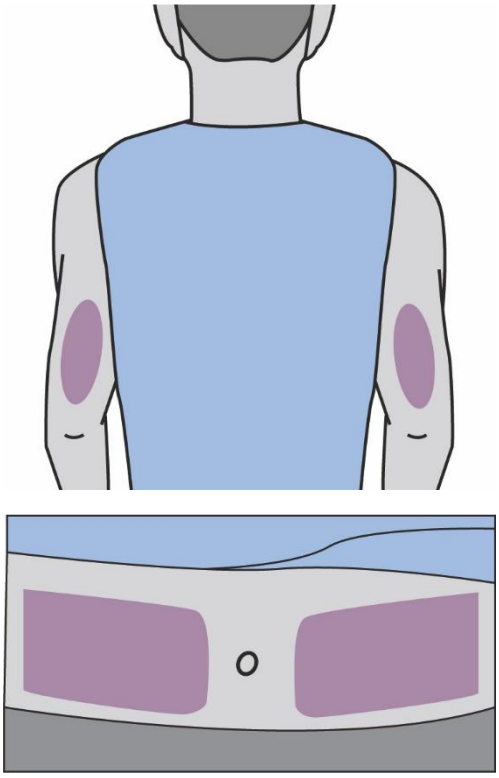
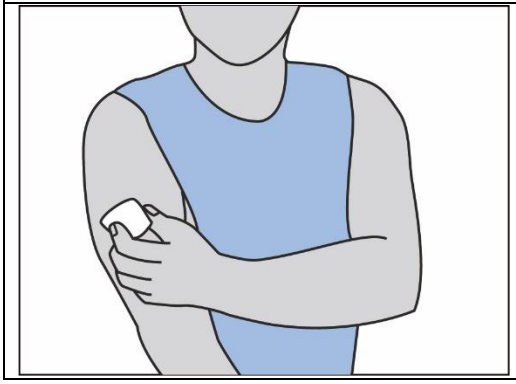
4.2. Sensor Application

4.2.1. Check Sensor Information

Before use, please check the packaging, expiration date, and tamper-evident label of the sensor:

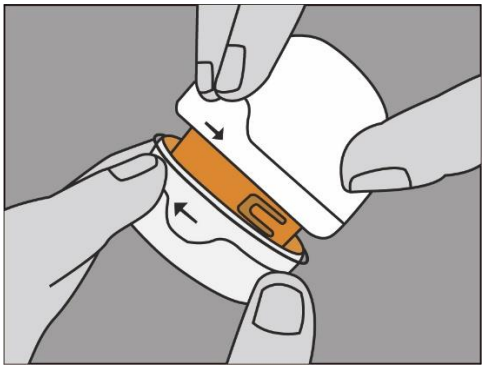
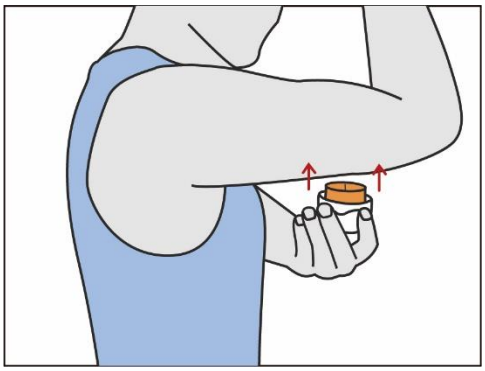
1) Do not use if the applicator and/or cap is damaged or already opened.
2) Carefully check the expiration date of the sensor and do not use if it has expired.
3) Do not use if the tamper-evident label on the sensor is damaged.

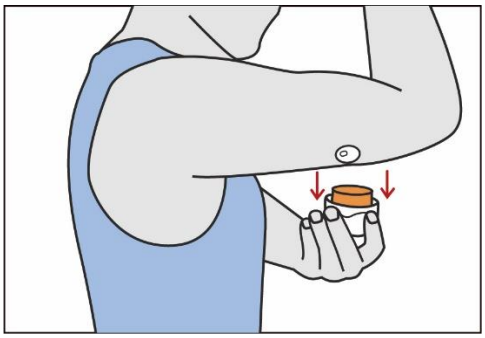
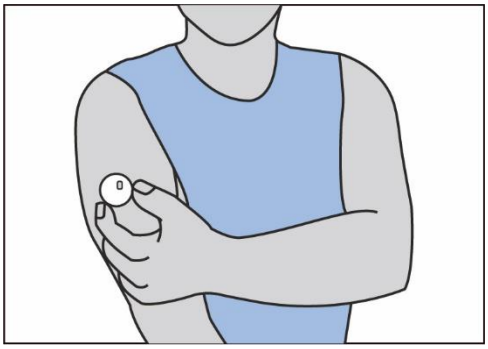
4.2.2. Clean Application Site

	**Select application site:** The Glunovo D3 can be worn on the back of upper arm and abdomen. **It is recommended to consult with a healthcare professional for advice on the placement.* **Select flat skin to apply, so that it is less prone to impact or compression.*
	**Clean application site:** Before wearing the sensor, please wash your hands and wearing area with soap, and dry them with a clean towel. Wipe the wearing area with an alcohol wipe and allow it to dry. **Make sure wearing area is clean and free of lotions, perfumes, and medications.*

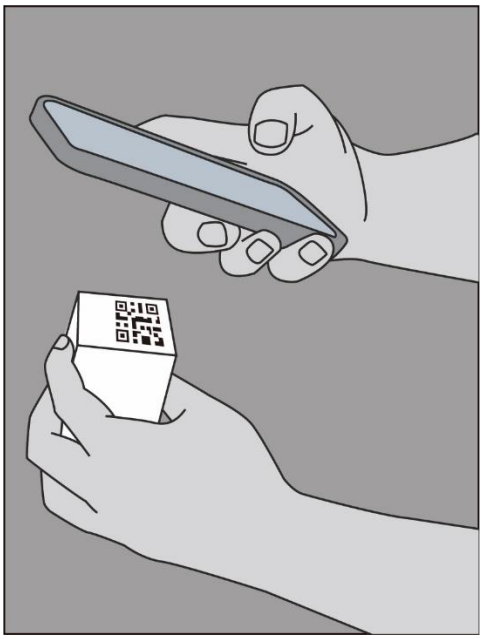
Caution:
Try to avoid wearing the sensor in the following areas:
1) Avoid areas where a CGM (continuous glucose monitor) has recently been worn.
2) Do not wear the sensor in areas where the skin is loose or lacks fat, such as muscle or bony areas.
3) Do not wear the sensor within a 5cm range of insulin injection sites.
4) Do not wear the sensor on areas with damaged skin, tattoos, or scars.
5) Do not wear the sensor on the waistline or where a belt is worn.
6) Avoid wearing the sensor in areas with excessive hair growth. If chosen, remove the hair before placement.
7) Do not wear the sensor on areas with fatty nodules.
8) The sensor placement should be at least 5cm away from the navel.
9) If you are pregnant, it is advisable to avoid wearing it on your abdomen. When selecting the placement site, please consult with your doctor or HCP for guidance.

4.2.3. Apply Sensor

	**Rotate the product casing and open the applicator.** **Do not use the product if it or the tamper-evident label is damaged.* **After opening the product, do not attempt to reattach the cover as it may damage the sensor.* **The sensor contains needles, do not touch them with your hands.* **Do not touch the inside of the applicator.*
	**Place the applicator on the desired wearing site and press downward with vertical force.** **Do not press down on the sensor before moving it to the intended wearing position to prevent accident.*

	**After hearing a "click" sound, wait for 3-5 seconds, then gently remove the applicator in a vertical direction.** **The sensor may cause skin abrasion or bleeding. Minor bleeding does not impact the wearing or monitoring effectiveness.*
	**After application，gently press the sensor and surrounding tape.** **Sensor may fall off before your complete 14-day monitoring without this process.*

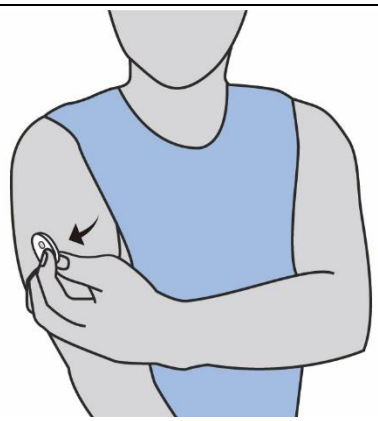
4.3. Start the Monitoring

	**Scan the QR code:** Please scan the QR code according to the APP's instructions.
	**After a 60-minute warm-up period, blood glucose data will be displayed.** **There will be no reading or alert during warm-up period.*

	**If you feel any discomfort during the warming up, please use BG meter.*

Caution:
If App shows “System stopped, please change sensor”, it is recommended to promptly remove and replace the sensor.
Continuous blood glucose testing cannot be used as a basis for diabetes diagnosis, such as insulin injection. It cannot replace the blood glucose meter.

4.4. Remove sensor

	When removing the sensor, carefully peel it off along the edge of the adhesive patch. **Avoid applying sudden force or pulling, as it may cause unnecessary injury or discomfort.*

Note:
After removing the sensor, it is normal to have a slight residue of adhesive left at the wearing site. You can gently use soap or water or an alcohol swab to remove it.
After the 14-day monitoring period, the Glunovo Pro application will automatically disconnect from the sensor. It is important to remove the sensor immediately.

4.5. Disposal

To properly dispose of the removed sensor, please follow the following optimized guidelines:

According to the Directive 2012/19/EU, collect the discarded sensor as electronic waste separately. Do not dispose of the sensor in the regular municipal waste system.

Since certain parts of the sensor may come into contact with bodily fluids, wipe the sensor with alcohol or disinfectant before discarding it. This helps reduce the potential risk of transmission.

Please note that the sensor contains non-removable batteries. It is strictly prohibited to incinerate the sensor as it may lead to explosions or other hazardous situations. Properly handling the batteries can minimize potential harm to the environment and human health.

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 rise or fall per minute).
	Slow increase: blood glucose increases by 0.06 to 0.11 mmol/L per minute.
	Increase: blood glucose increased by 0.11-0.17 mmol/L per minute.
	Rapid increase: blood glucose increased by more than 0.17 mmol/L per minute.
	Slow decrease: blood glucose decreased by 0.06 to 0.11 mmol/L per minute.
	Decrease: blood glucose decreased by 0.11-0.17 mmol/L per minute.

	Rapid decrease: blood glucose decreased by more than 0.17 mmol/L per minute.
No arrow	App can not 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. During Sensor Glucose below 2.2mmol/L or above 22.2mmol/L, there will no record in glucose curve, but sensor glucose reading 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 3-, 6-, 9-, or 12-hours.

5.1.3 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) 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.

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

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

5.3.1 Thresholds

Alarm	Introduction	Threshold setting	Default
Low Alarm	If the blood sugar is lower than this value, app will give an alarm of hypoglycemia.	3.3 - 5.6 mmol/L (60-101 mg/dL)	3.9mmol/L (71 mg/dL)
Urgent Low	If the blood glucose is at or below 3.1 mmol/l, app will give an urgent hypoglycemia alarm	3.1mmol/L (56 mg/dL)	3.1mmol/L (56 mg/dL)

High Alarm	If the blood sugar is higher than this value, app will generate hyperglycemia alarm.	7.9 mmol/L - 22.2 mmol/L (143 - 400 mg/dL)	13.0mmol/L (234 mg/dL)

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

5.3.2 Snooze Alarm

You can click the "Turn off current alarm" button during an Alarm to snooze Alarm for 3 mins.

You can click the "Snooze Alarm" button during an Alarm, and the alarm will remain snoozed during the time interval set by the user.

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. Faults and Troubleshooting

The Sensor’s adhesive tape is not sticky enough
Issue: sensor has fallen off from the body, or the adhesive tape is not sticky enough **Solution:** ● Before applying the sensor, clean the skin with alcohol wipe and wait for it dry, use soap to clean the intended applying area when necessary. ● 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. Do not apply the sensor on the tattoos or scars.

System stopped, please change sensor

Issue:

Application message: System sopped, please change the senor

Solution:

- Check the shelf life of the item
- Contact your local support if you have further questions

Connecting, please wait

Issue:

Application message: Connecting, please wait

Solution:

- Check Compatibility: check if your smartphone is in the compatibility list
- Reboot your smart phone and reenable Bluetooth
- Check the distance between the smartphone and the transmitter, if there are no obstacles within the Bluetooth range specified in the manual, and there is no electromagnetic interference around

System recovering, please wait

Issue:

Application message: System recovering, please wait

Solution:

Most of this kind of situation will resume normal use after about 4 hours, if it doesn't recover after 4 hours, please contact your local support

- Please use BG Meter during this recovering period
- Please check the installation status of the device

Calibration error

Issue:

The application doesn't apply the calibration

Solution:

- The device cannot be calibrated when the application is syncing the historic data from the device
- The device cannot be calibrated if the system is attempting to recovery
- **T**he transmitter cannot be calibrated for 24 hours after activation
- Calibration is not possible when blood sugar readings fluctuate greatly

Allergy

Issue:

Some people are allergic to related acrylic substances in the tape

Solution:

- Users are not recommended to use the tape if allergy to the acrylic substances
- Slight redness, swelling and itching can generally not be treated, which is a normal phenomenon when the tape is removed

7. Maintenance

This product has no serviceable parts, thus requiring no maintenance.

8. Travel information

Wearing sensor 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 applied in the skin.

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

9. Product Performance

Model	D3
Measurement range	2.2-22.2 mmol/L
Effective working time	14 days
Size (sensor)	φ24mm*3.5mm
Weight (sensor)	1.7g
Data receiving range	6 m
Calibration method	Factory calibration
Calibration range	2.2-22.2 mmol/L
Storage and Transport conditions	Temperature：2℃-30 ℃； Relative humidity：15%-85%
Working conditions	Temperature：10℃-40℃； Relative humidity：10%-95%
Atmospheric pressure	70kPa-106 kPa
Sterile state	Sterile
Sterilization method	Irradiation sterilization (γ-ray)
Validity period	12 months
Display interval	3 minutes
Rated voltage	d.c.1.5V
Classification	Type BF
Power support	Internal power supply
Protection grade	IP28 (Waterproof to 1.0 meter for up to 120 minutes)
Wireless	Bluetooth 5.0, 2402-2480 MHz, GFSK, 0 dBm

10. 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 or Professional healthcare facility 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 transients 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 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
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.

FCC STATEMENT

1. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.
2. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
Reorient or relocate the receiving antenna.
Increase the separation between the equipment and receiver.
Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
Consult the dealer or an experienced radio/TV technician for help.

RF warning statement:
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

11. Technical support Costume service

11.1.Technical support

Technical support: INFINOVO MEDICAL CO.,LTD.

Registration and Operation Address: 3rd Floor, 6th Building, No.888, Zhujiang Road, Rudong 226400 Jiangsu China

Tel. +86(513)81900808

ZIP-Code. 226400

11.2.Sales support

Sales support: INFINOVO MEDICAL CO.,LTD.

Registration and Operation Address: 3rd Floor, 6th Building, No.888, Zhujiang Road, Rudong 226400 Jiangsu China

Tel. +86(513)81900808

ZIP-Code. 226400

Website：www.infinovo.com

12. Reporting of serious incidents

In the event of a serious incident involving this device, it is crucial to report it immediately to Infinovo Medical Co, Ltd. To do so, please email us at service@infinovo.com. Alternatively, you can reach out to your local support team for assistance.

It is important to note that a 'serious incident' refers to any occurrence that has caused, might have caused, or could potentially cause:

- The death of a patient, user, or any other individual
- A significant decline in the health condition of a patient, user, or any other individual, whether temporarily or permanently.

Reporting such incidents ensures that appropriate measures are taken to prevent any recurrence and safeguard the well-being of patients, users, and others. Our team is committed to investigating each report promptly and taking necessary corrective actions to address the issue. Thank you for your cooperation in maintaining a safe and healthy environment.

13. The warranty

13.1.The scope and duration of warranty

The original purchaser of the device will receive a limited warranty in case of any quality issues with raw materials and processes during normal use. This warranty will cover a period of 12 months from the purchase date.

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.

13.2.The following conditions are not in the scope of warranty

This limited warranty is contingent upon proper usage of the continuous glucose monitoring system in accordance with the documentation provided by Infinovo. Any use of the system beyond these guidelines is strictly prohibited.

Any attempts to misuse, tamper with, or access the system or the information it processes and transmits in an unauthorized manner, including jailbreaking or rooting your continuous glucose monitoring system or cell phone, may not only result in malfunctioning of the device but also put your health at risk.

Such unauthorized actions are strictly prohibited and will void your limited warranty. We strongly advise our users to follow the instructions provided in the documentation to ensure optimal performance of the system.

This limited warranty does not cover:

The warranty does not cover any defects or damages caused by accidents, misuse, abuse, neglect, excessive physical, electrical, or electromechanical stress, any modifications to the product, or cosmetic damage.

13.3.Warranty liability

During the warranty period, Infinovo offers a replacement of any product that has quality problems without any charge to the purchaser. However, it is important to note that the buyer must notify the sales support department and return the product in its original packaging. Additionally, a purchase receipt or sales certificate, containing the date of purchase, seller's name and address should be furnished alongside the product. The address for the sales support department can be obtained by contacting them directly. Once the company receives the faulty product, a replacement will promptly be delivered. However, if the company determines that the product is not covered under the warranty, the purchaser will be responsible for all shipping charges for the returned product.

13.4.Warranty Statement

The company's limited warranty is a unique and comprehensive replacement for all other warranties, whether express or implied, and overrides any other legal regulations. With the exception of any provisions prohibited by law, the company will not be held liable for any special or incidental damages. This applies even if the company or its agents have recommended or been responsible for any failures to remedy any issues. The limited warranty is exclusively granted to the original

purchaser and provides the purchaser with the only form of compensation available. If any part of the Limited Warranty is deemed illegal or unenforceable, it will not impact the remaining parts' enforceability. The purchaser acknowledges and accepts that the other parts of the warranty are to be interpreted as a limited legal license.

14. Label symbol and graphic description

Symbol	Description	Symbol	Description
	Refer to the Instructions for Use	IP28	Dustproof and Waterproof class
	Do not reuse	REF	Catalogue Number
	Do not Use if Package is Damaged	SN	Serial Number
	Type BF Applied Part	MD	Medical device
	Temperature Limit		Environmental Protection
	Humidity Limitation		Non-ionizing Radiation
	Sterilized Using Irradiation		Date of Manufacture
	Keep Dry	CE 0197	After passed CE certification, mark the CE-marking on package;
	Keep away from Sunlight		INFINOVO MEDICAL Co., LTD. 3rd Floor, 6th Building, No.888, Zhujiang Road, Rudong 226400 Jiangsu China
	Caution	EC REP	Llins Service & Consulting GmbH Heinigstrasse 26, 67059 Ludwigshafen, Germany info@llins-service.com
	Use-by-date	LOT	Batch code

	Model Number		Unique device identifier
	Do not resterilize		Country of manufacture

Appendix-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	