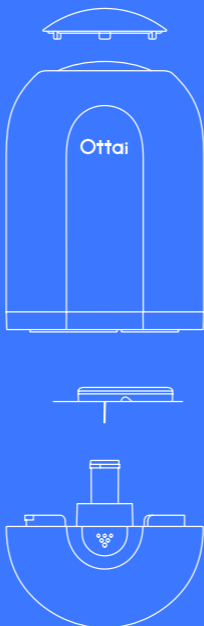


Ottai M8

CONTINUOUS GLUCOSE MONITORING SYSTEM

User Manual





IMPORTANT NOTE

01. Please ensure you have fully read and are familiar with the User Manual before using the Ottai Continuous Glucose Monitoring System. Failure to follow instructions may result in pain or injury and may affect product performance.
02. Please remove the Sensor before performing MRI, X-ray, or CT examinations. If you need to continue monitoring after the examination, please wear a new Sensor.
03. Product measurement results are not used as a basis for deciding and adjusting treatment plans for diabetic patients.
04. Don't ignore the possible symptoms of high or low glucose. If your symptoms are inconsistent with your Continuous Glucose Monitoring System readings, or you suspect your readings are inaccurate, check your glucose with a test using a blood glucose meter.
05. Due to the physiological differences between interstitial fluid glucose and capillary glucose, during periods of rapid changes in glucose (such as after meals, after insulin injection, and after exercise), it is easy for fingerpicks glucose values and sensor readings to be inconsistent, which is normal.
06. It is contraindicated for use by patients prone to skin ulcers.
07. Patients with allergic skin (allergic to disinfectants or medical tape) should use the Continuous Glucose Monitoring System with caution.
08. Do not use the Sensor if the packaging has been damaged or opened.
09. Do not use the damaged or broken Sensor for fear of any potential electrical safety hazards or electric shock injuries resulting from failures.
10. Seek professional medical help if symptoms of infection or inflammation "redness, swelling or pain" occur at the implant site.
11. The Continuous Glucose Monitoring System contains small parts that may be dangerous if swallowed. Please keep the product out of the reach of children.
12. If your Continuous Glucose Monitoring System is damaged, please contact the Ottai Support Team: 400-0860-509.

Ottai CGM Quick Guide

STEP 01

DOWNLOAD APP

Scan the QR code to download the "Ottai" App, or search for "Ottai" in the mobile App Store to download.



Please make sure your mobile phone:

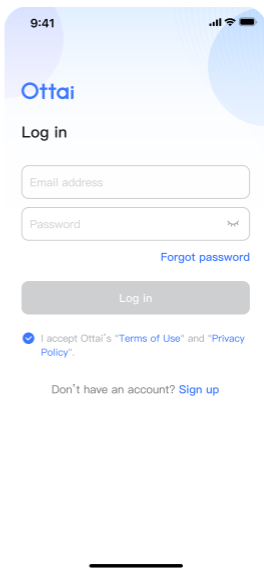
1. The operating system is Android 5.0 and above, or IOS 13.0 and above;
2. Is connected to the Internet (operator network or WIFI).



STEP 02

REGISTER & LOGIN

Ottai



9:41 📶 🔋

Ottai

Log in

Email address

Password 👁️

[Forgot password](#)

Log in

I accept Ottai's "Terms of Use" and "Privacy Policy".

Don't have an account? [Sign up](#)

STEP 03

TAKE OUT THE DEVICE

Open the product packaging and take out the device.

Caution: Do not use the device if the sealed bag or the device itself is broken. Please contact customer service.



STEP 04

SELECTION OF APPLICATION SITE

Choose the rear area of your upper arm as the application site.

Caution: Avoid areas with scars, moles, stretch marks, or lumps.



STEP 05

CLEAN APPLICATION SITE

Clean the application site with alcohol pads and wait until the skin becomes dry before proceeding to the next step.



STEP 06

COVER REMOVAL

Rotate open the bottom cover of the Applicator.



STEP 07

SAFETY CAP REMOVAL

Remove the safety cap on the top of the Applicator.

Caution: Do not touch the button under the safety cap yet.



STEP 08

LAUNCHING

Place the Applicator over the cleaned area of the arm, press the launch button on the top, and gently pull away the Applicator. The Sensor should now be attached to the skin.



STEP 09

TAPE FIXING

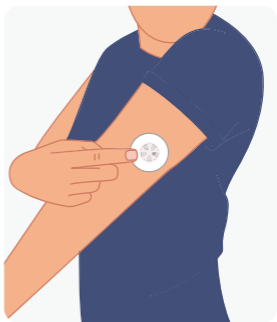
Gently press the tape around the Sensor to attach it firmly to the skin. Once done, follow the instructions on your mobile screen to start the Sensor.



STEP 10

OVERLAY PATCH

Each package has an overlay Patch to help with adhesion and stability.



STEP 11

CONNECT SENSOR

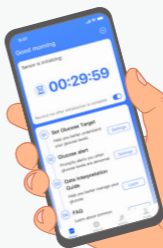


Bluetooth is connecting...

STEP 12

WARM-UP

A 30-minute warm-up period is required before the glucose data can be displayed.



User Manual

Thank you for your trust in the Ottai CGM product. We hope to present you the best experience and service with our Continuous Glucose Monitoring (CGM) System. Before using the CGM System, please ensure that you have fully read and familiarized yourself with the Instructions for Use. Any failure to follow the instructions may result in pain or harm or may even affect the performance of the system. For any questions about use of this product, please consult medical staff or contact customer service or the local distributor

1. Before Use

1.1 Information on User Safety

To keep you and the product safe during your use of the system, this section provides safety information including indications, contraindications (avoidance circumstance), precautions and warnings as follows:

- 01) Indications: to define the suitable user group.
- 02) Contraindications: to make you aware of the certain circumstances under which use of the product should be avoided and, if not avoided, may cause harm to yourself or damage the product.
- 03) Precautions: to remind you of the specific situations in which your attention is needed during the use to prevent any minor or moderate harm to you or damage to the product.

- 04) Warnings: to remind you of any severe or life-threatening environment that needs to be avoided when using the product as well as corresponding consequences and the way for danger avoidance. Upon unpacking the product, check whether the product is intact. If any parts are missing or damaged, please contact customer service at 400-0860-509.

1.2 Intended Use

The product can be used for continuous or periodic monitoring of interstitial fluid glucose levels in adult patients (≥ 18 years of age) with diabetes. The product provides and stores real-time glucose values for the user to track trends in glucose concentration and alerts the user if glucose levels fall below or above a preset value. The glucose sensor is intended for single-user use only, does not require calibration by the user, and can be used for up to 14 days. The results of the product are not intended to be used as a basis for determining or adjusting the treatment plan for diabetic patients.

1.3 Contraindications

The following principles should be followed for the use of the CGM System:

- 01) Patients with allergic skin should use the product with caution.
- 02) Patients prone to skin ulcers are prohibited to use the product.
- 03) Patients suffering from bodily fluid-borne diseases should consult the doctor before any use.
- 04) Patients with insufficient self-care abilities should use the product only when supervised by a caregiver who is at least 18 years of age.
- 05) Patients who lack good visual and auditory abilities to recognize and respond to alerts should use the product

only when supervised by a caregiver who is at least 18 years of age.

1.4 Warnings

- 01) Do not use the Sensor if the packaging has been damaged or opened.
- 02) Do not use the damaged or broken Sensor for fear of any potential electrical safety hazards or electric shock injuries resulting from failures.
- 03) Avoid applying the Sensor on the same site repeatedly, inserting the Sensor into the same site may cause scarring or skin irritation.
- 04) Never allow children to hold the device without adult supervision. The device includes small parts that may pose a choking hazard.
- 05) Always seek professional medical help when suffering an infection or inflammatory symptoms, swelling or pain, at the insertion site.
- 06) Do not ignore symptoms that may be caused by hyperglycemia or hypoglycemia. If you have symptoms that do not match well with the Sensor glucose readings or suspect that your readings may be inaccurate, check your glucose by conducting a finger-stick test using a blood glucose meter.
- 07) Contact customer service at 400-0860-509 if your Sensor is damaged.

1.5 Precautions

- 01) Please use the device according to the User Manual, otherwise, damage to the device may be caused.
- 02) Do not expose the Sensor to magnetic resonance imaging (MRI) equipment, X-ray equipment, computed tomography (CT) equipment, intensity modulated radiation therapy (IMRT) equipment or any other equipment that generates strong magnetic fields or

ionizing radiation.

- 03) Do not reuse this single-use product or share it with others.
- 04) Do not freeze this product.
- 05) Do not expose this product to direct sunlight or high temperature.
- 06) Do not apply the Sensor onto sites that may be frequently rubbed by clothing, have scars, or with frequent movement.
- 07) Store the product in a cool and dry place before opening. Do not open the package box with wet hands.
- 08) Do not use household cleaners, chemicals, solvents, bleachers, washing pads or sharp tools to clean the Sensor. Clean the Sensor surface with a small amount of rubbing alcohol is allowed.
- 09) Restart the Mobile APP each time after restarting your mobile phone.
- 10) Evaluation on the performance of the system when used with other implantable medical devices (i.e. pacemaker) has not been conducted.
- 11) It is unclear that to what extent the diseases suffered by critically ill patients, or their used drugs will affect the performance of the Sensor. Hence, glucose readings of the Sensor may be inaccurate when used to monitor critically ill patients.
- 12) Do not wear the Sensor for more than 14 days because no readings will be available after 14 days.
- 13) Taking ascorbic acid (vitamin C), salicylic acid (pain relievers such as aspirin and some skin care products), methyldopa (for high blood pressure treatment), or Tolbutamide (for diabetic treatment), acetaminophen (paracetamol) may affect the accuracy of glucose values measured by the Sensor.

- 14) Do not change or modify the device. Changing or modifying the device can result in improper insertion, pain, or injury.
- 15) The accuracy of glucose monitoring in patients with severe anemia and abnormal erythrocyte pressures was not validated to ensure the reliability of the measurements.
- 16) The performance of the product's high and low glucose reminder function has been evaluated through clinical trials. In the clinical trial, the thresholds for high and low glucose reminders were initially set at glucose > 11.1 mmol/L for high glucose reminders and glucose.
- 17) A loose or detached Sensor may result in no reading from the APP.
- 18) Sensor breakage, please do not handle it by yourself, please seek help from a healthcare professional.
- 19) The report generated by the continuous glucose monitoring system software is only used to improve the management and prevention of diabetes, and cannot be used as the basis for adjustment of therapeutic drugs.
- 20) When the storage space of the mobile computing terminal is insufficient, the continuous glucose monitoring system software may run abnormally, in which case the user needs to clean up the storage space of the mobile computing terminal, and can continue to use the application normally after running it again. Users are recommended to clean up the storage space of the mobile computing terminal regularly.
- 21) Ensure that the continuous glucose monitoring system software runs on a mobile computing terminal that is free of viruses or malware, and update it with the latest security patches.

1.6 RF Communication

The Continuous Glucose Sensor will generate, use, and radiate RF energy and may cause harmful interference to radio communications. So, interference may be inevitable in a particular usage environment. The Sensor uses RF energy only for its internal communication with the smart device. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Communication between your Sensor and your smart device may be blocked if any other common consumer electronic devices work at the same frequency band as the Sensor. However, such interference will not cause any inaccurate data or any damage to your device. The RF communication distance between the Sensor and the smart device is up to 10 meters (33 feet).

1.7 Waterproof Performance

When worn during showering, bathing or swimming, the Sensor is waterproof. However, hot water may shorten the service life of the monitoring device. It is strongly suggested that the Sensor should be dried with a clean towel when it is out of water. Note: The Sensor cannot communicate properly while immerse in water since the Bluetooth signal is weakened in water. Do not expose the product to water over 1.5 meter (4.92 feet) deep or for more than 30 minutes.

1.8 Waste Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to interstitial fluids. Contact Customer Service for further information on the appropriate disposal of system components.

2. Introduction to Ottai CGM System

2.1 Name and Model

Name: Continuous Glucose Monitoring System

Model: M8

Trade name: Ottai

2.2 Working Principle

The Continuous Glucose Monitoring System uses electrochemical sensor to monitor glucose levels in interstitial fluid. Based on the electrochemical reaction principle, the glucose in subcutaneous interstitial fluid is oxidated by glucose oxidase on the sensor and the electrons are transferred to the metal electrode, thereby generating current. The current intensity is proportional to the glucose content in the interstitial fluid. The sensor is in touch with the subcutaneous interstitial fluid, collects the electrochemical signal and outputs the analog signal. The transmitter receives the analog signal of the sensor, converts it into a digital signal through the analog front end, and transmits it to the mobile APP through radio frequency. The APP receives the signal and provides readings of the glucose level on mobile APP interface for users to read. Based on the monitoring graph, the patient's daily maximum and minimum glucose values and the pattern of glucose fluctuations can be analyzed. The real-time display of glucose values also provides the patient with a high and low glucose alert function, as well as information on the orientation and rate of change of glucose trend.

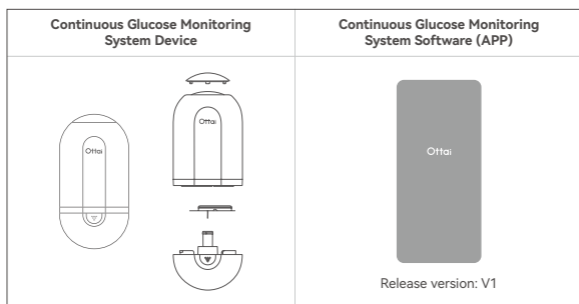
2.3 Scope of Application and Function

Continuous Glucose Monitoring System is intended for adults (aged 18 and above) with diabetes mellitus who need to monitor their glucose levels. The critical function of CGMs is real-time glucose monitoring. The system is

indicated for measuring interstitial fluid glucose levels in intended adult users and can provide users with real-time glucose readings, glucose trend and fluctuation characteristics, and alert information such as high/low glucose alerts. The results measured by the product should not be used as the basis for determining or adjusting the treatment regimens for patients with diabetes. The system is intended for single-patient use.

2.4 Product Composition

The product consists of Continuous Glucose Monitoring System device and Continuous Glucose Monitoring System software (release version: V1), of which the Continuous Glucose Monitoring System device includes a Sensor (the transmitter and the sensor are integrated into one unit) and an Applicator. All for single use only.



2.5 Device Installation

- 01) Open the product package and check if the device is complete and undamaged.
- 02) Clean the dorsal area of your upper arm with alcohol pads and allow the skin to dry before proceeding to the next step.
- 03) Remove the cover at the bottom of the Applicator by

rotating it counterclockwise.

04) Remove the safety cap on the top of the Applicator.

 **Caution:**

Do not touch the button under the safety cap yet.

05) Place the Applicator on the cleaned area of the arm, press the launch button on the top and gently pull away the Applicator.

06) Gently press the adhesive tape on the edge of the monitor to fit it to the skin.

 **Note:**

- 1). The specific operation can be started by following the quick operation guide in this manual.
- 2). Choose a soft, fatty area on the upper third of the area from the back of the arm to the elbow

3. Introduction to the Continuous Glucose Monitoring System Software

3.1 Functional Overview

The Continuous Glucose Monitoring System Software (hereinafter referred to as APP) is a component of the Continuous Glucose Monitoring System and can only be used in conjunction with the Continuous Glucose Monitoring System device. After the Sensor is worn, the user can use the mobile computing terminal with the APP installed to connect with the Sensor via Bluetooth to obtain data.

The APP can monitor your glucose data at any time and develop daily monitoring charts based on your cycle glucose changes, as well as provide you with high and low glucose alerts. The transmitter embedded software has the function of collecting, storing and transmitting data, this software cannot be installed by the user and does not require the user to configure the environment and parameters in advance.

Glucose update time

The Monitoring page of the Continuous Glucose Monitoring System software displays new glucose values every 5 minutes.

Restrictions of Use

When using the APP, you need to enter the correct cell phone number and SMS verification code to complete the login and subsequent operations. Input and output data types Input user's glucose parameters, output glucose statistics, glucose analysis report, high and low glucose alerts.

Interface

01) Application Interface - Not applicable. APP does not

provide an application program interface for external requests.

02) Network Interface

- Intended User: Individuals who use CGMS for glucose management.
- Intended use: To export glucose reports at the end of the session.
- Technical features: The Continuous Glucose Monitoring System software uses the https network protocol to communicate securely with the server.
- Restrictions on use: Glucose reports can be exported only at the end of wear. - Troubleshooting: None.

03) Bluetooth Interface

- Intended users: Individuals who use CGMS for glucose management.
- Expected Uses: App data interaction with CGMS, CGMS life cycle management, obtaining glucose data monitored by CGMS, etc.
- Intended use: data interaction between APP and CGMS, CGMS life cycle management, obtaining glucose data monitored by CGMS, etc.
- Technical features: Standard transmission protocol, Bluetooth 4.2 and above.
- Restrictions: The APP needs to run on a cell phone operating system that supports Bluetooth 4.2 and above.
- Failure countermeasures: Provide an abnormal disconnection retry mechanism between APP and CGMS.

3.2 Compliance

The Continuous Glucose Monitoring System software complies with the requirements of the following regulatory documents: "Regulations for the Supervision and Administration of Medical Devices", "Measures for

the Administration of Registration and Filing of Medical Devices", "Rules for Naming the Common Names of Medical Devices", "Provisions on the Administration of Instructions and Labeling of Medical Devices", "Guidelines for Technical Review of the Registration of Medical Device Software", "Guidelines for Technical Review of the Registration of Medical Devices for Cybersecurity", and "Guidelines for Technical Review of the Registration of Mobile Medical Devices".

3.3 Installation and Maintenance

a. APP Operating Environment

	Android	IOS	Server
Operating System	Android 5.0 and compatible	iOS 13.0 and compatible	Lower than AliyunOS 2.1903
CPU	1.4Ghz and compatible versions	1.4Ghz and compatible versions	No less than 4 cores
RAM	RAM 3GB and compatible versions	ROM 2GB and compatible versions	No less than 16 GB
Storage	Not less than 64GB	Not less than 16 GB	No less than 200 GB
Bluetooth	4.2 and compatible versions	4.2 and compatible versions	NA
Database	NA	NA	No less than MySQL 8.0
Screen Size	Not less than 5.0 inches	Not less than 4.7 inches	NA
Screen Resolution	Not less than 1280*720	Not less than 1334*750	NA
Maximum Screen Brightness	Not less than 150cd/m ²	Not less than 150cd/m ²	NA
Battery Capacity	Not less than 3000 mAh	Not less than 1715mAh	NA
Ambient Light	The mobile computing terminal running the Continuous Glucose Monitoring System software should have functions such as ambient light detection, display brightness correction, automatic and manual adjustment of screen brightness.		NA
Power on Self-test (POST)	Mobile computing terminals running the Continuous Glucose Monitoring System software are capable of detecting the operating environment upon power-up.		NA

b. Network Requirements

Network architecture: CS architecture; Network type: Internet with a bandwidth of not less than 5 Mbps.

Installation of Software

- 01) IOS system: If you are using a mobile computing terminal with IOS system, you can download APP from Apple App Store.
- 02) Android system: If you are using a mobile computing terminal with Android system, you can download APP from Android App Store.

Note:

In addition to the above two ways, you can also scan the QR code of the official APP on the box to download and install the official APP.

Maintenance and Support

Ottai Technology Wuxi Pty., Ltd. provides technical maintenance support for APP. In case of upgrading and maintenance of APP, Ottai Technology Wuxi Pty., Ltd. can provide professional technicians to maintain the version of APP which can be maintained by our company, and our company reserves the right to interpret this.

Ottai Technology Wuxi Pty., Ltd. will maintain the product by updating the APP. Uninstalling APP

Long press the icon of APP on the desktop of the mobile computing terminal where APP is installed, and "Uninstall" option will be displayed next to the icon, and you can uninstall APP by Taping the "Uninstall" option. In addition, you can uninstall APP at "Settings"- "Application Management" of the mobile computing terminal. In addition, you can uninstall the APP in "Settings"- "Application Management" of the mobile computing terminal.

3.4 APP Operation

First Time Users

01) Registration and Login

After installing the APP according to the requirements, open the APP on the desktop of the mobile computing terminal, register a new account and log in to the APP account.

02) Complete personal information

Follow the instructions in APP to complete your personal information, including date of birth, gender, height, weight, etc.

03) Connect the device

Wear the Sensor correctly according to the instructions, activate and connect the Sensor. Wait for the Sensor to initialize after connection. After the Sensor is connected, it takes 60 minutes to warm up before glucose data can be transmitted. Transmission of glucose data is not allowed.

04) Glucose Range Setting

Set the upper and lower target glucose range in order to receive alert messages from the system for high and low glucose. Note: Follow the Quick Start Guide in this manual to get started.

05) Start monitoring

After the Sensor is initialized, APP starts to display the monitoring data in real time.

Note:

The illustration of the software interface provided in this manual is for reference only, please refer to the actual display of the APP. Glucose Monitoring View real-time glucose data and glucose profiles from the Sensor in the "In App - Monitoring" section.

Glucose Change Indicator Arrow

↑	Glucose in rapid rise	The change in glucose is greater than 2mg/dL or 0.11mmol/L per minute
↗	Glucose in slight rise	The change in glucose varies in the range of 1-2mg/dL or 0.06-0.11mmol/L per minute
→	Glucose in stable state	The change in glucose is less than 1mg/dL or 0.06mmol/L per minute
↘	Glucose in slight drop	The change in glucose varies in the range of 1-2mg/dL or 0.06-0.11mmol/L per minute
↓	Glucose in rapid drop	The change in glucose is greater than 2mg/dL or 0.11mmol/L per minute

Glucose Change Indicator Arrow

Real-time Glucose Values (updated every 5 minutes)

Real-time Glucose Curve (updated every 5 minutes)



Sensor Connection Status

Optional display of 3h, 8h and 24h data graphs (default 24h view)

Glucose Target Range

Glucose Statistics

In the "App - Statistics" section, Tap on the calendar to switch the date and view the statistics of glucose indicators, such as: glucose line graph, maximum glucose, minimum glucose, average glucose, percentage of high glucose, percentage of low glucose, TIR rate. Note: Users can view the detailed data interpretation guide in the app.

Glucose Alert

If real-time glucose is higher than the upper limit of the target glucose range or lower than the lower limit of the

target glucose range, the APP sends an alert message to the user.

Personal Center

In the "App - My" section, you can view my device, device status and remaining time. Tap the arrow on the right side of your avatar to view your personal information, including nickname, date of birth, gender, height and weight.

Tap on the arrow to the right of "Glucose Target" to change the target glucose range.

Tap " Glucose Alert" to set abnormal glucose alert.

Tap "Settings" to view the software name, APP version number and user agreement.

Tap "Logout" to log out of your APP account.

Tap "Logbook" to view or record the events of blood test, diet, exercise, medication, insulin, and so on.

Tap "Glucose Report" to view the generated glucose report.

3.5 Network Security Instructions and Usage Guidelines User

Access Control Mechanism

APP only has basic access authorization users enter the software through cell phone number and SMS authentication code, and the privileges are to operate all functions of the software.

Interfaces, Data types and Technical features

Please refer to 3.1 Interface Description in this manual.

Data Backup and Disaster Recovery

Glucose data is stored in the transmitter. When the Bluetooth of the mobile computing terminal is turned on, the stored glucose data will be transmitted to the APP. The server side carries out database backup regularly, and data recovery can be accomplished by the tool that comes with the database.

Operating Environment

Please refer to 3.1 Interface Description in this manual.

3.6 Software Quality

3.6.1 Functionality

See section 3.4 of this manual for details.

3.6.2 Performance efficiency

Under the operating environment of the APP described in these instructions, new glucose data can be displayed every 5 minutes on the "Monitoring" function page of the APP.

3.6.3 Information Security

APP information security protection level classification: the security level of glucose monitoring, glucose statistics, glucose reminder and system settings is B level.

3.6.4 Compatibility

If the mobile computing terminal has the app installed and needs an update, installing a new version will overwrite the old version. Only one version of the app can be installed on the same mobile computing terminal at a time; multiple versions cannot coexist. The actual functionality will be determined by the last installed version. Running this app concurrently with other software will not result in the loss of functionality or operational errors in the other software. App Data Interface: Communication with monitoring devices is achieved through Bluetooth protocol. Using this app does not require pre-configuring environments or parameters.

3.6.5 Usability

To use this app, the following foundational knowledge is required:

- 01) Knowledge of using mobile computing terminals.
- 02) Proficiency in using the Android or iOS operating systems.

03) Ability to read English or Arabic numerals.

Prompt messages in the app include:

- 01) If users enter an incorrect verification code during login, a prompt will display 'Incorrect verification code.'
- 02) If Bluetooth is turned off, a prompt will indicate 'Bluetooth is not enabled; glucose data cannot be synchronized.'
- 03) Notification for abnormal glucose data.
- 04) Relevant prompts will be sent when mobile permissions need to be granted.

3.6.6 Reliability

Data is not lost when Bluetooth is disconnected, and historical data is automatically synchronized after Bluetooth is reconnected.

The service runs normally after the mobile computing terminal is restarted.

3.6.7 Maintainability

Navigate to the 'My' section within the app to access the user management interface and view user information. Tap on the settings button to perform software maintenance.

3.6.8 Portability

At a minimum, the application should operate in the environment described in Section 3.3, "Software Runtime Environment," of this manual.

4. Termination of Glucose Monitoring (removal, replacement of Sensors)

When using the Continuous Glucose Monitoring System, the APP will indicate the remaining time of product usage on the homepage, you can purchase or replace the Sensor in advance according to the remaining time of usage, so that you can continuously monitor your glucose changes.

4.1 Normal Termination of Glucose Monitoring

- 01) The Sensor should be stopped after 14 days (336h) of wear and no data can be obtained if the Sensor continues to be worn;
- 02) Make sure the Sensor is disconnected before removing it from the body;
- 03) After disconnecting the Sensor, gently remove the corner of the adhesive tape from the skin;
- 04) Remove the Sensor slowly and discard it safely.

4.2 Early Termination of Glucose Monitoring

When you need to stop using the Sensor, you can follow the instructions in the APP. Remove the Sensor as in 4.1 Normal termination of glucose monitoring.

 **Note:**

You can take action to terminate the glucose monitoring operation early when the following situations occur:

- 01) The Sensor is not in its normal service life;
- 02) The Sensor is detached or the adhesive is detached;
- 03) Other objects are rubbing against the Sensor (e.g., seat belt, etc.);
- 04) The application area you have selected is not a recommended area.
- 05) The application area was not clean and dry before installing the Sensor.

5. Sensor Specifications

Glucose concentration detection range	2~25 mmol/L
Sensor size (Diameter*Height)	24mm*3.5mm
Insertion depth of Sensor	5mm
Sensor power supply	lithium battery (3V)
Sensor service life	14 days
Transmitter memory	Stores up to 14 days of data
Operating temperature	5~40 °C, no freezing
Operating relative humidity	10 %~85 % RH, no condensation
Storage and shipping temperature range	2~30°C, no freezing
Storage and shipping relative humidity	10 %~85 % RH, no condensation
Atmospheric pressure	70~106KPa
Initiation time	60min
Wireless transmission distance	10m
Ingress protection level	IPX8
Sensor sterilization method	Sterilized using irradiation
Transmitter bandwidth	2.4~2.4835GHz
Modulation Type	GFSK (Gaussian Frequency-Shift Keying) Modulation
Effective radiated power	≤20dBm (EIRP)
CMIIT ID	2022DP20134

6. Maintenance and Repair

6.1 Warranty and Maintenance

This product is warranted to be free from defects in material and workmanship for 12 months from the date of manufacture. During the warranty period, this product will be replaced at the discretion of the equipment. This product warranty applies only to new equipment and shall not be extended if the Sensor is replaced.

This product warranty is valid only if the Sensor is used by the requirements and does not apply to the following cases:

- 01) Damage to the equipment caused by human dismantling of the equipment;
- 02) if any part of the service is damaged by anyone other than a professional repairer;
- 03) if the damage is caused by force majeure or other events beyond the control of the manufacturer;
- 04) if the damage is caused by negligence or misuse, including, but not limited to, improper storage or physical abuse, such as dropping or otherwise.

The warranty for this product applies only to the initial user. Any sale, lease or other transfer of use of this product by the initial user shall result in the immediate termination of this warranty. This product has no serviceable parts and requires no maintenance.

6.2 Storage and Transportation

Storage temperature is 2°C~30°C, storage humidity is 10%~85%RH, no condensation. Fragile items, avoid humidity, do not freeze.

7. Circuit Diagrams and Component Lists

All parts in the composition of this product can only be returned to the factory or by the company's designated professionals to repair, non-professionals may not repair this equipment. If the user needs technical information such as circuit diagrams, component lists and diagram notes from the manufacturer, it is necessary to contact the manufacturer for consultation to obtain them.

8. Electrical Safety

Safety Features of the Sensor

Classification by type of protection against electric shock	Internal power supply units
Classification by degree of protection against electric shock	BF-type application sections
Classification by the degree of protection against incoming fluids	IPX8
Classification by degree of safety when used in the presence of flammable anesthetic gases mixed with air or with oxygen or nitrous oxide.	Equipment not to be used in the presence of flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide.
Classification by mode of operation	Continuous operation equipment
Rated voltage and frequency of the equipment	Disposable lithium battery power supply, DC3V
Input power of the device	NA
Protected against defibrillation discharge effects in its applied part?	No
Does the device have a signal output or input section?	No
Is the equipment permanently installed or not permanently installed?	Non-permanent installation equipment

9. Electromagnetic Compatibility

9.1 Guidelines and Manufacturer's Instructions - Electromagnetic Emissions

Guidelines and Manufacturer's Declarations - Electromagnetic Emissions			
The Continuous Glucose Monitoring System is intended for use in the electromagnetic environment specified below, and the purchaser or user shall warrant that it is used in such electromagnetic environment			
Emission Test	Compliance	Electromagnetic Environment - Guidelines	
Radio Frequency Emission GB 4824	Group 1	The Continuous Glucose Monitoring System uses RF energy only for its internal functions. As a result, it has very low RF emissions and has little potential to interfere with nearby electronic equipment.	
Radio Frequency Emission GB 4824	Class B	Continuous Glucose Monitoring Systems are suitable for use in all installations, both domestic and those not directly connected to the public low voltage supply grid of domestic dwellings.	
Harmonic Emission GB17625.1	NA		
Voltage Fluctuation / Flicker Emission GB/T 17625.2	NA		


9.2 Electromagnetic Immunity

Guidelines and Manufacturer's Declarations - Electromagnetic Immunity			
The Continuous Glucose Monitoring System is intended for use in the electromagnetic environment specified below, and the purchaser or user shall warrant that it is used in such electromagnetic environment			
Immunity Tests	IEC 60601 Test level	Level of Compliance	Electromagnetic Environment - Guidelines
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor should be wood, concrete or tile, and if covered with a synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient Pulse Groups GB/T 17626.4	±2 kV to power line ±1 kV to input/output lines	NA	Grid power should be of a quality typically used in commercial or hospital environments
Surge (Electrical) GB/T 17626.5	±1 kV line to line ±2 kV line-to-ground	NA	Grid power should be of a quality typically used in commercial or hospital environments

Power Input Line Voltage Dips, Short-term Interruptions and Voltage Variations GB/T 17626.11	<5%UT, lasting 0.5 weeks (with >95% temporary reduction in UT) 40%UTT, lasting 5 weeks (with 60% temporary reduction in UT) 70%UT, lasting 25 weeks (with 30% temporary reduction in UT) <5%UT, lasting 5 seconds (with >95% temporary reduction in UT)	NA	The net power supply should be of a quality typically used in a commercial or hospital environment. If users of the continuous glucose monitoring system require continuous operation during power interruptions, then an uninterrupted power supply or battery power is recommended for the continuous glucose monitoring system.
Work Frequency Magnetic Field (50/60 Hz) GB/T 17626.8	3 A/m	3 A/m	The IF magnetic field shall be characterized by IF magnetic field levels typical of a typical commercial or hospital environment.
Note: UT is the AC grid voltage before applying the test voltage.			

Guidelines and Manufacturer's Declarations - Electromagnetic Immunity

The Ottai Continuous Glucose Monitoring System is intended for use in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such electromagnetic environment.

Immunity Tests	IEC 60601 Test level	Level of Compliance	Electromagnetic Environment - Guidelines
Radio-frequency Conduction (RFCT)	3 V (RMS) 150 kHz-80 MHz	3 V (RMS value)	The use of mobile and portable RF communications equipment is prohibited within closer proximity to any part of the continuous glucose monitoring system (including cables) than their commended isolation distance. This recommended isolation distance is based on equations that can be applied to transmitter frequencies. Recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz~800 MHz $d=2.3\sqrt{P}$ 800 MHz~6.0 GHz Here P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer's transmitter; d is the recommended separation distance in meters (m) The field strength of a stationary RF transmitter is determined by a survey of the electromagnetic field site c, which should be lower than the compliance level in each frequency band d. Interference may occur in the vicinity of equipment marked with the following symbols 
RF Radiation			
GB/T 17626.3	3 V/m 80 MHz-2.5 GHz	3 V/m	

NOTE 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher band should be used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

- a. The I&M frequency bands between 150 kHz and 80 MHz are 6.765 MHz~6.795 MHz, 13.553 MHz~13.567 MHz, 26.957 MHz~27.283 MHz and 40.66 MHz~40.70 MHz.
- b. The compliance level in the I&M band between 150 kHz~80 MHz and in the frequency range 80 MHz~2.5 GHz is used to reduce the possibility of interference caused by mobile/portable communication devices when they are incidentally brought into the patient area. For this purpose, an additional factor of 10/3 is used to calculate the recommended isolation distance for transmitters in these frequency ranges.
- c. Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, have field strengths that cannot be predicted with theoretical accuracy. To assess the electromagnetic environment of a fixed RF transmitter, a survey of the electromagnetic field should be considered. If the measured field strength of the site where the glucose monitoring system is located is higher than the applicable RF compliance level described above, the continuous glucose detection system should be observed to verify that it can function properly. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the continuous glucose monitoring system.
- d. The field strength shall be less than 3 V/m over the entire frequency range of 150 kHz to 80 MHz.

9.3 Recommended safety distances

Recommended Isolation Distances for Portable and Mobile RF Communications Equipment and Ottai Continuous Glucose Monitoring Systems			
<p>The Continuous Glucose Monitoring System is intended for use in an electromagnetic environment where radio frequency radiation disturbances are controlled. Depending on the maximum output power of the communication equipment, the purchaser or user of the continuous glucose monitoring system can prevent electromagnetic interference by maintaining the recommended minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the continuous glucose monitoring system.</p>			
Safe distance according to transmitter power (m)			
Transmitter Rated Power (W)	150 k Hz~80 MHz $d=1.2\sqrt{P}$	80 MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitter maximum output power ratings not listed in the table above, the recommended isolation distance d, in meters (m), can be used with the formula in the corresponding transmitter frequency column. Determine where P is the maximum rated output power of the transmitter in watts (W) as supplied by the transmitter manufacturer.</p> <p>NOTE 1: At the 80 MHz and 800 MHz frequency points, the formulas for the higher bands should be used.</p> <p>NOTE 2: These guidelines may not be appropriate in all cases, electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.</p>			

9.4 Warnings

Except for transducers sold by the manufacturer of the device or system as spare parts for internal components, the use of accessories, or transducers other than those specified may result in increased emissions or reduced immunity of the device or system.

The device or system should not be used in close proximity to or stacked on top of other equipment, and if it must be used in close proximity or stacked on top of other equipment, it should be observed and verified to function properly in the configuration in which it is used.

Active medical devices are subject to special EMC precautions and must therefore be installed and used in accordance with these guidelines.

Portable and mobile communication RF equipment may affect the use of medical electrical equipment. The device or system may be interfered with by other devices, even if the other devices comply with the emission requirements of the respective national standards.

10. Prompts and Troubleshooting

Prompt / Fault	Possible Reason	Solution
Bluetooth connection interrupted, resulting in failure of glucose data synchronization.	The smart device is too far away from the Sensor.	Shorten the distance between the phone and the Sensor.
Bluetooth turned off, resulting in failure of glucose data synchronization.	Bluetooth off.	Turn on Bluetooth.
Abnormal network connection, new device cannot be connected successfully.	No Internet connection.	Check the Internet connection or retry the Internet connection.
Internet connection abnormality, statistics page data can not be displayed normally.	No Internet connection.	Check the network connection or retry the network connection.
Abnormal glucose data.	The Sensor is falling off, the Sensor is severely rubbed, the adhesive is contaminated, the Sensor is not installed correctly.	Check whether the appearance of the Sensor is intact and replace it if there is any damage, or, if there is no damage, continue glucose monitoring and seek medical treatment if necessary.
Binding failed.	The Sensor has been used.	Bind a new Sensor.
	Bound devices are not monitors.	Select Sensor for Binding.
High glucose alert.	Glucose reading is exceeding the pre-set limit.	Continue glucose monitoring and seek medical treatment if necessary.
Low glucose alert.	Glucose reading is exceeding the pre-set limit.	Continue glucose monitoring and seek medical treatment if necessary.
Permission to be activated.	Required permission for Ottai has not been activated on the mobile phone.	Activate the corresponding permissions according to the instructions.
APP crashed or freezes.	Smart device system crash.	Open the App store and upgrade the App version.
Skin allergy after device implantation	Clothes, folds and other objects in the installation part rubs against each other.	Make sure the device is not rubbing against other objects.
	The user is allergic to the material of the product.	Contact your doctor.

Device start-up failed	The device is not properly installed due to improper operation.	Check the Instruction For Use of the Sensor or contact the customer service.
	Check if the device is outside the specified temperature.	Relocate the Sensor to the specified operating temperature (2°C (36°F) - 45°C (113°F)) and turn it on again.
	Another situation occurs	Contact the customer service.

11. Basic EMC performance

The Continuous Glucose Monitoring System provides real-time monitoring of glucose.

12. Information on Clinical Trials

Clinical Trial Overview

This product has been evaluated through clinical trials. The clinical trial was designed with a prospective, multicenter, single-group target value method. The experimental range was adult diabetic patients, and the product was worn on the lateral margin of the biceps muscle on the back of the upper arm, making the use period 14 days. After the qualified subjects were enrolled, the continuous glucose monitoring system was worn, and the EKF glucose detector was used as the gold standard to measure intravenous glucose. The effectiveness of the continuous glucose monitoring system was evaluated, and the safety of the product was evaluated during wearing.

The system performance accuracy indicators and results of the entire measurement range are as follows:

Types of Indicators	Evaluation Indicators	Clinical Trial Results
Primary evaluation indicators	20/20% concurrence with control reference value	93.3%
	Proportion of measurement points falling in the A+B region of the Clarke error grid analysis	99.6%
	Proportion of measurement points falling in the A+B region of the Consensus error grid analysis	99.8%
	Mean Absolute Relative Error Value (MARD%)	8.106%±3.869%
Secondary evaluation indicators	Correct Alert Rate	The success rate of high glucose alert was 95.8%; the success rate of low glucose alert was 84.1%. The success rate of high glucose detection was 95.7%; the success rate of low glucose detection was 88.0%.

	The Sensor Stability	<p>The 20/20% concurrence rate was higher than 90% for all time staging except for the late stage (day 14) where the 20/20% concordance rate was 86.8%.</p> <p>The mean MARD values for the anterior (day 1), anterior-intermediate (days 2-5), intermediate (days 6-9), middle-late (days 10-13), and late (day 14) phases were $8.591\% \pm 4.191\%$, $6.716\% \pm 2.852\%$, $8.525\% \pm 3.450\%$, $8.166\% \pm 3.930\%$, and $10.506\% \pm 6.564\%$, respectively.</p>
Security evaluation indicators	Repeatability of the Sensor	The mean value of the mean absolute difference (PARD) for primary/secondary sensor pairs was 0.065 ± 0.085 .
	Product Ease of Use	The total score of the questionnaire totaled 90 points, and the average of the total score was 86.0 ± 7.27 , suggesting that the ease of use of the product is good.
	Sensor Life	The primary/secondary sensors survived a median of 14 days of wear, with a cumulative overall failure rate of 11.6%.
	Adverse Events	A total of 5 (6.9%) participants experienced 6 adverse events. All adverse events were positively unrelated to the device.
	Device Defects	No device defects were found during the test.

Clinical performance description of high and low glucose alert function

This product has a high and low glucose alert function. Users can customize the upper and lower limits of the target glucose range according to their own conditions. When the glucose is higher than the upper limit of the target range, or lower than the lower limit of the target range, the APP will send an alert to the user.

The performance of the high and low glucose alert function has been evaluated through clinical trials. In the clinical trial, the range for the low glucose alert was set

to 4.4 mmol/L or 79 mg/dL, and the range for the high glucose reminder was set to 11.1 mmol/L or 200 mg/dL. The performance evaluation of high and low glucose alerts includes the success rate and failure rate of high and low glucose alerts (i.e. sensitivity), and the detection success rate and failure rate (i.e. specificity). The relevant definitions in clinical trials are as follows:

- 01) Low glucose alert success rate and failure rate (i.e. sensitivity). The success rate of a low glucose alert is the number of times the continuous glucose monitoring system successfully prompts a low glucose alert within the first 15 minutes and the next 30 minutes when the EKF measurement value is lower than the alert threshold. Proportion. The low glucose alert failure rate is the proportion of the continuous glucose monitoring system that did not prompt a low glucose alert during the above period.
- 02) Low glucose detection success rate and failure rate (i.e. specificity). The success rate of low glucose detection is the proportion of EKF also detecting low glucose within 30 minutes before and after the continuous glucose monitoring system prompts a continuous low glucose event. The low glucose detection failure rate is the proportion of EKF that does not detect low glucose within 30 minutes before and after the continuous glucose monitoring system prompts a low glucose event.
- 03) High glucose alert success rate and failure rate (i.e. sensitivity) The high glucose alert success rate is the number of times the continuous glucose monitoring system successfully prompts a high glucose alert within the first 15 minutes and the next 30 minutes when the EKF measurement value is higher than the alert threshold. Proportion. The high glucose alert failure rate is the proportion of continuous glucose monitoring systems that did not prompt a high glucose

alert during the above period.

- 04) High glucose detection success rate and failure rate (i.e. specificity). High glucose detection success rate is the proportion of EKF also detecting high glucose within 30 minutes before and after the continuous glucose monitoring system prompts a high glucose event. The high glucose detection failure rate is the proportion of EKF that does not detect high glucose within 30 minutes before and after the continuous glucose monitoring system prompts a high glucose event.

The clinical performance test results of this product's high and low glucose alerts are summarized as follows:

Hypoglycemia alert success rate and loss Failure rate (i.e. sensitivity)		Success and loss of hypoglycemia detection Failure rate (i.e. specificity)		Success and loss of hyperglycemia detection Failure rate (i.e. specificity)		Success and loss of hyperglycemia detection Failure rate (i.e. specificity)	
Success rate	Failure rate	Success rate	Failure rate	Success rate	Failure rate	Success rate	Failure rate
84.1%	15.9%	88.0%	12.0%	95.8%	4.2%	95.7%	4.3%




















 **Note:**

- 01) The high/low glucose alert function is only used to prompt the user to measure glucose with fingertip blood using a BGM, and is not used as a basis for deciding and adjusting treatment plans.
- 02) The performance of the product's high/low glucose alert functions has been evaluated through clinical trials. The alert thresholds for high/low glucose are initially set to: Glucose >11.1mmol/L or 200mg/dL will prompt a high glucose alert, and glucose <4.4mmol/L or 79mg/dL will prompt a low glucose alert. The high/low glucose alert thresholds in clinical trials are only recommended values for subjects in clinical trials. Users can customize the

high/low glucose alert thresholds according to their own glucose conditions.

- 03) In the clinical trial of this product, in the subgroups with glucose $<3.9\text{mmol/L}$ or 70mg/dL and $<4.4\text{mmol/L}$ or 79mg/dL , the proportion of measurement points falling in the A+B area of the Clarke error grid analysis was less than 90%. In case of a low glucose event, please use a BGM to test your fingertip glucose.
- 04) Sensor glucose value is based on interstitial fluid glucose level, which may be different from glucose level (finger), especially when glucose changes rapidly. If your glucose reading does not match your symptoms or expectations, please use a BGM to perform a glucose test to check the glucose reading measured by the system.

Appendix 1: Markers and Symbols

	Single use only. Do not re-use
	Do not use if package is damaged
	Attention! See Instructions for Use
	Radiation Sterilization
	Type BF Applied Part
	Do not throw in trash can
	Non-Ionizing Radiation
	Keep Dry
	Keep away from Direct Sunlight
	Temperature Limit
	Humidity Limit
	Serial Number
	Manufacture Date
	Use-by date
	Fragile, handle with care
	Refer to the Instructions for Use
	Recycling
	Manufacturer
	Medical Device

Annex 2: Glossary of Terms

CGMS	Continuous Glucose Monitoring System (CGMS) is a monitoring technology that indirectly reacts to blood glucose level by monitoring the glucose concentration of subcutaneous interstitial fluid through glucose sensors, which can provide continuous, comprehensive, and reliable information on blood glucose throughout the day, understand the characteristics of blood glucose fluctuations, and detect hidden hyperglycemia and hypoglycemia that are not easy to be detected by traditional monitoring methods. Hidden hyperglycemia and hypoglycemia cannot be easily detected by traditional monitoring methods.
Device	An integrated system consisting of components such as an Applicator and a Sensor.
The Sensor	Includes sensor and transmitter, uniformly referred to as "Sensor"; all-in-one design, no user assembly required for use.
Mobile Computing Terminal (MCT)	It refers to mobile computing technology product terminals for personal use, including general-purpose (commercial off-the-shelf) terminals and special-purpose (homemade medical) terminals, and the form of use can be categorized into hand-held (e.g., tablet computers, portable computers, smartphones, etc.), wearable (e.g., smart glasses, smartwatches, etc.), and hybrid (a combination of hand-held and wearable). The mobile computing terminals on which the APP can be installed in this product are handheld general purpose (commercial off-the-shelf) terminals.
APP (Mobile Application Program)	A mobile application designed to run on a smart device such as a smartphone or tablet. Continuous Glucose Monitoring (CGM) APP Used with Continuous Glucose Sensor for continuous monitoring of glucose.
Upper limits	When glucose goes above the set maximum, a high glucose alert will be triggered
Lower limits	When glucose goes below the set minimum, a low glucose alert will be triggered
Warnings	informs you of potential hazards.

Production / Expiry date

See product label.

Date of manufacture / Expiry date

See product label.

Registrant / Manufacturer's Name

Ottai Technology Wuxi Pty., Ltd.

Registrant's residence

Building 530, 18 Qingyuan Road, Xinwu District, Wuxi,
P.R.CHINA

Manufacturing Address

Room 210, East 2F, Building 3, No.58 Jinghai Road, Beijing
Economic-Technological Development Zone, Beijing, China

Registrant / Manufacturer Contact Information

400-0860-509

After-sales service unit

Ottai Technology Wuxi Pty., Ltd.