i3
Continuous Glucose Monitoring System

User Manual

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Warning

Please read the User Manual carefully before using the i3 Continuous Glucose Monitoring System. If you have any questions about these instructions or test results, please consult your healthcare professional or contact our Customer Service Department at 400-887-0036.

Special Note: Improper operation of the device may result in serious consequences.

Contents

Chapter 1 Introduction to i3 CGM

1.1 Introduction

The User Manual provides a comprehensive introduction of the i3 GGM system. Please use the i3 CGM according to the User Manual so as to prevent the risks from improper use.

In addition to the User Manual, the following documents may also provide assistance.

(1) Quick Start

It can be found in your product package, which can teach you how to use the i3 CGM step-by-step for the first time.

(2) Tutorial Videos

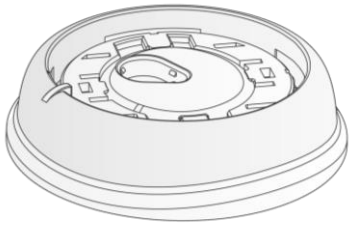
After you register on the i3 iCGM APP, you can read the Quick Start and watch the Tutorial Videos on the APP. Through the Tutorial Videos, you can learn:

- The instructions and the safety information before use;
- How to implant a sensor and bond a transmitter;
- How to change your settings in the APP;
- How to check your real-time glucose data in the APP;
- Other functions.

1.2 System Description

Sinocare i3 CGM System is an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose readings which are updated every 3 minutes providing user with real-time glucose measurements (glucose values) accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). The System consists of three main components: a Sensor Package, a Bluetooth Low Energy (BLE) Transmitter Package and a BLE enabled display device (iCGM app). The user can view glucose data on a compatible mobile device using iCGM app. The system provides alerts which warn the user of low or impending low and high or impending high glucose levels. The user may determine their treatment based on the glucose values provided by the system.

Sensor package (iCGM-S3)	Transmitter package (iCGM-T3)	iCGM APP (iCGM-APP)



Sensor Package: The sensor is to measure the glucose concentration level in subcutaneous interstitial fluid, and the applicator is used to apply a sensor your body.

Transmitter package: The transmitter incorporates and processes the sensor data, and contains a Bluetooth radio transceiver for communication with the smart device.

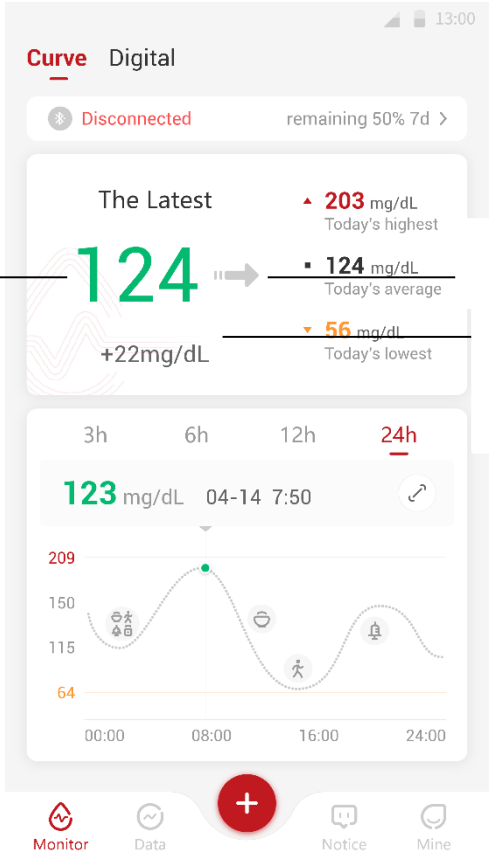
iCGM APP: The APP displays the current glucose reading and glucose trends to the user. It alerts the user when glucose levels are outside of a target zone and when other important system conditions occur.

The i3 CGM monitoring period can reach up to 15 days. No finger blood measurement or calibration is required, and it is intended for single use only. The glucose concentration measurement range is 36 to 450 mg/dL. Beyond this range, the indication of “High” or “Low” will appear on the smart device APP.

Data displayed on the Monitoring Page of the APP are as shown in the figure below..

Latest Glucose Level

Green: Within Normal Range
Red: Below the Lower Limit
Orange: Above the Upper Limit



Glucose Level Trend Arrow

Glucose Change Compared with the Previous Data

After the 15 day monitoring is over, you can view the continuous glucose monitoring report for 15 days, including the highest, lowest, average values of glucose, TAR, TIR, TBR and other relevant important information.

1.3 Glossary

In order to facilitate the user's query, the definitions of the often used terms in the User Manual are listed as follows:

Terms	Definition
Android or iOS	The operating system of the smart device.
APP/Application	Software installed on the smart device for continuous glucose monitoring.
Airplane Mode	A setting mode of the smart device in which certain functions are disabled to comply with the airline regulations.
Bluetooth	A technology enabling wireless communication between devices.
Continuous Glucose Monitoring	A sensor applied under the skin monitors the glucose level in interstitial fluid, and a transmitter sends the glucose data to the display device.

Default	The settings preset by a manufacturer.
Hyperglycemia	Hyperglycemia is characterized by too high blood glucose in the blood. The treatment to hyperglycemia is important, if left untreated, hyperglycemia may cause serious complications. For the i3 CGM, the upper alert limit of glucose level is preset to 200 mg/dL as the default.
Hypoglycemia	Hypoglycemia is characterized by too low blood glucose in the blood. Immediate treatment to hypoglycemia is important, if left untreated, hypoglycemia may cause consciousness loss in some severe cases. For the i3 CGM, the lower alert limit of glucose level is preset to 79 mg/dL as the default.
Alert	A method used by the APP on the smart device to notify the user when an event occurs. It can be given in the form of a message, sound or vibration, which depends on the settings of the smart device.
mg/dL	Milligrams per deciliter, an international standard unit for the measurement of blood glucose level commonly used in European countries and America.
mmol/L	Millimole per liter, an international standard unit for the measurement of blood glucose level commonly used in some countries, such as in China etc.
Safety Statement	A statement for the i3 CGM safety, including the indications, contraindications, warnings and precautions.
Indications	A brief description of the purpose of the CGM, and under what circumstances or conditions CGM can be used
Contraindication	Description of the specific situations where the CGM shouldn't be used，otherwise it may be harmful to you.
Warning	Description of the serious and life-threatening conditions, consequences and the ways to avoid the hazards when using the CGM.
Precaution	Special steps to be taken for the safe and effective CGM use.
TAR (Time above Range)	The time when the glucose level is above the range, which is between the Upper Alert Limit and the Lower Alert Limit.
TIR (Time in Range)	The time when the glucose level is within the range, which is between the Upper Alert Limit and the Lower Alert Limit.

TBR (Time below Range)	The time when the glucose level is below the range, which is between the Upper Alert Limit and the Lower Alert Limit.

Chapter 2 Safety Statement

The safety statement is a statement for the i3 CGM safety, including the indications, contraindications, warnings and precautions . The safety statement is to ensure the safety of you and CGM during use, please follow the requirements of the safety statement, otherwise it may cause pain, injury, incorrect monitoring results or other risks.

2.1 Indications and Contraindications

Indications/Intended Use

The i3 Continuous Glucose Monitoring System is a real time, continuous glucose monitoring device indicated for the management of diabetes for adult people (age 18 and older). It is intended to replace fingerstick blood glucose testing for diabetes treatment decisions.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System results should be based on the glucose trends and several sequential readings over time.

The System can be used alone or in conjunction with digitally connected devices where the user manually controls actions for therapy decisions..

Contraindications

- Remove the sensor and transmitter before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.
- This device is not intended for pregnant women, people on dialysis, or critically ill patients.
- When wearing the device, ask for hand-wanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner. Also avoid putting any part of the device through baggage x-ray machine.
- Taking ascorbic acid (Vitamin C) supplements while wearing the Sensor may falsely raise

- Sensor glucose readings. Inaccurate sensor readings due to ascorbic acid interference may be clinically significant and result in harm if relied on to make treatment decisions.

2.2 Warnings and Precautions

2.2.1 Warnings and Precautions for the System

- **Use CGM according to the User Manual.**

  Please read the User Manual carefully before using CGM, and use CGM according to the User Manual. Otherwise, it may result in you missing a severe hypoglycemia or hyperglycemia occurrence that may result in injury when treatment decisions are needed.

- **No modification is allowed**.

  The patient is an intended operator. No modification of this equipment is allowed.

  If the user makes the changes or modifications without the approval of Sinocare, Sinocare has the right to prohibit the user from operate this equipment. Without the approval and authorization of Sinocare to a modification, Sinocare will not be liable to the injuries or harms caused by any modification.

- **Risk of interfering substances**

  The medications you take may affect the performance of the CGM sensor. Before using the device, please consult your healthcare professionals about your health conditions and the probable interference from the medications to your CGM readings.

- **Use the transmitter with the sensor in the same package.**

  The Sensor Package and Transmitter are packaged as a set. Do not use the sensor and transmitter from the different sets. Otherwise CGM will not function properly and may result in incorrect CGM readings.

- **Keep out of reach of children and pet.**

  The CGM continuous glucose monitoring system contains small parts which may have choking hazard when using around children and pet, please keep the device out of reach of children or pet.

- **Storage conditions**

  You can store the CGM at room temperature or in a refrigerator between 2-30°C (35.6 -86°F)

temperature and 10~ 90%RH humidity. Please do not store the CGM in a freezer.

- **Operating environment**

  Temperature: 10-42°C (50-107.6°F),

  Humidity: 10~ 90%RH.

  Do NOT operate your transmitter in the presence of flammable anesthetics or explosive gases.

  Do not use insect repellent, sunscreen, perfume, lotion or cream on the sensor insertion site. Otherwise, you may run the risk of the medical tape not sticking firmly.

  CGM is waterproof and can be immersed in water to a depth of 2.5 meters at room temperature for up to 2 hours.

- **Accuracy of readings**

  Do not ignore any possible symptoms of hypoglycemia or hyperglycemia. If the readings or alerts do not match your symptoms or your feeling, or if you suspect the CGM reading is inaccurate, please have a finger blood test or consult a healthcare professional.

- **Glucose readings when glucose is falling/rising quickly**

  CGM monitors the glucose concentration in interstitial fluid, and there is a physiological lag between the glucose concentration in interstitial fluid and the venous blood glucose concentration or the capillary blood (fingersticks) glucose concentration. When blood glucose level changes rapidly, for example, after eating, exercising or taking medicine, CGM glucose readings may be higher or lower than the fingersticks blood glucose level. When the glucose level falls rapidly, the sensor glucose reading may be higher than the blood glucose level. On the other hand, when the glucose level rises rapidly, the sensor glucose level may be lower than the blood glucose level.

- **Discomfort when using**

  The sensor insertion may cause bleeding, pain or even infection. The medical tape may cause skin irritation. Usually these situations are unlikely to occur. If there are any severe discomforts during use, please contact your healthcare professionals or the Customer Service as soon as possible. If any serious adverse event occurs, it should be reported to the manufacturer and competent authority of the country where the user and/or patient is located.

- **Cleaning and maintenance**

Do not clean any part of the CGM system while in use. After the CGM immerses in water, it can be dried with a soft towel.

Do not dry CGM with a hair dryer, a microwave oven or a traditional oven.

- **Disposal**

The transmitters with batteries, sharp objects and substances exposed to body fluids shall be disposed appropriately in accordance with all applicable local regulations for the disposal of medical wastes and electronic products. For further information, please consult Sinocare Customer Service.

2.2.2 Warnings and Precautions for the Sensor

- Sensor tips break or loosen.

If the sensor tip breaks, loosen or come out from the insertion site, there will be no readings or the readings may not match your feeling. Please remove the device and replace it with a new CGM.

- **Do not use if expired.**

Do not use a sensor with a past expiration date, otherwise the monitoring results may be incorrect. Check the package label for the expiration date before using the CGM.

- **Check package.**

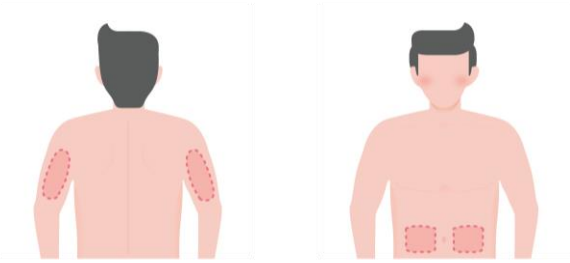
Do not use the sensor if the aseptic package is damaged or opened, otherwise it may result in infection. If the package is damaged, please contact Sinocare Customer Service.

- **Use the CGM as soon as possible after opening the package.**

The sensor is sterilized by radiation method, please use it as soon as possible after opening the package of the sensor kit.

- **Choose the insertion sites.**

The CGM continuous glucose monitoring system can be applied either in the abdomen or in the back of the upper arm, as shown in the figures below. Please do not insert the sensor in other sites, because The sensor is not tested for other sites, so the monitoring readings may be inaccurate. Avoid sensitive skin areas or areas with scars, moles, or lumps;



- **Do not reuse the sensor.**

  The sensor and the sensor applicator are designed for single use. Reusing the sensor may result in no glucose level reading or infection. If exercise or any other activities causes the inserted sensor loosen, the sensor needs to be removed. The removed sensor cannot be reused and must be replaced by a new sensor.

2.2.3 Warnings and Precautions for the Transmitter

- **Enter the correct transmitter number.**

  When starting a new CGM system, the correct transmitter number must be entered in the smart device and the transmitter must be bound successfully, otherwise no CGM readings or alerts will be received.

- **Check the device.**

  If the transmitter is damaged or is not in its original position, please contact Sinocare Customer Service.

  Check the label for the expiration date before using the transmitter. If transmitters are expired and they cannot be used, please contact Sinocareo Customer Service.

- **Operating environment**

  Please don't wear your CGM for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment; the magnetic fields and heat may damage the transmitter and result in the transmitter malfunction, incorrect glucose readings or alert failure.

2.2.4 Warnings and Precautions for the APP

- **Compatibility**

  The smart device must support Android 5.0 and above. For the release version number of the APP, please refer to the version number indicated in【Mine】page of the APP.

- **Check the smart device.**

When a severe hypoglycemia or hyperglycemia event occurs, if you cannot receive an alert to remind you, you may miss it. When using properly, those problems could not happen. i3 CGM has passed a strict test for the alert performance. To ensure the CGM functions properly, please check your smart device according to the following methods before use:

(1) Batteries charged

Keep the smart device batteries charged.

(2) Open the APP.

When using the CGM, please keep the APP running.

(3) Increase the volume of the smart device.

Keep the volume of the smart device loud enough for you to clearly hear the alert sound.

(4) Speaker and vibration

Disable the Mute and Do Not Disturb functions. Make sure the speaker or the vibration function of the smart functions work well. Test the speaker and the vibration function of your smart device regularly, and if needed, refer to the User Manual of the smart device. If the speaker or the vibration function does not work, please contact the customer service center of your smart device.

(5) Within the specified distance

Keep your smart device and transmitter within the working distance of 6 meters.

(6) Bluetooth connection

Keep your smart device well connected with the transmitter via Bluetooth.

(7) Please do not adjust the time of your phone, which may affect the blood glucose reading information on the APP.

Chapter 3 Using Your i3 CGM

3.1 APP Sign-up and Login

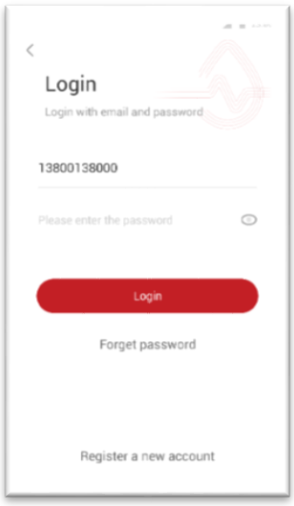
Step 1 Install the App

You can download iCGM-APP through the following channels:

- Scan the 2D barcode in the quick start to download the i3 iCGM-APP
- You can also visit Sinocare website at http://www.sinocare.com to download the APP

Step 2 Register a account

Tap 【Register a new account】on the “Login” page. Use your email to register a account.



The account password must be between 8 to15 characters long, which can contain digits(0 through 9) and English alphabetic characters(A through Z, not case sensitive) and must contain at least one alphabetic character.

3.2 Connect Transmitter

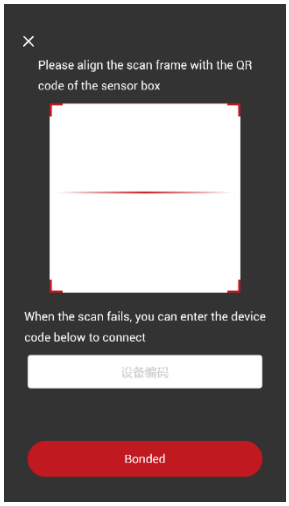
3.2.1 Check the SN on the packages

Open the packaging box, and take out the sensor and the transmitter packages from the box.

Caution: Make sure the sensor and the transmitter used are from the same packaging box and have the same SN. If different, please do not use them, and you could contact the custom service.

3.2.2 Connect Transmitter

Before the transmitter and sensor assembled together, connect the transmitter with the APP on the smart device.



Align the scanning frame with the 2D barcode on the sensor package and scan the 2D barcode. After successfully scanned, the device code will be appeared in the *Device code* text box. Tap 【Bind】 to connect the transmitter.

If the connection failure is due to 2D barcode scanning, rescan the 2D barcode or enter the transmitter code in the *Device code* text box to connect the transmitter again.

3.3 Assembly of Transmitter and Sensor

Step 1: Wash your hands

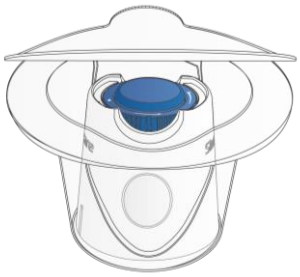
Wash your hands with detergent and dry your hands

Note: Please dry your hands completely.

Step 2 Check the sensor packages.

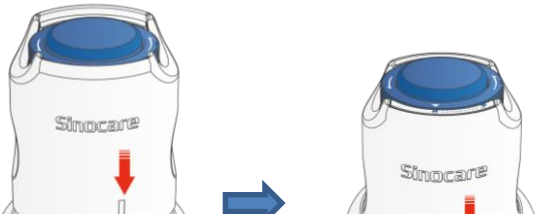
Do not use your CGM if the package are damaged or opened. If this happens, contact Sinocare Customer Service.

Step 3 Take out the sensor



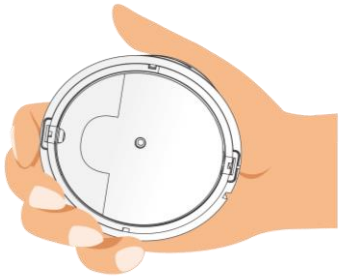
Step 4 Line up and press down

Line up the teeth on the sensor and the transmitter as shown in the figure and press the sensor down into the transmitter thoroughly.



Step 4 Pull out the sensor from the transmitter

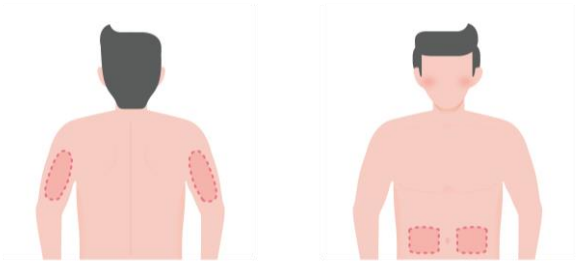
Step 5 The assembled sensor is as shown in the figure



Step 6 If your sensor is successfully assembled, you will to go to the "Confirm wearing" page below.

3.4 Sensor Insertion

（1） Select and clean the insertion area



You can choose either the back of the upper arm or the middle of the abdomen to insert the sensor.

Note: Consider the following factors to choose the sensor insertion positions:

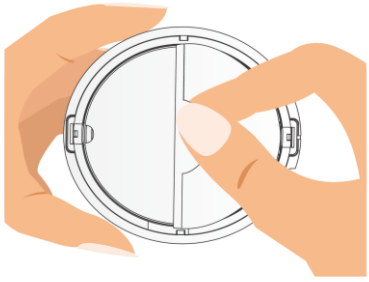
- Do not select other sites for insertion. No clinical trial has been conducted and approved on other sites. If placed in other sites, the sensor may not function properly and could give inaccurate readings.
- A flat area with more subcutaneous fat should be chosen;
- During your normal daily activities, the area of skin should be able to keep flat and without bending or folding;
- Areas restricted by clothing such as belts shall be avoided;
- Muscle or bone areas should be avoided;
- Areas with intense movement during exercise shall be avoided.
- Areas with scars and tattoos or sensitive areas shall be avoided;
- Areas with excessive body hair shall be avoided
- Area should be at least 7.5 cm (3 in.) away from the insulin pump injection position or the manual injection position.
- The area chosen for the last CGM insertion should be avoided, otherwise it may result in skin irritation or itching.

（2） Clean the insertion site

Please clean the insertion site with an 75% alcohol, and let it to try thorough.

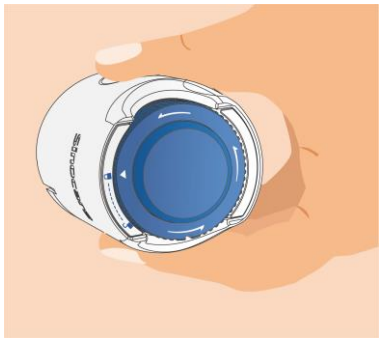
Note: do not use other cleaner or disinfectant clean the insertion site

（3） Pull off the adhesive tab



Note: Don’t touch adhesive on the medical tape surface

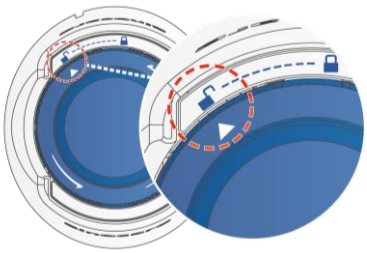
（4） Stick to your skin



Place the assembled sensor on the cleaned skin area. Stick the adhesive to your skin thoroughly

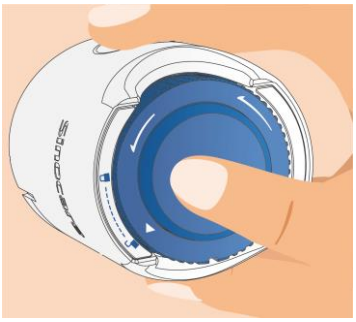
（5） Unlock the safety rotary switch

Turn the safety rotary switch counterclockwise to the unlocking position, where the arrow aligns with the unlock mark, to unlock the sensor. Now the sensor is ready for insertion.



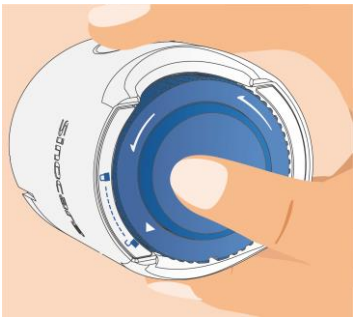
Note:

The assembled sensor contains puncture needles. Please do not unlock it until it is ready for insertion to prevent injury



（6） Insert the sensor

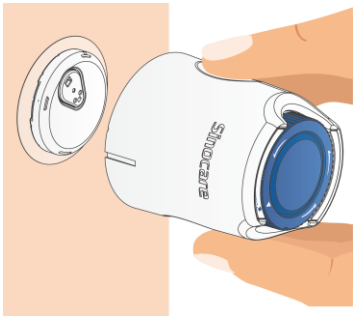
At the chosen insertion area, press the button in the middle of the top to insert the sensor into the skin.



Note:

The assembled sensor contains a puncture needle. After unlocking, do not press the top button before inserting the sensor to prevent injury

（7） **Remove the sensor applicator**



The sensor is left on the tape. Stick the medical tape tightly by hand.

Now, you have inserted the sensor successfully!

Note:

Please dispose of the sensor applicator in accordance with the local guidance on disposal of blood-contacting components.

In particular, there is a used piercing needle in the sensor applicator, be careful not to scratch your skin. If you have any questions, please contact Sinocare Customer Service.

At this point, the sensor has been successfully inserted, and the transmitter has been connected to the APP. Next, you can use the APP to display your glucose information.

Chapter 4 How to Use CGM APP

4.1 Glucose Monitoring

Device Status: Initializing

The device status is: "device initializing". At this time, there is no graph displayed, no glucose value displayed, and the display is "- -". When the countdown time displayed after "device initializing" is to "00: 00: 00", the initialization state ends.

Note:

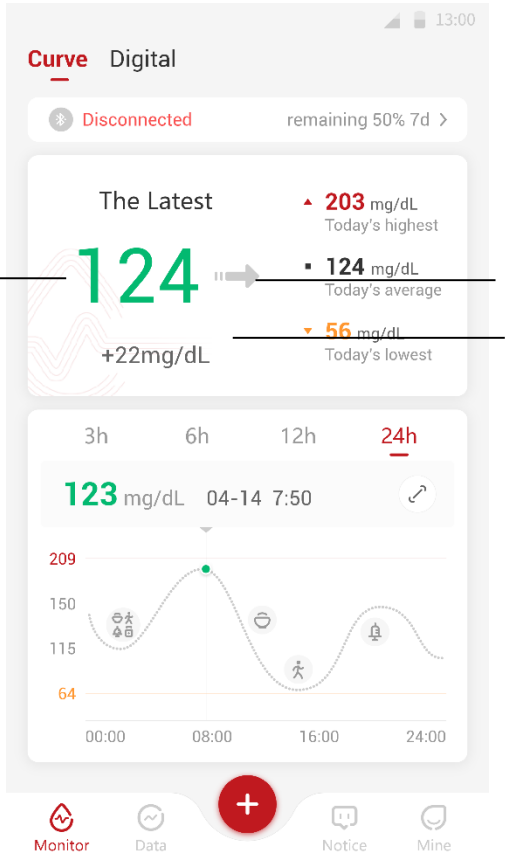
You will NOT receive real-time glucose data sent by CGM in the 2 hours of initialization period or after the 15 days of monitoring period. Please use a finger blood meter to monitor your blood glucose level..

Start Monitoring

The device initialization time is over, start monitoring, as shown in the figure below. Device status: “Connected”.

Latest Glucose Level

Green: Within Normal Range
Red: Below the Lower Limit
Orange: Above the Upper Limit



Glucose Level Trend Arrow

Glucose Change Compared with the Previous Data

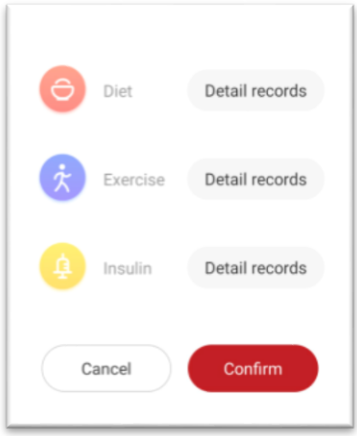
Landscape

On the "Graph" page of the monitoring home page, tap the landscape icon in the graph  to turn the page to landscape view.

On the landscape page, you can view graphs of “one day”, “several days”, “average daily” and “comparison”. In the "comparison" graph, you can tap the left or right arrows to select two dates for comparison of the glucose level graphs.

4.2 Add Events

Tap  icon in the navigation bar to go to the add event page, as shown in the figure below.



Tap 【Detail records】to enter the "details" page to add details to the event

4.3 Event Records

Tap 【Data】 in the navigation bar at the bottom of the page, and tap 【Data records】to view all events added,.

4.4 Mine page

Tap 【Mine】in the navigation bar at the bottom of the page to go to your personal information page, for example, the person's name is "Bac". At the personal information page, the *Mine* features are listed and they will be described in this section.

4.4.1 Change Personal Information

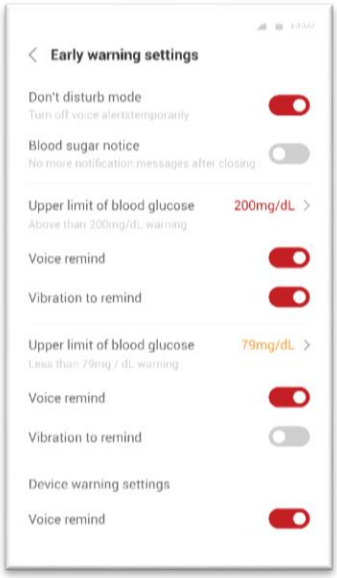
Tap【Mine】, and tap your portrait to go to the "Mine" page, where you can change your personal information. Tap 【Save】to save the updated personal information.

4.4.2 Instructions for Use

Tap 【Mine】, then tap【Instructions for use】to go to the "Instructions for use" page, where you can find the **Quick Start** and **Tutorial Videos** , which may help you in your subsequent use of the device.

4.4.3 Set Alert

Tap【Mine】, then tap【Alert】to go to the "Alert" page, as shown in the figures below. The upper limit and the lower limit of glucose level alert can be preset. After the limits are set, the lines of the upper and lower alert limits on the glucose graph will be changed accordingly. Before using the device for monitoring, please double check that your glucose level limits are appropriate for you.



The lower alert limit shall be set no less than 55 mg/dL, and the upper alert limit shall be no greater than 450 mg/dL.

Generally, the recommended settings are as below:

- Don't disturb mode: off
- Glucose alert: on
- Voice Alert: on
- Notification Alert: on

Alerts when the real-time glucose level is higher than the set upper limit:

- When the glucose level has been above the upper alert limit, and the glucose trend is steady, the alert will be generated with 2 times of vibration and 2 times of alert sounds at every 3 minutes;
- When the glucose level has been above the upper alert limit, and the glucose trend rises slowly, the alert will be generated with 3 times of vibration and 3 times of alert sounds at every 3 minutes;
- When the glucose level has been above the upper alert limit, and the glucose trend rises quickly, the alert will be generated with 6 times of vibration and 6 times of alert sounds at every 3 minutes;

Alarms when the real time glucose level is lower than the set lower limit:

- When the glucose level has been lower than the lower alert limit, and the glucose trend is steady, the alert will be generated with 2 times of vibration and 2 times of alert sounds at every 3 minutes;

- When the glucose level has been lower than the lower alert limit, and the glucose trend falls slowly, the alert will be generated with 3 times of vibration and 3 times of alert sounds at every 3 minutes;
- When the glucose level has been lower than the lower alert limit, and the glucose trend falls quickly, the alert will be generated with 6 times of vibration and 6 times of alert sounds at every 3 minutes.

4.4.4 Customer Service

Tap 【Customer Service】to go to the page from where you can dial the call to Sinocare Customer Service .

4.4.5 Change Your Password

Tap【Mine】, then tap【Change the password】to go to “Change the password” page. You can follow the instructions on the page to change your password. After successfully changed your password, you need to re-login.

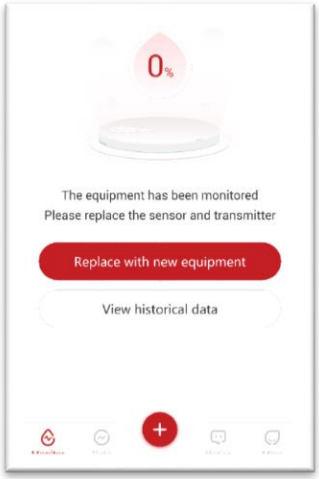
4.4.6 Device Information

Tap【Mine】, then tap 【Device Information】to review the details of the connected device information.

4.5 End Monitoring

4.5.1 End Monitoring Automatically

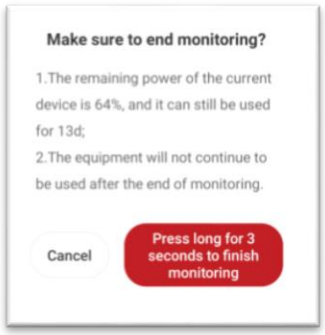
The device will stop monitoring automatically after 15 days of service, and the APP will go to the "Stop Monitoring" page, as shown in the figure below. Tap 【Replace the new requirement】to go to the 2D barcode Scanning page, refer to Section 3.2.2 for details, and please also refer to Chapter 5 for replacing the sensor and the transmitter.



Tap【View historical data】to go to the Historical Data page, please refer to Section 4.8 for details.

4.5.2 End Monitoring Manually

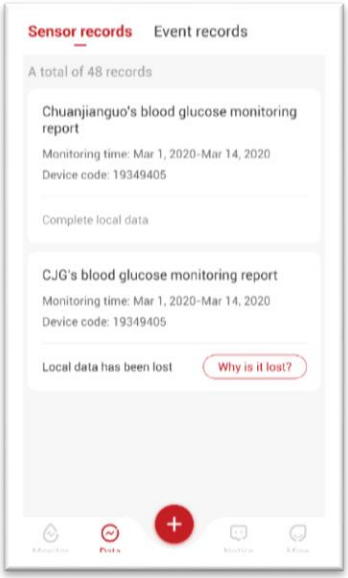
When the device is connected normally, tap the status bar of the device, and a dialog box will pop up, as shown in the figure below.



Press the “Press and hold for 3s to end monitoring” button for 3 seconds to stop the monitoring. After stopping successfully, the APP will go to the "Stop Monitoring" page.

4.6 Check Historical Data

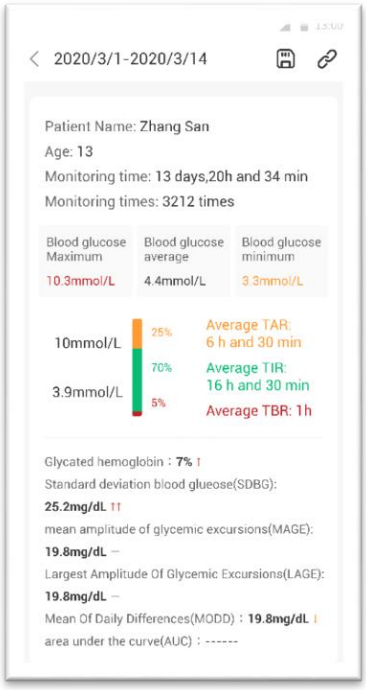
Tap【Data】in the navigation bar at the bottom of the page to go to records page, then tap 【Sensor Records】to check the records of all connected sensors under this account, as shown in the figure below.



4.7 Monitoring Report

Tap【Data】in the navigation bar at the bottom of the page to go to records page, then tap 【Sensor Records】, you can find all sensor records;

You can select any record you would like to review by tapping it to go to the Monitoring Report pages below for the detailed report.

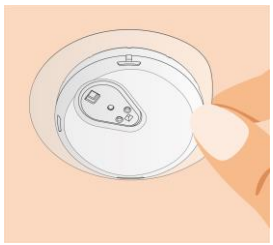


Chapter 5 Remove and Replace i3 CGM

5.1 Remove i3 CGM

If you want to remove the sensor at the end of 15 days of CGM monitoring, or if you want to remove the sensor before the end of 15-days monitoring for any reasons, such as your sensor loosed or sensor tip out of your skin, with glucose reading still displayed on the APP, you can follow the steps as described in Section 4.6 to end App monitoring.

After end APP monitoring, pull up the edge of the tape of your sensor, slowly remove the tape along with the sensor and the transmitter from the skin, as shown in the picture below.



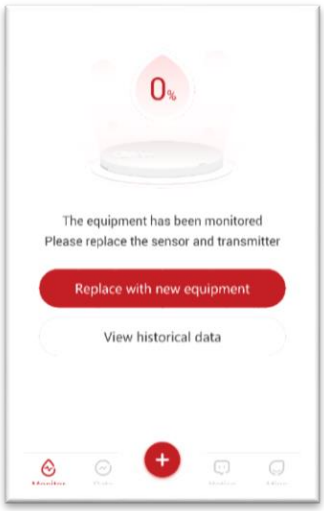
Note:

If the sensor tip does not come out with the tape, do NOT try to pull the sensor tip out of your skin by yourself, because it may cause infection. Though this kind of event is rare, if it does happen, please consult a health care professional or contact Sinocare Customer Service.

The removed sensor, the transmitter and the tape shall be properly disposed of in accordance with the local waste disposal regulations. If you have any questions, please contact Sinocare Customer Service.

5.2 Replace i3 CGM

A new i3 CGM should be used, and there is no need to sign up a new APP account. Or you can tap 【Replace with new equipment】on the end monitoring page of the APP and refer to the User Guide to start a new CGM.



Chapter 6 How to Use CGM Effectively

■ Please read carefully the User Manual and fully understand how to use i3 CGM as well as the meanings of the glucose readings, graphs, signs and alerts before using CGM. Make sure to use the device properly according to the User Manual.

■ Before using CGM, work with your health care professional to make a plan for managing your diabetes that includes when and how to use the CGM information for making treatment decisions. For example, what is the appropriate CGM settings for you, how to interpret the glucose readings and glucose trend arrows, what to do under different situations.

■ If your glucose readings are not correct or do not match how you feel, or if you believe the glucose reading is incorrect, please use the finger blood meter to test your glucose level, or consult your health care professional or contact Sinocare Customer Service.

■ It may take your days, weeks, or even months to get familiar with the use of CGM. To be able to interpret glucose readings correctly, and to effectively use CGM to manage your glucose. Please patiently observe how your CGM glucose readings change along with your diet, medication, exercise, disease or stress levels, etc.. You will understand how the CGM works for you. The information you collected may help you understand why your glucose reading is sometimes too high or too low, and how to prevent that happen in the future.

■ Consult your health care professional to learn how to use insulin correctly according to the

CGM readings to avoid the improper using time and the amount of insulin.

Chapter 7 Technical Information

7.1 FCC Declaration of Conformity

This transmitter complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this transmitter may not cause harmful interference, and

(2) this transmitter must accept any interference received, including interference that may cause undesired operation

FCC ID: 2AHX5001

7.2 EMC and EMI Declaration

This transmitter complies with the requirements for electromagnetic compatibility and immunity described in IEC 60601-1-2-2014, as shown in the Table below.

Guidance and Manufacturer Declaration	
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the CGM should assure that it is used in such an environment.	
Emissions Test	**Compliance**
RF emissions CISPR11	CISPR11 Group 1, Class B

Guidance and Manufacturer Declaration			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the CGM should assure that it is used in such an environment.			
Immunity Test	Home Use	Hospital Use	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV；±8 kV contact ±2 kV, ±4 kV , ±8 kV , ±15 kV air	±2 kV, ±4 kV；± 8 kV contact ±2 kV, ±4 kV , ±8 kV , ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Guidance and Manufacturer Declaration			
Power frequency magnetic field IEC 61000-4-8	30A/m, 50Hz and 60Hz	30A/m, 50Hz and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location environment.
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7GHz	3 V/m, 80 MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 80MHz - 800MHz 800MHz - 2.7GHz $d = 2.3\sqrt{P}$ Where: P - the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer); d - the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note a: At 80 MHz and 800 MHz, the higher frequency range applies. Note b: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Electromagnetic interference can still occur in the home health care environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in i3 readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

• If your symptoms don't match your i3 readings, use your BG meter when making treatment decisions. If your i3 readings don't consistently match your symptoms or BG meter values, then talk to your healthcare professional about how you should be using the Sinocare i3 to help manage your diabetes. Your healthcare professional can help you decide how you should best use this device.

• If display device misses 20 minutes of sensor glucose data (4 readings), the Signal Loss error displays. To resolve, see Chapter Troubleshooting.

• If display device shows the loading screen unexpectedly and does not display the trend screen within 3 minutes, contact customer Support.

7.3 Specifications

Model	Transmitter Package (iCGM-T3) Sensor Package（iCGM-S3）
Operational Conditions	Temperature：10℃ to 42℃（50 °F to 107.6 °F） Relative humidity: 10 % to 90% Pressure：700~1060 hPa Caution: When operating the transmitter on a tester in the air temperatures greater than 41℃（106 °F）the temperature of the transmitter may exceed 43℃（109 °F）
Storage and Transport Conditions	Temperature：2℃ ~ 30℃（35.6 °F to 86 °F） Relative humidity：10 % to 90% Pressure：700~1060 hPa
Battery	Built-in battery, DC 3.0V.
Battery Life	15 days
Waterproof Rating	IP28: Can withstand immersion into 2.5 meters of water for up to 2 hours. Protected against insertion of objects > 12.5mm diameter .
Classification	Type BF equipment, Continuous operation
The applied parts	Sensor Transmitter Tap
Data Storage	Transmitter can automatically store the previous 15 days' data
Transmission frequency	2.4 GHz
Wireless Communication Distance	6 m(in open space without obstacles)

Description of Communication Distance

The effective range of 6 meters between the i3 transmitter and the paired smart device can ensure

the quality of service of the wireless communication of the system using Bluetooth Low Energy. If the connection between the transmitter and the smart device is lost, after reconnecting, the data during the lost connection will be sent from the transmitter to the APP on the smart device.

Safety measures

The system only recognizes the industry standard BLE protocol to transmit data between the transmitter and the smart device. It will not accept radio frequency (RF) communication using any other protocol, including the Bluetooth classic communication protocol.

If it is not disabled, the APP will communicate with Sinocare server regularly. The communication between the APP and the Sinocare server is protected by a variety of mechanisms, which are designed to prevent data corruption

7.4 Network Security and Software Update

7.4.1 Software Version and Update

The current release version of the software is V01.

If a new version of the software is released, you will be reminded to update the APP on the home page of the APP after the APP is restarted

7.4.2 Running Environment

Operating environment: Android 5.0 and above、iOS 10.0 and above.

Network condition: It is recommended to use the APP under good network conditions.

7.4.3 User Access

Users must sign up with their email address and password to login before using the APP.

Chapter 8 Test Summary

It's not performed yet. After the completion of the clinical trial, it will be summarized according to the results of the trial.

Chapter 9 Troubleshooting

It's not performed yet.

Chapter 10 After Sale Services

Please use i3 CGM completely in accordance with this user manual. If there are any problems, please check the relevant chapters of the manual immediately. For problems that cannot be solved,

please contact Sinocare Customer Service, and Sinocare Customer Service will provide consultation and corresponding services.

Sinocare Customer Service: 400-887-003

Chapter 11 Labeling Information

Symbols used in i3 CGM labeling and their definitions are defined in the table below:

Symbol	Definition
	Manufacturer
	Date of manufacture
	Use-by date
	EC representative
	CE mark
	Serial number
	Lot number
	Catalog number
	Can withstand immersion into 2.5 meters of water for up to 2 hours. Protected against insertion of objects > 12.5mm diameter .
	Type BF applied part
	Sterile by Radiation
	Sterilization barrier system/aseptic packaging
	Temperature limitation

Symbol	Definition
	Humidity limitation
	MRI unsafe
	Cannot be reused
	Cannot be used if the package is broken
	This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations .
	Caution
	Refer to User Manual/Booklet
	Keep Away from Heat
	Keep dry
	Nonionizing radiation
FCC ID	A unique identifier for a device registered with the FCC
	Bluetooth