Sinocare

iCan™ i3

CGM User Guide



TABLE OF CONTENTS

TABLE OF CONTENTS I
LEGAL DISCLAIMER 1
IMPORTANT SAFETY INFORMATION 2
Getting started with iCan Continuous Glucose Monitoring System (CGM) 3
Resources 4
Section 1: System Overview 6
1.1 System Description 7
1.2 Intended Purpose 10
1.3 User Safety 10
Section 2: Start Your Sensor 19
2.1 Prepare the Sensor 20
2.2 Choose a Site 29
2.3 Pair Your Sensor with the Transmitter 30
2.4 Apply Your Sensor 33
2.5 Sensor Warmup 38
Section 3: Understand Your iCan i3 CGM Results 39
3.1 Home Screen Overview 40
3.2 Glucose Information 40
3.3 Navigation and Status Bar 46
3.4 Events 49

3.5 Alerts....51
3.6 Access....57
Section 4: Treatment Decisions....60
4.1 Talk with your Healthcare Professionals (HCPs)....61
4.2 When to Use Your Blood Glucose Meter....61
4.3 Using Your CGM to Help for Your Treatment Decisions....61
Section 5: End a Session....63
5.1 End Your Sensor Session....64
5.2 Remove Sensor....66
5.3 Start New Sensor Session....66
Attachment A: Troubleshooting....67
Attachment B: Security and Air Travel....71
Attachment C: Take Care of Your CGM....72
Attachment D: Technical Information....76
Attachment E: Label Symbols....83
Attachment F: Alerts Vibrations and Sounds....86
Glossary....96

LEGAL DISCLAIMER

©2022 Sinocare Inc. Sinocare iCan is a trademark of Sinocare Inc.

US and International Patents Pending. All rights reserved.

All trademarks and copyrights are the property of their respective owners.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sinocare Inc. is under license. Other trademarks and trade names are those of their respective owners.

Apple, the Apple logo, iPhone and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. APP Store is a service mark of Apple Inc.

Android is a trademark of Google LLC. Google Play and the Google Play logo are trademarks of Google LLC.

IMPORTANT SAFETY INFORMATION

Before you use the iCan i3 Continuous Glucose Monitoring (CGM) System, read the instructions included in the Instruction for Use. The Instruction for Use includes important safety information, and instructions for use. Discuss with your healthcare professional about how you should use the information from your iCan i3 CGM to help manage your diabetes.

Failure to use the iCan i3 CGM System and its components according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and result from the iCan i3 CGM do not match your symptoms or expectations, use a fingerstick blood glucose (BG) value from your blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

Any serious incident that has occurred in relation to the iCan i3 CGM should be reported to the Sinocare and the competent authority of the Member State in which you are established

Getting started with iCan Continuous Glucose Monitoring System (CGM)

Continuous Glucose Monitoring System (hereafter referred as CGM) gives you a more complete picture of your glucose control than blood glucose (BG) monitoring alone. Using a sensor allows you to receive up to 480 sensor glucose (SG) readings every 24 hours, filling the gaps between your BG checks. CGM alerts notify you of high and low glucose values.

Graphs and trend arrows show the speed and direction your glucose levels are moving.

This Instructions for Use (also called User Guide) is provided to help you understand the setup and operation of your iCan Continuous Glucose Monitoring (CGM) System. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the index at the end of the user guide. There is also a glossary of terms at the end of the user guide.

The following table describes certain terms, conventions, and concepts used in this user guide.

Convention	Description
Note	Provides additional helpful information.
CAUTION	Notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	Notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
Bold Text	To indicate screen items and buttons. For example, "Select **Next** to continue"

Resources

Tutorial:

Our tutorial walks you through your first sensor session, including picking a display device, inserting the sensor, and using alerts.

The tutorial is available at: iCan-cgm.com

In-App Videos:

There is an in-App Videos can help you learn:

- **Overview:** See how your CGM shows where your sensor glucose is now, where it is going, and where it has been
- **Sensor Insertion:** Walks through inserting your sensor

You can watch these videos when you set up your app or anytime at **Settings > Help > Videos**.

Guides:

- **Quick Reference Guide:** guides you through setting up your display devices, inserting your sensor, and starting your first sensor session. You can find it with your iCan box.
- **Instruction of Use (User Guide):** This User Guide is your encyclopedia. It gives you the most extensive overview of the iCan System, detailing features, important safety information, and so much more.

You can download both guides or ask for a printed version:

Download a PDF at iCan-cgm.com

Ask for a free copy by email: support@icancgm.com

Sinocare provides Customer Care email for assistance. If you experience problems, report the issue to support@icancgm.com. When you send the request, please make sure the serial number of your device is included in your email. The serial number is listed on your sensor kit package.

Contact Information	
Customer Care Email	support@icancgm.com
Website	iCan-cgm.com

Section 1: System Overview

- System Description
- Intended Purpose
- User Safety

1.1 System Description

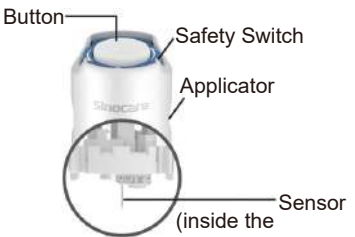
Thank you for choosing the iCan i3 Continuous Glucose Monitoring System (hereafter referred as CGM). The iCan i3 CGM System consists of three main components: a Sensor Pack, a Bluetooth Low Energy (BLE) Transmitter Pack, and a mobile application (APP).

The iCan i3 CGM provides real-time glucose levels and allows you to continuously view your sensor glucose values on your selected mobile device. The system tracks your glucose every 3 minutes by measuring the amount of glucose in the interstitial fluid. A sensor, inserted in your skin, sends glucose results to the transmitter, and the transmitter sends glucose results to the iCan Continuous Glucose Monitor System APP (CGM APP). The APP then displays your glucose levels and long-term glucose trends. The APP also provides alerts if your glucose is in or projected to be in an unsafe zone.

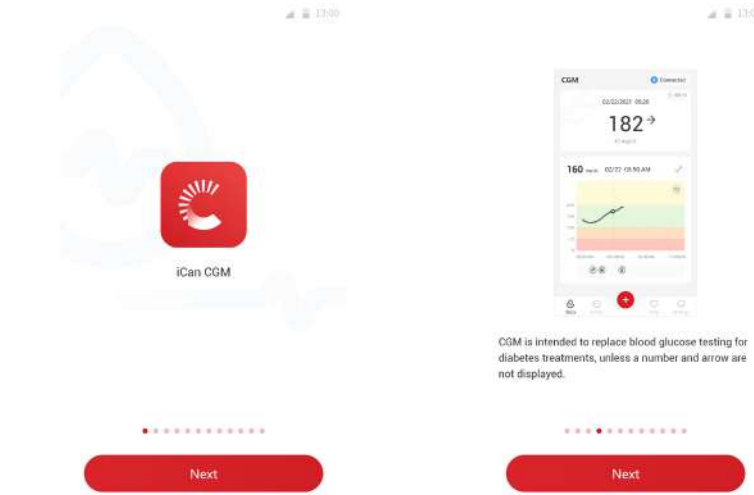
The iCan i3 CGM also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the system results should be based on the glucose trends and several sequential results over time.

Note: Please read all the instructions provided in this Instruction for Use before using the system.

1.1.1 Device Components

What you see	What it's called	What it does
	Sens or Pack	This is a sterile package where the Sensor is stored. The Sensor Pack is designed for single use.
	Sensor-Applicator	The Sensor-Applicator helps you insert the Sensor under your skin. It contains a needle which is used to puncture the skin to introduce the flexible sensor tip into skin but will be retracted into the canister once the sensor is placed. So there is no needle left. The Sensor can be worn for up to 15 days. See **Chapter 2** for details how to use your Sensor.
	Transmitter Pack	The Transmitter snaps into the Sensor and sends real- time glucose readings wirelessly to your compatible display device via Bluetooth. When you use it, you don't need take the Transmitter out of the Tray. See Chapter 2 for details how to use your Transmitter.

1.1.2 The iCan CGM APP



The iCan CGM APP serves as the display for the iCan i3 CGM and supports Android and iOS devices (mobile devices). The APP is available on Google Play (Android) and the APP Store (iOS). To see a list of compatible mobile devices, visit iCan-cgm.com

WARNING: Missing alerts from the iCan CGM APP may result in undetected low and high glucose levels. Follow the instructions and safety warnings in this Instruction for Use to make sure you receive alerts as intended.

1.2 Intended Purpose

The 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 CGM 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 CGM can be used in conjunction with smart devices with corresponding application where the user manually controls actions for therapy decisions.

1.3 User Safety

This section includes important safety information such as indications, contraindications, safety warnings, potential adverse reactions, and how to protect the system from radiation exposure damage.

1.3.1 Contraindications

- Do not use the iCan i3 CGM if you are pregnant, on dialysis, implanted with a pacemakers or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. iCan i3 CGM results may be inaccurate in these populations.

- No MRI/CT/Diathermy

  Do not wear your iCan i3 CGM (sensor, transmitter, receiver, or mobile device) for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

  The iCan i3 CGM has not been tested in those situations. The magnetic fields and heat could damage the components of the iCan i3 CGM, which may cause it to display inaccurate sensor glucose results or may prevent alerts. Without iCan i3 CGM results or alert notifications, you might miss a severe low or high glucose event.

  To get the most out of your session, we advise that you try to schedule your procedure near the end of your sensor session to avoid needing an extra sensor. Please consult your doctor for recommendations with any other medical procedures.

  Bring your Blood Glucose Meter with you when you go to your procedure.



MR UNSAFE

- Do not use iCan i3 CGM, if you are suffering from coagulation disorders or taking anticoagulant drugs.

1.3.2 Safety Warnings

1.3.2.1 General Warnings

WARNINGS:

- Do not Ignore Low/High Symptoms

  Do not ignore symptoms that may be due to low or high blood glucose. Keep your blood glucose meter close to you. If you have symptoms that do not match the sensor glucose results or suspect that your results may be inaccurate, check the result by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose results, consult your healthcare professional.

- No Treatment Decision if….

  If your iCan i3 CGM does not show a number or arrow, or your results do not match your symptoms, use your Blood Glucose Meter to make diabetes treatment decisions.

- No modification is allowed.

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

- No Use if….

WARNING: Do not use the iCan i3 CGM if you are pregnant, on dialysis, implanted with a pacemakers or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. iCan i3 CGM results may be inaccurate in these populations.

1.3.2.2 APP and Mobile Device

- When you start a new sensor, you will not get any CGM results or alerts during the 2- hour sensor warmup period. Use a blood glucose meter to make diabetes treatment decisions.
- Make sure Bluetooth is on, even if your mobile device is in Airplane mode. If Bluetooth is off, you will not get sensor glucose information or alerts.
- Do not use the iCan CGM APP if your mobile device screen or speakers are damaged. If your mobile device is damaged or lost, you may not get sensor glucose alerts and sensor glucose information may not be shown correctly.
- Alerts for the iCan CGM APP will sound through your headphones when headphones are connected. If you leave your headphones connected when not in use, you may not hear sensor glucose alerts.
- If your mobile device restarts, the iCan CGM APP may not restart automatically. If you do not open the APP again, you may not get sensor glucose alerts. Always make sure to open the APP after your mobile device restarts.

1.3.2.3 Transmitter

- Do not use the device if you see any cracking, flaking, or damage to the transmitter. A damaged transmitter could cause injuries from electrical shocks and may make the iCan i3 CGM not work correctly.
- Do not allow children or pets to put small parts in their mouth. This product poses a choking hazard for young children and pets.
- Do not use the transmitter adjacent to other electrical equipment that may cause interference with the normal system operation. For more information on other electrical equipment that may compromise normal system operation, see Attachment D for details.

- Do NOT operate your transmitter in the presence of flammable anesthetics or explosive gases.
- Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in injury.

1.3.2.4 Sensor

- Do not ignore broken or detached sensor tip. A sensor tip could remain under your skin. If this happens, please contact our Customer Care Email or your Healthcare Professional. If a sensor tip breaks off under your skin and you cannot see it, do not try to remove it. Seek for professional medical help or contact our Customer Care Email.
- Store your iCan i3 CGM between 2°C and 30°C. Do not store Sensors Pack in the freezer.
- Do not use a sensor past its expiration date because it may give incorrect results. The expiration date is in YYYY-MM-DD (Year-Month-Day) format on the sensor package label beside the hourglass symbol.
- Do not use sensor if its sterile package has been damaged or opened, because it might cause an infection.
- Do not open the sterile package until you are ready to insert the sensor because an exposed sensor can become contaminated.
- Use of barrier methods or patches may affect the performance of the device. If you are having skin reactions to this sensor, contact your healthcare professional to discuss if you should continue to use this device.

1.3.2.5 Bleeding

- In order to insert the sensor to reach the interstitial fluid, it must penetrate the dermis layer of the skin using a needle, which has blood vessels scattered throughout.
- Penetration of these blood vessels may cause bleeding if the needle pierces them. If the sensor is inserted too deep into the body, it may also bleed. Ensure you are not using excess pressure when inserting with the applicator.
- If bleeding occurs, do the following:
  - Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes.
  - If bleeding stops, connect the APP to the sensor.
  - If bleeding does not stop, remove the sensor and clean the area using sterile gauze. Apply a new sensor on a different location at least 7 cm (3 inches) from the bleeding site.

1.3.3 Precautions

1.3.3.1 General Precautions

- Avoid exposing your iCan i3 CGM to insect repellent and sunscreen. Contact with these skin care products may cause damage to your CGM.
- Do not wear the iCan i3 CGM in a hot tub.
- If you notice significant skin irritation around or under your sensor, remove the sensor and stop using the CGM. Contact your healthcare professional before continuing to use the CGM.
- The CGM system is designed for single use. Reuse may cause no glucose results and infection.

- Monitoring results of the product can only be used as a reference for the auxiliary diagnosis of diabetes, not as the basis for clinical diagnosis.
- If there is a burning sensation, or any discomfort, please remove the CGMS immediately

1.3.3.2 Testing Your Blood Glucose

Glucose levels in the interstitial fluid can be different to blood glucose levels and may mean that sensor glucose results are different to blood glucose. You may notice this difference during times when your blood glucose is changing quickly; for example, after eating, taking insulin, or exercising. If you suspect that your result may be inaccurate, check the result by conducting a fingerstick test using a blood glucose meter.

1.3.3.3 Get Ready Before Start

- Clean and dry your hands and your insertion site before inserting your sensor. Wash your hands with soap and water, not gel cleaners, and then dry them before opening the Sensor Pack. If your hands are dirty when you insert the sensor, you may get germs on the insertion site and get an infection.
- Clean your insertion site with alcohol wipes to prevent infections. Do not insert the sensor until your skin is dry. If your insertion site is not clean and completely dry, you run the risk of infection or the transmitter not sticking well.
- Make sure you do not have insect repellent, sunscreen, perfume, or lotion on your skin.
- Things to check before insertion:
  - Keep the safety guard locked until you put the armed applicator against your skin. If you remove the safety guard to unlock first,

you may hurt yourself by accidentally pushing the button that inserts the sensor before you mean to.

- Change your insertion site with each sensor. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.

- The sensor placement site must:
  - At least 7 cm (3 inches) from insulin pump infusion set or injection site;
  - Away from waistband, scarring, tattoos, irritation, and bones;
  - Unlikely to be bumped, pushed, or laid on while sleeping

1.3.3.4 Potential Risks Related to Sensor Use

- Going Through Security Check Point
  - When wearing your iCan i3 CGM, ask the Transportation Security Administration (TSA) for a full-body pat-down with a visual inspection of your sensor and transmitter. Don't put your iCan i3 CGM System components through x-ray machines. The effect of AIT body scanner and x-ray machine have not been evaluated or know the damage they may cause the iCan i3 CGM.
- Bathing, Showering and Swimming
  - The sensor can be worn while bathing and showering but not hot tub, exposure to heat for longtime may damage the sensor or cause inaccurate results. You can also swim while wearing the sensor in place up to a depth of 2.5 meters for up to 2 hours (IP28). Exceeding the depth or time may damage the sensor or cause inaccurate results.

- Mild to severe related to sensor-wear reactions

  e.g. allergic reaction, moderate to severe itching, rash, erythema, edema, induration, bleeding, insertion-site symptoms, bruising, pain, minor infection at the insertion site, discomfort during insertion.
- Hyperglycemia or hypoglycaemia

  Failure to use the iCan i3 CGM according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence.
- Underutilized or incorrectly use of CGM

  The CGM system provides significant amount of data and information for users to use. Please read the instructions thoroughly and work with your HCP to help you fully utilize the CGM system capabilities and personalize your specific diabetes management and treatment plan.

Section 2: Start Your Sensor

- Prepare the Sensor
- Choose a Site
- Pair Your Sensor with the Transmitter
- Apply Your Sensor
- Sensor Warmup

2.1 Prepare the Sensor

2.1.1 Before starting, make sure you have everything you need.

iCan i3 CGM System:

- Sensor Pack
  - Check expiration date on Sensor Pack. Do not use if expired.
  - Do not open the sensor sterile package until you are ready to insert the sensor
- Transmitter Pack
  - Check the first 8 digits SN codes on the Sensor Pack and the Transmitter Pack are the same
- Quick Start Guide
- Alcohol wipes
- Your Blood Glucose Meter

Familiarization of iCan i3 CGM System:

Whether you're new to CGM or experienced, you must review the Quick Start Guide and complete the In-APP tutorials before using.

User Requirement: Adult diabetes user who can read, understand and follow the iCan i3 CGM Instruction of Use and Quick Start Guide could use the device safely.

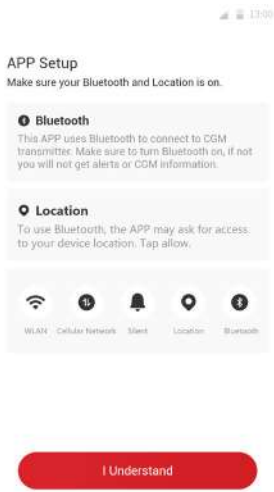
2.1.2 APP Installation and Set up

Step 1: APP Setup

Tap CGM APP to open the APP.

Step 2: Enable notification and location access

Tap **“Allow”** to enable Bluetooth, Location access, and allow notifications on your mobile device, so you will not miss the alerts or being denied of Bluetooth service.



Recommended Mobile Device Settings

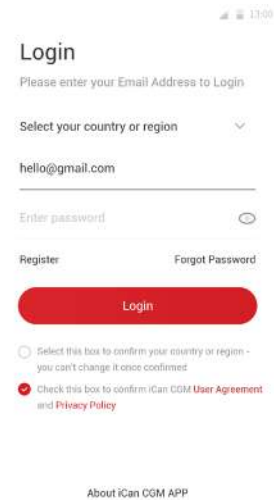
See your mobile device instructions to learn how to change its settings. Use the following with your CGM system:

- Bluetooth on: Your transmitter and APP communicate via Bluetooth. If it is not on, you will not get alerts and CGM results.
- Notifications on:
  - Enable CGM APP notifications so that you can get alerts.
  - Make sure you allow CGM APP notifications to show on your locked screen.
- Battery charged: The APP must always be running in the background and may drain your battery. Keep the battery charged. If the CGM APP is turned off in the background, you will not get alerts.
- Device and APP on: If you restart your mobile device, reopen the CGM APP.
- Turn on sound and alerts function, and ensure the device is not in "Do not Disturb" mode. If the device is muted, you will not hear the sound of any notifications, including urgent low alert.
- Keep the volume of the smartphone loud enough: Make sure you can hear the sounds of alerts.
- Distance between transmitter and smartphone must be under 6 meters to ensure good connection between the smartphone & transmitters at all times.
- Update manually: your device operating system can change settings or shutdown the APP. Always update manually and verify correct device settings afterward.
- Compatibility: For a list of mobile devices and operating systems that work with the CGM APP, check iCan-cgm.com.

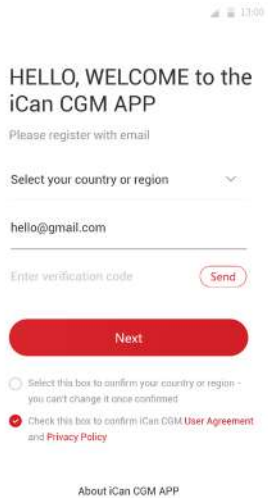
- Time: If you are crossing various time zones, DO NOT change your smart device time manually, wait until you have arrived at your final destination to let your smart phone switch the time automatically. Note that CGM APP displays all the glucose readings of the on-going session with their testing time in the current time zone.

Step 3: Login

Enter existing Username and Password.

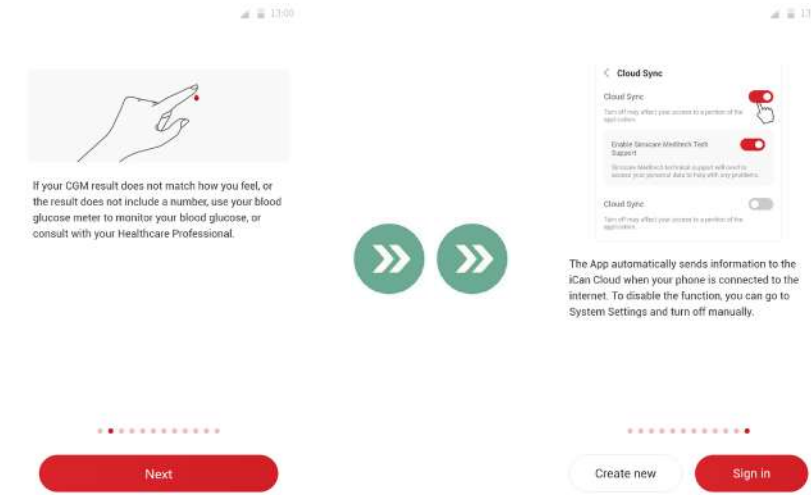


Or, if you need to create a new iCan account, follow the onscreen instructions below.



Step 4: Review Tutorials

Next, the App will prompt you to review safety instruction including a tutorial video that guides you on using your iCan system.



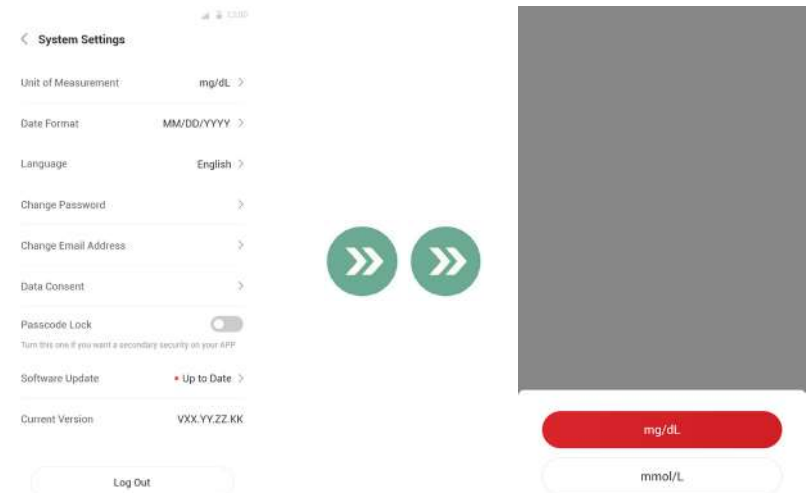
Note: This in-APP overview of iCan system does not replace this Instruction for Use. Read all of the information in this Instruction for Use before using CGM APP.

2.1.3 System Settings

The “**System Settings**” option under “**Settings**” button is where you can change your account profile, such as password and email.

Changing the glucose unit of measurement used throughout the APP (mg/dL or mmol/L)

Tap the “**System Settings**” button, select “**Unit of Measurement**”. If you decide to use a different unit of measurement from the default setting, you will see a confirmation message notifying that the unit of measurement has been changed.



Changing your email

Your email address is used to log in to your account, as well as for important communications about your CGM.

In the APP, tap the "**System Settings**" button, select "**Change Email Address**". Enter the new email address you want to use, and press "**Next**".

You will receive a confirmation code through your new Email address, type it in and press "**Confirm**".

Changing your password

A good password is important to keep your data safe. We recommend you to change your password occasionally, especially when you believe your password may have been compromised.

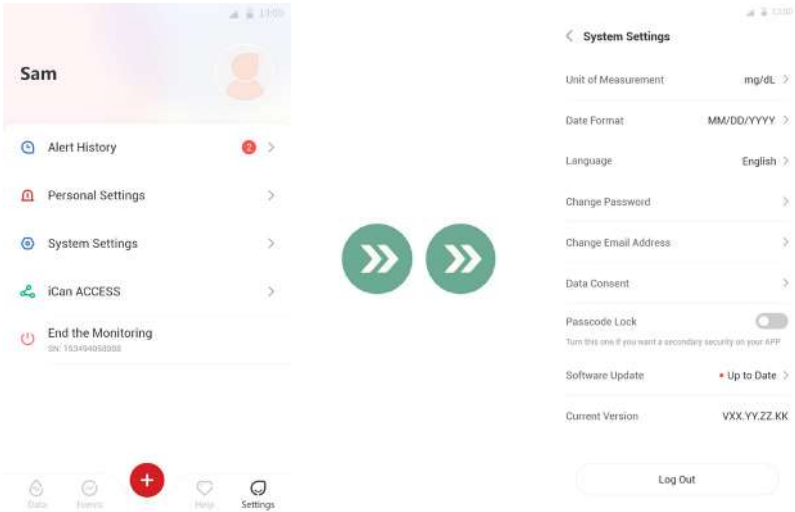
In the APP, tap the "**System Settings**" button, select "**Change Password**".

Enter the email address you use to sign in and tap "**Send**", a verification code will be sent to you.

Tap "**NEXT**" and enter your new password.

Data Consents

Please Review and revise data consents. In the APP, tap the “**System Settings**” button, select “**Data Consents**”



2.2 Choose a Site

Choosing a comfortable, effective place for your sensor is important. Discuss ideal sensor insertion sites with your Healthcare Professionals (HCP).



WARNING: Do not choose other sites. As the other sites have not been clinically evaluated, your sensor glucose results could be inaccurate.

TIPS:

- Place the sensor at least 7 cm (3 inches) from your insulin pump infusion set or injection site.
- Make sure the insertion area is dry, clean and free of lotions, perfumes, and medications. If needed, shave the area so adhesive tape sticks securely.
- Avoid areas near waistbands or with scars, tattoos, irritation, and bones. Contact your HCP if sensor adhesive irritates your skin.
- Do not use the same site for 2 sensors in a row.

- Do not use sites that have muscles or areas constrained by clothing or accessories, areas with rough skin or scar tissue, sites subjected to rigorous movement during exercise, or in sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

Cleaning:

- Wash hands thoroughly with soap and water. Choose a site to apply the sensor. Clean the insertion site with alcohol. Let the area air dry.

2.3 Pair Your Sensor with the Transmitter

The iCan i3 CGM transmitters communicate with the APP via Bluetooth, so it must be connected with the APP before using the system. This process is also called “Pairing”.

Step 1: APP Setup

Follow Sec.2.1.2 to setup your APP, make sure your phone Bluetooth is on. Location access must be granted in order to sync via Bluetooth.

Step 2: Check the 8-digit SN Code

The Sensor Pack and the Transmitter Pack are packaged as a set and share the first 8 digits of Serial Number (SN) codes. Check the first 8 digits of SN codes match before Pairing.



Step 3: Scan the SN Code



Following Step 4 from Sec 2.1.2, scan the SN 2D barcode located on the Sensor Pack label or enter the full SN Code on Sensor Pack by typing manually. The SN Code is unique to the sensor and the Transmitter, make sure you enter the correct code. If you enter the wrong code or code from another Sensor Pack, you will not be able to use the iCan i3 CGM or your glucose result could be incorrect.

Step 4: Pairing

After clicking the "**Next**", the APP will instruct you how to attach Sensor to the Transmitter. You can follow the in-APP instructions below to apply your CGM. The Paring will start automatically.







2.4 Apply Your Sensor

The sensor probe is inside the Sensor-Applicator. Before applying the sensor, get familiar with the Sensor-Applicator.



Button
Insert sensor under your skin

Sensor
Sensor probe inserts through this hole

Transmitter
Send your glucose information from the sensor to the APP

Adhesive Tape
Keeps the sensor and transmitter on skin

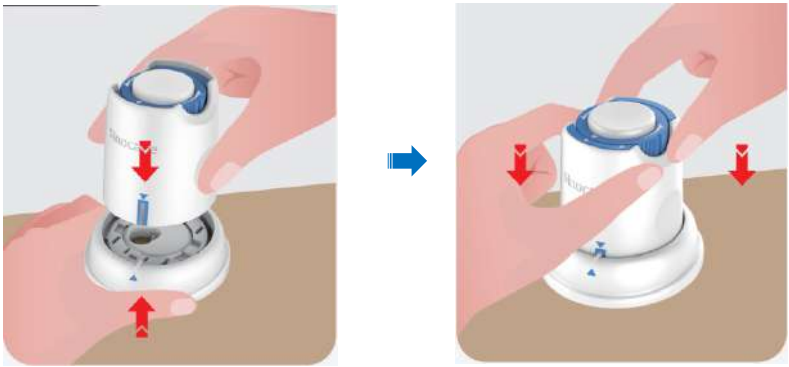
Step 1: Open the Sensor Pack

Take the Sensor Pack you used from **Sec 2.3.** Do not use if the package is broken, damaged or opened. Do not open the package until you are ready to apply the Sensor.

WARNING: The Sensor-Applicator contains a needle. Do NOT touch inside the Sensor-Applicator or put it back into the Sensor Pack.

Step 2: Apply the Sensor

- Line up the blue arrow mark on the Sensor-Applicator with the matching blue arrow mark on the Transmitter Tray. On a hard surface, press down firmly until it comes to a stop and hear a click.



- Gently turn the safety switch from the "Locked icon" to the "Unlocked icon" until you hear a click.



CAUTION: Do not press the white button in the middle once the Safety Switch is fully released to prevent unintended results or injury

- Lift the Sensor-Applicator out of the Transmitter Tray



- Now it's ready to apply the sensor.



Step 3: Apply the sensor

- Place the Sensor Applicator over the prepared site and push down firmly.



- Press down the button in the middle to apply the CGM Sensor. You will hear a click sound, that means the insertion is completed.

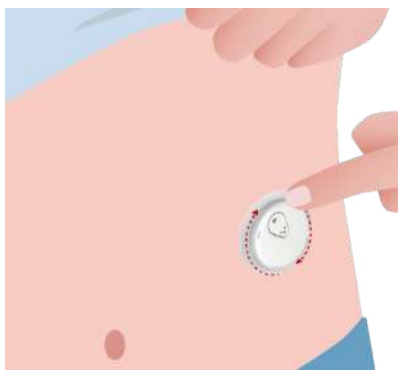


- Gently pull the Applicator away from your body.



CAUTION: Discard the used Applicator according to local regulations.

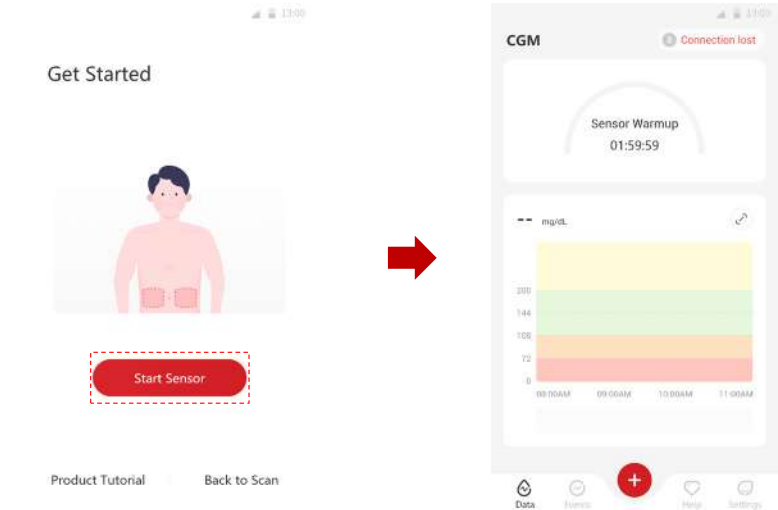
- Smooth down the sensor adhesive tape with a finger to ensure the sensor stays on the body for the entire duration of wear.



CAUTION: Once inserted, the sensor is waterproof up to 2.5 meters, but the smart phone may not. If you're in or near water, the display device may need to be kept closer (less than 6 meters) to get sensor readings. If the sensor is under water, you may not be able to get sensor readings until you emerge from the water.

2.5 Sensor Warmup

After inserting your sensor, the transmitter will automatically pair with your iCan CGM APP. You need to press "**Start Sensor**" to initiate the 2-hour sensor warmup period.



During the warmup period, you will not receive alerts or CGM results. Your first results begin after the 2-hour sensor warmup has passed. During sensor warmup, use your blood glucose meter if need.

CAUTION: Keep your CGM Sensor and mobile device within 6 meters with no obstructions (i.e. walls or metal) between them. Otherwise, they might not be able to communicate. If water is between your Sensor and the mobile device – for example, if you are showering or swimming – keep them closer to each other. The range is reduced because Bluetooth does not work as well through water.

Section 3: Understand Your iCan i3 CGM Results

- **Home Screen Overview**
- **Glucose Information**
- **Navigation and Status Bar**
- **Events**
- **Alerts**

3.1 Home Screen Overview

The home screen below is from the iOS APP, the Android APP looks similar.

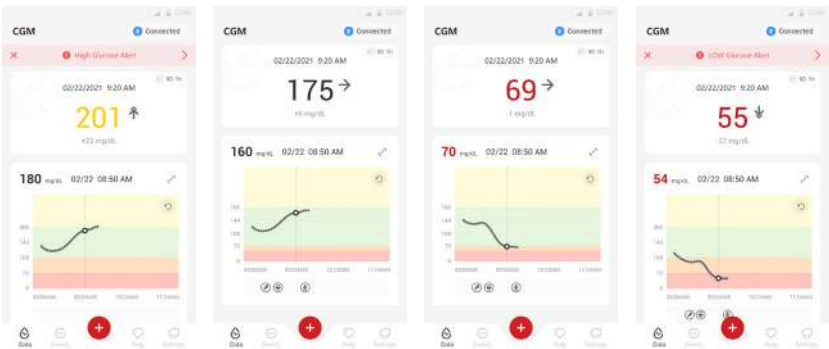


Glucose Graph

Graph of your current and stored glucose readings



3.2 Glucose Information



① Sensor Glucose Result

Starting at the top, the number shows where your sensor glucose is now in milligrams per deciliter (mg/dL). The background color of the Glucose Graph can be yellow, green, orange, or red, it means:

200 mg/dL (11.1 mmol/L) Yellow: Above High Glucose Level (pre-set at 200 mg/dL)

175 mg/dL (9.7 mmol/L) Green: Within the target range

69 mg/dL (3.8 mmol/L) Orange: Below Low Glucose Level (per-set at 70 mg/dL)

55 mg/dL (3.1 mmol/L) Red: Hypoglycemia Alert (set at 55 mg/dL)

When your most recent CGM result is above 450 mg/dL (25.0 mmol/L) or below 36 mg/dL (2.0 mmol/L), you will not get a number. Instead, your display device will display LOW (Low) or HIGH (High). If you do not have a number, use your blood glucose meter to measure your glucose. These LOW or HIGH will be displayed as a blank spot on your trend graph.



② Trend Arrow

Trend arrows show the speed and direction of your glucose trends based on your recent CGM results Use the arrows to know when to take action before you are too high or too low.

Trend Arrow: Steady →

Glucose is changing but less than 3 mg/dL (0.16mmol/L) per 3 minutes.

Trend Arrow: Rising or Falling slowly ↗ ↘

Glucose is changing slowly, more than 3 mg/dL (0.16mmol/L) or up to 6 mg/dL (0.33mmol/L) per 3 minutes.

Trend Arrow: Rising or Falling quickly ↑↓

Glucose is changing quickly, more than 6 mg/dL (0.33mmol/L) or up to 9 mg/dL (0.5mmol/L) per 3 minutes.

Trend Arrow: Rising or Falling rapidly ⇈⇊

Glucose is changing rapidly, more than 9 mg/dL (0.5 mmol/L) per 3 minutes.

③ Trend Graph

The graph below shows where your CGM results have been for the past few hours. It plots your CGM results every 3 minutes. The most recent CGM result is the black dot on the right. The white hollow dot in the middle is your glucose level on the selected time (for example in the picture below, 143 mg/dL (7.9 mmol/L) is the glucose result at 2:00 PM). The numbers on the left show glucose levels in mg/dL (mmol/L). The numbers on the bottom show the time.

CAUTION: If you are crossing various time zones, the CGM APP displays all the glucose readings of the on-going session with their testing time in the current time zone.



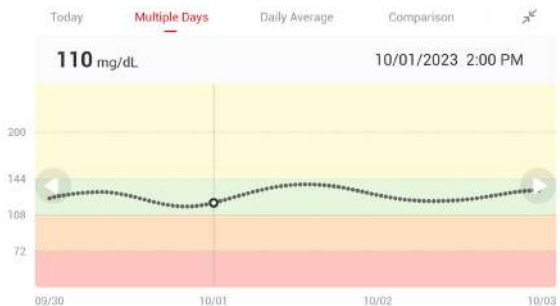
The horizontal lines show your High and Low Alert levels. Your glucose is:

- High when your dots are in the yellow area of the graph.
- In your target range (between your high and low alert settings) when in the green area
- Low when in the red area.



When the transmitter reconnects with the display device after a Signal Loss or similar issue, up to 360 hours of missed CGM results can fill in on the graph.

To see events with your graph and to see your graph over 24 hours, turn your mobile device on its side (for landscape view). Touch and hold a dot to see the time for a past CGM result, or slide your finger across the screen to view CGM results from other times. To switch between different days viewing on your APP, tap “Multiple Days” in the landscape view menu. The white hollow dot indicates a selected result in 1 of the days, the glucose result shows up on the top left panel.



④ Daily Average

The APP shows you trends from your CGM data in 1-day segments that summarize the 15 days in view. The white hollow dot indicates the selected daily review you are looking at the top panel.



A. Average Glucose is the average of all your CGM glucose results from the selected date. Knowing your average glucose gives you a good place to start when trying to get your numbers into target.

B. Highest/Lowest indicates the time that your glucose level reach to the highest and lowest.

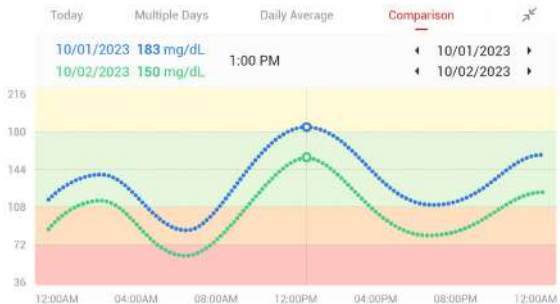
C. Time in Range (TIR) is the percentage of time that your glucose levels are in target range. CGM APP default in-target range is 70-200 mg/dL (3.9-11.1 mmol/L), which may not be what you set for your CGM. You can change the ranges in Settings.

D. Time above Range (TAR) is the percentage of time that your glucose levels are high, above target range. CGM APP default high range is above 200 mg/dL (11.1 mmol/L).

E. Time below Range (TBR) is the percentage of time that your glucose levels are low, below target ranges. CGM APP default low range is below 70 mg/dL(3.9 mmol/L).

⑤ Comparison

The CGM APP allows you to select any 2 days from your past monitoring and compare your monitoring results. The color coated line in the graphic indicates the dates you select (on the right of the top panel) and the white hollow dot means the glucose level (on the left of the top panel) on a certain time.



3.3 Navigation and Status Bar

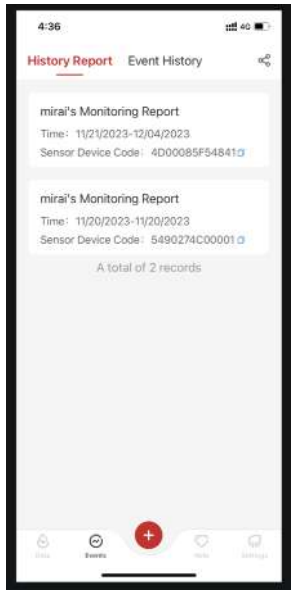
The APP includes sections where you can view a glucose overview report, events history, and find helpful information such as sensor insertion instructions and the full Comprehensive Instruction for Use.

3.3.1 Glucose overview report

The glucose overview report allows you to create and share a report of your previous glucose data, up to the last 15 days.

- In the APP, tap the “Events” button on the status bar at the bottom.
- Tap “History Report” and select the date range for which you want to view.

- Tap “Event History” and you can review all Alerts information.
- Tap the “SHARE” button to email the report to whom you want to share with.



3.3.2 Help Guide

The “Help” section provides a digital version of the iCan i3 CGM System user’s instructions including the “Quick Start Guide”, “Product Tutorials”, “Instruction for Use” and other device information.



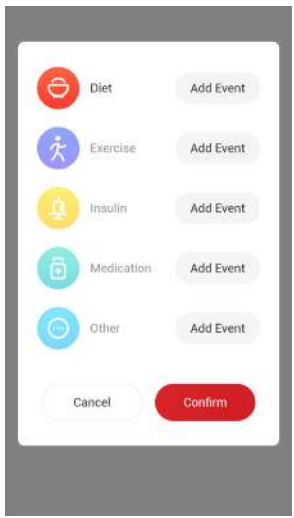
3.4 Events

An event is an action or situation that affects your glucose levels. With the iCan i3 CGM System you can track your daily events so you can reflect on their effect on your glucose trends. Once entered into the APP, events can be viewed in the home screen as well as in the reports. The reports help you review how each event influenced your glucose trends. You can review the reports with your healthcare professional (HCP) and create a plan to manage your diabetes.

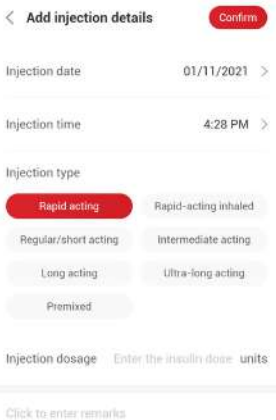
3.4.1 Enter Insulin Event

Step 1: From the Home screen, tap "+"

Step 2: Then tap "Add Event" next to Insulin



Step 3: Choose the Insulin Type



Step 4: Enter insulin units for each dose, up to 99 units.

3.4.2 Other Events

Besides insulin on your APP, you can add other events such as diet, exercise, medication and others. Adding these events is very similar to adding insulin.

For your convenience, there is no need to stop everything and enter your events as they are happening. When you have a moment, you can enter past events. Events are meant to be entered as individual occurrences.

3.5 Alerts

When your CGM result goes from your target range to your pre-set alerts level, your mobile device tells you with a visual notification, and vibrations or sound, depending on the alert and your mobile device. Until you confirm the glucose-related alert, every 3 minutes you will get the alert screen along with a notification and a vibration. Until you are back in your target range, the alert information will stay on your home screen.

Before using the APP, go to Attachment F Alerts Vibrations and Sounds to check our iPhone and Android phone setting recommendation.
Also talk with your HCP about your alert settings. They may suggest changing them to different values.

3.5.1 Urgent Low Alert

While there are a variety of alerts, there is just one special: the Urgent Low Alert at 55 mg/dL (3.1 mmol/L). The urgent low alert cannot be changed or turned off with one exception. If you have an Android phone, and you turned on Do Not Disturb, you will not get any alerts, including your Urgent Low.

What you hear, feel, and see

- Initial alert: Vibrates 4 times and beeps 4 times
- Until confirmed: Vibrates and beeps 4 times every 5 minutes

Otherwise, as long as your mobile device is getting CGM results and notifications, you will get your alert at 55 mg/dL (3.1 mmol/L) or lower.

3.5.2 Alert

An alert is a message telling you your glucose trend levels or CGM system needs attention. You can customize the Alerts in your APP.

When you have your mobile device sound on, it vibrates and makes a sound on the alert. If you have turned off the sound, it only vibrates. Each alert has its own vibration pattern.

When making treatment decisions using your CGM, it is best to keep your device sound turned up, not muted, and the speaker works.

WARNING: If you use headphones, alerts will only sound through the headphones, not on your smart device speaker. If your device volume is not turned up, the device is muted, or headphones are plugged in, you will not hear the sound of any notifications, including urgent low alert.

Low Alert

When your CGM result is below the target glucose range you set, you get your Low Alert. What you hear, feel, and see:

- Initial alert: Vibrates and beeps with APP notification.
- Until confirmed: Vibrates and beeps 2 times every 3 minutes.

High Alert

This notifies you when your CGM results are above your target glucose range.

What you hear, feel, and see:

- Initial alert: Vibrates and beeps with APP notification.
- Until confirmed: Vibrates and beeps 2 times every 3 minutes.

Rise or Fall Rate Alert

- Slowly Rise or Fall: Until confirmation vibrates and beeps 3 times every 3 minutes with APP notification.
- Quickly Rise or Fall: Until confirmation vibrates and beeps 6 times every 3 minutes with APP notification.
- Rapidly Rise or Fall: Until confirmation vibrates and beeps will be continued.

Signal Loss Alert

This tells you when you are not getting iCan results. Your mobile device may be too far from your transmitter or there may be something, such as a wall or water, between your transmitter and your display device.

Unlike other alerts, Signal Loss cannot make a sound or vibrate, you will receive APP notification for every 3 minutes until reconnected.

To fix this problem, keep your transmitter and display device within 6 meters of each other. If that does not work, turn Bluetooth off and on. Wait 10 minutes, if this still does not work, restart the mobile device and reopen the CGM APP.

During signal loss, use your BG meter to check your glucose and make any treatment decisions.

3.5.3 Customizing Your Alerts

How you set up your alerts can help you reach your diabetes management goals. Work with your HCP to come up with the best alert customization for you and your goals.

The default glucose alert settings are 200 mg/dL (11.1 mmol/L) (high) and 70 mg/dL (3.9 mmol/L) (low).

To change the default glucose alert levels:

a. Tap “Settings” at the bottom of the Sensor Warmup screen or the home screen.

b. Select “Personal Settings.”

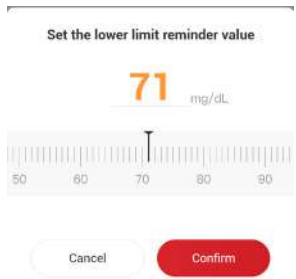
c. Tap the alert level to be changed.



Low Glucose Alert

The Low Glucose Alert is on by default. Tap the slider to turn the alert off.

If the alert is on, you will be notified when your glucose falls below the pre-set level, which is initially set to 70 mg/dL (3.9 mmol/L). Tap to change this value between 55 mg/dL (3.1 mmol/L) and 99 mg/dL (5.5 mmol/L).



Choose the sound and message for this alert. Volume and vibration will match your mobile device settings.



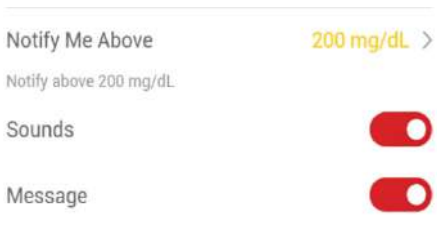
High Glucose Alert

The High Glucose Alert is on by default. Tap the slider to turn the alert off.

If the alert is on, you will be notified when your glucose rises below the pre-set level, which is initially set to 200 mg/dL (11.1 mmol/L). Tap to change this value between 117 mg/dL (6.5 mmol/L) and 450 mg/dL (25.0 mmol/L).



Choose the sound and message for this alert. Volume and vibration will match your mobile device settings.

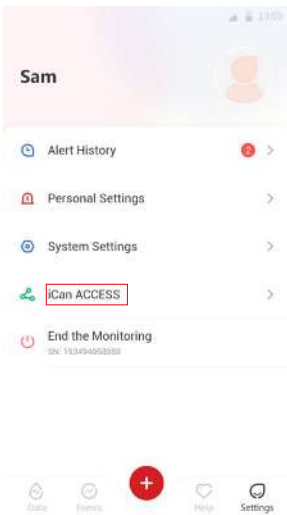


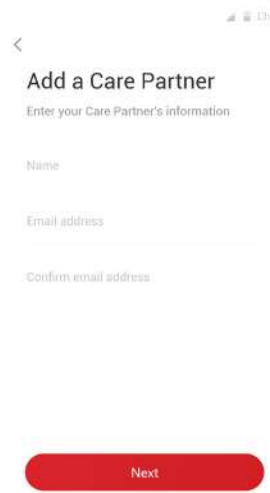
3.6 Access

Use iCan CGM APP's "Access" feature to let up to 10 friends, family, or another trusted caregiver view your glucose information. You can give them access to just your Sensor readings and trend arrow, or include the trend graph. You can even set up glucose notifications for them to get when your glucose goes high or low, similar to the alerts you get on your iCan CGM APP. You can edit, stop sharing with, or remove a "Care Partner" any time.

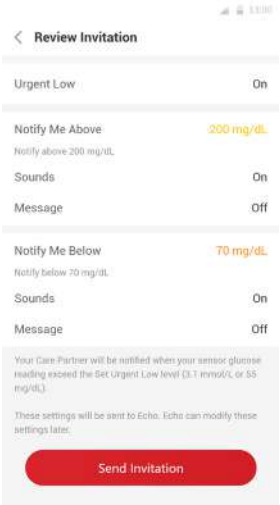
3.6.1 Invite "Care Partner"

Your "Care Partner" does not need to have the iCan CGM APP on their mobile devices. They only need to download the iCan REACH APP. To invite someone to follow you, go to **Settings > iCan ACCESS**. Then follow the instructions on the APP screens. You can invite them by entering their name and email.



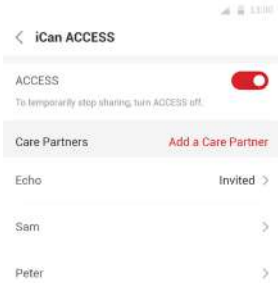


This shows what your “Care Partner” can see. To customize it, you can switch between “**On/Off**” to enable or disable an item, then tap “**Send Invitation**”



3.6.2 Edit Status

The Access screen shows the status of your “Care Partner” and lets you invite new ones.



Section 4: Treatment Decisions

- **Talk with your Health Care Professionals (HCPs)**
- **When to Use Your Blood Glucose Meter**
- **Using Your CGM for Treatment Decisions**

4.1 Talk with your Healthcare Professionals (HCPs)

Working with your HCP, define your target glucose range and your alert settings. Discuss how to stay within your target using the iCan i3 CGM System. Let your HCP guide you through the system features, including adjusting your alert settings to match your needs and goals, working with CGM results and trend arrows for treatment decisions, and managing your diabetes with the system.

Remember, changes to your insulin routine should be made cautiously and only under medical supervision.

4.2 When to Use Your Blood Glucose Meter

WARNING: If your symptoms do not match your CGM results, use your blood glucose meter when making treatment decisions. If your CGM results do not consistently match your symptoms or blood glucose meter values, then talk to your healthcare professional.

Make sure you always carry or have immediate access to your blood glucose meter.

4.3 Using Your CGM to Help for Your Treatment Decisions

Work with your healthcare provider to figure out what's best for you when making treatment decisions. Always follow their instructions in treatment decision. You should keep using your BG meter until you're comfortable with iCan i3 CGM.

Trend arrows show the speed and direction of your CGM results so you can see where you are heading. Talk to your healthcare provider about using the trend arrows to determine how much insulin to take. The following information can assist you in making treatment decisions.

Steady Arrow

Actions to consider:

- Low: Eat
- High: Watch and wait if you took insulin recently. Otherwise, adjust insulin dose up
- In target range: No action needed

Arrows Going Up

Actions to consider:

- Low: Watch and wait
- High: Watch and wait if you took insulin recently. Otherwise, adjust insulin dose up
- In target range: Watch and wait if you took insulin recently. Otherwise, adjust insulin dose up

Arrows Going Down

Actions to consider:

- Low: Eat. Did you have too much insulin or exercise?
- High: Watch and wait. Did you have too much insulin or exercise?
- In target range: Eat

Section 5: End a Session

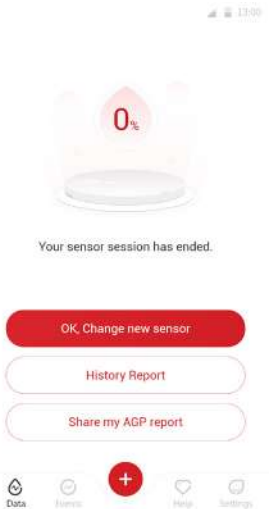
- **End Your Sensor Session**
- **Remove a Sensor**
- **Start New Sensor Session**

5.1 End Your Sensor Session

Your iCan i3 CGM is intended to last for 15 days. The Sensor will automatically stop when the 15-day session is over. You can also end the sensor session early by manually stopping it. Before it ends, you will get notifications letting you know your sensor session is ending. Before you start a new sensor session, you must remove your existing sensor.

5.1.1 Automatically stopping a session

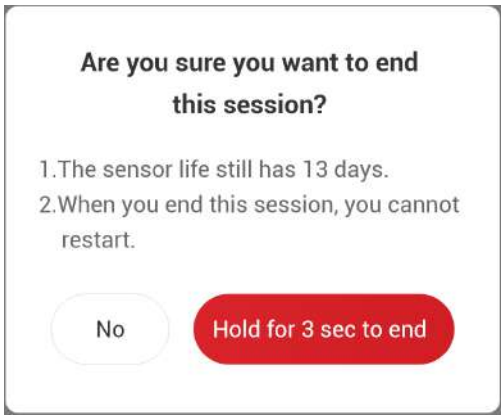
After 15 days, the CGM session will automatically stop. In the APP, you will see a notification indicating that the session has ended. Once the session has stopped, you should remove the sensor and tap **“OK, Change New Sensor”** to start a new CGM session.



5.1.2 Manually stopping a session

If you choose to stop a session before the end of the 15 days, you will need to stop it manually.

In the CGM APP, tap the "**Setting**" button and choose "**End the Monitoring**", hold the button for 3 seconds to end the current session.



5.2 Remove Sensor

Pull up the edge of the adhesive tape that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.

CAUTION: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.



Discard the used Sensor. See Disposal from Attachment C.

5.3 Start New Sensor Session

When you are ready to apply a new sensor, follow the instructions in **Section 2: Start Your Sensor** to start a new sensor session. You will need to scan or enter a new sensor code because the code is specific to each sensor.

Attachment A: Troubleshooting

Troubleshooting sections are categorized by function or system component. The solutions here are meant to be brief and not all-inclusive. References to specific Sections for more detailed answers or preventative measures there.

Are you still not sure what to do after reading this Section? If your problem is not listed, or the recommended solution here does not fix issue, contact Customer Care

Email: support@icancgm.com

Web: iCan-cgm.com

A.1. Sensor Issues

Things to Examine / Questions to Ask	Solutions
Insertion Site is red, irritated, or painful	Change the sensor and insert it into a different location. • Avoid sites where clothes may rub, where your body bends a great deal or near the beltline, if possible. These areas present a higher risk of the sensor and transmitter being accidentally pulled out. • Do not insert the sensor into an area that is lean, scarred, or hardened. If inserted in these areas it may decrease the flow of interstitial fluid or the sensor may kink. **Caution:** If you continue notice skin irritation around or under your Sensor, remove the Sensor and stop using the System. Skin reaction may appear sometime after the first time using the device. If you have a reaction to the adhesive, please contact your healathcare professional before continuing use.
Sensor did not fully insert	If your Sensor is not fully inserted or comes loose, you may not get glucose readings on the APP. Stop the session and remove the sensor. Insert a new sensor to start a new session.
Insertion site is bleeding	Remove the sensor and discard. Check the site for bleeding, irritation, pain, tenderness or inflammation and treat accordingly. Insert a new sensor in a different location.

Things to Examine / Questions to Ask	Solutions
Broken sensor	If a sensor tip breaks off under your skin and you cannot see it, do not try to remove it. Contact your HCP. Also seek professional medical help if you have symptoms of infection or inflammation (such as redness, swelling, or pain at the insertion site).
Sensor adhesive tape will not stick to skin	Prior to insertion, make sure the site is properly cleaned and dried. See Section 2 for cleaning instructions. If you notice the edges of the adhesive tape are becoming frayed or not sticking to your skin, apply the overpatch or medical tape to the edges to help secure the it.
Sensor not working after immersing in water	If the issue is not resolved after 1 hour, stop the session, remove the sensor and insert a new sensor to start a new session.
Insertion site still not relieved after sensor removal	If you notice pain, swelling, redness, discharge, or any obvious signs of lymphangitis, such as enlarged local lymph nodes or fever, at the insertion site after removing the sensor, you should contact your healthcare professional immediately. If you have any doubts or questions, please consult your doctor or other healthcare professional.
Applicator is stuck and will not come off your skin after you push the button to insert the sensor	Gently pull applicator up until you see adhesive tape. Using your finger or thumb, hold the edge of tape and gently rock back applicator, away from your body. Do not try to reuse the applicator. If you have any concerns, contact Customer Care Email: support@icancgm.com
Overpatch or medical tape over the patch.	May cause additional allergenic adhesive tape applied to the user's skin. If you notice significant skin irritation around or under your sensor, remove the sensor and stop using the CGM. Contact your healthcare professional before continuing to use the CGM.

A.2. Transmitter Issues

Things to Examine/ Questions to Ask	Solutions
Transmitter did not pair with mobile device	Check the following: -The QR code on the Transmitter matches the one on the Sensor Pack (see Section 2 for details) - The transmitter and the mobile device are within 6 meters of each other and Bluetooth is on -If the transmitter was previously connected to your mobile device but now will not connect: - Navigate to the Bluetooth settings on your mobile device (not in the CGM APP). -Try pairing again. See Section 2 for details. If these solutions do not fix the issue, please contact Customer Care Email: support@icancgm.com
Current abnormality warning	In the monitoring process, if the current is abnormal, the current abnormality warning will be given. Please contact Customer Care Email: support@icancgm.com

A.3. CGM APP Issues

Things to Examine/ Questions to Ask	Solutions
Your mobile device can not download the CGM APP	Check iCan-cgm.com for a list of mobile devices that work with the CGM APP. If your device is not listed, change to a new mobile device that is compatible. Install the APP on your new mobile device.
CGM results are not displayed on the HOME screen	The CGM is warming-up. During the first 2 hours, the Home screen will not display CGM results. Your transmitter may have lost communication with the APP. Make sure the transmitter and APP are within 6 meters of each other and Bluetooth is on. Check to make sure the HOME screen shows a Bluetooth connection signal icon on the upper right.

Things to Examine/ Questions to Ask	Solutions
Data missing on the trend chart on the HOME screen	If your transmitter and APP lose communication, there may be a gap in the data because results were not sent to the APP. Once communication is restored, the gap may be filled in if the transmitter was collecting data during that period.
Cannot Hear Alerts	If you cannot hear your alerts on your APP, verify that the APP, Bluetooth, volume, and notifications are on. If you restart your mobile device, reopen the CGM APP. Make sure that a session is in progress.
Signal Loss	Keep your transmitter and display device within 6 meters of each other. If that does not work, turn Bluetooth off and on. Wait 10 minutes. If that does not work, restart the mobile device and reopen the CGM APP. Wait up to 30 minutes. System may correct problem itself. If not, then contact Customer Care Email: support@icancgm.com
Home screen shows Low or High instead of CGM result	System is working as it should. Use your Blood Glucose Meter and treat your high or low blood glucose. When your result is between 36 and 450 mg/dL your iCan i3 CGM will display your result instead of Low or High.

Attachment B: Security and Air Travel

For help with your iCan i3 CGM System, contact Customer Care Email: support@icancgm.com.

WARNING: In case of emergency, contact your HCP or emergency medical response.

B.1. Security Check

You can use any of the following methods to go through security when wearing or carrying your iCan i3 CGM without worrying about damaging your CGM components:

- hand-wanding,
- pat-downs,
- visual inspection,
- walk-through metal detectors

CAUTION: Security equipment to **AVOID**

- Do not go through an advanced imaging technology (AIT) body scanner (also called a millimeter wave scanners).
- Do not put your CGM components through x-ray machines.

If you are concerned about the security equipment, talk with the Security Officer and ask for hand-wanding or get a full-body pat-down with a visual inspection of your sensor and transmitter. Let the Security Officer know you cannot remove the sensor because it is inserted under your skin.

B.2. During your flight

In order to use the APP while you are on the plane, make sure to switch your mobile device to airplane mode, and keep Bluetooth on.

Attachment C: Take Care of Your CGM

C.1. Maintenance

Components	What you shall do…….
Sensor-Applicator	• Keep it in the sterile package until ready for use • Do not use if it has expired
Transmitter	• Keep it in kit box until ready for use. Check transmitter and do not use if damaged • Do not spill liquid or soak it with water • Do not use if Transmitter has expired
Sensor	• After apply the senor and wear it on the body, do not use lotions, sunscreen, insect repellent, or similar items on it

No cleaning methods are recommended or tested for the applied iCan i3 CGM. Only wipe with a clean, dry cloth. Do not dry transmitter with a hair dryer, the heat may damage the transmitter.

C.2. Storage and Transport

Store at temperatures between 2-30°C (36°F and 86°F).

Store between 10% and 90% relative humidity.

CAUTION:

- Storing outside this range may cause inaccurate CGM results.
- May store sensor in refrigerator if it is within temperature range.
- Store sensors in a cool, dry place. Do not store in parked car on a hot or freezing cold day or in a freezer.

C.3. Checking System Setting

You can check your APP for information about your CGM System any time.

Here is the recommended mobile device setting for your iPhone and Android mobile device.

	Screen Time	Screen Time's Downtime and APP Limits can temporarily disable apps. You can: - Turn off Downtime and APP Limits or - Add CGM APP to the Always Allowed APP list
	Do Not Disturb	Do Not Disturb silences all alerts except for the Urgent Low alert. For iOS, you can • Go to Settings, tap on Do Not Disturb, and turn it off
	Do Not Disturb Permission	You must allow Do Not Disturb Permission for the CGM APP to work. The Do Not Disturb Permission ensures you always get the Urgent Low alert and important iCan alerts even when you put your phone in the most restrictive Do Not Disturb setting. For Android, you can: • Follow in APP instructions, or go to Settings, find DND Permission or DND Access, choose CGM APP, tap Allow DND, and tap Allow.
	Low Power Mode	Low Power Mode may prevent the CGM APP from running in the background. For iOS, you can • Go to Settings, tap Battery, and turn Low Power Mode off.
	Battery Saver Mode	For Android, you can: • Go to Settings, and turn Battery Saver Mode off, or choose the highest battery performance on certain phones.
	Device Bluetooth	Your CGM APP uses Bluetooth to connect with your transmitter. You must keep your phone Bluetooth turned on to get alerts and sensor results. You can: • Go to Settings, find Bluetooth, and turn it on.
	App Bluetooth Permission	Apple requires you to give the CGM APP permission to use Bluetooth. You must keep Bluetooth Permission turned on for the CGM APP to work.

	Notifications Permission	Notifications let you get alerts on your phone. If notifications for the CGM APP are off, you will not get any alerts. We recommend turning CGM APP notifications on. On iOS 15 and above, do not add the APP to Scheduled Summary. You can: • Go to Settings, choose CGM APP, tap Notifications, turn Allow Notifications on.
	Background App Refresh	Background APP Refresh allows the CGM APP to continue running in the background. If Background APP Refresh is turned off, your CGM APP alerts may be delayed. You can: • Go to Settings, find CGM APP, and turn Background APP Refresh on.
	Focus Mode	On iOS 15 and above, the Focus feature will silence alerts and notifications for chosen APPs. If you add CGM APP to any Focus mode, your iCan APP alerts may be delayed. You can: • Not use Focus modes • For iOS, Go to Settings, find Focus, choose a Focus mode, add CGM APP as an Allowed APP, and repeat for each Focus mode. • For Android, Go to Settings, find Digital Wellbeing, and confirm CGM APP is not in the Distracting APPs list.
Location		Location must be turned on to use Bluetooth. If Location is off, you will not get alerts, or sensor results. The location of each setting may be different based on your iOS version. Please refer to your mobile device instructions for detailed information. Android 10 and above: Go to Settings, find CGM APP, tap Location Permission, and choose Allow All the Time. Android 9 and below: Go to Settings, find CGM APP, tap Location Permission, and turn it on.
App Pause		On Android 10 and above, Pause temporarily disable Apps. Using Pause with the CGM APP stops all alerts, and sensor results. You can: Tap the CGM APP icon on the desktop or in the APP drawer, and tap Uncaused APP.

Make sure your display devices is online	logging in, creating a new account, pairing the transmitter require your display devices online, or you cannot use the CGM, which may cause a treatment delay. Sharing your glucose data to others also requires your display devices online, or you cannot share, which may cause inconvenience.

Note: Must have secure internet access during setup. Changes to the IT-NETWORK (including network configuration, connection or disconnection of other items, update or upgrade of the iCan CGM) could introduce new risks that require additional analysis

C.4. System Disposal

Different places have different requirements for disposing of electronics (Transmitter) and parts that have come in contact with blood or other bodily fluids (Sensor). Follow your area's local waste management requirements.

Attachment D: Technical Information

D.1. Device Performance Characteristics

Summary

Sinocare assessed iCan i3 CGM performance in a clinical study with 60 adults (18 years and older) participants. The participants all had type 1 or type 2 diabetes.

Participants wore devices for up to 15 days on their abdomen.

Each participant attended least one of clinical session during the beginning (Day 2), middle (Day 7-9), or end (Day 15) of the 15 days wear period to have their venous blood glucose measured every 15minutes with a laboratory reference method, the Yellow Springs Instrument 2900D Biochemistry Analyzer.

The iCan i3 CGM device was compared to the laboratory reference method to evaluate accuracy in participants aged 18 years and older.

Accuracy

The accuracy of the iCan i3 CGM is shown in the table below.

Mean absolute relative difference (MARD) is a measure that shows on average how far away the glucose sensor reading is from a blood glucose reading The iCan i3 CGM MARD is 8.71%, meaning it may read 8.71% lower or higher than your blood glucose. For example, if your blood glucose was 270 mg/dL (15.0 mmol/L), the sensor may read, on average, 24 mg/dL (1.4 mmol/L) lower or higher.

Performance Metrics*	Result	Notes
Overall Accuracy	8.71%	Mean absolute relative difference versus across the range of glucose levels, 36-450 mg/dL(2.0–25.0 mmol/L). Lower number is better.

Performance Metrics*	Result	Notes
Clinical Accuracy	100%	% of readings in Consensus Error Grid Zone A (% CEG Zone A+B) Glucose readings in zones A and B are considered to be clinically acceptable, whereas results outside of zones A and B may have a negative clinical outcome. Higher numbers are better.

*Reference is venous plasma glucose value measured on YSI glucose analyzer (Yellow Springs Laboratory Instrument)

Potential Clinical benefits

Some potential benefits of using your iCan i3 CGM System are

- Improved management of glycemic control
  - Improved management of HbA1c/A1c value (denoting improvement of glycaemic control)
  - Reduced events of severe hypoglycemia in hypoglycemia unawareness
  - Reduced events and duration of hyperglycemia
- Potential for increased self-management
  - Increased patient insight regarding food, portions, physical activity, stress, diabetes medication choices
  - Increased proactive and retroactive decision-making by patients as a result of easy and timely access to more data, including post-prandial and overnight data.
  - Increased ability and speed to self-assess validity of management changes which can increase sense of empowerment and self-efficacy
  - Increased types of glycemic metrics available (% time in range, etc)

- Potential for improved quality of life
  - Decreased fingerstick testing, Increased ease of glucose monitoring
  - Decreased manual record keeping
  - Increased ability to identify and treat hypoglycemia;
  - Increased reassurance for those fearful of hypoglycemia during sleep, sports, driving etc
- Reduced limitations of fingerstick blood glucose tests:
  - CGM overcomes some limitations of fingerstick blood glucose monitoring include: inconvenience; physical intrusiveness of "poking" multiple times daily; limited single “point-in-time” glucose measurement; missed data (between meals, overnight, with sports or with asymptomatic hypo/hyperglycemia).
  - CGM provides real-time blood glucose readings throughout the day, using the device as close to daily as possible could provide real-time, dynamic glucose information, increase tighter glycemic control and result in fast, proactive response, therefore enable maximal clinical benefit to the user.

D.2. Product Specifications

Sensor	
Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose result range	36.0 mg/dL – 450.0 mg/dL (2.0–25.0 mmol/L)
Sensor life	Up to 15 days
Shelf life	Up to 1 year
Storage and transport temperature	2°C to 30°C (36°F to 86°F)
Storage and transport humidity	10% - 90% Relative humidity
Operating temperature	10°C to 42°C (50°F to 108°F)

Operating humidity	10% - 90% Relative humidity
Applied part	Type BF applied part
Transmitter	
Transmitter battery type	1 non-serviceable, non-rechargeable button cell inside the transmitter, DC 1.5 V
Applied part	Type BF applied part
Operation Mode	Continuous operation
TX Frequency	2.402 GHz–2.480 GHz
Bandwidth	1.06 MHz
Maximum Output Power	1+1 dBm
Modulation	Gaussian Frequency-Shift Keying
Data Communication Range	6 meters (20 ft) unobstructed
Storage and transport temperature	2°C to 30°C (36°F to 86°F)
Storage and transport humidity	10% - 90% Relative humidity
Operating temperature	10°C to 42°C(50°F to 108°F) **Caution:** When operating the transmitter in the air temperatures greater than 41°C (106 °F) the temperature of the transmitter may exceed 42.7°C (109 °F)
Operating humidity	10% - 90% Relative humidity
Atmosphere Pressure	700hPa-1060hPa
Shelf life	Up to 1 year
Release Version	V01

The iCan CGM APP operation environment minimum requirements:

Platform	Android 8.1 and above, iOS 14.1 and above
Bluetooth version	Bluetooth 5.0
Memory	1G and above
CPU	Main frequency 1.4GHz and above
Screen	No less than 12 cm (4.7 inches)
Resolution	No less than 1280*720

Storage capacity	No less than 500M
Network	WLAN (Wireless Local Area Network) or cellular network(4G and above), as well as Bluetooth function

Note: Must have secure internet access during setup. Connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS, such as unauthorized access, malware and viruses, data breaches etc. If you do identify such risks when you using the iCan CGM by connecting to networks, please stop the app once you find such risks and contact Customer Care Email: support@icancgm.com for help with your iCan i3 CGM System.

D.3. Quality of Service Summary

Quality of Service for the iCan i3 CGM System wireless communication using Bluetooth Low Energy is assured within the effective range of 6 meters, unobstructed, between the iCan transmitter and paired display device at regular 3-minute intervals. If connection is lost between the transmitter and display device, upon re-connection any missed packets (up to 360 hours) will be transmitted from the transmitter to the display device. The iCan i3 CGM System is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

D.4. Security Measures

The iCan i3 CGM System is designed to transmit data between the transmitter and designated display devices in accordance to the industry standard BLE protocols. It will not accept radio frequency (RF) communications using any other protocol, including Bluetooth classic communication protocols.

In addition to the security provided by the BLE connection, communication between the iCan transmitter and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various methods to verify data integrity and to detect potential instances of data tampering. While the format is proprietary, industry standard encryption protocols (e.g., RSA and AES) are used in different parts of this proprietary data format.

Unless disabled, the iCan mobile application regularly communicates with local Servers. Communication between the CGM application and local Servers is protected by a number of mechanisms, designed to safeguard against data corruption. This includes industry standard JWT token based authentication and authorization. All such communication takes place exclusively over encrypted data path using industry standard SSL format. We take your privacy seriously and provides the full suite of GDPR rights to all our users globally.

The removal of limitations and security measures set by the manufacturer on a smart device. The removal poses a security risk and your data may become vulnerable.

CAUTION:

Don't install iCan CGM app on a jailbroken (Apple) or rooted (Android) smart device. It won't work correctly

D.5. Guidance and Manufacturer Declaration – Electromagnetic Emissions

Immunity Test	Transmitter Compliance Level
2014/53/EU RED	In conformity with the essential requirement of Article 3.1(a) the protection of the health, 3.1(b) an adequate level of electromagnetic compatibility and 3.2 effective use of the spectrum of 2014/53/EU RED

D.6. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity Test	Transmitter Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air
Magnetic Field (50Hz and 60Hz) IEC 61000-4-8	30 A/m
Radiated Fields Disturbance IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)

Electromagnetic interference can still occur in the home healthcare environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in CGM results or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:
If your symptoms do not match your CGM results, use your blood glucose meter when making treatment decisions. If your CGM results do not consistently match your symptoms or blood glucose meter values, then talk to your healthcare professional about how you should be using the iCan i3 CGM to help manage your diabetes. Your healthcare professional can help you decide how you should best use this device.

D.7. iCan ACCESS and iCan REACH APP safety statements

iCan ACCESS lets you send your sensor information from your App to your Care Partners' smart devices (iCan REACH APP). iCan REACH APP's information is always older than your App. The information on iCan REACH APP is not meant to be used for treatment decisions or analysis.

Attachment E: Label Symbols

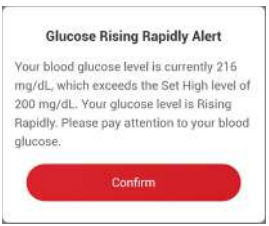
Symbol	Description
	Manufacturer
EC REP	Authorized representative in the European Community/European Union
UK REP	UK Responsible Person
	Date of manufacture
	Use-by date
SN	Serial number
LOT	Batch code
IP28	IP28: Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from long term immersion up to a specified pressure.
	Type BF Applied Part
STERILE R	Sterilized using irradiation

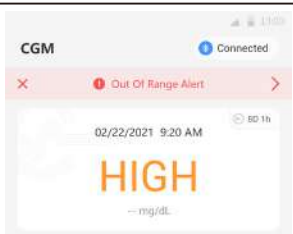
	Single sterile barrier system
	Temperature limit
	Humidity limitation
	MR Unsafe
	Do not re-use
	Do not use if package is damaged
	This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EC in the European Union is required. Contact the manufacturer for details.
	Caution
 iCan-cgm.com	Consult the electronic instructions for use

	Keep Away from sunlight
	Keep Dry
	Bluetooth
	This symbol suggests that the CGM has acquired European technical conformity in accordance with (EU) 2017/745
	Medical device
	Indicates a carrier that contains unique device identifier information
	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
	Follow instructions for use
	Indicates the entity importing the medical device into the locale

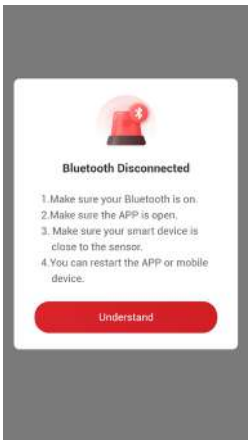
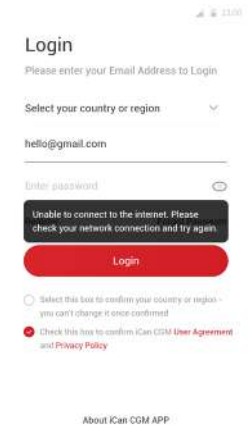
Attachment F: Alerts Vibrations and Sounds

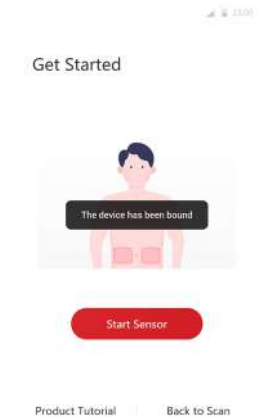
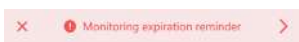
F.1 Glucose Alerts

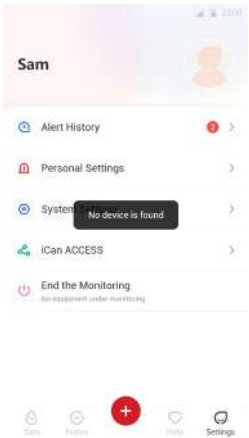
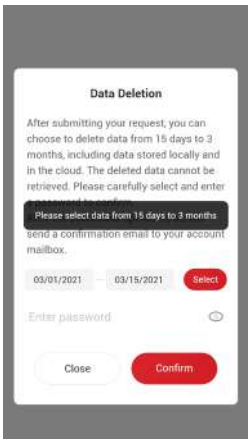
Screen	Description
	Notify when the result is below the default low glucose level (default is 55 mg/dL)
	Rise rate alert. Notify when the glucose result is above the High Alert level and rising quickly.
	Fall rate alert. Notify when the glucose result is below the Low Alert level and falling quickly.

	Notify when the glucose result is above the High Alert level
	Notify when the glucose result is below the Low Alert level.
	Notify when the glucose result is above result range (default is 450 mg/dL)
	Notify when the glucose result is below result range (default is 36 mg/dL)

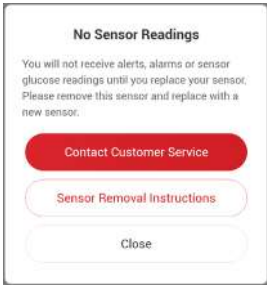
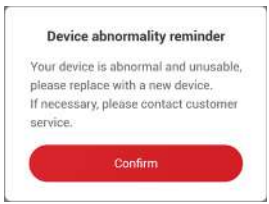
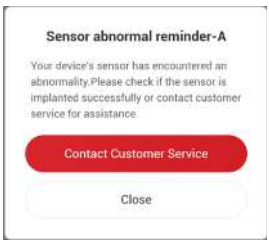
F.2 System Alerts

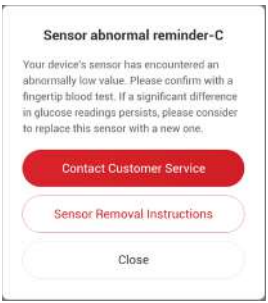
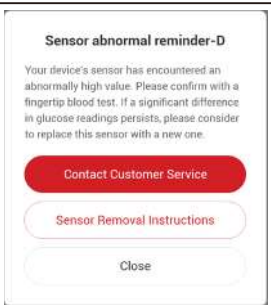
Screen	Description
	Notify when the transmitter and mobile device Bluetooth connection is off
	Notify when user cannot connect to network, unable to connect to server.

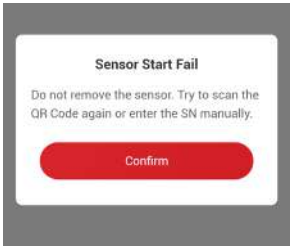
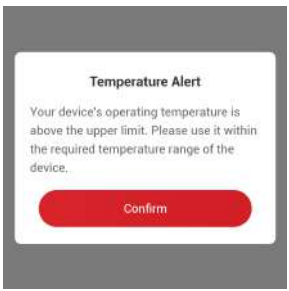
	Notify when an incorrect QR code is scanned.
	After the QR code scanning is completed, it will automatically connect between smartphone and transmitter. Notify if it has not been connected for 3 minutes.
	Notify when binding a device that has already been bound and the monitoring session has ended.
	Sensor expiring alert. Will remind in 24 hours and 30 minutes before the current session will end.
	Transmitter battery low alert.

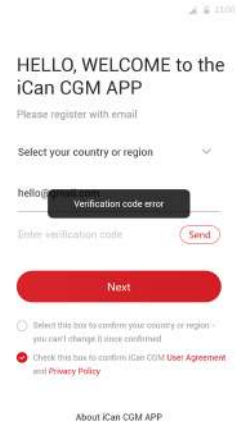
	Notify when the equipment status is already at the end of detection, User repeatedly click the "End Monitoring" button.
	Notify when there is no data within the query time period

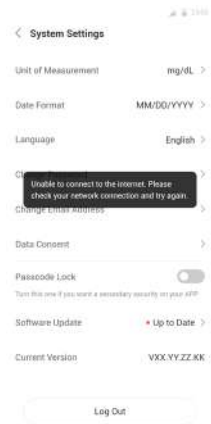
F.3 Abnormal Alert

Screen	Description
	Notify when there is no sensor reading or glucose reading for a while. Replace it with a new device. Or use your BG meter during the transition period. If needed, please contact your Healthcare professional
	Notify when the sensor produces abnormal electrical signal for a while. Replace it with a new device. Or use your BG meter during the transition period. If needed, please contact your Healthcare professional
	Notify when the sensor cannot produce electrical signal for a while during sensor warmup period.

	Notify when the sensor produces abnormal electrical signal for a while.
	Notify when the sensor produces abnormal low value.
	Notify when the sensor produces abnormal high value.

	Sensor start anomaly warning
	Low operating temperature alert
	High operating temperature alert

	Notify when unable to connect to server during uploading data (automatically or manually)
	Notify when user enter an incorrect verification code

	Notify when unable to connect to server while viewing personal details.

Glossary

Blood glucose meter

A device used to measure the levels of glucose in the blood.

Blood glucose result

The concentration of glucose in the blood, measured as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L).

Continuous glucose monitor (CGM)

A CGM uses a small sensor inserted below your skin to measure the amount of glucose in the fluid in your skin, called interstitial fluid. Those glucose results are then sent to an App, where they are displayed as glucose levels and long-term glucose trends.

Hyperglycemia (high blood glucose)

High levels of glucose in the blood, also known as high blood glucose. When left untreated, hyperglycemia can lead to serious complications. Talk to your healthcare professional to determine your high glucose level.

Hypoglycemia (low blood glucose)

Low levels of glucose in the blood, also known as low blood glucose. When left untreated, hypoglycemia can lead to serious complications. Talk to your healthcare professional to determine your low glucose level.

Interstitial fluid

The fluid that surrounds all the cells of the body.

Insulin

A hormone produced by the pancreas that regulates the metabolism of glucose and other nutrients. Insulin injections may be prescribed by a healthcare professional to help people with diabetes process glucose (sugar), if their pancreas is damaged and does not produce insulin.

Limitations

A safety statement outlining specific situations in which the iCan i3 CGM should not be used because it may be harmful to you or damage the system.

mg/dL

Milligrams per deciliter; one of two standard units of measure for the concentration of blood glucose (sugar).

mmol/L

Millimoles per liter; one of two standard units of measure for the concentration of blood glucose (sugar).

Changsha Sinocare Inc.
265 Guyuan Road, Hi-Tech Zone, Changsha, 410205,
Hunan Province, P.R. China

Email: support@icancgm.com **Website: iCan-cgm.com**

EC REP

OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels, Belgium

mail@obelis.net

UK REP

SUNGO Certification Company Limited
3rd floor, 70 Gracechurch Street,
London. EC3V 0HR

ukrp@sungoglobal.com

CE 0197

Publication Date: 2024-02-02
P/N: 36301426-A.8

Sinocare