

Sinocare

iCanTM i3

CGM User Guide



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LEGAL DISCLAIMER

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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 Instruction for Use (also called User Guide) is provided to help you understand the setup and operation of your iCan Health 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 are in-APP videos that 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:** Walk through inserting your sensor.

You can watch these videos when you set up your app or anytime at

Settings > Help > Videos.

Guides:

- **Quick Start Guide:** Guide 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 for 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: iCansupport@sinocare.com

Sinocare provides Customer Care email for assistance. If you experience problems, report the issue to iCansupport@sinocare.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	iCansupport@sinocare.com
Website	iCan-cgm.com

Section 1: System Overview

- System Description
- Intended Purpose
- User Safety

1.1 System Description


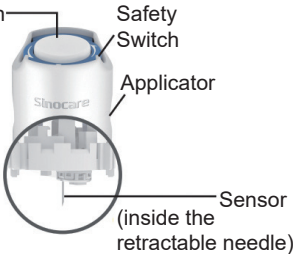

Thank you for choosing the iCan i3 Continuous Glucose Monitoring System (hereafter referred as CGM). The iCan i3 CGM System consists of three main components: a Sensor Pack, a Bluetooth Low Energy (BLE) Transmitter Pack, and a mobile application (APP).

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 Health Continuous Glucose Monitoring System APP (iCan Health 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.

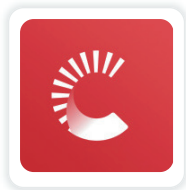
The iCan i3 CGM also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the system results should be based on the glucose trends and several sequential results over time.

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
	Sensor Pack	This is a sterile package where the Sensor is stored. The Sensor Pack is designed for single use.
	Sensor-Applicator	<p>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.</p> <p>See Chapter 2 for details on how to use your Sensor.</p>
	Transmitter Pack	<p>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.</p> <p>See Chapter 2 for details on how to use your Transmitter.</p>

1.1.2 The iCan Health APP



The iCan Health 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), APP Store (iOS) and HUAWEI AppGallery (Android). To see a list of compatible mobile devices, visit iCan-cgm.com

WARNING: Missing alerts from the iCan Health 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

Continuous Glucose Monitoring System is a real time, continuous glucose monitoring device indicated for the measurement of glucose in interstitial fluids for people 2 years 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 in conjunction with smart devices 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.

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



MR UNSAFE

1.3.2 Safety Warnings

1.3.2.1 Safety 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.
- 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.
- The patient is an intended operator. No modification of this equipment

is allowed.

- 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.
- For patients aged 2-11 years, the caregiver is the intended operator; for patients over 12 years old, the patient is the intended operator. No modification of this device is allowed.
- For safety reasons, CGM insertion must be performed by a caregiver for children 2 to 11 years of age and the caregiver must monitor the child's glucose level during use. When children wear CGMs, their caregivers should always carry a mobile phone connected to the CGM and often open the APP to check glucose readings to keep track of changes in the children's glucose level.

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 Health 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 Health 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 Health 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 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.
- 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 allergies 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 CGM immediately.

1.3.3.2 Comparison of 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 pads 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:
 - Change your insertion site with each sensor. Using the same site too often might not allow the skin to heal, causing scarring or skin allergies
- The sensor placement site must:
 - At least 7 cm (3 inches) from insulin pump infusion set or injection site
 - Away from waistband, scarring, tattoos, allergic areas, and bones
 - Unlikely to be bumped, pushed, or laid on while sleeping

1.3.3.4 Potential Risks Related to Sensor Use

- Missed Alerts

You need to receive the alerts and respond to them. Follow the settings recommended by your healthcare professional (HCP) to configure your alerts. See 3.5 Alerts, 1.3.2 Safety Warnings, and Attachment A: Troubleshooting in the User Guide for useful information on avoiding undetected low or high glucose.

- No Treatment Decision if:
 - If your iCan health App does not show a number or arrow
 - or your sensor readings do not match your symptoms;In these cases, the use of iCan CGM may lead to errors in diabetes treatment.

For more information, see the "Treatment Decisions" Section in the User Guide.

Some users find that the accuracy varies between different sensors. Before choosing to use each sensor for treatment decisions, make sure your symptoms match the readings and be aware of their accuracy.

- 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 to 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 a long time 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 Instruction 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.

1.3.3.5 Overpatch (Optional)

- Avoid sensitive skin and wounds
- Clean the area to be attached with alcohol pads and let the alcohol dry before attaching
- Do not use any overpatch beyond the expiration date
- When peeling off the overpatch, slowly pull up the edge of the patch, and peel it away from your skin in one motion

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 whether first 8 digits SN codes on the Sensor Pack and the Transmitter Pack are the same
- Quick Start Guide

iCan i3 CGM System does not provide the following things:

- Alcohol pads
- 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.

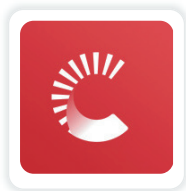
User Requirement: Adult diabetes user or their caregivers who can read, understand and follow the iCan i3 CGM Instruction of Use and Quick Start Guide could use the device safely. Children aged 2 to 11 must be helped by their caregivers.

2.1.2 APP Installation and Set up

Step 1: APP Setup

The APP is available on Google Play (Android), APP Store (iOS) and HUAWEI AppGallery (Android).

Tap and open the iCan Health 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.



WLAN



Cellular Network



Notifications



Location



Bluetooth

WLAN/Cellular Network: Internet is required when you create and/or login to your account, share data, and watch product tutorials, etc.

Notifications: If you use Silent mode, all alerts won't sound or vibrate but just display.

Location: To use Bluetooth, the APP may ask for access to your device location. Tap allow.

Bluetooth: This APP uses Bluetooth to connect to CGM transmitter.

Make sure to turn Bluetooth on, and if not you will not get alerts or CGM information.

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 iCan Health 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 iCan Health APP is turned off in the background, you will not get alerts.
- **Device and APP on:** If you restart your mobile device, reopen the iCan Health 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.
- **You can "Cancel Do Not Disturb" mode in the APP** so that your device can still receive urgent low alert when it is muted.
- **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's 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 iCan Health 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 iCan Health APP displays all the glucose readings of the on-going session with their testing time in the current time zone.

Step 3: Login

If you are new to the iCan Health APP, you need to create a new iCan account following the onscreen instructions.

If you already have an account, enter existing Username and Password.

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 APP system does not replace this Instruction for Use. Read all of the information in this Instruction for Use before using iCan Health 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, and 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, and 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, and 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, and select **"Data Consents"**.

You can manage your permission for the APP here. Besides, you can recover, share, package, or delete the historical data.

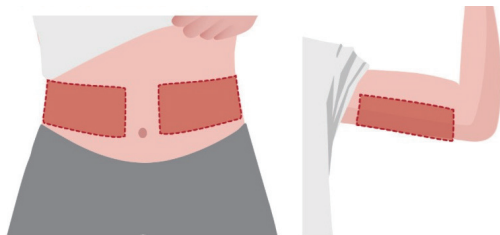
2.2 Choose a Site

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

2 to 12 years old: Choose abdomen

13 years old and above: Choose abdomen or upper arm back

CAUTION: For children aged 2-11 years old, the caregiver is responsible for the insertion of the sensor.



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, allergies, and bones. Contact your HCP if sensor adhesive makes your skin allergic.
- 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 pads. Let the area air dry.

2.3 Pair Your Sensor with the Transmitter

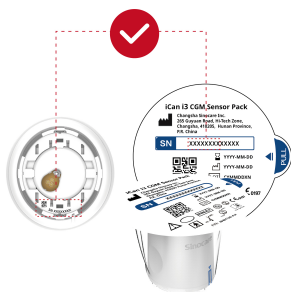
The iCan i3 CGM transmitters communicate with the APP via Bluetooth, so it must be connected with the APP before using the system. This process is also called "Pairing".

Step 1: APP Setup

Follow Sec.2.1.2 to setup your APP, and 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 whether 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, and 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

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 Pairing 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.



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



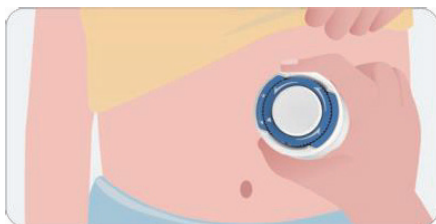
- Now it's ready to apply the sensor.



Step 3: Insert the Sensor

CAUTION: The caregiver is responsible for sensor insertion for children aged 2 to 11 years. Please refer to step 3.1, step 3.2, step 3.3 and step 3.4. To prevent insertion failure, the caregiver should ensure that the child's body remains still throughout the procedure.

- Step 3.1: Place the Sensor Applicator over the prepared site and push down firmly.



- Step 3.2: Press down the white button on the top to apply the CGM Sensor. You will hear a click sound, which means the insertion is completed.



- Step 3.3: Gently pull the Applicator vertically away from child's body.



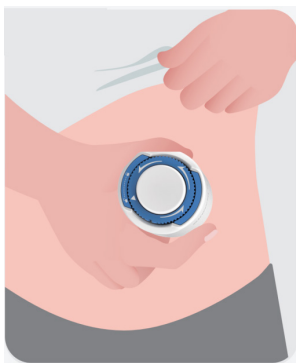
CAUTION: The used applicator has come in contact with bodily fluids. Discard the used applicator according to local regulations.

- Step 3.4: Smooth down the sensor adhesive tape with a finger to ensure the sensor stays on the body for the entire duration of wear.

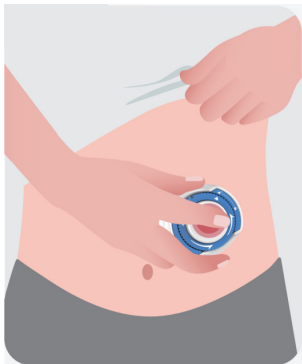


CAUTION: Once inserted, the sensor is waterproof up to 2.5 meters, but the display device (smartphone) may not. If you're in or near water, the display device may need to be kept closer (less than 6 meters) to get sensor readings. If the sensor is under water, caregivers may not be able to get sensor readings until you emerge from the water. For patients 12 years and older, you can insert the sensor by themselves. To insert the sensor, see Step 3.5, Step 3.6, Step 3.7, and Step 3.8.

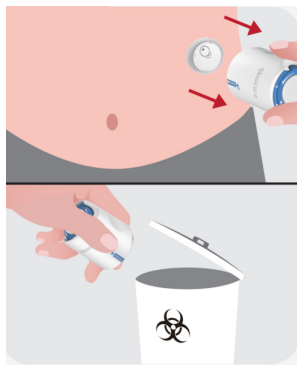
- Step 3.5: Place the Sensor Applicator over the prepared site and push down firmly.



- Step 3.6: Press the top white button to insert the CGM sensor. You will hear a click sound, that means the insertion is completed.

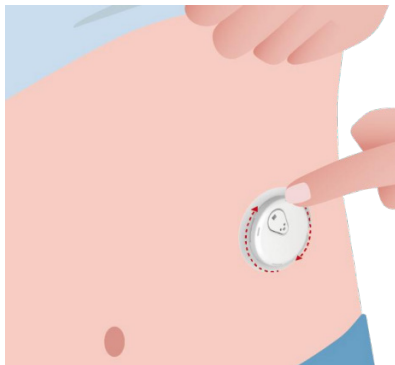


- Step 3.7: Gently pull the Applicator vertically away from your body.



CAUTION: The used Applicator has come in contact with bodily fluids. Discard the used Applicator according to local regulations.

- Step 3.8: 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 display device (smartphone) may not be. 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 underwater, 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 Health APP. You need to press the **"Start Sensor"** button 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 needed.

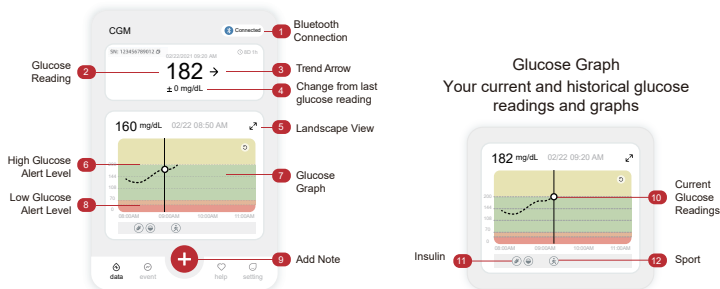
CAUTION: Keep your CGM Sensor and mobile device within 6 meters with no obstructions (e.g. walls or metal) between them. Otherwise, they might not be able to communicate. If water is between your Sensor and the mobile device – for example, if you are showering or swimming – keep them closer to each other. 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, and the Android APP looks similar.



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). 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) Black: Within the target range

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

55 mg/dL (3.1 mmol/L) Red: Urgent Low Alert (pre-set at 55 mg/dL)

The background color of the Glucose Graph can be yellow, green, orange, or red.

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 HIGH (High) or LOW (Low). If you do not have a number, use your blood glucose meter to measure your glucose. These HIGH or LOW will be displayed as 450 mg/dL (25.0 mmol/L) or 36 mg/dL (2.0 mmol/L) on the trend chart.



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 your glucose is are too high or too low.

Trend Arrow: Steady →

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

Trend Arrow: Rising or Falling slowly ↗ ↘

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

Trend Arrow: Rising or Falling quickly ↗ ↘

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

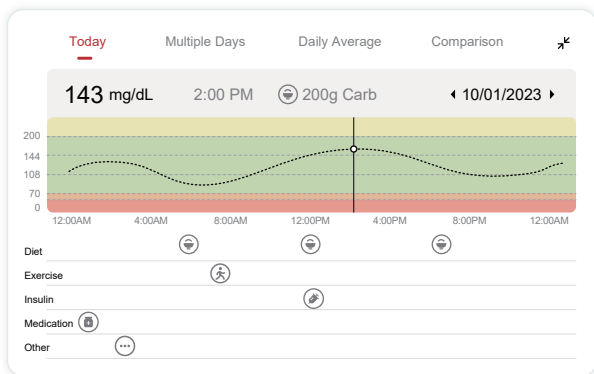
Trend Arrow: Rising or Falling rapidly ↗ ↘

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 level 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 iCan Health APP displays all the glucose readings of the on-going session with their testing time in the current time zone.

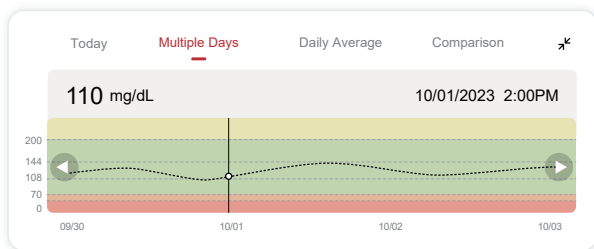


The horizontal lines show your High and Low Alert levels. Your glucose is:

- 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.

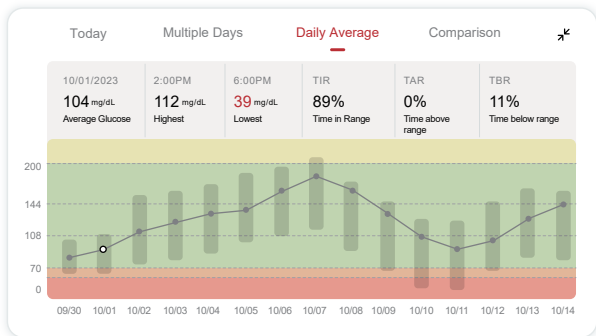
When the transmitter reconnects with the display device after a Signal Loss or similar issue, up to 360 hours of missed CGM results can fill in on the graph.

To see events with your graph and to see your graph over 24 hours, tap the "Landscape View" button and 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, and 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 viewing and reviewing the summary data for the selected date.

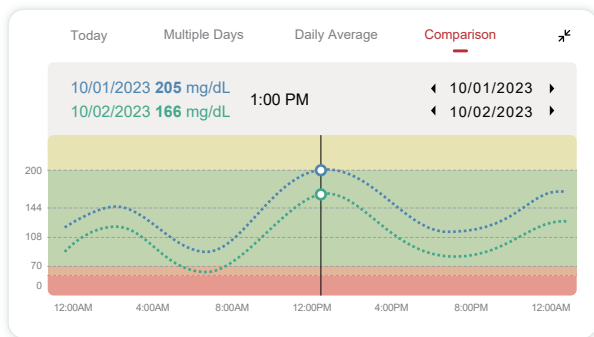


- A. Average glucose is the average of all your CGM glucose results from the selected date. Knowing your average glucose gives you a good place to start when trying to get your numbers into target.
- B. Highest/Lowest indicates the time that your glucose level reach to the highest and lowest.
- C. Time in Range (TIR) is the percentage of time that your glucose levels are in target range. iCan Health APP default in-target range is 70-180 mg/dL (3.9-10.0 mmol/L), which may be different from the ranges you set for your CGM high and low glucose level alerts. Target ranges can't be modified.

- D. Time above Range (TAR) is the percentage of time that your glucose levels are high, above target range. iCan Health APP default high range is above 180 mg/dL (10.0 mmol/L).
- E. Time below Range (TBR) is the percentage of time that your glucose levels are low, below target ranges. iCan Health APP default low range is below 70 mg/dL (3.9 mmol/L).

⑤ Comparison

The iCan Health 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 multiple modules where you can view an overview report of glucose levels, event record assistance (such as sensor insertion instructions and Instruction for Use), and settings.

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.

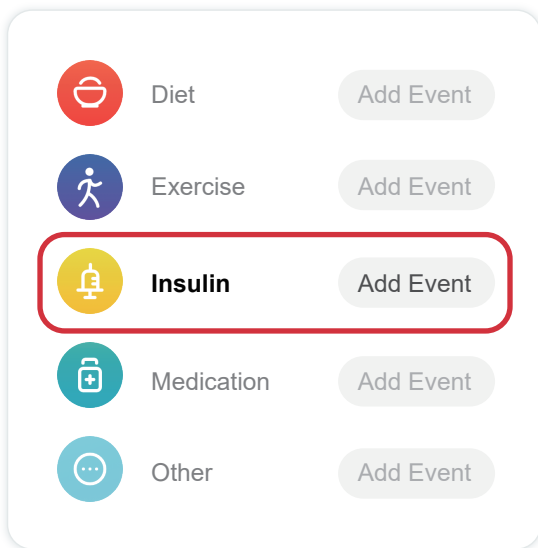
3.4 Events

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

You can choose your insulin type – Rapid acting, Rapid-acting inhaled, Regular/short acting, Intermediate acting, Long acting, Ultra-long acting or Premixed here.

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 iOS 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 Silent Mode

It is used to control all sounds and vibrations. When activated, notifications will not trigger sounds or vibration alerts, without affecting floating windows, notification bars, or pop-up window prompts.

When enabled, the duration of Silence All can be confirmed in the pop-up window, where users can choose the time duration (0.5-6 hours, internal of 0.5 hour). After confirmation of the related risks prompted in

this pop-up window, ① “silence” is displayed on the banner of the home page, which can be closed at any time by clicking and confirming it in the pop-up window; ② in the Personal Settings page, the options for Vibrate Only, Notify Me Above, Notify Me Below, and System Alert are grayed out and unselectable. A Countdown is shown under the Silence All bar, which can be closed at any time by clicking and confirming it in the pop-up window; ③ the floating window or notification bar (when the function is enabled) also needs to display Silence All and Countdown. Select it to enter the APP, and a pop-up window will be displayed to confirm the closing option.

3.5.2 Vibrate Only Mode

It is used to control the sound of all notifications. When turned on, all notifications will be silenced, without affecting floating windows, notification bar, and pop-up window prompts.

When enabled, a second pop-up window will appear for confirmation. After confirmation, the sound settings for Notify Me Above, Notify Me Below, and System Alert will be grayed out and cannot be adjusted.

3.5.3 Override Do Not Disturb Mode

iOS system: It is used to control Urgent Low Alert and glucose changing rapidly alert to always play sounds even when the phone is muted or in Do Not Disturb mode. These alerts will be displayed on the Lock Screen. Enabling this feature requires obtaining permission from the phone's system.

Android system: It is used to control all alerts to always play sounds even when the phone is muted or in Do Not Disturb mode. However, the specific implementation method may vary across different phone models and Android platform systems.

3.5.4 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 necessary, you can also turn off the sound or vibration of the alert.

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:

- 6 vibrations and 6 sound alerts when the glucose level reaches the lower target limit;
- 2 vibrations and 2 sound alerts every 3 minutes when the glucose level is within the lower target limit and steady;
- 3 vibrations and 3 sound alerts every 3 minutes when the glucose level is within the lower target limit and falling slowly;
- 6 vibrations and 6 sound alerts every 3 minutes when the glucose level is within the lower target limit and is falling rapidly;
- Continuous vibrations and sound alerts with a pop-up to be confirmed by the user when the glucose level is within the lower target limit and falling rapidly.

High Alert

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

What you hear, feel, and see:

- 6 vibrations and 6 sound alerts when the glucose level reaches the upper target limit;
- 2 vibrations and 2 sound alerts every 3 minutes when the glucose level is within the upper target limit and steady;
- 3 vibrations and 3 sound alerts every 3 minutes when the glucose level is within the upper target limit and rising slowly;
- 6 vibrations and 6 sound alerts every 3 minutes when the glucose level is within the upper target limit and rising rapidly;
- Continuous vibrations and sound alerts with a pop-up to be confirmed by the user when the glucose level is within the upper target limit and rising rapidly.

Bluetooth Disconnection 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, Bluetooth Disconnected Alert cannot be turned off. You can only turn off the sound by turning on DND mode or turning off System Alert. The vibration cannot be turned off, and 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. and if that does not work, turn Bluetooth off and on. Wait 10 minutes, and if this still does not work, restart the mobile device and reopen the iCan Health APP.

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

3.5.3 Customizing Your Alerts

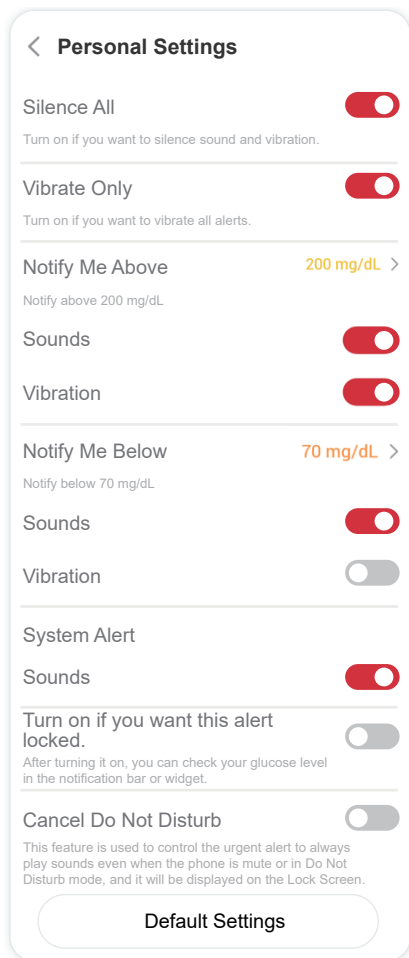
How you set up your alerts can help you reach your diabetes management goals. Work with your HCP to come up with the best alert customization for you and your goals.

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."**

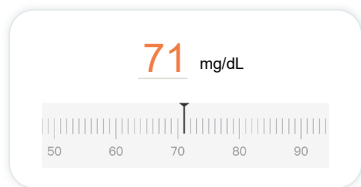
c. Tap the alert level to be changed.



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 60 mg/dL (3.3 mmol/L) and 100 mg/dL (5.6 mmol/L).



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

Notify Me Below

70 mg/dL >

Notify below 70 mg/dL

Sounds

☒

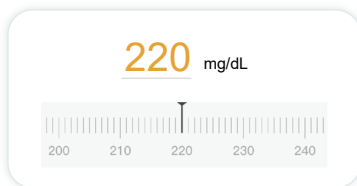
Vibration

☐

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 level rises above 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 vibration for this alert. Sound and vibration will match your mobile device settings.

Notify Me Above

200 mg/dL >

Notify above 200 mg/dL

Sounds

☒


Vibration

☒


3.6 iCan Access

Use iCan Health APP's "iCan Access" feature to let up to 10 friends, family, or another trusted caregivers view your glucose information. You can give them access to access 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 Health 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 Health 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 and then tap **"Send Invitation"**

 **Review Invitation**

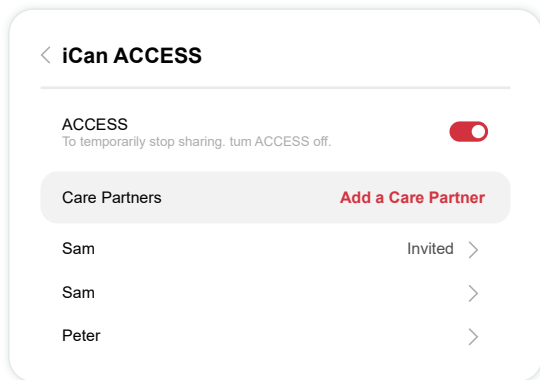
Urgent Low	On
------------	----

Notify Me Above	200 mg/dL
Notify above 200 mg/dL	
Sounds	On
Vibration	Off

Notify Me Below	70 mg/dL
Notify below 70 mg/dL	
Sounds	On
Vibration	Off

3.6.2 Edit Status

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



3.7 My Practices

Using the "My Practices" feature of the iCan Health APP, users can share data with healthcare professionals or teams to receive professional health guidance. Authorized professionals or teams can view, export, and share the patient's basic information and blood glucose reports. Users can proactively add professionals or teams, accept or decline invitations from professionals or teams, and remove those who have been authorized.

3.7.1 Invite “Care Partner”

Go to **Settings > My Practices**, and add healthcare professionals or teams by entering their IDs. Healthcare professionals or teams do not need to download the iCan Health APP on a mobile device; they can simply use the iCan Review APP in a browser. After the professionals or teams send an authorization request, users can accept or decline the invitation in My Practices. Users can also remove professionals or teams from the authorization list once they have completed their authorization.

3.7.2 View Blood Glucose Report Generated by Authorization Object

Users can view reports generated by authorized healthcare professionals or teams in the iCan Review APP, including continuous glucose evaluation reports and AGP reports.

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

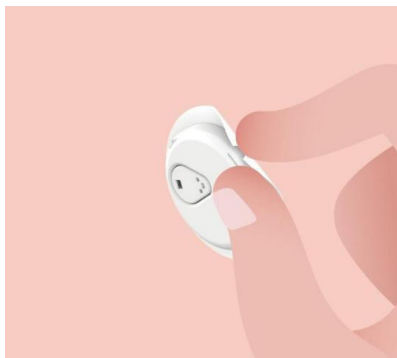
After 15 days, the CGM session will automatically stop. In the APP, you will see a notification indicating that the session has ended. Once the session has stopped, you should remove the sensor and tap **"OK, Change New Sensor"** to start a new CGM session.

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 iCan Health APP, tap the **"Setting"** button, choose **"End the Monitoring"**, and 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 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: iCansupport@sinocare.com

Web: iCan-cgm.com

A.1. Sensor Issues

Things to Examine / Questions to Ask	Solutions
Insertion site is red, allergic, or painful	<p>Change the sensor and insert it into a different location.</p> <ul style="list-style-type: none">• 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. <p>Caution: Skin reaction may appear sometime after the first time using the device. If you continue notice skin allergies around or under your Sensor, remove the Sensor and stop using the System. If you have a reaction to the adhesive, please contact your healthcare professional before continuing use.</p>
Sensor did not fully insert	<p>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.</p>
Insertion site is bleeding	<p>Please check the site for bleeding, allergic reactions, pain, tenderness, or inflammation, and treat according. If bleeding persists, please remove the sensor, dispose of it as medical waste, and insert a new sensor in different location.</p>

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 2.2 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: iCansupport@sinocare.com
Overpatch or medical tape over the patch.	Too much allergic adhesive tape applied to the user's skin may cause allergic reactions. If you notice significant skin allergies 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	<p>Check the following:</p> <ul style="list-style-type: none">• Whether the serial number on the transmitter is consistent with the first 8 digits of the SN code on the Sensor Pack (see Section 2.3 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: <p>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: iCansupport@sinocare.com</p>
Current abnormality warning	<p>In the monitoring process, if the current is abnormal, the current abnormality warning will be given. Please contact Customer Care Email: iCansupport@sinocare.com</p>

A.3. iCan Health APP Issues

Things to Examine/ Questions to Ask	Solutions
Your mobile device can not download the iCan Health 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	<ul style="list-style-type: none"> 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. <p>Check to make sure the HOME screen shows a Bluetooth connection signal icon on the upper right.</p>
Data missing on the trend chart	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 iCan Health APP. Make sure that the APP is in progress.
Signal Loss	<p>Keep your transmitter and mobile device within 6 meters of each other, ensuring there are no obstacles in between.</p> <p>If that does not work, turn Bluetooth off and on. Wait for 10 minutes.</p> <p>If that does not work, restart the mobile device and reopen the iCan Health APP. Wait for up to 30 minutes. System may correct problem itself. If not, then contact Customer Care Email: iCansupport@sinocare.com</p>
Home screen shows Low or High instead of value	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: iCansupport@sinocare.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 check 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	<ul style="list-style-type: none">• Before preparation for use, keep it in the sterile packaging and do not open the package• Do not use if it has expired
Transmitter	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• After apply the sensor 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 the transmitter with a hair dryer, as the heat may damage it.

C.2. Storage and Transport

Store at temperatures between 2°C-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 iOS and Android mobile device.

	Screen Usage Time	Screen Usage Time has been stopped and APP Limits can temporarily disable apps. You can: <ul style="list-style-type: none">• Turn off Downtime and APP Limits or Add iCan Health 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: <ul style="list-style-type: none">• 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 iCan Health 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: <ul style="list-style-type: none">• Follow in APP instructions, or go to Settings, find DND Permission or DND Access, choose iCan Health APP, tap Allow DND, and tap Allow.
	Low Power Mode	Low Power Mode may prevent the iCan Health APP from running in the background. For iOS, you can <ul style="list-style-type: none">• Go to Settings, tap Battery, and turn Low Power Mode off.
	Battery Saver Mode	For Android, you can: <ul style="list-style-type: none">• Go to Settings, and turn Battery Saver Mode off, or choose the highest battery performance on certain phones.
	Device Bluetooth	Your iCan Health APP uses Bluetooth to connect with your transmitter. You must keep your phone Bluetooth turned on to get alerts and sensor results. You can: <ul style="list-style-type: none">• Go to Settings, find Bluetooth, and turn it on.
	App Bluetooth Permission	iOS requires you to give the iCan Health APP permission to use Bluetooth. You must keep Bluetooth Permission turned on for the iCan Health APP to work.

	<p>Notifications Permission</p>	<p>Notifications let you get alerts on your phone. If notifications for the iCan Health APP are off, you will not get any alerts. We recommend turning iCan Health APP notifications on. On iOS 15 and above, do not add the APP to Scheduled Summary.</p> <p>You can:</p> <ul style="list-style-type: none"> Go to Settings, choose iCan Health APP, tap Notifications, turn Allow Notifications on.
	<p>Background App Refresh</p>	<p>Background APP Refresh allows the iCan Health APP to continue running in the background. If Background APP Refresh is turned off, your iCan Health APP alerts may be delayed.</p> <p>You can:</p> <ul style="list-style-type: none"> Go to Settings, find iCan Health APP, and turn Background APP Refresh on.
	<p>Focus Mode</p>	<p>On iOS 15 and above, the Focus feature will silence alerts and notifications for chosen APPs. If you add iCan Health APP to any Focus mode, your iCan APP alerts may be delayed.</p> <p>You can:</p> <ul style="list-style-type: none"> Not use Focus modes For iOS, go to Settings, find Focus, choose a Focus mode, add iCan Health APP as an Allowed APP, and repeat for each Focus mode. For Android, go to Settings, find Digital Wellbeing, and confirm iCan Health APP is not in the Distracting APPs list. For Android, when you use CGM, in order to receive the pop-up alerts in time and experience all functions of iCan Health APP, please do not turn on Child mode on your Android phone.
<p>Location</p>		<p>Location must be turned on to use Bluetooth. If Location is off, you will not get alerts, or sensor results.</p> <ul style="list-style-type: none"> 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 iCan Health APP, tap Location Permission, and choose Allow All the Time. Android 9 and below: Go to Settings, find iCan Health APP, tap Location Permission, and turn it on.
<p>App Pause</p>		<p>On Android 10 and above, Pause temporarily disable APPs. Using Pause with the iCan Health APP stops all alerts, and sensor results.</p> <p>You can:</p> <p>Tap the CGM APP icon on the desktop or in the APP drawer, and tap Uncaused APP.</p>

Make sure your display devices is online	<p>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.</p> <p>Sharing your glucose data to others also requires your display devices online, or you cannot share, which may cause inconvenience.</p>
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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 Health) 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 CGM performance via three clinical studies. One study included 60 adults age 18 years and older (Study 1), one study included 78 pediatric participants whose body weight not less than 10.0 kg and age 2 to 17 years old (Study 2) and one included both adult and pediatrics (Study 3). The participants all had type 1 or type 2 diabetes.

Regarding Study 1 and Study 2, 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 15 minutes with a laboratory reference method, Yellow Springs Instrument 2900D Biochemistry Analyzer (Study 1) and EKF Biosen C-Line Glucose and lactate measurement (Study 2) .

Regarding Study 3, participants aged 12 years and older wore devices for up to 15 days on their arm. Each participant attended up to three clinical session during the beginning, middle, or end of the 15-days wear period to have their venous blood glucose measured every 15 minutes with a laboratory reference method, Yellow Springs Instrument 2300 Stat Plus Glucose and Lactate Analyzer (YSI). The iCan CGM device was compared to the laboratory reference method to evaluate accuracy in participants age 2 years and older.

Accuracy

The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference.

Performance Metrics	Adult (Abdomen)	Adult (Arm)	Pediatrics (Abdomen)	Pediatrics (Arm)	Notes
Overall Accuracy	8.71%	9.4%	Left: 8.30% Right: 8.89%	8.6%	Mean ARD% (MARD), 36–450 mg/ dL (2.0–25.0 mmol/L) (% average absolute difference versus reference glucose across the range of glucose levels)

Potential Clinical benefits

Some potential benefits of using your iCan i3 CGM System are

- Helped with glucose level control
 - Used iCan CGM system to make treatment decisions without the need for fingerstick test.
 - Provided hypoglycemia and hyperglycemia alerts, including low glucose level alert or high glucose level alert as well as glucose level falling rapidly alert or glucose rising rapidly alert, to help control glucose level.
- Potential to help improve diabetes management
 - Provided glucose level trends, glucose level charts and 15-day glucose level reports to help self-manage diabetes.
 - Shared glucose level data with caregivers and healthcare providers via iCan Health App.

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 mmol/L~25.0 mmol/L)
Sensor life	Up to 15 days
Shelf life	Up to 18 months
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	4.99 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	700 hPa-1060 hPa
Shelf life	Up to 18 months
Release Version	V01

The iCan Health 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 use the iCan Health by connecting to networks, please stop the app once you find such risks and contact Customer Care Email: iCansupport@sinocare.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 Health APP on a jailbroken (iOS) 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. The complete text of the declaration of EU conformity is available at https://uk.icancgm.com/wp-content/uploads/2024/03/RED-Declaration-of-Conformity.pdf .

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
	Date of manufacture
	Use-by date
	Serial number (SN code)
	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
	Sterilized using irradiation
	Single sterile barrier system

	Temperature limit
	Humidity limit
	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 instruction for use

	Keep Away from sunlight
	Keep dry
	Bluetooth
	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 instruction for use
	Indicates the entity importing the medical device into the locale
	Packing box made of non-corrugated cardboard, recyclable

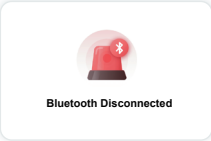



Attachment F: Alerts Vibrations and Sounds

F.1 Glucose Alerts

Screen	Description
<div><p>Urgent Low Alert</p><p>Your glucose level is currently 53 mg/dL, which is below the Set Urgent Low level of 55 mg/dL. Your glucose level has been in the danger range. Please pay urgent attention to control your glucose level.</p><p>Confirm</p><p>Remind me later</p></div>	<p>Notify when the result is below the default low glucose level (default is 55 mg/dL)</p>
<div><p>Glucose Rising Rapidly Alert</p><p>Your glucose level is currently 216 mg/dL, which exceeds the Set High level of 200 mg/dL. Your glucose level is rising rapidly. Please pay attention to your glucose level.</p><p>Confirm</p><p>Remind me later</p></div>	<p>Rise rate alert.</p> <p>Notify when the glucose result is above the High Alert level and rising rapidly.</p>

<p>Glucose Falling Rapidly Alert</p> <p>Your glucose level is currently 60 mg/dL, which exceeds the Set Low level of 70 mg/dL. Your glucose Level is Falling rapidly. Please pay attention to your blood glucose.</p> <p>Confirm</p> <p>Remind me Later</p>	<p>Fall rate alert.</p> <p>Notify when the glucose result is below the Low Alert level and falling rapidly.</p>
<p>✕ High Glucose Alert ></p>	<p>Notify when the glucose result is above the High Alert level</p>
<p>✕ Low Glucose Alert ></p>	<p>Notify when the glucose result is below the Low Alert level.</p>
<p>✕ Out Of Range Alert ></p> <p>02/22/2021 09:20 AM ⓘ 80 th</p> <p>HIGH</p> <p>-- mg/dL</p>	<p>Notify when the glucose result is above result range (default is 450 mg/dL)</p>
<p>✕ Out Of Range Alert ></p> <p>02/22/2021 08:50 AM ⓘ 80 th</p> <p>LOW</p> <p>-- mg/dL</p>	<p>Notify when the glucose result is below result range (default is 36 mg/dL)</p>

F.2 System Alerts

Screen	Description
 <p>Bluetooth Disconnected</p>	<p>Notify when the transmitter and mobile device Bluetooth connection is off</p>
<p>Fail to Pair</p> <ol style="list-style-type: none"> 1. Please make sure device assembly is correct. 2. Keep smart device within 6 meters of transmitter. <p>Back to Scan</p> <p> Help</p>	<p>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.</p>
<p> Battery low reminder </p>	<p>Transmitter battery low alert.</p>

F.3 Abnormal Alert

Screen	Description
<p>No Sensor Readings</p> <p>You will not receive alerts, alarms or sensor glucose readings until you replace your sensor. Please remove this sensor and replace with a new sensor.</p> <p>Contact Customer Service</p> <p>Sensor Removal Instructions</p> <p>Close</p>	<p>Notify when there is no sensor reading or glucose reading for a while.</p> <p>Replace it with a new device. Or use your BG meter during the transition period. If needed, please contact your Healthcare professional.</p>
<p>Device abnormality reminder</p> <p>Your device is abnormal and unusable, please replace with a new device. If necessary, please contact customer service.</p> <p>Confirm</p>	<p>Notify when the sensor does not produce electrical signal for a while.</p> <p>Replace it with a new device. Or use your BG meter during the transition period. If needed, please contact your Healthcare professional.</p>
<p>Sensor abnormal reminder-A</p> <p>Your device's sensor has encountered an abnormality. Please check if the sensor is inserted successfully or contact customer service for assistance.</p> <p>Contact Customer Service</p> <p>Close</p>	<p>Notify when the sensor cannot produce electrical signal for a while during sensor warmup period.</p>

<p>Sensor abnormal reminder-B</p> <p>Your sensor has encountered an error. Please check to see if your sensor has become detached. You may need to replace this sensor.</p> <p>Contact Customer Service</p> <p>Close</p>	<p>Notify when the sensor produces abnormal electrical signal for a while after warmup period.</p>
<p>Sensor abnormal reminder-C</p> <p>Your device's sensor has encountered an abnormally low value. Please confirm with a fingertip blood test. If a significant difference in glucose readings persists, please consider to replace this sensor with a new one.</p> <p>Contact Customer Service</p> <p>Sensor Removal instructions</p> <p>Close</p>	<p>Notify when the sensor produces abnormal low value.</p>
<p>Sensor abnormal reminder-D</p> <p>Your device's sensor has encountered an abnormally high value. Please confirm with a fingertip blood test. If a significant difference in glucose readings persists, please consider to replace this sensor with a new one.</p> <p>Contact Customer Service</p> <p>Sensor Removal instructions</p> <p>Close</p>	<p>Notify when the sensor produces abnormal high value.</p>

<p>Sensor Starts Fail</p> <p>Do not remove the sensor. Try to scan the QR Code again or enter the SN manually.</p> <p>Confirm</p>	<p>Sensor starts anomaly warning</p>
<p>Temperature Alert</p> <p>Your device's operating temperature is below the lower limit. Please use it within the required temperature range of the device.</p> <p>Confirm</p>	<p>Low operating temperature alert</p>
<p>Temperature Alert</p> <p>Your device's operating temperature is above the upper limit. Please use it within the required temperature range of the device.</p> <p>Confirm</p>	<p>High operating temperature alert</p>

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).



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