ENGLISH

GlucoMen® iCan CGM o3

USER GUIDE

CE 0197

A.MENARINI diagnostics

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LEGAL DISCLAIMER

IMPORTANT SAFETY INFORMATION

Before you use the GlucoMen® iCan Continuous Glucose Monitoring (CGM) System, read the instructions included in the Instruction for Use.

The Instruction for Use include important safety information, and Instruction for Use. Discuss with your healthcare professional about how you should use the information from your iCan CGM to help manage your diabetes.

Failure to use the iCan CGM System and its components 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 and/or making a treatment decision that may result in injury. If your glucose alerts and result from the iCan 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 CGM should be reported to A.Menarini Diagnostics and the competent authority of the Member State in which you are established or Swissmedic.

Getting started with GlucoMen ® iCan Continuous Glucose Monitoring System (CGM)

GlucoMen® iCan Continuous Glucose Monitoring System (Model: o3, hereafter referred as iCan 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.

These Instruction 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: www.glucomen.com

In-App Videos :

There are In-App Videos to 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 Reference 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 find both guides at www.glucomen.com

SECTION 1: SYSTEM OVERVIEW

- System Description
- Intended Purpose
- User Safety

1.1 System Description

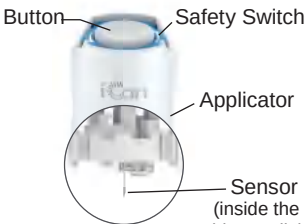
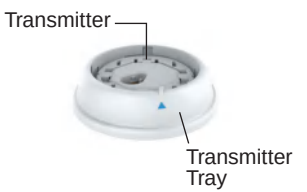
Thank you for choosing the GlucoMen® iCan Continuous Glucose Monitoring System (Model: o3, hereafter referred as iCan CGM). The iCan CGM System consists of three main components: a Sensor Pack, a Bluetooth Low Energy (BLE) Transmitter Pack, and a Mobile Application (APP).

The iCan 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.

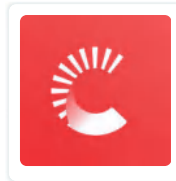
The iCan CGM also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the system results should be based on the glucose trends and several sequential results over time.

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	The Sensor-Applicator helps you insert the Sensor under your skin. It contains a needle which is used to puncture the flexible sensor tip into the skin but will be retracted into the applicator 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 to take the transmitter out of the Tray. See **Chapter 2** for details on how to use your Transmitter.

1.1.2 The iCan CGM APP



The iCan CGM APP serves as the display for the iCan CGM and supports Android and iOS devices (mobile devices). The APP is available on Google Play (Android), App Store (iOS), and Huawei AppGallery. To see a list of compatible mobile devices, visit www.glucomen.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

GlucoMen® iCan Continuous Glucose Monitoring System (iCan CGM 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 iCan CGM 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 iCan CGM System results should be based on the glucose trends and several sequential readings over time.

The iCan CGM System can be used in conjunction with a smart device 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 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 CGM results may be inaccurate in these populations.
- No MRI/CT/Diathermy

  Do not wear your iCan 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 CGM has not been tested in those situations. The magnetic fields and heat could damage the components of the iCan CGM, which may cause it to display inaccurate sensor glucose results or may prevent alerts. Without iCan 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 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 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 CGM if you are pregnant, on dialysis, implanted with a pacemaker or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. iCan CGM results may be inaccurate in these populations.
- 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 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 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 the improper 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 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 (Year-Month) 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 CGM to insect repellent and sunscreen. Contact with these skin care products may cause damage to your CGM.
- Do not wear the iCan 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 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 lock engaged before placing the sensor-applicator against the skin. If you unlock the safety lock first, you might unintentionally press the button on the applicator, potentially causing injury to yourself.
  - 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:
  - On abdomen, 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 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 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 CGM.

- Bathing, Showering and Swimming

  The sensor can be worn while bathing and showering but not hot tubs, 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 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 incorrect 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 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.

The iCan CGM system does not provide the following:

- Alcohol wipes.
- Your Blood Glucose Meter.

Familiarisation of iCan 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.

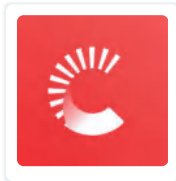
User Requirement: Only diabetic patients or their caregivers who can read, understand and follow the iCan CGM Instruction for Use and Quick Start Guide can use the device safely. The caregiver must carry out the entire procedure for children 2 to 11 years of age.

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.

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.

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, 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 readings.
- Notification 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 ff 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 sounds of any notifications, including urgent low alert.
- Keep the volume of the mobile device 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 www.glucomen.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

If you are new to the iCan CGM APP, you need to create a new iCan account follow 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 instructions 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 a 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 thy **“System Settings”** button, 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

The iCan CGM is intended for the use on the abdomen only.

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

CAUTION: The caregiver is responsible for sensor insertion for children 2 to 11 years of age.

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 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”.

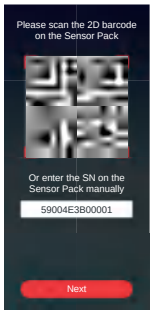
Step 1: APP Setup

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 CGM or your glucose result could be incorrect.

Step 4: Pairing

The APP will instruct you on how to attach Sensor to the Transmitter. You can follow the in-APP instructions on 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

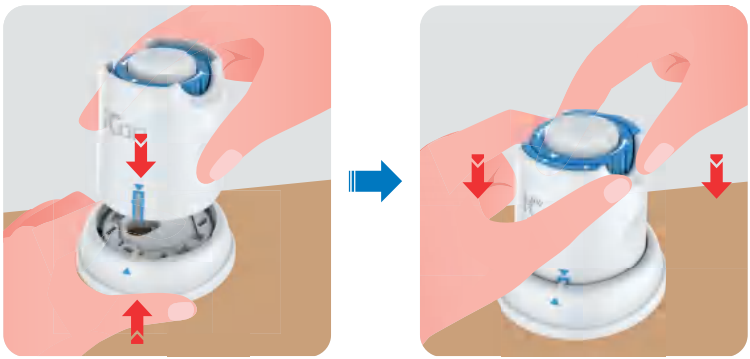
Step 1: Open the Sensor Pack

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.

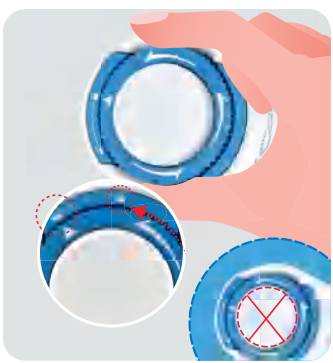
WARNING: The Sensor-Applicator contains a needle. Do NOT touch inside the Sensor-Applicator or put it back into the Sensor Pack.

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 and cannot turn further.



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

- Lift the Sensor-Applicator out of the Transmitter Tray.

- Now it's ready to apply the sensor.

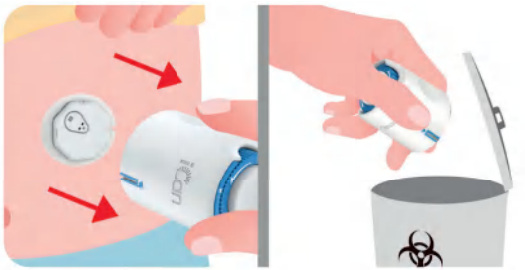
Step 3: Insert the Sensor

CAUTION: The caregiver is responsible for sensor insertion for children 2 to 11 years of age. Refer to step 3.1, sensor insertion steps 3.2, 3.3 and 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.

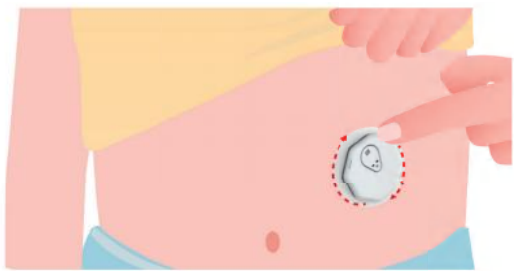
- Step 3.2: Press down the button in the middle to apply the CGM Sensor. You will hear a click sound, that means the insertion is completed.

- Step 3.3: Gently move the Applicator vertically away from the 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.



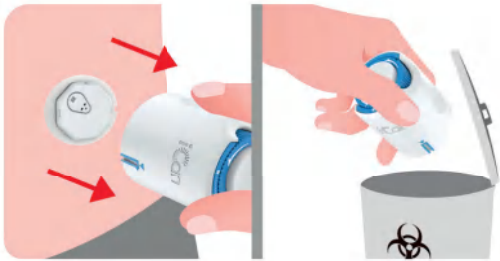
CAUTION: Once inserted, the sensor is waterproof up to 2.5 meters, but the display device (smartphone) may not be. If the child is in or near water, the display device may need to be kept closer (less than 6 meters) to get sensor readings. If the sensor is under water, the caregiver may not be able to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

For patients aged 12 years and older, you can insert the sensor yourself. Please refer to steps 3.5, 3.6, 3.7 and 3.8 for sensor insertion.

- Step 3.5 : Place the sensor applicator on the prepared insertion site and press down firmly.

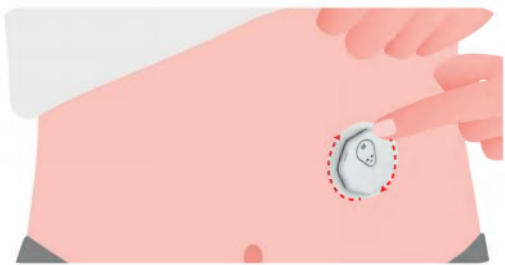
- Step 3.6 : Press the top white button to insert the CGM sensor. When you hear a click sound, the insertion is complete.

- Step 3.7 : Gently move the implant vertically away from the body.



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

- Step 3.8 : Gently press and smooth the sensor tape with fingers to ensure that the sensor is always kept on the body during wear period.



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 underwater, you may not be able to obtain a reading until you come out of 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 Session”** 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.

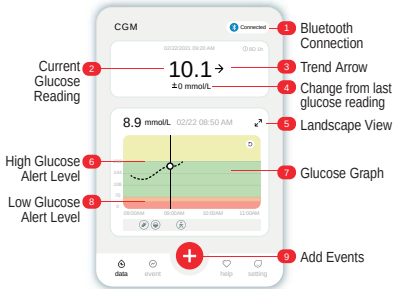
CAUTION: Keep your CGM Sensor and mobile device within 6 meters with no obstructions (i.e. walls or metal) between them. Otherwise, they might not be able to communicate. If water is between your Sensor and the mobile device – for example, if you are showering or swimming – keep them closer to each other.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

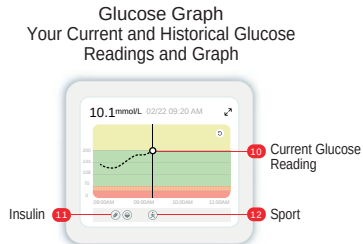
SECTION 3: UNDERSTAND YOUR iCan CGM RESULTS

- 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.





3.2 Glucose Information

1 Sensor Glucose Result

Starting at the top, the number shows where your sensor glucose is now in millimol per liter (mmol/L). It means:

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

9.7 mmol/L Black: Within the target range

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

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

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

When your most recent CGM result is above 25.0 mmol/L or below 2.0 mmol/L, you will not get a number. Instead, your display device will display HI (High) or LO (Low). If you do not have a number, use your blood glucose meter to measure your glucose. These HI or LO will be displayed as 25.0 mmol/L or 2.0 mmol/L 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 0.16 mmol/L per 3 minutes.

Trend Arrow: Rising or Falling slowly ↗ ↘

Glucose is changing slowly, more than 0.16 mmol/L or up to 0.33 mmol/L per 3 minutes.

Trend Arrow: Rising or Falling quickly ↑ ↓

Glucose is changing quickly, more than 0.33 mmol/L or up to 0.5 mmol/L per 3 minutes.

Trend Arrow: Rising or Falling rapidly ⇈ ⇊

Glucose is changing rapidly, more than 0.5 mmol/L per 3 minutes.

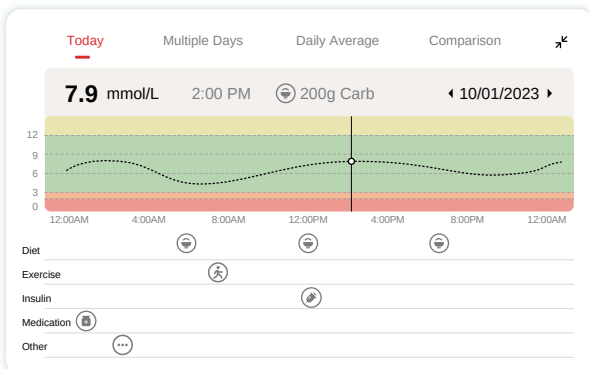
3 Trend Graph

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, 7.9 mmol/L is the glucose level at 2:00 PM).

The numbers on the y axis show glucose levels in mmol/L.

The numbers on the x axis 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.

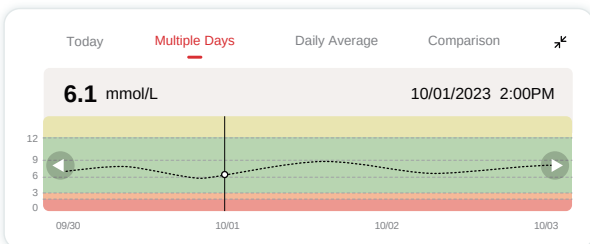


The horizontal lines show your High and Low Alert levels. Your glucose is:

- 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.

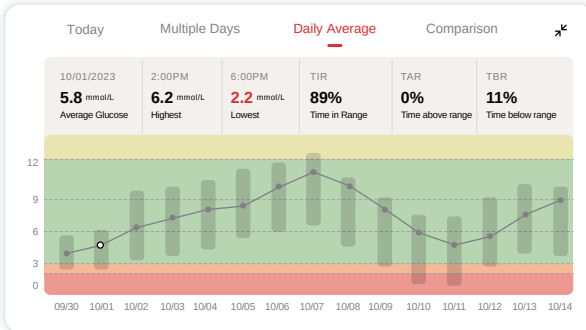
When the transmitter reconnects with the display device after a Signal Loss or similar issue, up to 360 hours of missed CGM results can fill in on the graph.

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 MCG 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 reached the highest and lowest on the selected day.

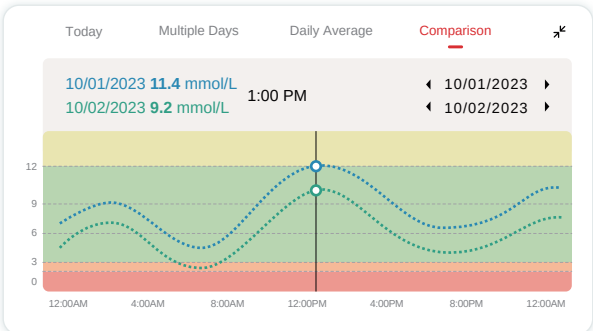
C. Time in Range (TIR) is the percentage of time that your glucose levels are in target range. CGM APP default in-target range is 70-180 mg/dL (3.9-10.0 mmol/L), which may not be the alert range you set for high and low glucose levels of CGM. The in-target range cannot be modified.

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 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. 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 fr omyour 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 a glucose overview report, access event record assistance (such as sensor insertion instructions and Instruction for Use), and configure 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 CGM System user’s instructions including the “Quick Start Guide”, “Product Tutorials”, “Instruction for use” and other device information.

3.4 Events

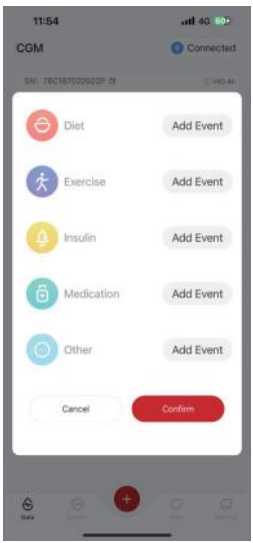
An event in an action or situation that affects your glucose levels. With the iCan CGM System you can track your daily events so you can reflect on their effect on your glucose trends. Once entered into the APP, events can be viewed in the home screen as well as in the reports.

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 results reaches your pre-set alerts level, your mobile device will advise you by means of visual, vibrational or audible notifications, depending on the kind of alert and on your mobile device notification settings.

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 your 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 Silence All Mode

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

When enabled, the duration of Silence All can be confirmed in the pop-up window (which can be set to 8 hours at most). The user will be prompted about relevant risks. After confirmation, within the effective time range:

① The silence countdown is displayed on the banner of the home page. Tapping it will jump to the Personal Settings page to disable Silence All; ② The settings for Notify Me Above, Notify Me Below, and device alert on the Personal Settings page will only be enabled after Silence All is disabled; ③ The silence countdown is displayed in the floating window or notification bar. Tapping it will enter the Personal Settings page of the APP to disable Silence All.

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 and vibration of Notify Me Above, Notify Me Below, as well as the device prompt tone, cannot be adjusted and hidden.

3.5.3 Override Do Not Disturb Mode

If you use your phone's "Do Not Disturb Mode" setting or have your phone silenced, and want to always receive Urgent Low Alert and other important glucose level alerts, make sure that "Override Do Not Disturb Mode" is enabled in the APP.

If you want the alerts to follow your phone's silence settings for Urgent Low Alert and other important glucose level alerts, and remain silent when "Do Not Disturb Mode" is enabled, you can disable the "Override Do Not Disturb Mode" in the APP.

To enable the "Override Do Not Disturb Mode" on iOS, you need to obtain the permissions of your phone system.

After enabling "Override Do Not Disturb Mode" in the Android system, 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 turned off.

You can only turn off the sound by turning on DND mode or turning off System Alert. The vibrate cannot be turned off, 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.

3.5.5 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.

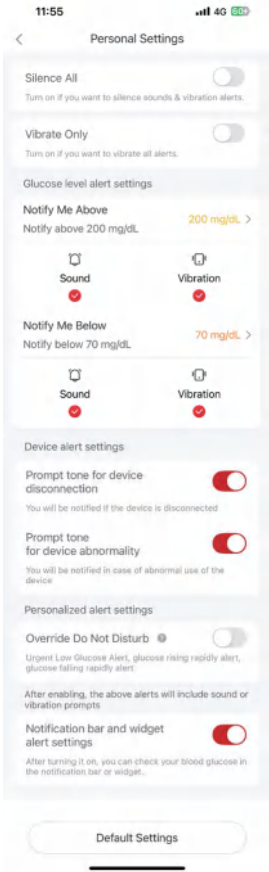
The default glucose alert settings are 11.1 mmol/L (high) and 3.9 mmol/L (low).

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”**;

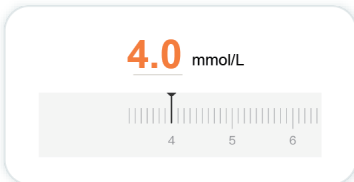
C. Tap the alert level to be changed.



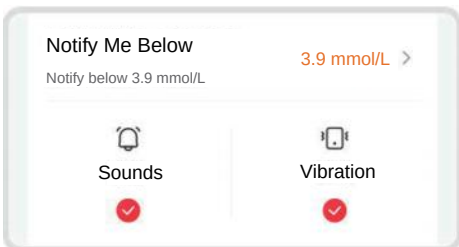
Low Glucose Alert

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 3.9 mmol/L. Tap to change this value between 3.3 mmol/L and 5.6 mmol/L.



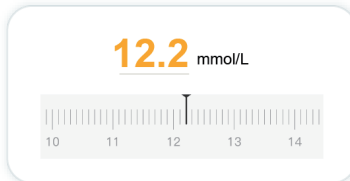
Choose the sounds and vibration for this alert. Sounds and vibration will match your mobile device settings.



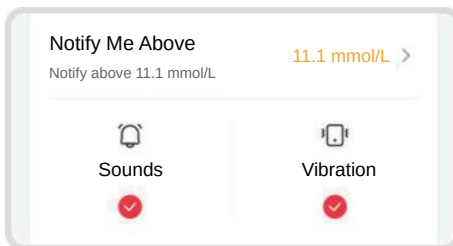
High Glucose Alert

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 level rises above the pre-set level, which is initially set to 11.1 mmol/L.
Tap to change this value between 6.5 mmol/L and 25.0 mmol/L.



Choose the sounds and vibration for this alert. Sounds and vibration will match your mobile device settings.



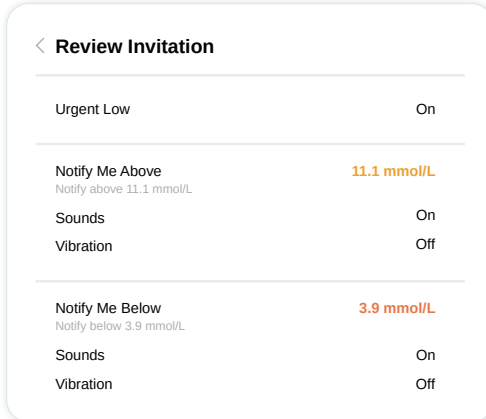
3.6 iCan Access

Use iCan CGM APP's "iCan 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"

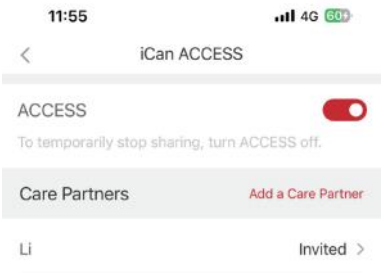
Your "Care Partner" does not need to have the iCan CGM APP on their mobile devices. They only need to download the iCan REACH APP.
To invite someone to follow you, go to **Settings** > **iCan ACCESS**.
Then follow the instructions on the APP screens. You can invite them by entering their name and email.

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 iCan 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 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 professional 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 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 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 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 **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.

A.1. Sensor Issues

Things to Examine / Questions to Ask	Solutions
Insertion Site is red, allergic, 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 this areas it may decrease the flow interstitial fluid or the sensor may kink. 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.
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	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.

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.
Overpatch or medical tape over the patch	The use of overpatch or medical tape over the sensor may cause skin reactions. 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: • 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; 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.
Current abnormality warning	In the monitoring process, if the current is abnormal, the current abnormality warning will be given. If assistance is needed, please contact Customer Care.

A.3. CGM APP Issues

Things to Examine / Questions to Ask	Solutions
Your mobile device can not download the CGM APP	Check www.glucomen.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 glucose 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, and the glucose chart will be completed.
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 mobile device within 6 meters of each other, ensuring there are no obstacles in between. 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 this does not work, contact Customer Care.
Home screen shows Low or High instead of value	System is working as it should. Use your Blood Glucose Meter and focus on your low blood glucose or high blood glucose. When the value is between 2.0 and 25.0 mmol/L, the home screen will display the value instead of Low or High.

Attachment B: Security and Air Travel

For help with your iCan CGM System, contact Customer Care.

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 CGM without worrying about damaging your CGM components:

- Hand-held metal detector;
- 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-held metal detector, 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 not use if damaged; • Do not spill liquid or soak it with water; • Do not use if Transmitter has expired.
Sensor	• After applying the sensor and wearing it on the body, do not use lotions, sunscreen, insect repellent, or similar items on

No cleaning methods are recommended or tested for the applied iCan CGM. Only wipe with a clean, dry cloth. Do not dry transmitter with a hair dryer, the heat of the hair dryer 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;
- You 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 system mobile device.

	Screen Usage Time	Screen Usage 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 Setting, 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 readings. You can: • Go to Settings, find Bluetooth, and turn it on.
	App Bluetooth Permission	iOS 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 readings. • 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 Setting, 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 sensors 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 to be 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 CGM performance via two clinical studies. These studies included 60 adults (age 18 years and older) and 78 pediatric participants

(body weight not less than 10.0 kg and age 2 to 17 years old). The participants all had type 1 or type 2 diabetes. They wore devices for up to 15 days on their abdomen.

Each participant attended at least one clinical session during the beginning (Day 2), middle (Days 7–9), or end (Day 15) of the 15-day wear period to have their venous blood glucose measured every 15 minutes using the laboratory YSI 2900D Biochemistry Analyzer (adult) and EKF Biosen C-Line Glucose and Lactate Measurement devices (children) as reference methods.

The iCan CGM device was compared to the laboratory reference method to evaluate accuracy in participants aged 2 years and older.

Accuracy

The overall accuracy of the iCan 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 CGM MARD of adults with diabetes is 8.71%, meaning it may read 8.71% lower or higher than your blood glucose. For example, if your blood glucose was 15.0 mmol/L, the sensor may read, on average, 1.4 mmol/L lower or higher.

Performance Metrics*	Adult	Children	Notes
Overall Accuracy	8.71%	Left abdomen: 8.30% Right abdomen: 8.89%	Mean absolute relative difference versus across the range of glucose levels, 2.0–25.0 mmol/L.
Clinical Accuracy	100%	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.

Potential clinical benefits

The reference value is the venous plasma glucose value measured using the YSI glucose analyzer (Yellow Springs Instrument).

Some potential benefits of using your iCan CGM System are:

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

D.2. Product Specifications

Sensor	
Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose result range	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	700hPa-1060hPa
Shelf life	Up to 18 months
Release Version	V01

The iCan 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 1.4 GHz 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 are using the iCan CGM by connecting to networks, please stop the app once you find such risks and contact Customer Care.

D.3. Quality of Wireless Communication

Quality of Service for the iCan 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 CGM System is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

D.4. Security Measures

The iCan 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 paths using industry standard SSL format. We take your privacy seriously and provide 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 (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 www.red.menarinidiagnostics.com.

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 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: Symbols

Symbol	Description
	Manufacturer
EC REP	Authorized representative in the European Community/European Union
UK REP	Authorized Representative of the United Kingdom
CH REP	Authorized Representative of Switzerland
	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 ut to a specified pressure
	Type BF Applied Part
REF	Catalogue number
STERILE R	Sterilized using irradiation
	Single sterile barrier system
	Temperature limitation

	**Humidity limitation**
	**Do not reuse**
	**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**
	**Consult the electronic instruction for use**
	**Distributor**
	**Keep Away from sunlight**
	**Keep Dry**
	**Bluetooth**
CE 0197	**This symbol suggests that the CGM has acquired European technical conformity in accordance with (EU) 2017/745**
MD	**Medical device**

UDI	**Indicates a carrier that contains unique device identifier information**
MR	**An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment**
	**Follow instruction for use**
	**Importer**

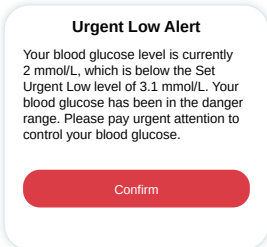
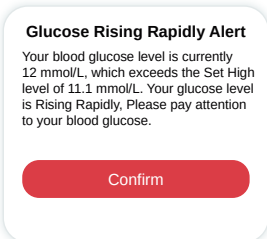
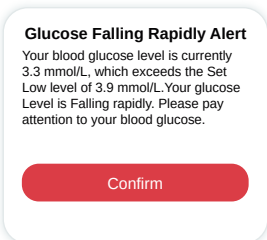
Product Item		Symbol	Description	Separate waste collection
Carton Box			Recyclable Non-corrugated fibreboard	Paper collection
Instruction for Use			Recyclable Paper	Paper collection
Sensor Pack	White seal		HDPE High density polyethylene (Tyvek®)	Plastic collection
	Thermoformed transparent plastic container		Other plastic (PETG)	Plastic collection

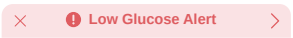
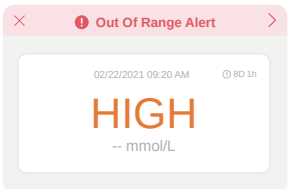
Follow the local regulations for waste management or for the correct recycling of packaging materials.

To know the identification of the packaging material of the products please also visit: www.packagingwaste.menarinidiagnostics.it

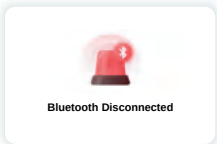
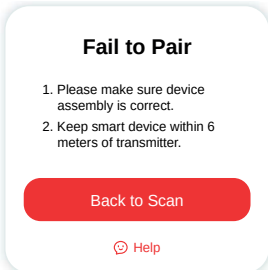
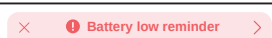
Attachment F: Alerts Vibrations and Sounds

F.1 Glucose Alerts

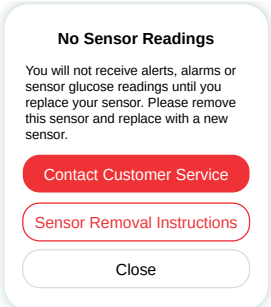
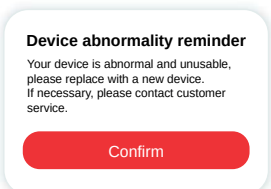
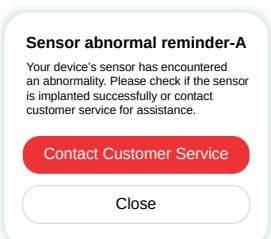
Screen	Description
	Notify when the result is below the default Urgent Low glucose level (default is 3.1 mmol/L)
	Rise rate alert. Notify when the glucose result is above the High Alert level and rising quickly.
	Fall rate alert. Notify when the glucose result is below the Low Alert level and falling quickly.

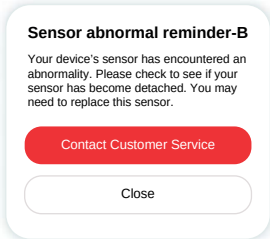
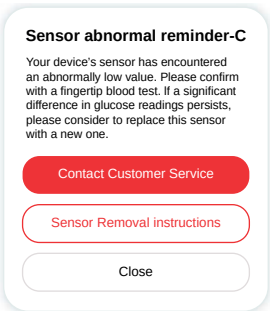
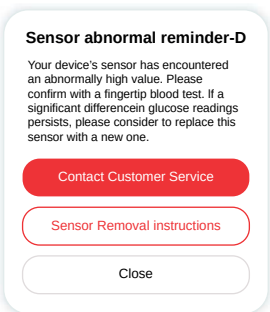
	Notify when the glucose result is above the High Alert level
	Notify when the glucose result is below the Low Alert level
	Notify when the glucose result is above result range (default is 25.0 mmol/L)
	Notify when the glucose result is below result range (default is 2.0 mmol/L)

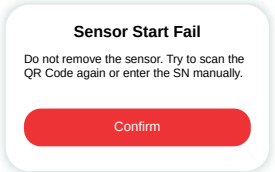
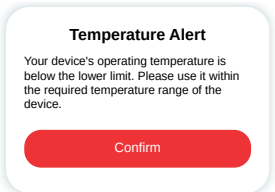
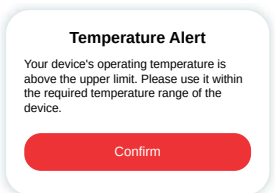
F.2 System Alerts

Screen	Description
	Notify when the transmitter and mobile device Bluetooth connection is off
	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.
	Transmitter battery low alert

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 does not produce 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 after warmup period
	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

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 intestitial 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 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.

mmol/L

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

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