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User manual

CareSens™ Air

15-Day

Continuous Glucose Monitoring System

This manual is intended to help you use CareSens Air correctly.
Please read this manual carefully before using the product, and follow all instructions.

i-SENS, Inc. has carefully prepared the information in this manual to be as accurate as possible.

Note

Make sure to read the user manual before use to ensure correct usage. Failure to use CareSens Air according to the instructions, warnings, and cautions provided may lead to failure to detect severe hypoglycemia or hyperglycemia, or incorrect treatment decisions.

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Contents

Before use

- CareSens Air is intended for people aged 18 years or older who have diabetes or need glucose level management. It continuously monitors glucose concentration in interstitial fluid in real-time. Continuous glucose monitoring calculates the concentration of glucose in the blood by measuring the concentration of glucose in the interstitial fluid. However, when the concentration of glucose in the blood changes, the concentration of glucose in the interstitial fluid changes about 5 to 15 minutes later.
- This product only makes use of personal information which the user has agreed to allow to be collected.
- Contact the manufacturer or visit the website for details of this product.
- In the event of any serious incident with the CareSens Air Continuous Glucose Monitoring System, please report to the manufacturer and the competent authority in your country.

Note

- All standards and regulations mentioned are in effect as of the date this manual was issued.
- i-SENS, Inc. has carefully prepared the information in this manual to be as accurate as possible. However, i-SENS is not responsible for any errors or omissions contained in the manual. i-SENS may change the product described in this manual or any related software applications without notice in order to enhance the product reliability, features, or design.
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Document conventions

Notational conventions

This manual uses the following notational conventions to aid in understanding its content.

Notational conventions	Description
Boldface	Boldface is used to display elements of the graphic user interface, including menus and directories.
' '	Single quotation marks are used to indicate pages, portals, and screens from the graphical user interface.
'Cross-references'	'Cross references' are used to refer to different sections of this document.
Visual aids	Visual aids in the form of graphics, illustrations, or screen captures are used to help the reader understand the text.
Tables	Tables are used to present large amounts of data in an easy-to-read format.

Supplementary descriptions and explanations

You can refer to these for information about exceptions and limitations.

Note
This indicates reference situations to note which can provide helpful information or help you avoid danger when using the product.

Safety Messages

This manual uses the following types of safety messages to alert the user of situations in which they need to take precautions when using the product:

Warning
This marks a potential danger that could result in serious injury or death if not avoided.

Caution
This marks a situation that could result in minor injury or property damage if not avoided.

Definitions of symbols

The following table lists graphical symbols for electrical equipment in medical practice set by the IEC (International Electrotechnical Commission). These symbols not only provide additional information on the product and product use, but also on safety.

Symbol	Description
CE	CE Mark
EU REP	Authorised representative in the European Community/European Union
MD	Medical device
	Caution
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Refer to instruction manual/booklet
	Type BF Applied Part
	Keep away from sunlight
	Keep dry
	WEEE (waste electrical and electronic equipment)
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged and consult instructions for use
IP	Degree of protection against ingress of foreign material or water
STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system with protective packaging outside
	Manufacturer
LOT	Batch code
SN	Serial number
	Use-by date

Safety information

You must read, understand, and strictly comply with the indications, contraindications, warnings and precautions listed in this chapter before using CareSens Air.

Indications for Use

The CareSens Air Continuous Glucose Monitoring System (CareSens Air CGM System) is indicated for continuous monitoring of blood glucose levels via measurement of glucose in the interstitial fluid in persons with diabetes mellitus aged 18 years and older. CareSens Air CGM System is intended to replace standard blood glucose testing for diabetes treatment decisions, unless otherwise indicated. CareSens Air CGM System helps to detect trends such as hyperglycemia and hypoglycemia by providing continuous blood glucose information, to manage changes in blood glucose levels through trend detection and pattern tracking, and to assist in diagnosis and treatment when consulting with medical staff.

Contraindications

- Remove the sensor before an X-ray, MRI, CT scan, radiofrequency ablation, high frequency electrical heat, or high intensity focused ultrasound. Magnetic fields or heat can damage the device, leading to inaccurate glucose level readings or alert errors.
- This product has not been evaluated or approved for the following individuals:
  - Infants and children under 18 years of age
  - Pregnant and breastfeeding women
  - Dialysis patients and critically ill patients

Warnings

- Severe hypotension or shock may result in abnormal measurements. Do not use this product for patients with severe symptoms, as ketoacidosis or a hyperosmolar hyperglycemic nonketotic state may result in abnormally low measurements.
- The sensor must be used according to the guidelines in the user manual and must be attached to the part of the body as indicated in the user manual.
- Wash your hands thoroughly with soap and running water and dry them before attaching the sensor. Wipe the area where the sensor will be attached to the skin with an alcohol swab and dry it completely. Failure to comply may lead to infection.
- Do not use the product if the sensor package has been damaged or opened. This may lead to infection.
- Do not use a damaged or defective sensor. This may lead to infection.
- Attach the sensor to the back of your upper arm. There is insufficient evidence that the sensor operates correctly when attached to another part of the body.
- The sensor should be attached immediately after opening the applicator package to avoid airborne contamination.
- Do not remove the safety cap of the applicator until you are ready to attach the sensor. Failure to comply may lead to infection caused by exposure to bacteria.
- After you separate the safety cap from the applicator, be careful not to face it toward any person.
- Do not press the release button on the applicator until you are ready to attach the sensor.
- If you use an insulin pump, attach the sensor at least 8 cm away from it.
- If a sensor sensing part breaks or disconnects in the process of attaching the sensor, you must check whether the sensing part has remained under the skin. If you cannot see the sensing part with the naked eye, seek medical help. If you experience inflammation, redness, swelling, or pain due to an infection at the site where the sensor was attached, seek assistance from a medical professional.
- If you experience bruising or severe bleeding at the location where the sensor has been attached, stop use and remove the sensor, then consult immediately with a physician or medical professional.
- In the event of bleeding when attaching the sensor, an improperly attached sensor, or abnormal measurements, you must remove the sensor and attach a new one to a different part of the body.
- Choose a new location to attach each new sensor. Continuing to attach new sensors to a previously used location may cause skin irritation or scarring.

Warnings

- The location chosen for insertion must meet the following criteria:
  - It must be at least 8 cm away from an insulin pump infusion set or infusion location.
  - It must not be close to the waistband, tattoos, bone, scars, or irritated skin.
  - It must be a location which will not be bumped, pushed, or pressed during sleep.
- The adhesive tape used to secure the sensor to the skin and the guide needles used to help with sensor insertion may trigger allergic reactions (erythema or edema) or itchiness in some users. If this occurs, remove the adhesive tape and/or sensor immediately and consult a physician or medical professional.
- Keep the desiccant included in the package out of the reach of infants or children.
- Do not eat the desiccant included in the package.
- If the contents of the desiccant get in your eyes, wash them thoroughly with running water right away. You should consult a physician if you experience any problems.
- Swallowing the sensor could result in choking. Please supervise the children so that they do not touch the sensor.
- Blood glucose readings obtained using CareSens Air cannot substitute for the care of a medical professional and cannot be used to diagnose diabetes. They are only intended to provide glucose data to patients in order to help them manage their diabetes, and to assist medical professionals with diagnosis and treatment.
- If you find that the displayed blood glucose level does not accurately reflect your symptoms, you should immediately use a glucose meter to check and make treatment decisions. Take medical action or follow your physician's instructions.
- Be aware of potential variations in sensor performance, especially during the early phase after sensor attachment.
- If you cannot check the real-time blood glucose levels (e.g. during the sensor warm-up period, when a system error occurs, or when the blood glucose trend arrow is displayed as '…'), or if the current sensor glucose reading does not align with your symptoms or expectations, do not make treatment decisions based on these readings. Instead, use a glucose meter to make treatment decisions.
- Caregivers should not make treatment decisions based on data received from the Sens365 app. The blood glucose data shared with caregivers may be delayed and is not real-time, and therefore it is not suitable for making treatment decisions or taking action. This blood glucose data also includes the low or high blood glucose level alerts that are sent to the caregivers. Treatment decisions must be made solely based on the real-time data displayed in the user's app, not the caregiver's app.

Warnings

- If you find that the sensor readings don't accurately reflect your health status, you may align them using a blood glucose meter.
- Do not calibrate if your blood glucose level is changing rapidly (by 2 mg/dL (0.1 mmol/L) or more per minute). This may affect the accuracy of the sensor.
- Do not use a measurement taken from any part of the body (palm, forearm, etc.) other than your fingertip for calibration. The result may be different from one taken by pricking a finger, and this can affect the accuracy of the sensor glucose readings.
- If the result of the finger prick reading is lower than 10 mg/dL (0.6 mmol/L) or higher than 600 mg/dL (33.3 mmol/L), it cannot be used as a calibration value.
- If the calibration value is inaccurate, CareSens Air cannot provide accurate glucose readings. If you notice that the sensor readings do not accurately reflect your health status after calibration, do not make treatment decisions based on CareSens Air.
- To help you make appropriate treatment decisions, adjust your current alert settings to more easily recognizable ones and check your display device frequently to avoid missing alerts.
- Make sure that the volume of your smart device is turned up and not muted. You will not be able to hear alerts if the volume is turned off.
- When another sound device, such as headphones, is connected, alerts will only play through the connected device and not through your smart device's speaker. Make sure that the connected device is properly configured to receive alerts.
- When your smart device or app notifications are set to mute, you will not receive sound or vibration for any alerts. However, you will still receive visual alerts on your smart device.
- Disable your smart device's automatic operating system (OS) updates to manually update the OS each time. Some OS features may affect CareSens Air app settings and your ability to receive alerts. After an OS update, always check your device settings to ensure the CareSens Air app is functioning properly.
- CareSens Air app data may be lost if it is not uploaded to the cloud server.
- If you delete the smart device app while using the sensor, all the data saved by the app will be lost. If you need to delete the app or switch to a different smart device, upload all important data to the cloud server and save a backup file on a separate storage device.
- This product contains a button battery. If swallowed, a lithium button battery can cause severe or fatal injuries within 2 hours. Keep batteries out of reach of children. If you think batteries may have been swallowed or placed inside any part of the body, seek immediate medical attention.

Precautions

- The applicator and the sensor are intended for single-use only and cannot be reused.
- If a skin care product such as sunscreen or insect repellent gets on the sensor, wipe it immediately with a clean cloth. These products may affect the operation of CareSens Air.
- The dedicated sensor, applicator, and user app must be used together to obtain accurate measurements.
- Do not store the sensor in a freezer. It is recommended to store it at a temperature of 5–30 °C.
- The sensor has been sterilized with Ethylene Oxide gas (EO) after packaging. Do not clean the product with water or any other solution before use.
- Do not use an expired sensor.
- Do not repair this product without the authorization of the manufacturer.
- Do not repair, disassemble, and assemble the product on your own.
- Do not use a damaged device. The product may not function normally.
- Do not disinfect the product. CareSens Air has already been sterilized. Failure to follow this instruction may affect product performance.
- This product is composed of highly sensitive electronic components and thus can be easily damaged by improper use. User precautions must be taken when using the device to avoid damage.
- The product is waterproof for up to 24 hours at a depth of 1 meter. Please do not submerge the product deeper than 1 m or longer than 24 hours.
- You can go through Advanced Imaging Technology (AIT) body scanners or metal detectors while wearing the CareSens Air. If you cannot temporarily use your smart device in the security checkpoint area, please measure and manage your blood glucose levels using a blood glucose meter. Please check the latest status of security checkpoints at the airport prior to travel.
- Do not expose the product to direct sunlight. This may affect product life and performance.
- Do not wash the sensor. Using an unsuitable solution could damage the device. When using iOS, do not close the app after connecting the sensor. It will be disconnected from the sensor.
- Avoid contacting the sensor's outer surface for more than 10 minutes in environments with temperatures above 41 °C. This may lead to low-temperature burns.

Precautions

- Vitamin C does not significantly affect blood glucose levels even when consumed orally in excess. However, when administered as an injection (infusion), blood glucose readings may appear higher than they actually are, and the change in blood glucose levels and the duration of its impact depend on the dosage. Additionally, with larger doses, sensor errors can occur, potentially causing the sensor connection to be lost. The increase in blood glucose levels and the duration of this effect due to Vitamin C can vary from person to person. It is recommended not to receive Vitamin C injections while wearing a sensor. If it is determined that the readings have been affected by Vitamin C, use alternative methods for measuring blood glucose levels.

Risks and benefits

Risks

The Risks of Using CareSens Air CGM System are:

- Missing your alerts
- Adhesion reactions
- Retained sensing part
- Improper treatment decisions

Missing your alerts

In order not to miss the alerts from the CareSens Air CGM System, your smart device must follow the settings recommended by i-SENS. For detailed information, please refer to **Settings** > **Tutorials** in the CareSens Air app. See the 'Recommended smart device specifications', 'Using alerts', and 'Frequently asked questions' in the user manual for more information.

Adhesion reactions

The skin adhesive tapes and sensor tapes used in the CareSens Air CGM System have passed the biological compatibility test. Adhesion reactions are mild or do not occur in most cases. Some people who took part in the clinical study experienced some redness and swelling but this did not pose a major medical risk. If symptoms persist, please consult your healthcare professional.

Residual risks

The sensing part of the CareSens Air sensor is unlikely to break or disconnect to remain under the skin as it never did in clinical trials. Sterilized sensing parts that are left under the skin do not usually pose a significant medical risk. If the sensing part breaks or disconnects and remains under the skin, showing signs of infection or inflammation, please contact your healthcare provider or the nearest authorised distributor.

Improper treatment decisions

Users can make treatment decisions using CareSens Air. However, if treatment measures are taken in situations where treatment decisions should not have been made, there is a risk of dangerous outcomes occurring, such as duplicate or excessive amounts of insulin being administered to the user. To prevent such situations, be sure to review the 'Safety information' and '4 Treatment Decisions' sections before making any treatment decisions.

Benefits

Benefit of using your CareSens Air CGM System are:

- Receiving high and low glucose level alerts for the detection of hyperglycemia and hypoglycemia
- Tracking glucose trends and patterns for better diabetes management
- Reducing the hassle of fingertip blood sampling

Tracking trends and patterns

CareSens Air CGM System helps to detect hyperglycemia and hypoglycemia by providing continuous blood glucose information, to help managing changes in blood glucose levels through analyzing trends and patterns, to encourage you to make better decisions on food and exercise habits, and to assist in diagnosis and treatment when consulting with medical staff.

Keeping informed

If you have diabetes, it is extremely important to manage your glucose levels in real time. The CareSens Air CGM System uses alerts to notify you when your glucose level is too high or too low, or rapidly changing. With the alerts, you can better manage your diabetes.

Reducing the hassle of fingertip blood sampling

You can make treatment decisions using CareSens Air. It can replace the fingertip blood sampling needed for glucose meters, reducing pain and hassle for the user, as long as their symptoms and continuous monitoring of their glucose levels are consistent. Refer to section '4 Treatment Decisions' for more details on events.

1 Understanding CareSens Air

⚠ Warning

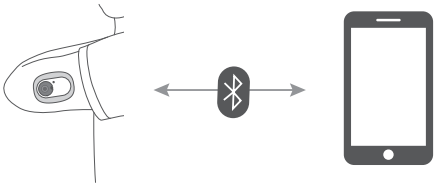
Glucose readings obtained from the CareSens Air CGM System cannot substitute for professional medical care. They are only intended to provide the patient with data on glucose level changes in order to help with diagnosis and treatment through consultation with a medical professional.

Significance of use

Conventional glucose meters measure blood glucose levels at specific times, and do not show how the level is changing or give an overview of glucose level changes over time. However, CareSens Air CGM System helps manage diabetes by continuously measuring glucose levels in interstitial fluids and providing the user with data on trends in glucose level changes.

Continuous glucose monitoring calculates the concentration of glucose in the blood by measuring the concentration of glucose in the interstitial fluid. However, when the concentration of glucose in the blood changes, the concentration of glucose in the interstitial fluid changes about 5 to 15 minutes later.

Operating mechanism



Sensor User app

The user attaches the sensor to their body by pressing the Release button of the applicator. The sensor attached to the back of your upper arm measures glucose levels in interstitial fluid and sends the measurements to a smart device.
All the data on your smart device can be backed up on a cloud server to prevent loss of data. Healthcare professionals can refer to the blood glucose values and trends taken by the CareSens Air sensor to help with diabetes management.

The user can monitor the blood glucose level data received from the sensor in the CareSens Air app on a smart device. You can also use the app to record information on life events and to input calibration values taken with a glucose meter, which can lead to more effective diabetes management.

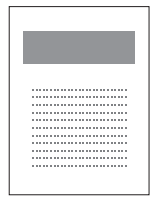
1.1 Product components

CareSens Air sensor is only designed for single-use. Once it has been attached, a sensor cannot be re-used.
The contents of the package are as follows. Make sure that all of the contents are present before opening the package.

⚠ Warning

- Do not use the product if the sensor package has been damaged or opened. This may lead to infection.
- Keep the desiccant included in the package out of the reach of infants or children.
- Do not eat the desiccant included in the package.
- If the contents of the desiccant get in your eyes, wash them thoroughly with running water right away. You should consult a physician if you experience any problems.

Applicator



Instructions for Use

Sensor tape

Note

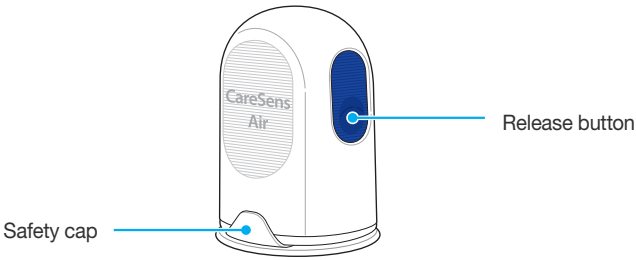
- The sensor is inside the applicator.
- The provided sensor tape may vary depending on the manufacturing period and circumstances.

Applicator

The applicator is used to protect the sensor and attach the sensor to the skin.

Note

- The applicator is intended for single-use only and cannot be re-used.
- Do not press the Release button until you have removed the safety cap of the applicator and are ready to attach the sensor.



The following names are used for the parts of the applicator:

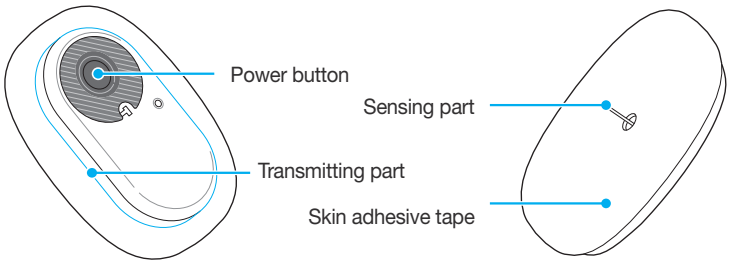
Name	Function
Safety cap	This prevents the sensor from being released unintentionally.
Release button	When this button is pressed, the sensor is released and attaches to the user's body.

Sensor

The sensor measures glucose levels and sends the readings to a smart device.

Note

- The sensor is water resistant. The product has been tested as waterproof over the course of 24 hours and at a depth of 1 meter.
- Take caution that solid objects smaller than 1.0 mm in diameter do not enter the sensor.
- The smart device and the sensor must be kept within 6 meters of each other. If there is liquid or obstacle between the smart device and sensor, the range of transmission may be reduced.
- The sensor is valid for 15 days after it is attached. There will be an alert before the expiration date.
- Please ensure you remove the sensor at or before the expiration date.



The table below shows the names and functions of the sensor's various parts.

Name	Function
Power button	Turns on power to the sensor.
Transmitting part	It has a built-in battery and transmits the glucose concentration value measured through the sensing part to the user app.
Skin adhesive tape	Attaches the sensor to the user's skin.
Sensing part	Measures the user's glucose levels.

CareSens Air app

You can use the CareSens Air application to monitor your glucose levels.

Note

Scan the barcode on the sensor package label to connect the sensor to your smart device. For more information, please refer to 'Connecting the sensor to Android app' or 'Connecting the sensor to iOS app'.

1.2 Conditions for use

Expiration date

The sensor's product lifespan ends 12 months after its date of manufacture. The expiration date is indicated on the sensor package label. Check the sensor expiration date before using the product.

The sensor can be used for 15 days, and it cannot be re-used. The sensor must be disposed of once it is expired.
Different countries may have different regulations on how to dispose of a medical device that has been in contact with bodily fluids. Follow your country's regulations for disposing of medical waste.

Refer to '10.3 Disposing of this product' for more information on sensor disposal.

⚠ Caution
Expired sensors cannot be used. Please check the expiration date before use.

Conditions for use and storage

The following table explains the necessary environmental conditions for storing, transporting, and using CareSens Air.

Category	While in use	While storing	While transporting
Temperature	10–45 °C (The maximum outer surface temperature of the sensor: 48 °C)	5–30 °C	5–30 °C
Humidity	10–95 %	15–85 %	15–85 %
Altitude	-382–3,011 m	-382–3,011 m	
Pressure	700–1,060 hPa	700–1,060 hPa	

⚠ Caution
Avoid contacting the sensor’s outer surface for more than 10 minutes in environments with temperatures above 41 °C. This may lead to low-temperature burns.

2 Installing the CareSens Air app

You can use the CareSens Air app to monitor glucose readings from the sensor in real time.
The following smart device specifications are required to install the app.

Recommended smart device specifications

To install and use the app on a smart device, the following minimum system requirements must be met.

Operating System	Version	Resolution	App Storage	App Memory
Android	Android 8.1 or higher	360 x 640 px or higher	950 MB	200 MB
iOS	iOS 15.0 or higher	375 x 667 px or higher	990 MB	200 MB

Note

- Make sure to secure the minimum required storage space, before using the app. If there is insufficient storage, the app may not function properly.
- Check the minimum requirements for your smart device before installing the app. The app may not function properly if you update the OS of your smart device after installing the app.
- Visit the official CareSens Air website (https://caresensair.com/content/compatibility) to find smart devices that have passed our compatibility test. The app may not work properly on smart devices that have not been tested for compatibility.
- You can set the date and time automatically from the settings menu of your smart device. If the date and time are not set automatically, you must set them manually if you travel to a different time zone.
- Do not install the app on a smart device that has been tampered with through hacking. The app may not work properly.

2.1 Installing the app on an Android smart device

1 Tap to launch the Play Store app on your Android smart device.

2 Type 'CareSens Air' into the search bar of the Play Store, then tap .

3 Select the CareSens Air app from the list of apps and tap **Install**.

4 Wait for installation to be completed, then tap **Open**. The CareSens Air app will launch.

2.2 Installing the app on an iOS smart device

1 Tap to launch the App Store on your iOS smart device.

2 In the App Store, tap and enter 'CareSens Air' into the search bar.

3 Select the CareSens Air app from the list of apps and tap **GET**.

4 Enter your Apple ID and password.

5 Wait for installation to be completed, then tap **Open**. The CareSens Air app will launch.

3 Using the app

Users can monitor blood glucose readings measured with the sensor through the CareSens Air app on their smart devices. The glucose trend arrows, glucose trends, events, and calibration values available on the app allow you to manage your blood glucose more effectively.
You should sign up and log in to upload the data saved on the CareSens Air app to the cloud server. If you have logged in to the app to use CareSens Air, you can load the backup data even if you lose your smart device.

This section will help you to:

1. Register and log in to the app.
2. Connect the app with the sensor to allow stable operation.
3. Use the app to configure your glucose monitoring environment.
4. Learn to interpret your glucose levels and the glucose trends shown in the app.
5. Learn about and use the features provided by the app.

⚠ Caution
If you delete the smart device app while using the sensor, all the data saved by the app will be lost. If you need to delete the app or switch to a different smart device, upload all important data to the cloud server and save a backup file on a separate storage device.

Note
The CareSens Air app requires permission to use the following features of your smart device:

- Android 12 or higher: Camera, Alerts, Bluetooth
  Below Android 12: Camera, Location, Alerts
- iOS: Alerts, Bluetooth, Apple Health

3.1 Logging in

To use the CareSens Air app, you need to register an account and log in to it. When registering an account you will enter your user information, and then your email address will be verified. The app only provides data on the user currently logged in.

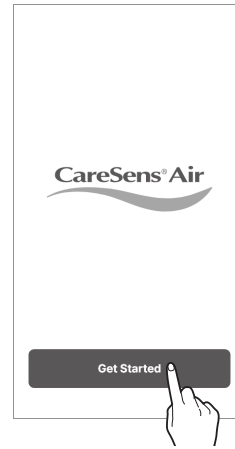
For first-time users

If you sign up for an i-SENS account, you can use all i-SENS apps with one account. Follow the steps below to sign up for an i-SENS account.

1 Run the **CareSens Air** app on your smart device.

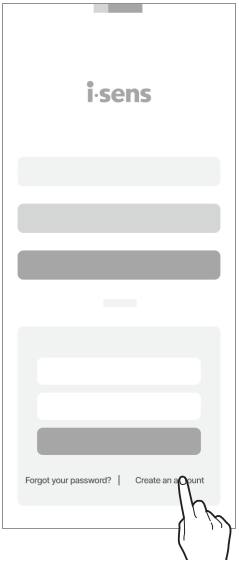
CareSens Air

2 Tap **Get Started** on the start screen.

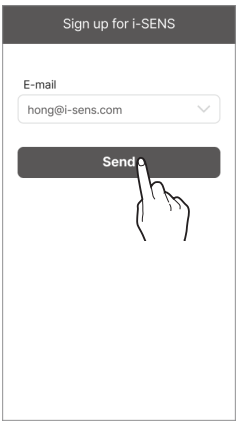


3 Move to the i-SENS login screen.
Tap **Create an account**.

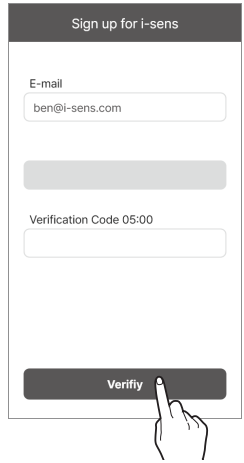
- Even if you select Social Login, it is possible to sign up using an account.
- Select your country of residence, and language, then enter your information for Social Login.



4 Enter the email you want to sign up with and tap **Send**.
A verification code will be sent to the email address you provided.



5 Enter the six-digit code from the verification email and tap **Verify**.

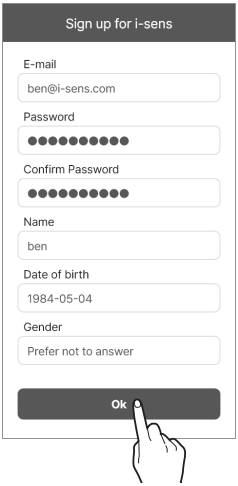


Note

- You should enter the code within 5 minutes after the email has been sent. Tap **Resend** to issue a new code if you fail to enter the code within the time limit.
- You cannot create an account without completing the verification.

6 After accepting the required terms and conditions, tap **Ok**.

7 Enter the user information and tap **Ok**.



8 On the i-SENS login screen, enter your email address and password, then tap **Log In**.

- If you have signed up with Social Login, keep using the same account that was selected in Social Login.

Previously registered users

If you are already a registered user, take the following steps to log in to the CareSens Air app.

1. Tap the  on your smart device to run the CareSens Air app.
2. Tap **Log In** on the start screen.
3. On the i-SENS login screen, enter your email address and password, then tap **Log In**.
4. If you enter a correct email address and password, you will be logged in as a registered user.

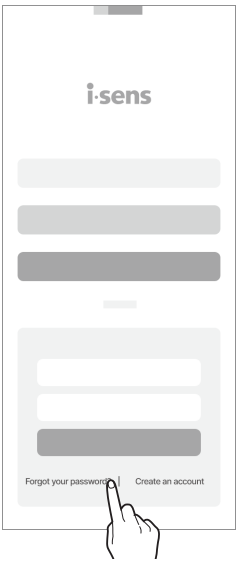
Reset password

Take the following steps if you have forgotten your i-SENS login password.

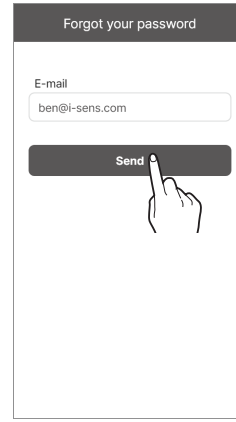
1 Find the CareSens Air app on your smart device and tap .

2 Tap **Get Started** on the start screen.

3 Move to the i-SENS login screen.
Tap **Forgot your password?**

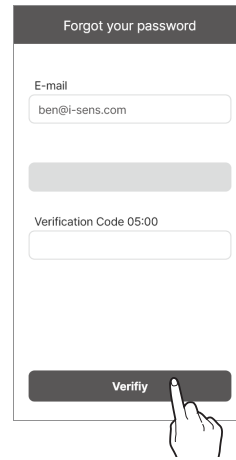


4 Enter your email address on the 'Forgot your password?' screen and tap **Send**.
The verification code is sent to the user's email address.

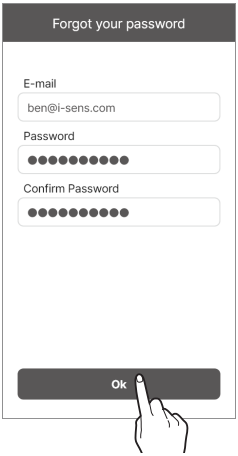


5 Enter the six-digit code from the verification email and tap **Verify**.

- You should enter the code within 5 minutes after the email has been sent. Tap **Resend** to issue a new code if you fail to enter the code within the time limit.
- You cannot reset your password without completing the verification.



6 Enter your new password and confirm password, then tap **Ok**. Your password has been reset.



Use without login

CareSens Air can be used without creating and logging in to an i-SENS account.

Follow these steps to use CareSens Air without logging in.

1 Launch the CareSens Air application on your smart device.

2 Tap **Continue Without Login** on the top right of the login screen.

3 The app will launch without logging in.

Note

- If you use the CareSens Air app without logging in, the user name will appear as 'Guest,' and data saved on the app will not be uploaded to the server.
- We recommend that you log in to prevent data loss.

3.2 Connecting to a sensor

Make sure that the sensor has been attached to the skin and that the power has been turned on. Connect the sensor to the app. Once it is successfully connected, the sensor will warm up. The smart device and the sensor communicate via Bluetooth. You must maintain the connection between the sensor and the smart device when in use.

Follow these steps to connect the sensor to the app.

1. Connect the sensor to the app. Configure the alert settings in the app.
2. Sensor warmup will occur.
3. Once the sensor warmup is completed successfully, the glucose reading will be displayed. If sensor warmup is not completed successfully, check whether the sensor or smart device is malfunctioning and try again. The sensor and the device must always remain connected.

Note

- Expired sensors cannot be used.
- The sensor in use uses the same account, and can be reconnected to the same device as long as it is valid. If you use the sensor without logging in, you cannot reconnect to it if the app is deleted and then reinstalled.
- If the sensor in use is connected to a different device, only one more connection is permitted. When connecting to a new device, it is recommended to use the sensor after disconnecting it from the previous device. When using the sensor without logging in, it is not possible to change to a different device.
- Once the sensor is connected to the app, it cannot be connected to another app. When reconnecting or changing devices, it can only be connected to the app that was first connected to.
- Keep the sensor and the smart device within 6 meters of each other, without any obstacles such as walls or metal objects in between. The distance from the sensor to the smart device must be closer if there is any solid object between them. Otherwise, the connection may fail.

Connecting the sensor to Android app

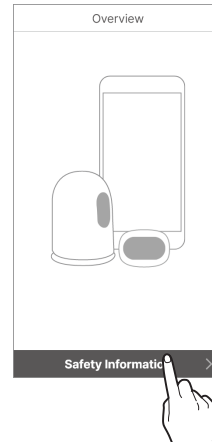
Connect the sensor to the app. Scan the barcode shown on the sensor package label, or manually enter the sensor PIN code.

Follow the steps below to connect the sensor to the app:

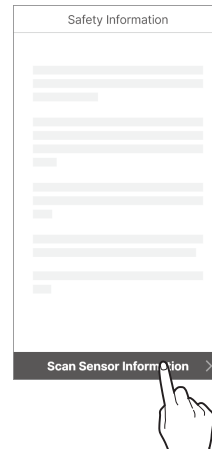
1 Turn on Bluetooth on your smart device.

2 Tap on your smart device and log in.

3 Tap **Safety information** on the 'Overview' screen.

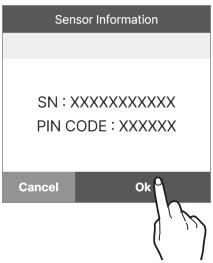


4 Read the information on the 'Safety information' screen, then tap **Scan Sensor Information**.

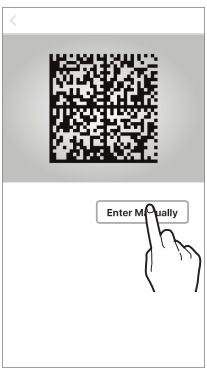


5 On the 'Scan Sensor Information' screen, scan the barcode on the package label.

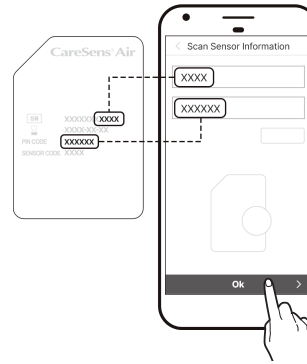
6 When the sensor information appears, check that it is the same as the sensor information on the package label and tap **Ok**.



7 You can manually enter the barcode instead. Tap **Enter Manually**.



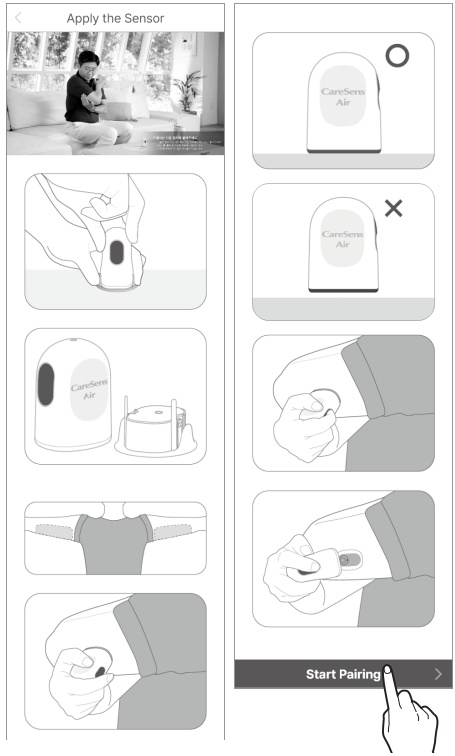
8 Enter the 6-digit PIN code and the last 4 digits of the serial number written on the sensor package label, then tap **Ok**.



Note

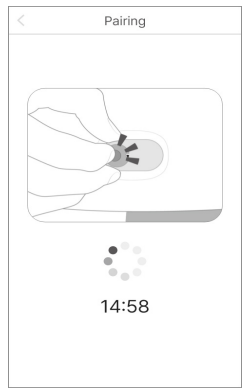
When entering the sensor information manually, please make sure to enter the numbers correctly. The sensor will fail to connect if you enter the wrong serial number or PIN code.

9 Once the barcode is successfully recognized or the information is manually entered, you will see the 'Apply the Sensor' screen. Follow the steps below to attach the sensor on the back of your upper arm, and tap **Start Pairing**. Read the details and words of caution on 'Attaching the sensor' before attaching the sensor.



10 Attach the sensor to the back of your upper arm and press the power button until it clicks. The button is then recessed inward. Wait until the sensor connection is completed.

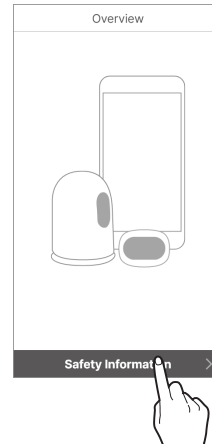
- Press the button within the 15 minutes shown on the screen to start connecting the sensor. It may take up to 15 minutes depending on your communication environment. After 15 minutes, the sensor connection process will restart.



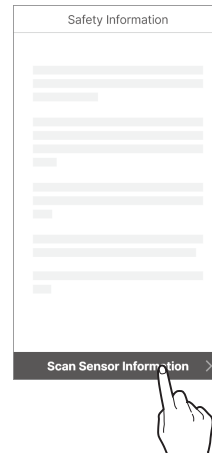
Connecting the sensor to iOS app

Follow the steps below to connect the sensor to the app:

1. Turn on Bluetooth on your smart device.
2. Tap on your smart device and log in.
3. Tap **Safety Information** on the 'Overview' screen.



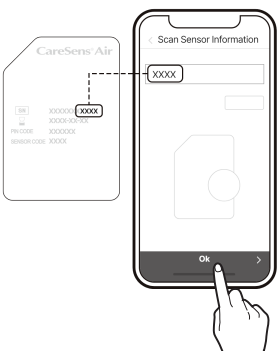
4. Read the information on the 'Safety Information' screen, then tap **Scan Sensor Information**.



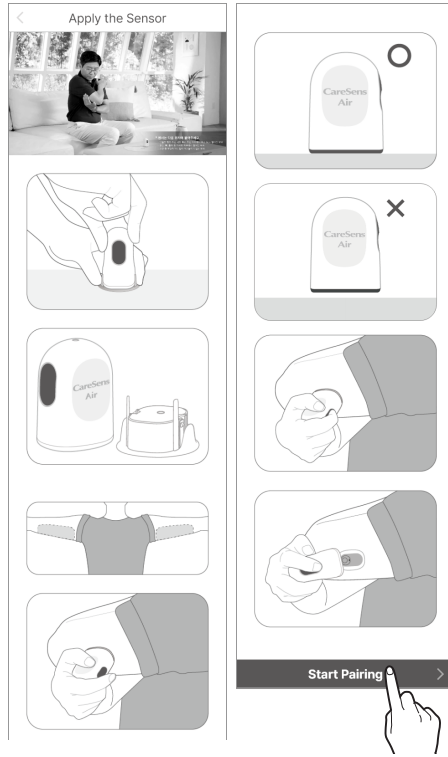
5 On the 'Scan Sensor Information' screen, scan the barcode on the package label.

6 You can manually enter the barcode instead. Tap **Enter Manually**.

7 Enter the last 4 digits of the serial number written on the sensor package label, then tap **Ok**.

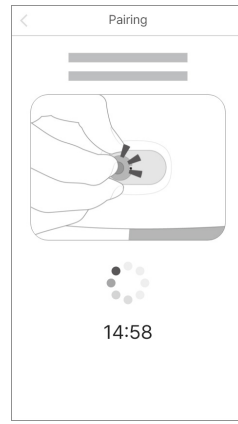


8 Once the barcode is successfully recognized or the information is manually entered, you will see the 'Apply the Sensor' screen. Follow the steps below to attach the sensor on the back of your upper arm, and tap **Start Pairing**. Read the details and words of caution on 'Attaching the sensor' before attaching the sensor.

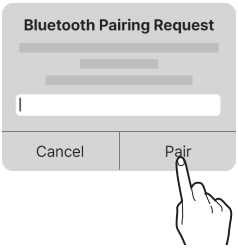


9 Attach the sensor to the back of your upper arm and press the power button until it clicks. The button is then recessed inward. Wait until the sensor connection is completed.

- Once the barcode is successfully recognized, the serial number and PIN code are displayed on the screen.
- If manually entered, only the serial number is displayed.
- Press the button within the 15 minutes shown on the screen to start connecting the sensor. It may take up to 15 minutes depending on your communication environment. After 15 minutes, the sensor connection process will restart.



10 When a Bluetooth connection request appears on the screen, enter your PIN code and tap **Pair**.



⚠ Warning

When using iOS, do not close the app after connecting the sensor. It will be disconnected from the sensor.

Attaching the sensor

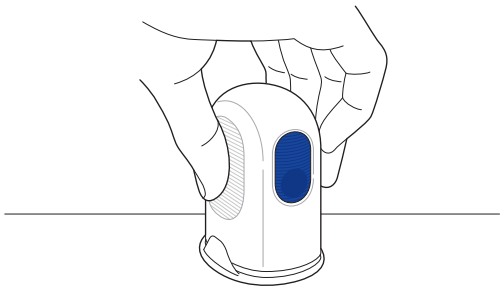
Follow the steps below to attach the sensor to the back of your upper arm:

1 Check the expiration date on the sensor package label.

⚠ **Caution**
Expired sensors cannot be used. Please check the expiration date before use.

2 Open the CareSens Air sensor package.

3 Take the applicator out of the package and set it on a flat, stable surface.



4 Wash your hands well with soap and running water, and dry them with a clean cloth.

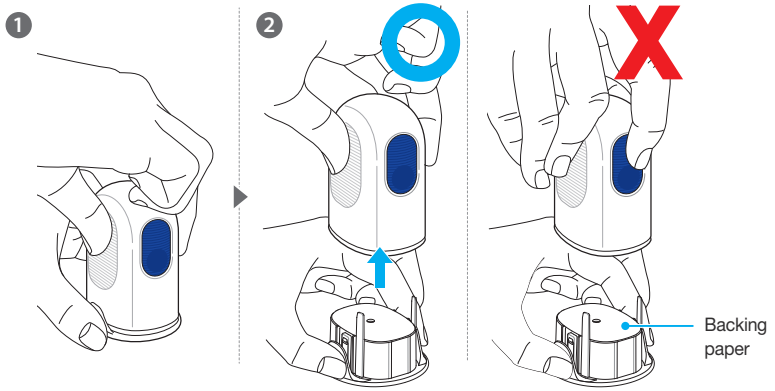
5 Wipe the area where the sensor will be attached to the skin with an alcohol swab and wait for it to dry completely.

⚠ **Caution**

- Choose a new location to attach each new sensor. Continuing to attach new sensors to a previously used location may cause skin irritation or scarring.
- The sensor should be attached immediately after opening the applicator package to avoid airborne contamination.
- The location chosen for insertion must meet the following criteria:
  - It must be at least 8 cm away from an insulin pump infusion set or infusion location.
  - It must not be close to the waistband, tattoos, bone, scars, or irritated skin.
  - It must be a location which will not be bumped, pushed, or pressed during sleep.
- After you separate the safety cap from the applicator, be careful not to point it toward any person.

6 Hold the applicator and remove the safety cap.
When the safety cap is removed, the backing paper covering the skin adhesive is removed at the same time.

Note
Make sure that the backing paper has been completely removed from the skin adhesive and is on top of the safety cap.



Note
The applicator and sensor cannot be reused, so be careful not to press the release button unintentionally.

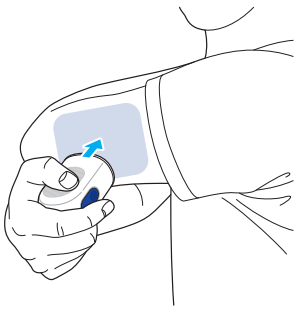
7 Remove the safety cap, and place the applicator as shown in the figure on the back of your upper arm where the sensor will be attached.
The sensor may not attach properly if the applicator is positioned as shown in the figure.

Note

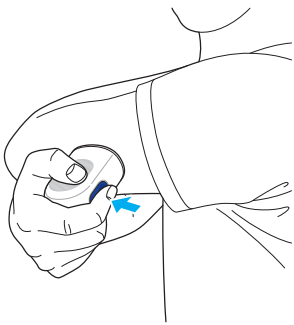
Place the applicator as shown in the figure on the area of attachment and then press the Release button.

Do not leave any space between the area and the applicator.

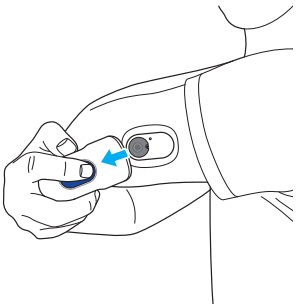
Do not tilt the applicator onto the area.



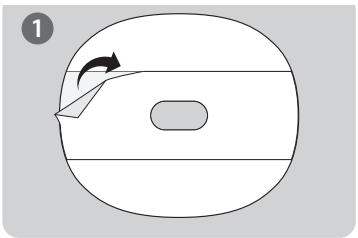
8 Press the Release button on the applicator. The sensor from the applicator will be attached to the back of your upper arm.



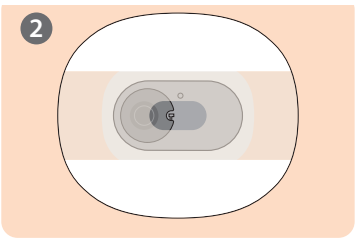
9 Remove the applicator and make sure that the sensor has been properly attached.



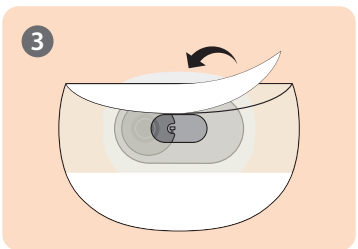
- If the adhesive on the sensor has weakened during usage, you can use sensor tape to keep the sensor in place more securely. For example, you can use sensor tape to prevent the sensor from coming off your skin after it has been attached for seven days.



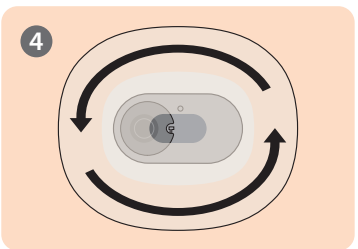
Remove the middle back side of the sensor tape.



Attach the sensor in the center of the sensor tape.



Remove both back sides of the sensor tape.



To affix the sensor to the area, press the sensor tape.

- The provided sensor tape may vary depending on the manufacturing period and circumstances.

10 The applicator is intended for a single use only. Discard it after use.

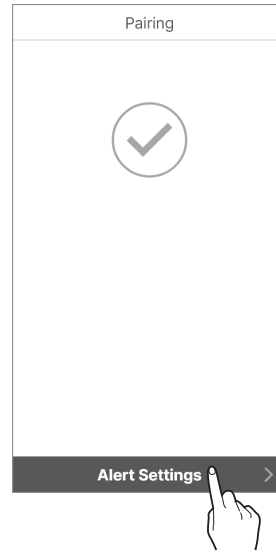
Configuring your alert settings after connecting to the sensor

After the sensor is connected successfully, enter threshold values for very low, low, and high and proceed with setting up your alerts. Consult your healthcare professional for the appropriate threshold values for 'Very Low', 'Low', and 'High'.

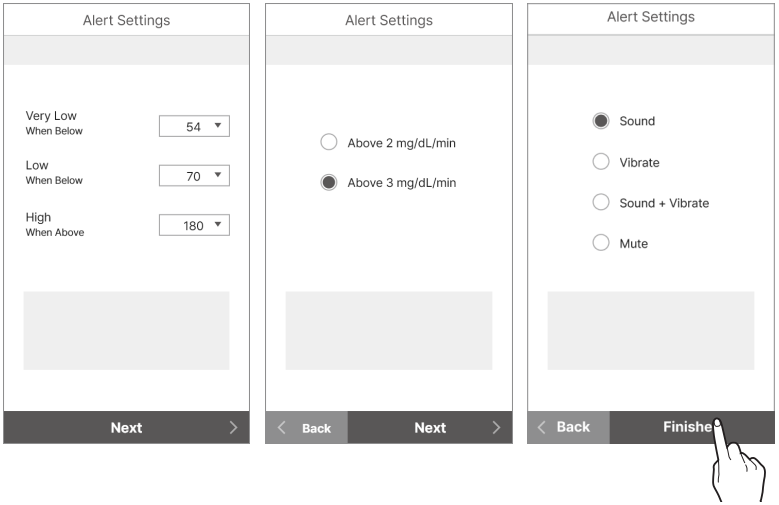
Take the following steps to configure your alert settings after connecting with the sensor.

1 Make sure that the sensor is attached and that the power is on. Refer to 'Attaching the sensor' for more information on attaching sensors.

2 Tap **Alert Settings** on the 'Pairing' screen if you would like to receive app alerts while using the sensor.



3 On the 'Alert Settings' screen, enter threshold values for very low, low, high, rapidly changing blood glucose levels and alert types, then tap **Finished**.



Note

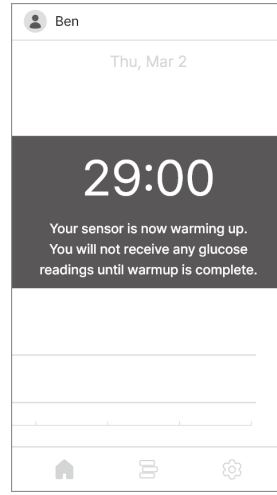
If you set it to mute, you'll receive alerts without any sound or vibration. If you want to be sure to recognize alerts, set it to sound or vibrate.

4 Sensor warmup will start automatically.

Note

If you need to make a treatment decision during the 30 minutes needed for sensor warmup, use a glucose meter.

- The home screen shows the status of sensor warmup, which takes about 30 minutes.
- If the sensor fails to warm up, contact your place of purchase or customer service.



5 Once the sensor warmup is completed, the glucose reading will be displayed and will change from gray to blue. If needed, you can tap the blue to enter a calibration value.

If the sensor fails to connect

If the sensor fails to connect, a pop-up window explaining the cause of the failure will appear. Depending on the cause of the failure, follow these steps to try connecting the sensor again:

- If a sensor is malfunctioning: The sensor is defective and cannot be used. Disconnect the sensor if necessary. Then, attach and connect a new sensor. Read 'Disconnecting and removing the sensor' for more information on how to disconnect the sensor. For more information on connecting the sensor, please refer to 'Connecting the sensor to Android app' or 'Connecting the sensor to iOS app'.
- If the connection is not secure: The sensor cannot be connected due to unstable connection with your mobile device. Take the following steps and try connecting again:
  - Keep the sensor and the smart device close to each other.
  - In the settings of your smart device, turn Bluetooth off and then back on.
- If the sensor is already in use: You have tried to connect to a sensor that is already being used by another user. Check whether the sensor information on the package has been entered correctly. Enter the serial number and PIN code accurately and connect again.

If the connection between the sensor and the smart device is interrupted

A communication error between the sensor and the smart device may occur in the following cases:

- If Bluetooth is turned off on your smart device.
- If the sensor is not within connection range of the smart device.
- If the sensor's battery has gone flat.
- If the sensor is broken.
- If the smart device has insufficient storage space.

If a communication error occurs, a normally operating sensor will store the data it collects and transfer it to the smart device when the connection is reestablished. The sensor can save data for 12 hours. After 12 hours, any additional data may be lost.

If a connection error occurs, follow these steps and try connecting again:

- Keep the sensor and the smart device close to each other.
- Exit the app, then restart it.
- Turn off and restart Bluetooth on your smart device.
- Turn the power of the smart device off and then back on.

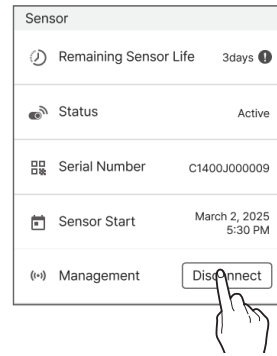
Disconnecting and removing the sensor

The sensor is automatically disconnected when it expires. You can manually disconnect from a sensor while it is still in use. You can disconnect from a sensor if it malfunctions due to damage. You may lose any data that hasn't been transferred when you disconnect the sensor. Check that all recent data has been received before you disconnect it.

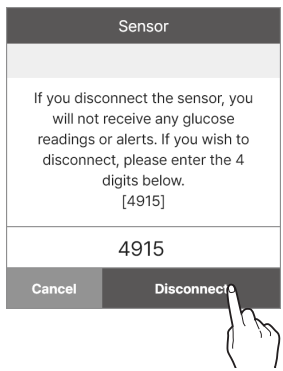
Follow these steps to disconnect from the sensor:

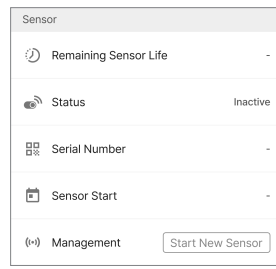
1 Open the app and tap ⚙ at the bottom of the home screen.

2 Tap **Disconnect** on the right of 'Management'. The sensor disconnection pop-up window will appear.

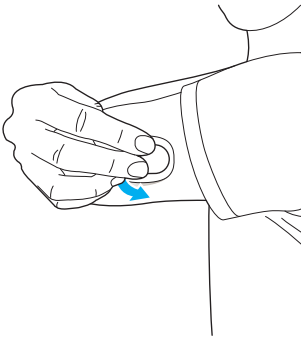


3 Enter the 4-digit code in the sensor disconnection pop-up window and then tap **Disconnect**. Once the sensor is successfully disconnected, the connection status will change to 'Inactive'.





4 Remove the sensor attached to the back of your upper arm. Remove it slowly, starting from the edge of the skin adhesive tape.



3.3 Understanding the home screen

If the sensor is operating stably, a real-time graph of changes in glucose level will be displayed on the home screen of the app. The CareSens Air app home screen contains the following:

- Basic information: Profile, Name, Silent status notification, Notification of new announcements
- Menu bar: Home, Log book, Settings
- Glucose data: Connection status, Glucose statistics, Previous Data, Glucose trends, Calibration button, Date, Screen mode, Alert history, Glucose trend arrows, Glucose level, Last received time of glucose

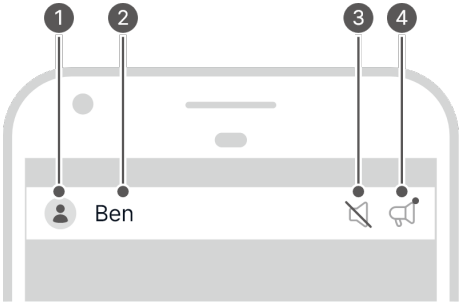
The glucose level and glucose trend arrow on the home screen can help you understand your glucose status. You can check the changes in the sensor's glucose levels in the glucose trends. Understanding the content and features of the app will help you use CareSens Air to manage your diabetes more effectively.

This section will help you to:

- Understand what is displayed on the Home screen.
- Learn what the icons on the Home screen do.
- Learn how to check past glucose trends.
- Check glucose levels.
- See your low and high alert in the glucose trends.
- Check whether a sensor has been calibrated.
- Check the event logs and the details of events.

Basic information

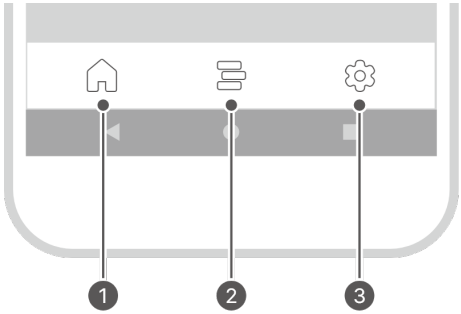
The table below explains the basic information which the CareSens Air app displays at the top of the home screen.



No.	Icon	Name	Description
1		Profile	The image uploaded to your profile is shown. You can change this image on the 'Profile' screen by tapping your name.
2	Ben	Name	The name you entered when you registered is displayed. It can be changed on the 'Profile' screen by tapping it.
3		Silent status notification	The image appears when the volume of the smart device is set to 0.
4		Notification of new announcements	If there is an unchecked announcement, an icon will be displayed. Tap the icon to go to the 'Announcements' screen.

Menu bar

The following table explains the icons and features available on the Home screen menu.



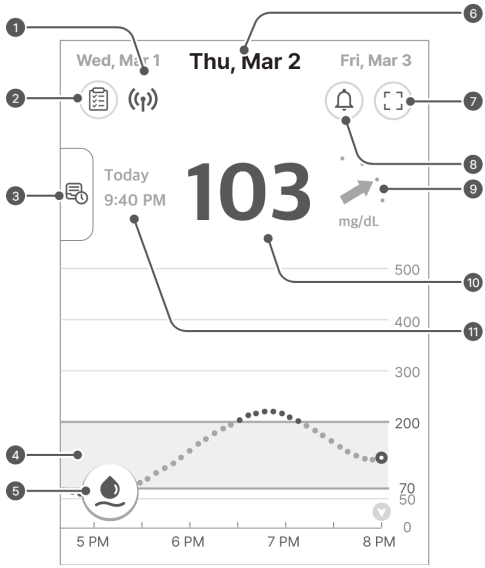
No.	Icon	Name	Description
1		Home	Return to the Home screen that shows blood glucose trends.
2		Log book	• When you tap this icon, a list of events registered by the user will be displayed. You can add, edit, or delete events. • Refer to '7 Using events' for detailed information on events.

No.	Icon	Name	Description
❸		Settings	• When you tap this icon, you will see a display telling you about the sensor connection status, the calibration status, alert type, and your glucose level alerts. • All data saved on the app can be uploaded and saved to the cloud server. You can instantly upload data whenever you want. • You can connect to a new sensor, or disconnect from a currently connected sensor. • You can check the user manual, FAQs, and app info. • Refer to 'Changing your settings' for more information on changing your settings. • Refer to 'Updating the app' for more information on updating to the latest version of the app. • You can check the glucose meter that is connected to your smart device, or register a new one. Refer to 'Connecting with a glucose meter' for more information on connecting with your glucose meter.

Glucose data

The CareSens Air app displays your current glucose level and the glucose trend arrow as shown below. You can choose whether to display them vertically or horizontally on your smart device screen.

The table below explains how the home screen displays glucose level data:



No.	Icon	Name	Description
1		Connection status	The status of the connection between the smart device and the sensor is displayed in the following colors: • Blue: The communication status is good. • Red: The smart device has not received any signal for 25 minutes. • Grey: The smart device's Bluetooth is turned off.

No.	Icon	Name	Description
2		Glucose statistics	When you tap this icon, statistics of your glucose levels over the past 24 hours will be displayed: • Average level, standard deviation, how much time your level was within the target glucose level, and the low and high ranges.
3		Previous Data	When you tap or drag the bar on the left of the screen right, your previous glucose trends will appear in sections. When you select a section, a detailed screen will be displayed in the same format as the home screen.
4		Glucose trends	Changes to your glucose level while the sensor is in use are displayed as a graph.
5		Calibration button	• If you tap this icon, the calibration input screen will be displayed. Enter a glucose reading taken with a glucose meter by pricking a finger. • Users can adjust the sensor readings if they need to, but they don't have to. If the option to calibrate isn't available, it means it's not needed at that time. • See '7 Using events' for more information on calibration.
6	**Thu, Mar 2**	Date	The date when the data was received from the currently connected sensor is displayed. Tap another date to see the glucose trends for that date.
7		Screen mode	Tap to switch between landscape and portrait screen orientation.
8		Alert History	Move to the 'Alert History' screen.

No.	Icon	Name	Description
❾		Glucose trend arrows	The current rate of change in your glucose level compared with the previous measurement is displayed. Each point indicates a glucose trend reading taken every 5 minutes. See 'Trend arrows' for more information on the glucose level trend arrow.
❿	103	Glucose level	The most recently measured glucose reading is displayed, either as a number or as one of the following: • - : No data has been received within the last 25 minutes • Low: Lower than 40 mg/dL (2.2 mmol/L) • High: Higher than 500 mg/dL (27.8 mmol/L)
⓫	Today 9:40 PM	Last received time of glucose level	The date and time when the blood glucose level was last received.

Trend arrows

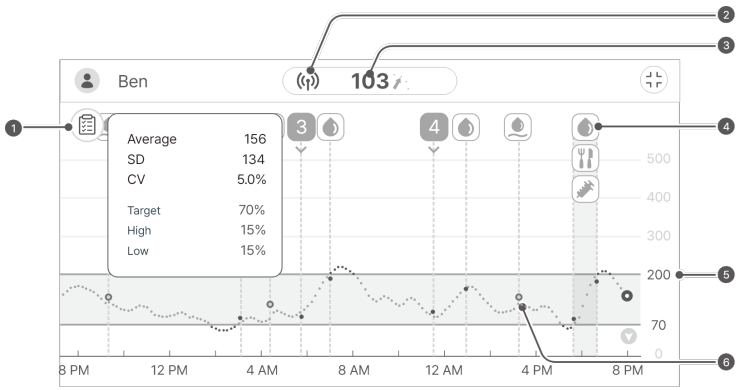
The glucose trend arrow shows the direction and velocity of change between the most recent glucose reading and the second most recent reading.
It is shown as an arrow on the right of the most recent glucose reading on the home screen.

Velocity arrow	Change in glucose level	Description
	Stable	The glucose level has been increasing or decreasing below 30 mg/dL (1.6 mmol/L) in the past 30 minutes.
	Increasing slowly	The glucose level has been increasing by 31–60 mg/dL (1.6–3.3 mmol/L) over the past 30 minutes.
	Increasing	The glucose level has been increasing by 61–90 mg/dL (3.4–5.0 mmol/L) over the past 30 minutes.
	Increasing rapidly	The glucose level has been increasing by more than 91 mg/dL (5.1 mmol/L) in the past 30 minutes.
	Decreasing slowly	The glucose level has been decreasing from 31–60 mg/dL (1.6–3.3 mmol/L) in the past 30 minutes.
	Decreasing	The glucose level has been decreasing by 61–90 mg/dL (3.4–5.0 mmol/L) in the past 30 minutes.
	Decreasing rapidly	The glucose level has been decreasing by more than 91 mg/dL (5.1 mmol/L) in the past 30 minutes.
	Unknown	The volume of data is insufficient to calculate the direction and speed of changes in glucose levels.

Interpreting trends in glucose data

Interpreting trends in glucose data shown on the home screen can help you manage your diabetes more effectively. The most recent glucose reading is displayed, and the pace and direction of change in comparison with the last measurement is indicated with an arrow. See 'Trend arrows' for more information on the glucose level trend arrow.

Interpreting trends in glucose data will allow you to choose appropriate ways based on the glucose level intervals and the pace and direction of change to manage your diabetes in advance. This will help you keep your glucose level within the target range. Refer to the example cases below to understand glucose level trends.



No.	Description
1	You can use the statistics based on your glucose trends to check your glucose level management status. If the amount of time your blood glucose level remains within the target range is high, but the standard deviation is also high, this indicates large changes in blood glucose level. If the sensor was functioning normally within the given period, you can check your events and use this information to make lifestyle improvements which will help you maintain a stable level.
2	This shows that the sensor attached to your body is operating normally. An alert will occur if the sensor and the smart device is out of range.

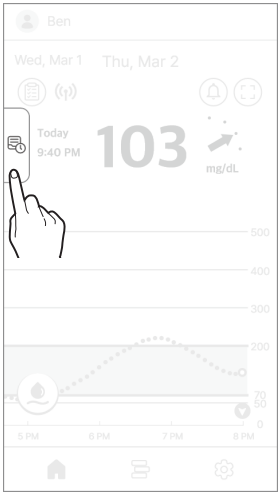
No.	Description
3	The most recent glucose reading is 103 mg/dL (5.7 mmol/L), which is within the target range. It has increased in comparison to the previous value, but is still within the target range. However, even if the glucose reading value is 103 mg/dL (5.7 mmol/L), it may increase to 160 mg/dL (8.9 mmol/L) or higher after 30 minutes when you see the trend arrow. *  : means that the glucose level has been increasing by 61–90 mg/dL (3.4–5.0 mmol/L) over the past 30 minutes. Refer to 'Trend arrows' for more information. In this case, the CareSens Air user and those who use glucose meters may take different actions. • With CareSens Air: Interpreting glucose trends allows you to predict a rapid increase in the glucose level to 160 mg/dL (8.9 mmol/L) or higher after 30 minutes by looking at the trend arrow. This means that observing the graph can help you know that you should take actions to prevent a serious incident occurring due to hyperglycemia. • Only using a glucose meter: If your glucose level is increasing rapidly, it could reach 160 mg/dL (8.9 mmol/L) in 30 minutes. But you cannot see the change in level unless you take another finger prick measurement. This may make it difficult to take action before a hyperglycemia event occurs.
4	By checking the events displayed in the glucose trends, you can check the change in your glucose level according to your lifestyle. For example, you may see that jogging for 30 minutes every day brings down your high value to the target level and helps you maintain it.
5	The glucose level alerts have been set to 70 mg/dL (3.9 mmol/L) for low and 200 mg/dL (11.1 mmol/L) for high. Check whether your glucose level is staying within the target range.
6	You can check calibration values which have been applied normally on your glucose trends.

Viewing previous data

You can click the vertical bar on the left of the app home screen to view previous data. You can view all the data delivered from any sensor used on your account. The glucose trend screen appears when you tap on the sensor usage period.

Take the following steps to view earlier glucose trends:

1 Drag the **Previous Data** from the left side of the home screen to the right.



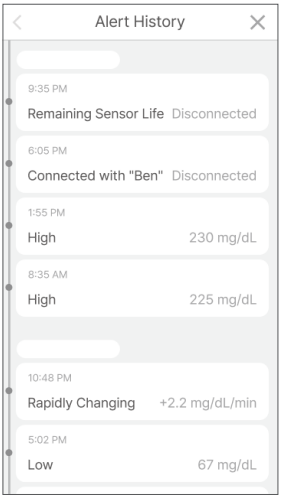
2 Tap the date list on the 'Previous Data' screen. A detail screen will appear. Tap ✕ to go back to the home screen.

Alert history

Tap on the upper right corner of the home screen to see the alert history.
You can check the history of blood glucose alerts (very low, low blood glucose, high blood glucose, sudden fluctuations), sensor alerts, and follow-related alerts.

Follow the steps below to check the alert history.

1 Tap in the top right of the home screen.
The 'Alert History' screen will be displayed.



2 Tap to go back to the home screen.

3.4 Exploring the app features

You can use various features of the CareSens Air app to manage your diabetes in your daily life. All the glucose readings collected by the sensor appear together on the glucose trends display. You can record your food intake, physical activity, insulin intake, and other items as events. Observing changes in your glucose level and comparing them with these events can help you make lifestyle improvements or make effective treatment decisions. All the data measured by the CareSens Air CGM System can be uploaded and saved on the cloud server.

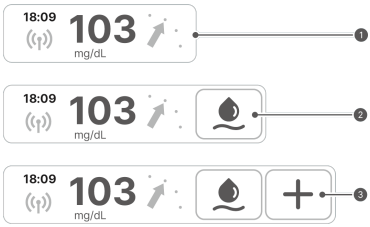
Reading this section will allow you to:

- Record events and check past events
- Configure your alert settings
- Update the app to the newest version
- Check help or the tutorial as needed
- Register a glucose meter

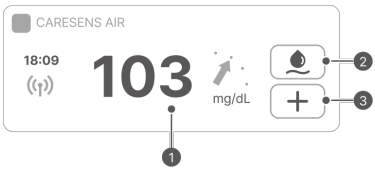
Running the widget

CareSens Air can display important information and features as a widget so that you can view them on the main screen of your smart device. You can use the CareSens Air widget to check your sensor connection status, sensor glucose readings, and trend arrows, or to enter a calibration value.

You can choose from three different widget layouts for Android.



You can check the widget layout for iOS.



⚠ Caution

The glucose reading displayed on the iOS widget may differ from the latest glucose reading, so be sure to check the latest glucose reading by running the app.

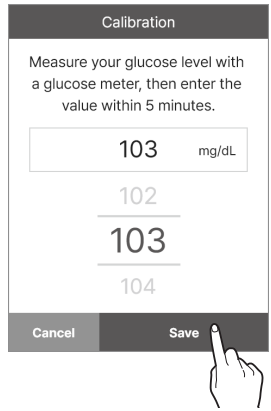
No.	Name	Description
1	Glucose data	This display shows your sensor connection status, most recent glucose reading, and a trend arrow. It appears on the home screen when you tap the widget.
2	Calibration value input	You can enter a calibration value when is blue. If you tap , the 'Calibration' screen will be displayed. You cannot enter a calibration value when is gray.
3	Entering an event	Tapping + causes the 'Add New Event' screen to be displayed.

Entering a calibration value

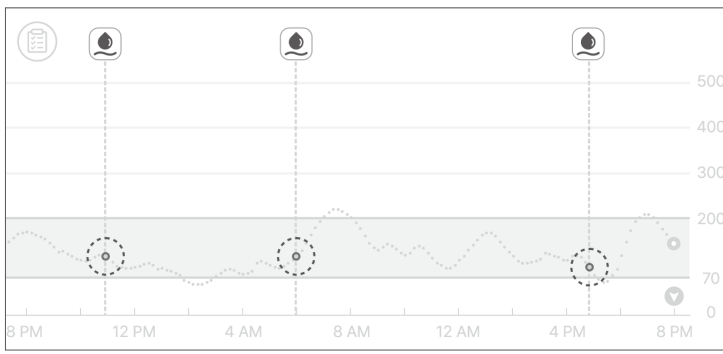
When you need to enter a calibration value, you should use a glucose meter to obtain a blood glucose level from a fingerprick sample. Enter this reading as a calibration value for CareSens Air.
Refer to '6 Calibration' for more information on glucose level calibration.

Follow these steps to enter a calibration value in the app.

1. Tap at the bottom of the home screen. The 'Calibration' screen will be displayed.
2. Use your glucose meter to measure your blood glucose level with a finger prick.
3. Enter the finger prick reading within 5 minutes and tap **Save**. The calibration value is displayed by CareSens Air.



4. Check your glucose trends on the home screen to see whether the calibration value has been applied.
   - The calibration value is shown as a skyblue dot on the glucose trends at the date and time of entry.



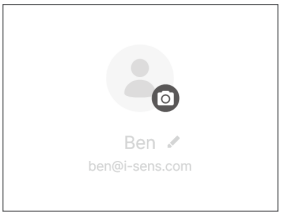
Editing and checking your profile

You can view or edit the information in your user profile.

Follow these steps to enter profile information.

1 Tap at the top of the home screen. The 'Profile' screen is displayed.

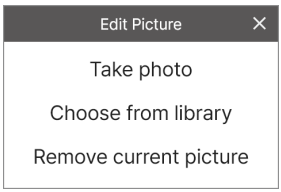
2 Tap on the 'Profile' screen to change your profile photo. The 'Edit Picture' screen will be displayed.



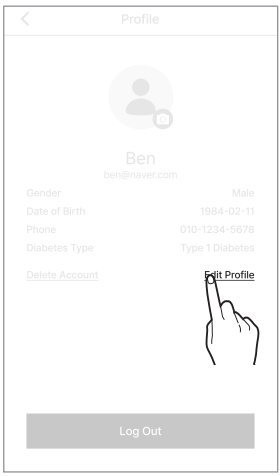
Note

If you use the CareSens Air app without logging in, your user name will be displayed as 'Guest' and member information such as gender and date of birth will not be displayed.

3 In the 'Edit Picture' pop-up window, tap **Take photo** or **Choose from library**.



4 Tap **Edit Profile** on the 'Profile' screen to change user information.



5 On the 'Edit Profile' screen, change your information and tap **Save**.

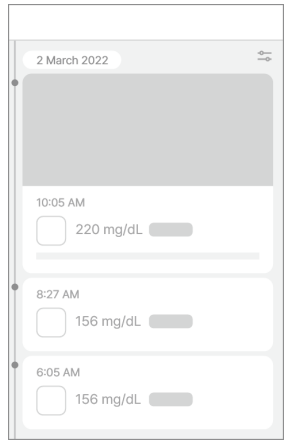
Viewing the log book

The log book displays all the events registered by the user, beginning with the most recent.

Follow these steps to check event details in the log book.

1 Tap at the bottom of the home screen.
Events registered by the user are displayed.

- The table below explains the icons used on the log book screen.



Icon	Name	Description
	Blood Glucose	The value entered by the user or measured using the blood glucose meter is displayed as follows at the time the event occurred. • : If the entered value indicates a glucose level • : If the entered value indicates a calibration value
	Ketone	The value entered by the user or the ketone value measured by the ketone meter is displayed at the time the event occurred.
	Insulin	The name of the insulin and the dosage taken at the time the event occurred are displayed. You can enter up to 2 insulin administration records.
	Medication	The name of the medication and the dosage taken at the time the event occurred are displayed. You can enter up to 5 doses of medication.

Icon	Name	Description
	Meal	The amount of carbohydrates, protein, and fat consumed at the time the event occurred are displayed in grams (g).
	Exercise	The number of minutes spent exercising is displayed, along with the time.

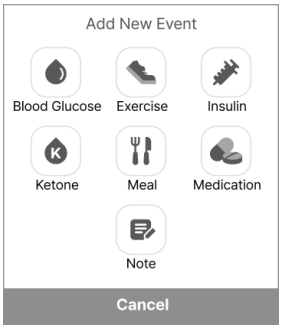
Recording an event

Activities or situations that may affect your glucose level can be registered as events. Refer to '7 Using events' for more information on how to use events to manage your diabetes.

Follow these steps to register an event.

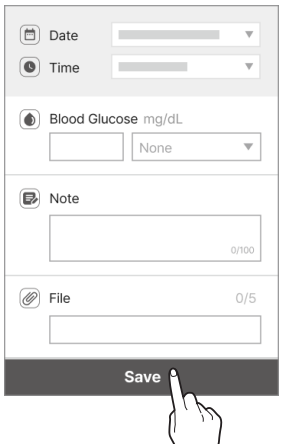
1 Tap at the bottom of the home screen and then tap ⊕ on the log book screen. The 'Add New Event' screen will be displayed.

2 Tap the event icon you want to enter.



3 Enter the event details, including the date and time, on the 'Add New Event' screen, then tap **Save**.

- A maximum of 2 types of insulin can be entered.
- A maximum of 5 doses of oral medication can be entered.
- If necessary, you can enter notes or attach files such as photos and audio.



Changing your settings

The following table explains the icons and features available on the home screen menu: Your settings are displayed when you tap at the bottom of the home screen.

Icon	Name	Description
	CareSens Air Website	Move to the CareSens Air website.
	Contact Us	Move to the 'Contact Us' screen.
	Purchase	Move to the website to purchase the product.
	Remaining Sensor Life	The remaining life of the sensor is displayed.
	Status	If a sensor is connected, 'Active' is displayed. If a sensor is not connected, 'Inactive' is displayed.
	Serial Number	This is a unique number assigned to the sensor.
	Sensor Start	The date and time when the sensor was first connected are displayed.
	Management	• Tap **Disconnect** to disconnect the sensor currently in use. • If a sensor is 'Inactive', **Start New Sensor** is displayed, refer to '3.2 Connecting to a sensor' for more information on how to connect the sensor.
	Last Calibration	The time of the last calibration is displayed.
	Mute	• Set all alerts to mute. • Alerts that are excluded from mute mode - Signal loss, Sensor error, Remaining Sensor Life, Sensor warmup.
	Very Low	Enter the threshold value for 'Very low' to receive alerts and select the alert method.

Icon	Name	Description
	Low	Enter the threshold value for 'Low' to receive alerts and select the alert method.
	High	Enter the threshold value for 'High' to receive alerts and select the alert method.
	Rapidly Changing	Enter the threshold value for 'Rapidly Changing' to receive alerts and select the alert method.
	System Alerts	You can set the notifications for signal loss, remaining sensor life, sensor error, and signal anomaly detection.
	Text-to-Speech	You can choose to have your glucose level and alerts read aloud.
	Passcode	You can set the passcode feature.
	Care Providers	You can share your data to the Sens365 app. Refer to '9 Sharing your blood glucose information' for detailed information on how to share data.
	Blood Glucose Meter	Register and connect a glucose meter with your smart device.
	Last Upload	The last time data was uploaded to the app is displayed.
	Upload Now	Tap **Upload** to save data stored in the app on the cloud server.
	Manage Data & Connections	Set to link and share data with Samsung Health and Apple Health.
	Unit	Indicates the unit of blood glucose measurement (mg/dL or mmol/L).
	Graph Height	Set the maximum value for the Y axis indicated on the chart.

Icon	Name	Description
	Tutorials	You can access information related to the product.
	FAQs	You will be directed to the 'FAQs' screen.
	Announcements	Move to the 'Announcements' screen.
	About	The current version of the app is displayed. If a new version of the app is available for installation, it will be shown to the right of the current version. Refer to 'Updating the app' for detailed information on how to update the app to the newest version.

Follow the steps below to change your alert settings:

1 Tap at the bottom of the home screen.

2 Make changes on the settings screen and tap **Apply**.
The settings screen offers the following options:

- **Alert type**: Choose from **Sound**, **Vibrate**, **Sound and Vibrate**, or **Mute**.
- **Text-to-Speech**: Choose whether you would like to have your **Glucose level** and **Alerts** read aloud.
- **Glucose level alert**: Enter your very low, low and high alert levels.
- **Rapidly changing**: Choose between **Above 2 mg/dL/min (0.1 mmol/L/min) and Above 3 mg/dL/min (0.2 mmol/L/min)**.
- **System Alerts**: Set whether to receive alerts for signal loss, remaining sensor life, sensor error, and signal anomaly detection.
- **Graph Height**: Choose among Auto, 300 mg/dL (16.7 mmol/L), 400 mg/dL (22.2 mmol/L), and 500 mg/dL (27.8 mmol/L) for the max value of the Y axis.

Setting passcode

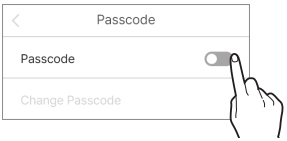
You can set the passcode feature to protect your personal data.

Follow the steps below to set up the passcode feature:

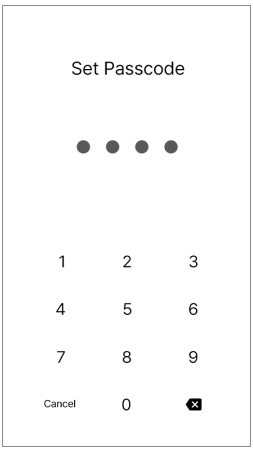
1 Tap ⚙ at the bottom of the home screen.

2 Tap › of **Passcode**.

3 Tap ⬭.



4 Enter the 4-digit password.



5 Enter the password again to confirm.

Note

- Once the lock setting is complete, you need to enter your password to access the app.
- If you have forgotten the password, you can reset it after following the on-screen instructions to go through the verification process.

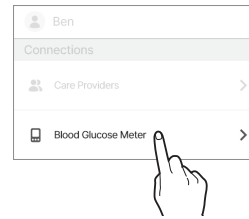
Connecting with a glucose meter

You can connect your CareSens glucose meter with Bluetooth functionality to the CareSens Air app and download your glucose meter data.

Follow these steps to connect a glucose meter:

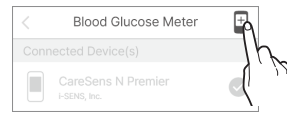
1 Tap at the bottom of the home screen.

2 Tap next to **Blood Glucose Meter**.



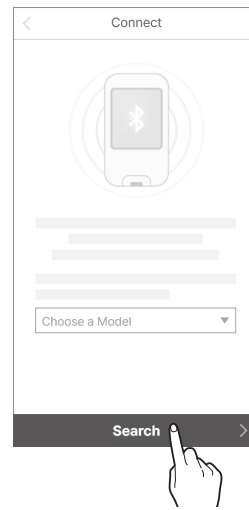
3 Tap to connect with a new glucose meter.

- Turn on your glucose meter on and connect using Bluetooth. The method for connecting with Bluetooth may differ depending on the type of glucose meter you use.

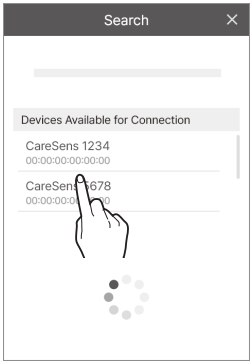


4 Enable the Bluetooth mode of the blood glucose meter, then tap **Search**.

- Refer to the on-screen how to set up Bluetooth for instructions on enabling Bluetooth mode.

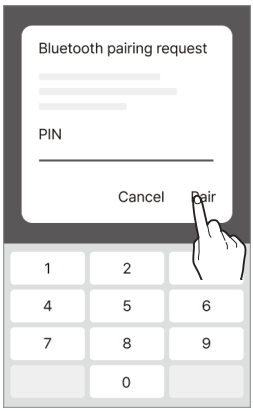


5 From the list of connectable devices, tap the glucose meter you want to connect to.

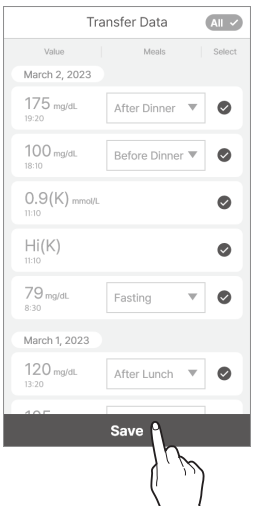


6 Enter the PIN code displayed on the glucose meter screen and tap **Pair**.

- Depending on the blood glucose meter model, pincodes may not be required or connection approval may be required from the blood glucose meter.



7 When the process is completed, the download will proceed. When the download is completed, you will be directed to the 'Transfer Data' screen, and the downloaded glucose level will be displayed. Tap **Save** to complete the process.



Note

Data that has unchecked retrieval is not shown on the app and is excluded from statistics.

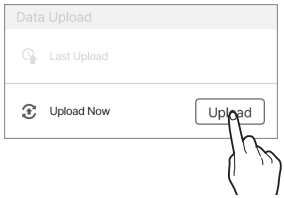
Uploading data

All the data saved on your smart device by the CareSens Air app can be saved and used on the cloud server.

Follow the steps below to upload your app data:

1 Tap ⚙ at the bottom of the home screen.

2 Tap **Upload** to instantly save your app data on the cloud server.



Manage Data & Connections

You can share CareSens Air app data by linking with other apps.

Follow the steps below to share your app data.

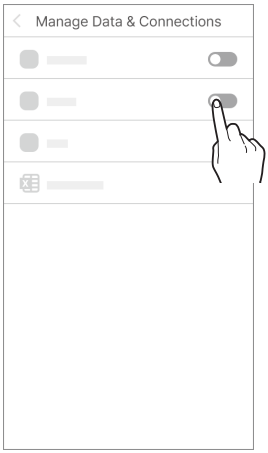
This feature may not be available in all countries or regions.

1 Tap at the bottom of the Home screen.

2 Tap **Manage Data & Connections**.

3 The apps available for data sharing are displayed. Tap to share data.

- For iOS users, the tab is not supported. However, you can check whether you are linked to Apple Health.



4 Tap **Export Data in CSV** to save the data as a CSV file.

Updating the app

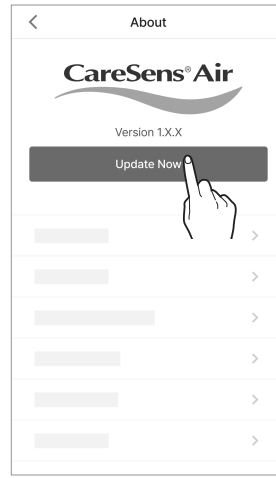
If a new version of the CareSens Air app is available and has not be downloaded, it will be shown on the settings screen.
Go to the App Store to download and install the most recent version.

Follow these steps to update the CareSens Air app to the most recent version.

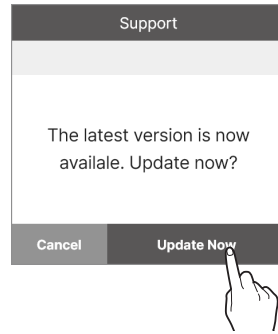
1 Tap at the bottom of the home screen.

2 On the settings screen, tap > next to **About**.

3 Tap **Update Now** in the 'About' screen.
Update is enabled only when a new version of the app is available.



4 Tap **Update Now** in the popup window. You will be taken to the app store.



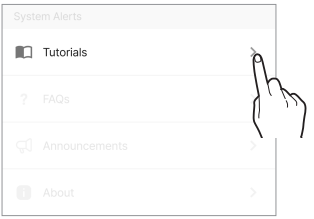
5 Download and install the newest version of the app from the app store. Your existing data will not be affected as the app is updated to the most recent version.

See tutorial

Follow these steps to view the CareSens Air app user guide.

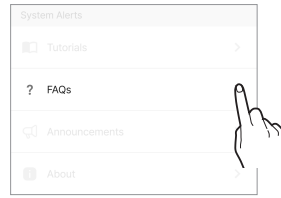
1 Tap ⚙ at the bottom of the home screen.

2 On the settings screen, tap › next to **Tutorials**.

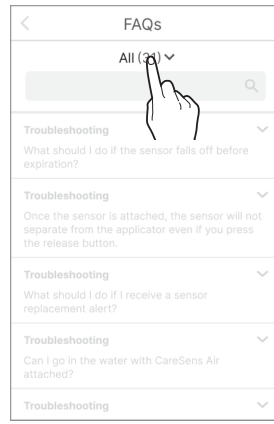


See FAQs

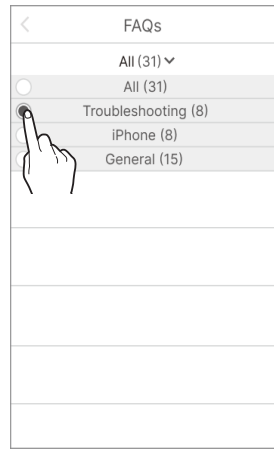
1 Tap > next to **FAQs** to read frequently asked questions and answers. You will be taken to the 'FAQs' screen.



2 Tap ⌄ on the 'FAQs' screen to check the categories.



3 Tap a FAQs category to see a list of topics.



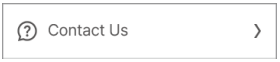
Making an inquiry

You can use the app to ask questions about CareSens Air. The manufacturer's customer service representatives will check your inquiry and reply by email.

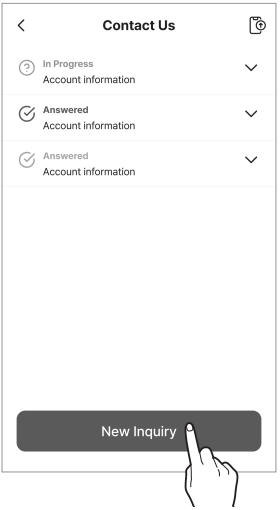
Take the following steps to view inquiries or register a new inquiry.

1 Tap ⚙ at the bottom of the home screen.

2 Tap **Contact Us** on the settings screen. Move to the 'Contact Us' screen and view the inquiries list.

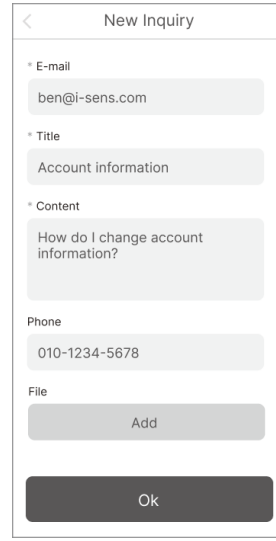


3 Tap **New Inquiry** on the 'Contact Us' screen to make a new inquiry.

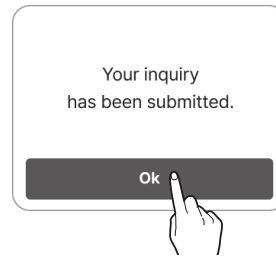


4 On the 'New inquiry' screen, tap **Ok** after making an inquiry.

- **E-mail**: The email address associated with the account is entered automatically and cannot be changed by the user.
- **Title**: Enter the title of the inquiry.
- **Content**: Enter the details of your inquiry.
- **Phone**: Enter the inquirer's phone number.
- **File**: Attach a photo or file related to the question.



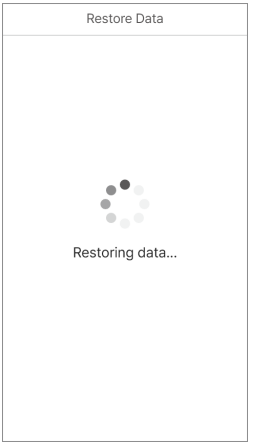
5 Tap **Ok** on the pop-up window which confirms receipt of the inquiry.



Retrieve previous data

If an existing app user reinstalls the app due to changing smart devices, etc., data can be downloaded again from the server.

1 After reinstalling the CareSens Air app, launch the app and log in with your account to restore previous data.



2 A completion message will appear after restoring previous data.

Note

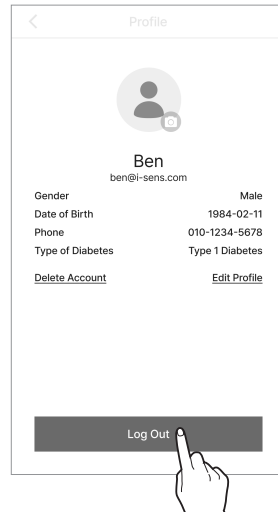
Click on the top of the 'Previous Data' screen (Previous Data on the left-side of the home screen) to retrieve previous data on the app.

3.5 Logging out

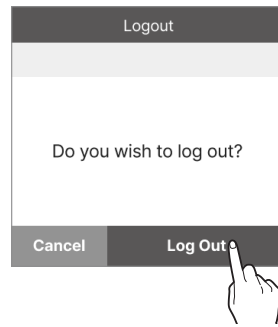
Follow these steps to log out of the app:

1 Tap at the top of the home screen. The 'Profile' screen is displayed.

2 Tap **Log Out** on the 'Profile' screen to log out.



3 Tap **Log Out** on the 'Logout' pop-up window.



Note

- You cannot view your account information while you are logged out. You need to log in to view your existing account information.
- You cannot upload data to the server while you are logged out.

4 Treatment Decisions

4.1 Precautions before treatment decisions

By using CareSens Air, you can make treatment decisions without using a glucose meter. However, before switching from using a glucose meter to making treatment decisions with CareSens Air, some preparation is required.

- You need to understand how a continuous glucose monitoring system works in parallel with CareSens Air and a glucose meter.
- Treatment decisions may include the following actions:
  - Injecting insulin in a hyperglycemic state
  - Having sugar or food in a hypoglycemic state
  - Considering suspending additional treatment and monitoring the glucose level trend when glucose levels are stable or when not much time has passed since treatment was administered.
- Check the situations where a glucose meter should be used for treatment instead of CareSens Air.
- Find out when to refrain from treatment decisions when using CareSens Air.
- Consult your physician thoroughly before making any treatment decisions with CareSens Air, and always prioritize their instructions.

4.2 Cases where you should use a glucose meter instead of CareSens Air

You can make treatment decisions using CareSens Air, but in the following situations, you should use a glucose meter instead:

- When you determine that your physical condition or symptoms are inconsistent with the measurements from CareSens Air
- When glucose levels are not displayed numerically or cannot be confirmed
  - When glucose levels are <40 mg/dL (2.2 mmol/L) or ≥ 500 mg/dL (27.8 mmol/L), exceeding the device's measurable range, it will display only 'Low' or 'High'.
  - Real-time blood glucose values cannot be confirmed if the sensor is stabilizing or a system error occurs.
  - Real-time blood glucose values cannot be confirmed in airport security screening areas due to the smart devices and CareSens Air receivers being submitted for screening.
- When blood glucose values can be numerically confirmed, but the blood glucose velocity arrow appears as •••, making it impossible to determine the velocity of the change in glucose levels

4.3 When to temporarily suspend treatment decisions

When using CareSens Air to make treatment decisions, there may be situations where treatment needs to be temporarily suspended. Consult your doctor to understand the properties of insulin and determine the appropriate administration dosage and timing to prevent hypoglycemia.

- Take care to ensure that the intervals between insulin injections are not too short, and avoid duplicate or excessive dosing.
- During meals and after administering insulin, continuously monitor your blood glucose trends, and do not rush to administer additional insulin before its effects appear.

4.4 Follow your physician's advice when making treatment decisions

CareSens Air users should consult their physician for advice when making treatment decisions. They can seek and apply their physician's advice on the following matters:

- How to manage blood glucose level using CareSens Air
- Understanding insulin use: Mechanism of action, time to onset of effects, dosage, etc.
- Action(s) that users or caregivers should take for hyperglycemia and hypoglycemia
- How to set blood glucose value alerts in the Sens365 app
- Action(s) to take when the glucose meter and CareSens Air values differ
- When to use a continuous glucose monitoring meter and a glucose meter in parallel

4.5 Using blood glucose levels and glucose trend arrows in treatment decisions

You can adjust the insulin dosage by taking into consideration the glucose trend arrow along with the blood glucose level.
Make decisions after consulting your physician.

Velocity arrow	Description
	If your blood glucose levels are rising, consider increasing your insulin dose beyond the usual amount.
	Blood glucose levels are stable, so it is recommended you administer an appropriate dose of insulin.
	If your blood glucose levels are dropping, consider reducing your insulin dose from your usual amount.
	Use a glucose meter to make treatment decisions as the rate of change in blood glucose levels is unknown.

When blood glucose levels are rising

Velocity arrow	Description
	• Hypoglycemia (<70 mg/dL (3.9 mmol/L)): Follow the hypoglycemia management methods recommended by your physician. • Target blood glucose level: Before a meal, consider taking a slightly higher insulin dose to match the rate at which your blood glucose rises. If you have already taken insulin, do not take additional insulin and instead monitor the trend in your blood glucose levels. Avoid administering insulin twice. • Hyperglycemia (>250 mg/dL (13.9 mmol/L)): Before meals, consider taking a slightly higher insulin dose to account for the high glucose level and the rate at which it rises. If between meals, consider taking insulin if you have not taken it recently. If you have already taken insulin, do not take additional insulin and instead monitor the trend in your blood glucose levels. Avoid administering insulin twice.

When blood glucose levels are stable

Velocity arrow	Description
	• Hypoglycemia (<70 mg/dL (3.9 mmol/L)): Follow the hypoglycemia management methods recommended by your physician. • Target blood glucose level: Take the appropriate amount of insulin before meals. If between meals, blood glucose levels will remain stable, so do not take additional insulin and instead monitor the trend in your blood glucose levels. • Hyperglycemia (>250 mg/dL (13.9 mmol/L)): Before meals, consider taking a slightly higher insulin dose to account for the high glucose level and the rate at which it decreases. If between meals, consider taking insulin if you have not taken it recently. If you have already taken insulin, do not take additional insulin and instead monitor the trend in your blood glucose levels. Avoid administering insulin twice.

When blood glucose levels are decreasing

Velocity arrow	Description
	• Hypoglycemia (<70 mg/dL (3.9 mmol/L)): Follow the hypoglycemia management methods recommended by your physician. • Target blood glucose level: Before a meal, consider taking a slightly lower insulin dose to account for the rate at which your blood glucose level is decreasing. If between meals, consider consuming sugar or carbohydrates to maintain blood glucose levels • Hyperglycemia (>250 mg/dL (13.9 mmol/L)): Before meals, consider taking a slightly higher insulin dose to account for the high glucose level and the rate at which it decreases. If you have already taken insulin, do not take additional insulin and instead monitor the trend in your blood glucose levels. Avoid administering insulin twice.

5 Using the watch app

The glucose level received by your smart device with the CareSens Air app can be monitored using a smart watch with the CareSens Air app.

The following smart watch specifications are required to install the watch app.

Recommended smart watch specifications

To install and use the watch app on a smart watch, the following minimum system requirements must be met.

Operating System	Version	Resolution	App Memory	App Storage
Wear OS (Galaxy Watch)	3.0 or higher	192 x 192 px or higher	100 MB	81 MB
watchOS (Apple Watch)	9 or higher	324 x 394 px or higher	100 MB	81 MB

Note

- Make sure to secure the minimum required storage space, before using the watch app. If there is insufficient storage, the watch app may not function properly.
- Check the minimum requirements for your smart watch before installing the watch app. The watch app may not function properly if you update the OS of your smart watch after installing the app.
- Visit the official CareSens Air website(https://caresensair.com/content/compatibility) to find smart watches that have passed our compatibility test. The app may not work properly on smart watches that have not been tested for compatibility.
- The warning notification method may change if the smart watch is used with the CareSens Air app.
- The smart watch communicates with the smart device (mobile phone), not the sensor.
- If the smart watch is not connected to the smart device and the smart device is not connected to the sensor, the smart watch will not receive warnings or glucose levels.

Note

- Make sure to familiarize yourself with how the connected smart watch receives alerts.
- The smart watch must be worn in order for the user to check the warnings and detect the vibrations.
- Ensure that alerts are set to be sent to both the smart device and the smart watch in the smart device settings.
- Do not disable or block alerts from the CareSens Air app.
- When the smartwatch screen is turned on, CareSens Air data is synchronized with the smart device. There may be a slight delay before the latest information appears on the smartwatch app.

5.1 Installing the watch app

Installing on the Galaxy Watch app

Installing the app on a smart device

1 Launch the Play Store app on your smart device.

2 Search 'CareSens Air'.

3 Tap **Install**. After the installation is completed on your smart device, the watch app will automatically install on the smartwatch.

Note

- If you are already using the mobile app, the watch app can be installed under 'Install on more devices' on the Play Store app page.
- The watch app can be found and installed under 'Other devices' or 'Watch' on the Play Store.

Installing the app on a smartwatch

1 Launch the Play Store app on your smartwatch.

2 Search 'CareSens Air'.

3 Tap **Install**. The app will install on your smartwatch.

Installing the Apple Watch app

1 Search 'CareSens Air' in the App Store and tap Install.

2 Launch the Watch app on the iPhone where the CareSens Air app is installed.

- If the Watch app is already installed, close and restart the app.

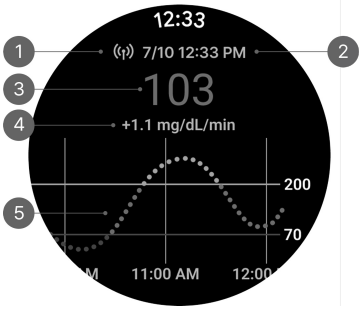
3 The CareSens Air app is now displayed in the 'AVAILABLE APPS' list, and the watch app will automatically install on your Apple Watch. Installation may take a few minutes to complete.

5.2 Understanding the watch app screen

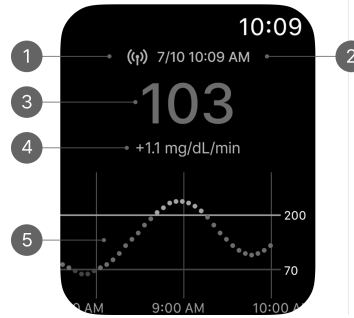
Basic information

The following table explains the basic information displayed on the watch app screen.

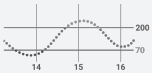
Galaxy Watch



Apple Watch



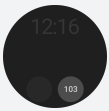
No.	Icon	Name	Description
❶	((ı))	Connection status	The status of the Bluetooth connection between your smart device and the sensor is displayed.
❷	7/10 12:33	Last received time of glucose level	The date and time when the blood glucose level was last received.
❸	103	Glucose level	The most recently measured glucose level is displayed as one of the following. • - : No data has been received within the last 25 minutes • Low: Lower than 40 mg/dL (2.2 mmol/L) • High: Higher than 500 mg/dL (27.8 mmol/L)

No.	Icon	Name	Description
❹	-2.2 mg/dL/min	Glucose changes	The current rate of change in your glucose level compared with the previous measurement is displayed.
❺		Glucose chart	Changes to your glucose level while the sensor is in use are displayed as a graph.

5.3 Using the watch app

Running the watch widget

You can choose from the following 4 types for Galaxy Watch widgets.

Icon	Name	Description
	Glucose trends	The glucose trend arrows are displayed.
	Glucose level	The unit and glucose level are displayed.
	Gauge + glucose level	The glucose level gauge and glucose level are displayed.
	Reception date and time + glucose level	The recent reception date and time, as well as the glucose level, are displayed.

You can choose from the following 5 types for Apple Watch widgets.

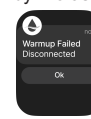
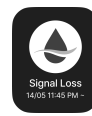
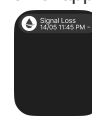
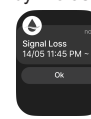
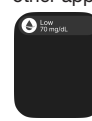
Icon	Name	Description
	Gauge + glucose level	The glucose level gauge and glucose level are displayed.
	Gauge + glucose level + reception time	The glucose level gauge, glucose level, and reception time are displayed.
	Reception date and time + glucose level	The recent reception date and time, as well as the glucose level, are displayed.
	Reception date and time + glucose level + chart data	Reception date and time, glucose level, and chart are displayed.
	Reception date and time+glucose level+trend+changes	Reception date and time, glucose level, trend arrows, and changes are displayed.

Using the watch app alerts

When the app is closed or the smartwatch is locked, the following alerts for each situation are displayed.

Note

Ensure that alerts are set to be sent to both the smart device and the smartwatch in the smart device settings.

Situation	Galaxy Watch	Apple Watch		
		Screen Off status	While using other apps	Checked by the user
When the sensor attached to the sensor user has completed the stabilizing process				
When the sensor attached to the sensor user has failed the stabilization process				
When a signal loss has occurred between the sensor attached to the sensor user and the app				
When the glucose level of the sensor user is lower than the specified 'Very Low' threshold				
When the glucose level of the sensor user is lower than the specified 'Low' threshold				

Situation	Galaxy Watch	Apple Watch		
		Screen Off status	While using other apps	Checked by the user
When the glucose level of the sensor user is higher than the specified 'High' threshold				
When the changes in the glucose level of the sensor user are higher than the specified 'Rapidly Changing' threshold				
When the sensor used by the sensor user is close to expiring				
When the sensor used by the sensor user has expired				
When an error has occurred in the sensor attached to the sensor user				
When a signal anomaly is detected in the signal of the sensor attached to the sensor user				

6 Calibration

Continuous Glucose Monitoring provides the value of the concentration of blood glucose by measuring the concentration of glucose in interstitial fluid. However, if the glucose concentration in the blood changes, the 'glucose' concentration in the interstitial fluid changes about 5 to 15 minutes later. In order to minimize such errors, CareSens Air calibrates the sensor by using readings taken by a glucose meter using finger pricks that must be entered within 5 minutes by the user. The calibration is used to match sensor glucose readings as accurately as possible to the actual glucose level in the interstitial fluid, optimizing the performance of the CareSens Air.

⚠ Caution

Do not calibrate if your blood glucose level is changing rapidly (by 2 mg/dL (0.1 mmol/L) or more per minute). This may affect the accuracy of the sensor.

Note

- Conditions that may cause calibration to be limited.
  - Bad connection between the sensor and CareSens Air app.
  - Rapid changes in the glucose level
  - A lot of sensor noise
- CareSens Air works well without needing calibration. But if user want, they can choose to calibrate it using a glucose meter, following normal steps.

How to calibrate a sensor

Use a glucose meter to measure your glucose level using a finger prick and enter it within 5 minutes into the CareSens Air app. This calibration value will be immediately reflected by the app.

6.1 Measuring a calibration value

If you find that the sensor readings don't accurately reflect your health status, you may align them using a blood glucose meter. A glucose meter is used to measure your glucose level. Refer to 'Connecting with a glucose meter' for more information on how to connect a glucose meter to a smart device.

⚠ Caution

- Do not use a measurement taken from any part of the body (palm, forearm, etc.) other than your fingertip for calibration. The result may be different from one taken by pricking a finger, and this can affect the accuracy of sensor glucose readings.
- If the result of the finger prick reading is lower than 10 mg/dL (0.6 mmol/L) or higher than 600 mg/dL (33.3 mmol/L), it cannot be used as a calibration value.

Note

- If the calibration value is inaccurate, CareSens Air cannot provide accurate blood glucose values. Do not make treatment decisions based on the current blood glucose value.
- It is recommended that you use the same glucose meter for every measurement. The accuracy of glucose meters differs between models.
  If you switch to a different glucose meter while using a sensor, this may result in inaccurate glucose readings.
- Before starting the calibration, make sure that the glucose meter is operating correctly according to manufacturer specifications, and that the date and time on the glucose meter and smart device match.

Follow these steps to measure your glucose level from a finger prick using a glucose meter:

1. Before the finger prick test, wash your hands (including the area you will prick) with warm water and soap, and dry them thoroughly. Do not apply any moisturizer or skin care product to the area you will prick.

2. Follow the instructions on the glucose meter when you prick your fingertip. Make sure to use a fingertip. Measurements made using other parts of the body may be inaccurate.

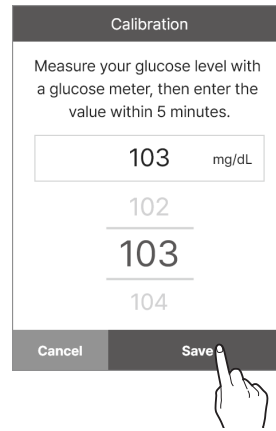
3. Enter the glucose measurement taken using a finger prick within 5 minutes into the CareSens Air app as a calibration value. Refer to '6.2 Entering a calibration value' for more information on how to enter a calibration values.

6.2 Entering a calibration value

In order to ensure that the readings of CareSens Air are accurate, measure the glucose level using finger pricks and enter the calibration value within 5 minutes.

Entering a calibration value

If you want to enter a calibration value, you can do so as shown on the right.



7 Using events

You can use events to record activities and situations which may affect your glucose levels. You can manage events you have recorded on the CareSens Air app using the log book. You can also view them on your glucose trends, allowing you to manage your glucose levels more effectively. Managing your events allows you to track specific activities or situations that affect your glucose levels, allowing you to manage your diabetes more effectively with the help of a medical professional. You have the option of uploading and saving the events you record on the cloud server.

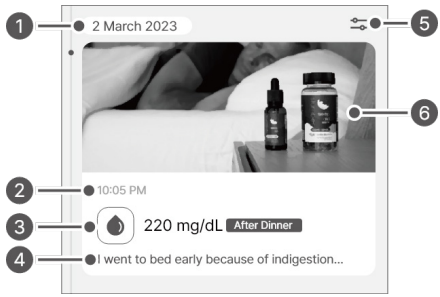
This section will help you to:

- Record, edit, or delete an event.
- Check the event icon on the CareSens Air app.
- See the effect of events on your glucose levels.

7.1 Checking your event information

Viewing the log book

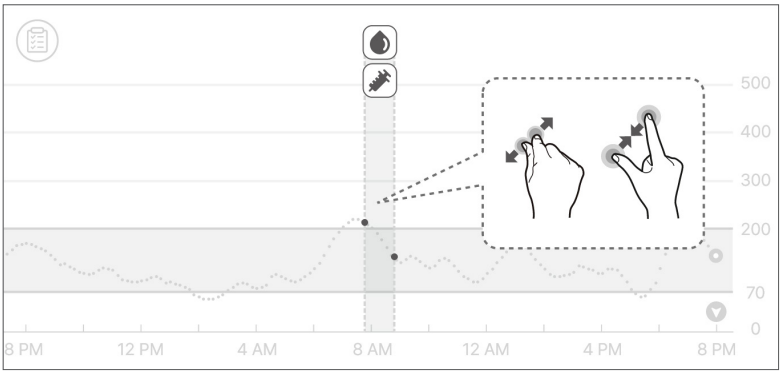
Using the log book, you can record appropriate types of events for a variety of situations, and check your glucose levels before and after they occurred. Events are displayed by the CareSens Air app as shown below. Tap on the bottom of the home screen to view a list of events you have recorded.



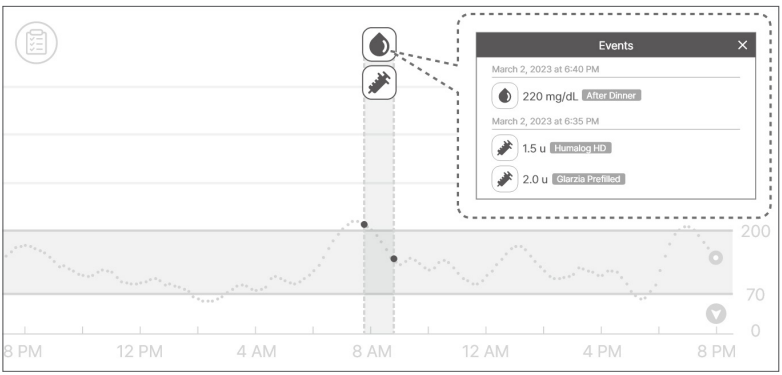
Index	Name	Description
❶	Date	The year, month, and day that the event occurred are displayed.
❷	Time	This displays the time that the event occurred.
❸	Event value	The event value entered by the user and additional information are displayed.
❹	Note	The memo entered with the event is displayed.
❺	Event filter	The results are filtered by the selected item.
❻	File	Displays the picture, audio and files attached to Events.

Viewing events on your glucose trends

When the screen is oriented horizontally, event details are displayed using the icons above your glucose trends at each specific time. The app displays events from the last 24 hours by default, and you can zoom in or out to view events from the past 6 hours, 12 hours, or 24 hours. When multiple categories are recorded as a single event, the number of items entered is expressed as a number, not as an icon. Tap ⌄ under the number to display the event category icons.



You can view the event details by tapping the event icon.



7.2 Recording an event

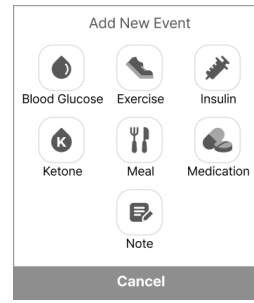
You can record glucose levels, ketones, insulin, oral medication, diet, and exercise that may affect your diabetes management to register them as events

Take the following steps to register an event using the CareSens Air app.

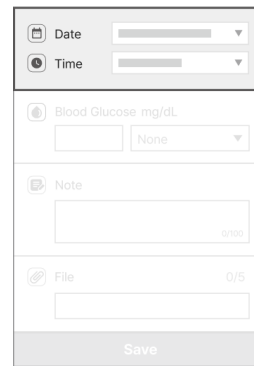
1 Tap on the menu bar of the home screen. A list of events you have recorded is displayed in chronological order, beginning with most recent.

2 Tap (+) at the bottom right of the event list.

3 Tap the event icon you want to enter.



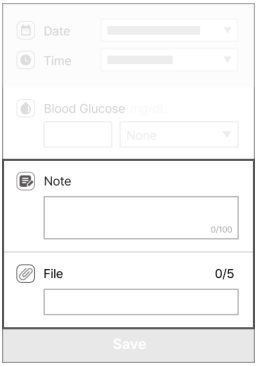
4 On the 'Add New Event' screen, select the date and time of the event.



5 On the 'Add New Event' screen, enter desired information such as blood glucose level, ketone level, insulin, oral medication, meal, and exercise, and then tap **Save**.

- **Blood Glucose**: Enter your blood glucose value and diet information. The unit selected in the Unit section of the settings is displayed.
- **Ketone**: Enter the ketone value.
- **Insulin**: Enter the type and the dose of insulin administered. You can enter up to 2 items.
- **Medication**: Enter the name and the dose of medication administered. You can enter up to 5 items.
- **Meal**: Enter the amount of carbohydrates, proteins, and fat in grams.
- **Exercise**: Enter the type and duration of the exercise.

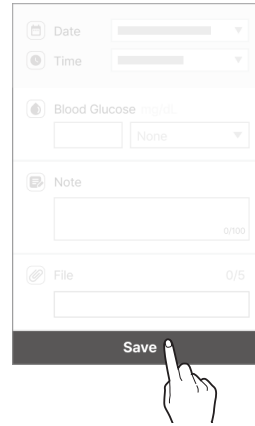
6 If necessary, additional information about the event can be recorded in notes and attachments.



- **Note**: Record any significant information at the time of the event.
- **File**: You can attach files such as photos and audio.

> ⚠ **Caution**
> Depending on the size of the attached file, there may be limitations on the attachment function.

7 Tap **Save** when you finish entering information.



7.3 Changing an event

You can also change or delete any event details you have recorded.

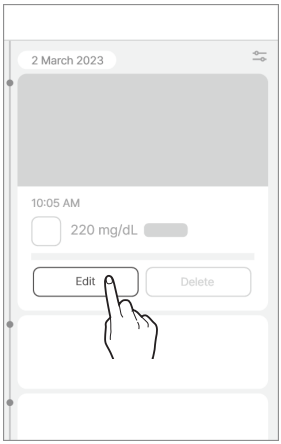
Editing an event

You can edit the event information you have recorded. If the event includes a blood glucose reading taken with a glucose meter or a calibration value entered by you, the date, time, and glucose level of the event cannot be changed. When you edit an event, any category which cannot be edited is disabled.

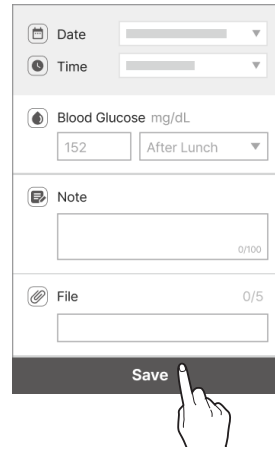
Follow these steps to edit an event you have recorded.

1 Tap ☰ on the menu bar of the home screen.

2 Select the event you want to edit from the event list and tap **Edit**.



3 Edit the category you want to edit and tap **Save**.

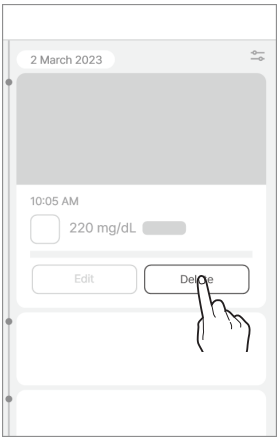


Deleting an event

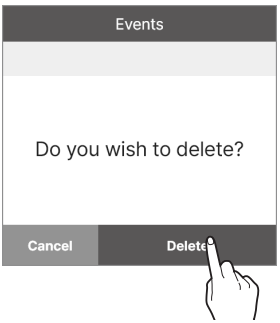
Follow these steps to delete an event you have recorded.

1 Tap ☰ on the menu bar of the home screen.

2 Select the event you want to delete and tap **Delete**.



3 Tap **Delete** to delete an event on the pop-up window.
The event data has been deleted.



Note
Calibration values entered by users and blood glucose readings downloaded from a connected glucose meter cannot be deleted.

8 Using alerts

If you have diabetes, it is extremely important to manage your glucose levels in real time. The CareSens Air app uses alerts to update you with your glucose levels even when it is not running. With the alerts, you can manage your glucose levels as well as your use of CareSens Air in real-time.

The alert function incorporated in this device is characterized as an information signal, as defined by the IEC 60601-1-8 standard.

This chapter will help you to:

- Configure your initial alert settings.
- Understand the differences between various alerts.
- Select appropriate alert settings based on the sound mode of your smart device.
- Change the alert settings to suite you.
- Alerts can notify you of the appropriate times to make treatment decisions.

8.1 Changing your smart device settings

To receive alerts from the app, you must enable app notifications in your smart device's settings.

Note

- Make sure that the volume of your smart device is turned on. You will not be able to hear alerts if the volume is turned off.
- If your smart device is connected to other devices, you can only hear alerts on one device.
  If you connect your smart device to another device, check the settings and make sure that you can receive alerts

Caution

To help you make appropriate treatment decisions, adjust your current alert settings to more easily recognizable ones.

Follow these steps to enable the CareSens Air app to send alerts on your smart device:

1. Open the settings of your smart device.
2. Tap **Notifications**. A list of apps which send notifications will appear.
3. Find CareSens Air on the list of apps on the 'Notifications' screen and tap the icon.
4. In app details, tap **Notifications** and enable **Show notifications**.

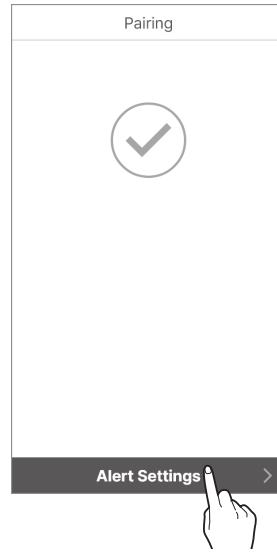
8.2 Initial app alert settings

The initial alert settings are made when you connect a new sensor to the CareSens Air app. You can change your alert settings in the app settings. For more information, please refer to 'Connecting the sensor to Android app' or 'Connecting the sensor to iOS app'.

You can set alerts in the CareSens Air app for glucose level alerts (very low, low, and high) and rapidly changing (2 mg/dL/min (0.1 mmol/L/min) or higher, 3 mg/dL/ min (0.2 mmol/L/min) or higher).

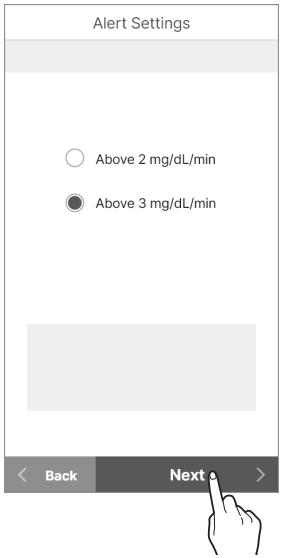
Follow these steps to configure your alert settings on the app.

1 Use the app to finish connecting the sensor and then tap **Alert Settings** on the 'Pairing' screen.

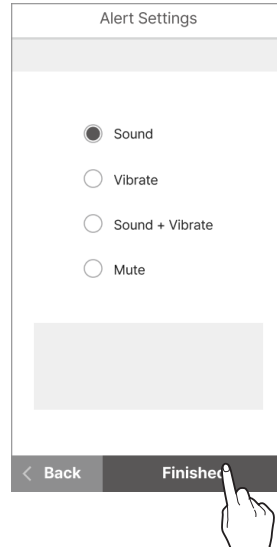


2 On the 'Alert Settings' screen, set the threshold alert levels for Very Low, Low and High and tap **Next**.

3 On the 'Alert Settings' screen, set the rapidly changing glucose level alert and tap **Next**.



4 Choose an alert type, then tap **Finished**.



Note

If you set it to mute, you'll receive alerts without any sound or vibration. If you want to be sure to recognize alerts, set it to sound or vibrate.

8.3 Checking your alerts

CareSens Air uses various alerts to let you know about changes to your glucose level or the sensor status. If multiple alerts are triggered at the same time, the most important will be delivered, in the following order of priority:

- Signal anomaly detection alert > Glucose level alert > Rapidly changing glucose level alert

Note

- If the system notification settings of your smart device and the notification settings of the CareSens Air App are different, those of the CareSens Air App will take priority.
- An alert pop-up will always be displayed, even if the smart device is in 'Mute' or 'Do not disturb' mode.
- It may be difficult to tell the difference between CareSens Air alerts and notifications sent by your smart device or other apps if the app alert type is set to sound or vibration.

This chapter will help you to:

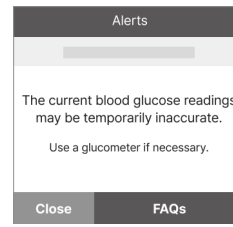
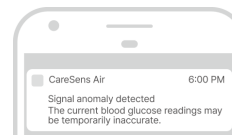
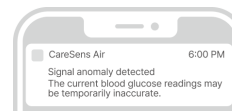
- Tell the difference between the types of alerts sent by the CareSens Air app
- Understand how the CareSens Air app delivers alerts to users
- When alerts occur, you can make appropriate treatment decisions or address system notifications.

Signal anomaly detection alert

Signal anomaly detection alert occurs if an abnormal sensor signal is detected.

This occurs when an abnormal sensor signal is detected. Signal anomalies can result from factors such as improper sensor attachment or pressure, leading to temporary inaccuracies in blood glucose readings. Please check if the sensor is properly attached to your body and ensure there is no pressure on it and wait until the readings stabilize.
Use a glucose meter for up to 1 hour if treatment decisions are required at a time when a anomaly detection alert is occurring.

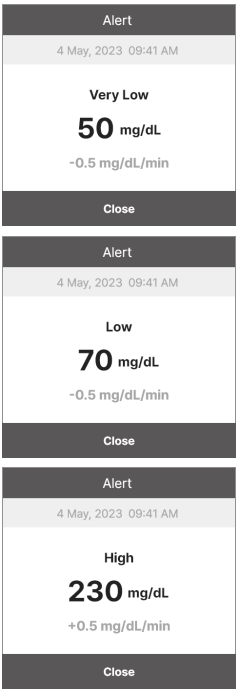
On the following table, you can see the signal anomaly detection alert settings and the content of the messages based on what mode the app is running in.

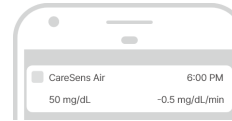
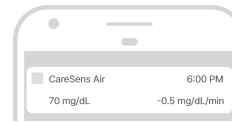
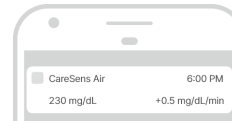
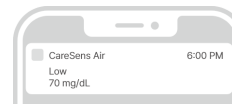
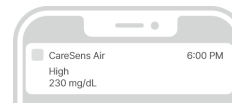
Situation	Alert type	Screen
With app running	Popup alert	
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	
	iOS banner alert	

Glucose level alert

These alerts occur if your glucose level falls below the very low level, above the high alert level, or below the low alert level you have set. Refer to '8.4 Changing alert settings' for information on how to change your blood glucose level alert settings.
When blood glucose value alerts occur, make any necessary treatment decisions.

On the following table, you can see the alert settings and the content of messages based on what mode/situation the app is running in.

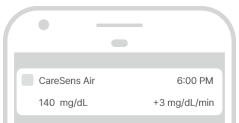
Situation	Alert type	Screen
With app running	Popup alert	

Situation	Alert type	Screen
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	  
	iOS banner alert	  

Rapidly changing glucose level alert

Rapidly changing glucose level alert occurs if your glucose level changes faster than the set rate. You can select above 2 mg/dL/min (0.1 mmol/L/min) or higher and 3 mg/dL/min (0.2 mmol/L/min) or higher as the standard rate for rapidly changing glucose level. Refer to '8.4 Changing alert settings' for more information on how to change your rapid change alert settings.
When a rapid glucose change alert occurs, make any necessary treatment decisions.

On the following table, you can see the rapid change alert settings and the content of the messages based on what mode the app is running in.

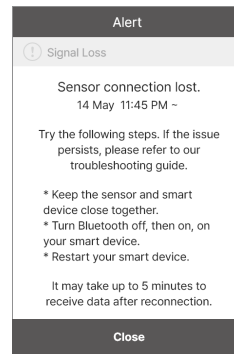
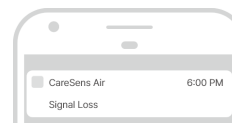
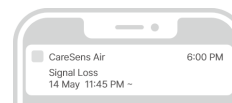
Situation	Alert type	Screen
With app running	Popup alert	
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	
	iOS banner alert	

Signal loss alert

The Signal loss alert occurs when the connection between the sensor and your smart device is lost for 25 minutes or longer.

- Measures to take upon signal loss alerts: Refer to 'If the connection between the sensor and the smart device is interrupted'.
- Change signal loss alerts: Refer to '8.4 Changing alert settings' for information on how to change your alert settings.
- Use a glucose meter if treatment decisions are required during a time when sensor signal loss is occurring.

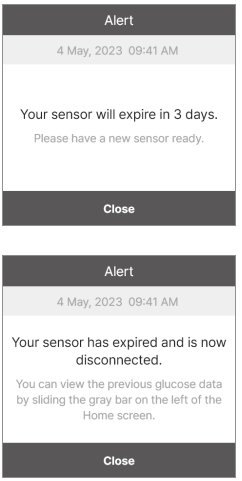
On the following table, you can see the signal loss alert settings and the contents of the messages based on what mode the app is running in.

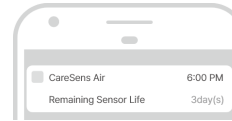
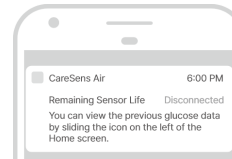
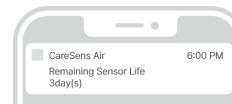
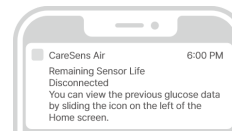
Situation	Alert type	Screen
With app running	Popup alert	
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	
	iOS banner alert	

Sensor replacement alert

The sensor can be used for a maximum of 15 days. This alert occurs 5 days, 3 days, 1 day, and 1 hour before the sensor expires. The sensor is automatically disconnected when it expires.

On the following table, you can check the sensor replacement alert settings and the content of messages based on what mode the app is running in.

Situation	Alert type	Screen
With app running	Popup alert	

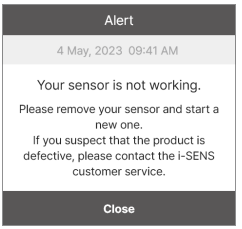
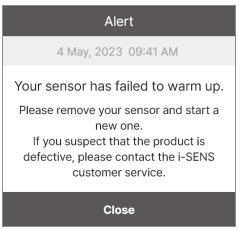
Situation	Alert type	Screen
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	 
	iOS banner alert	 

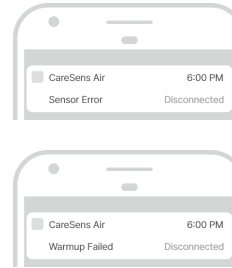
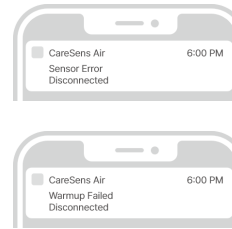
Sensor error alert

When an error occurs in the sensor, the following notification occurs:

If an error occurs during warmup, 'sensor warmup failure' will appear. If an error occurs after warmup has been completed, a 'sensor error' alert occurs. When this alert occurs, the app disconnects from the sensor and can no longer be used. Remove the sensor from the arm as instructed.
Use a glucose meter if treatment decisions are required at a time when a sensor error alert is occurring.

On the following table, you can check the sensor error alert settings and the content of messages based on what mode the app is running in.

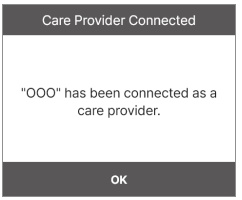
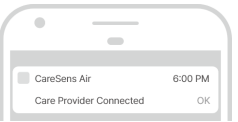
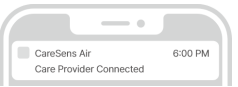
Situation	Alert type	Screen
With app running	Popup alert	 

Situation	Alert type	Screen
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	
	iOS banner alert	

Care provider connection alert

When a new care provider is registered, an alert like the one below will occur.

On the table below, you can check the new care provider alert method and the message content depending on the app running status.

Situation	Alert type	Screen
With app running	Popup alert	
• If you are using your smart device after closing the app • If the smart device screen is locked	Android banner alert	
	iOS banner alert	

8.4 Changing alert settings

In the 'Alerts' settings, you can choose whether to receive alerts for the following categories:

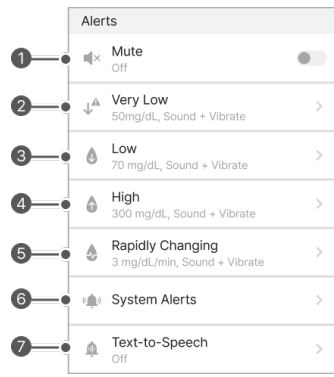
- Glucose level alert.
- Rapidly changing.
- System alerts.
- Text-to-Speech.

Note
Consult with your healthcare professional regarding the appropriate glucose level alert settings for managing your diabetes.

Follow the steps below to change your alert settings:

1 Tap ⚙ on the home screen.

2 On the settings screen, change the alert settings as follows.



No.	Icon	Name	Description
1		Mute	• If mute mode is activated, all alerts are set to mute. When deactivated, all alerts return to the set alert method. • Alerts that are excluded from mute mode - Very low, Signal loss, Sensor error, Sensor expiration, Sensor warmup
2		Very low	Set the threshold value for very low. The values entered are displayed on the target range of the glucose trends on the home screen.
3		Low	Set the threshold value for low. The values entered are displayed on the target range of the glucose trends on the home screen.
4		High	Set the threshold value for high. The values entered are displayed on the target range of the glucose trends on the home screen.
5		Rapidly Changing	Choose between above 2 mg/dL/min (0.1 mmol/L/min) or higher and 3 mg/dL/min (0.2 mmol/L/min) or higher to receive the rapid change alerts.
6		System Alerts	You can set the notifications for signal loss, remaining sensor life, sensor error, and signal anomaly detection.
7		Text-to-Speech	You can receive an additional voice alert when a change in glucose concentration is detected or another alert occurs.

9 Sharing your blood glucose information

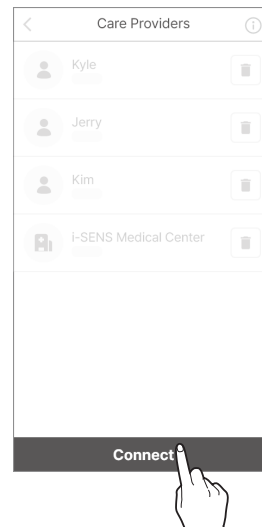
Blood glucose data can be shared with a care provider such as family and friends. Data from the CareSens Air user app is shared in real time with the Sens365 app on the care providers' smart device.

9.1 Invite care providers

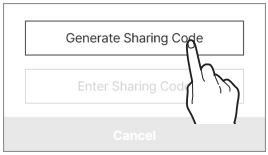
The user can authorize care providers to view the user's blood glucose trends, such as glucose levels and changes in the glucose level arrows, through the connection with the user's CareSens Air app. Care providers can check the history of blood glucose alerts (Very low, Low, High, Rapidly changing) and event history. The user can stop sharing with care providers at any time. Care providers only need to install the Sens365 app on their smart device, not the CareSens Air app.

Follow these steps to connect to the care providers.

1. After running the CareSens Air app, tap ⚙ at the bottom of the home screen.
2. Tap **Care Providers**.
3. Tap **Connect** on the 'Care Providers' screen.

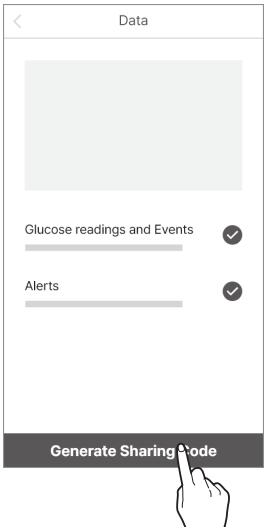


4 Tap **Generate Sharing Code**.



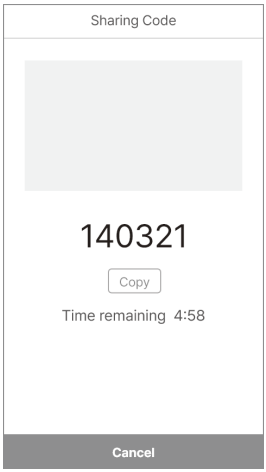
5 On the 'Data' screen, select the data and permissions you want to share and tap **Generate Sharing Code**.
Data for sharing includes

- Glucose readings and Events
- Alerts

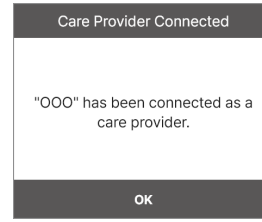


6 Send the generated code to the care provider you want to share your data with.

- The time limit for entering the generated sharing code is 5 minutes.
  If the code expires, please create a new sharing code.
- You can share the sharing code to other media by tapping **Copy**.
- The care provider can have access to the user's blood glucose data by entering the share code into the Sens365 app. For more details, please refer to the Sens365 app user manual.



7 When a care provider is added, an alert notifying that a new care provider has been successfully added is displayed on the CareSens Air app.



Note

For more details on using the Sens365 app, refer to the Sens365 app user guide.

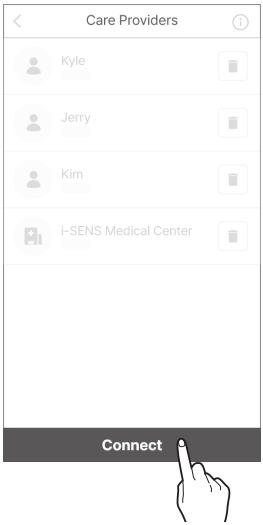
9.2 Enter sharing code to invite care providers

Follow the following steps to enter sharing code to connect care provider.

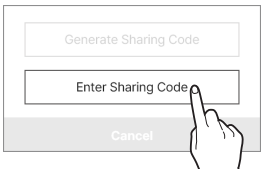
1 After running the CareSens Air app, tap at the bottom of the home screen.

2 Tap **Care Providers**.

3 Tap **Connect** on the 'Care Providers' screen.

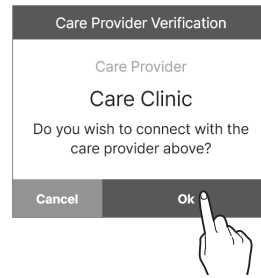


4 Tap **Enter Sharing Code**.

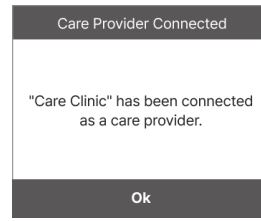


5 On the 'Enter Sharing Code' screen, enter the sharing code and tap **Ok**.

6 If the share code is valid, a care provider confirmation pop-up will appear. Check that it is the correct care provider and tap **Ok**.



7 When a care provider is added, an alert notifying that a new care provider has been successfully added is displayed on the CareSens Air app.



9.3 Changing sharing options

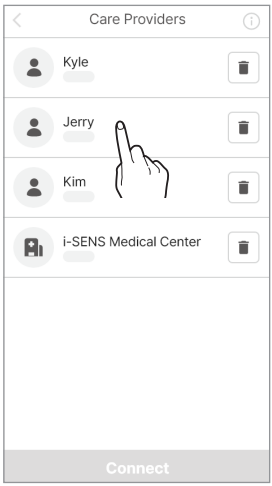
You can temporarily stop sharing your blood glucose data with your care provider or change your options.

Follow the steps below to change the sharing options.

1 Tap at the bottom of the home screen.

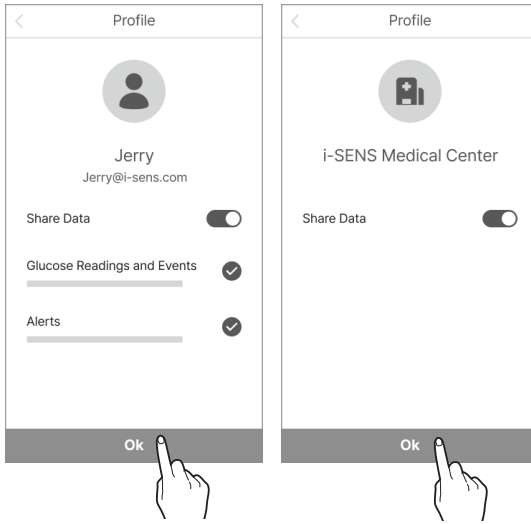
2 Tap **Care Providers**.

3 On the 'Care Providers' screen, tap the care provider whose options you want to change.



4 Change your sharing options and tap **Ok**.

- Data sharing can be enabled/disabled with the enable sharing option.
- You can cancel sharing by unchecking each item.



Note

When CareSens Air users change their sharing options, care providers are notified of the change in sharing options.

9.4 Removing care providers

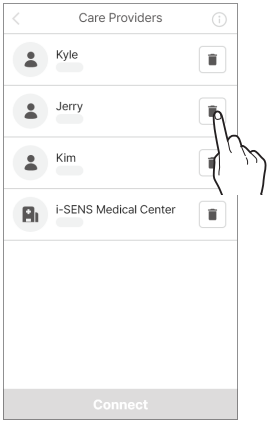
If you no longer want to share data with your care providers, you can turn off data sharing.

Follow the steps below to disconnect.

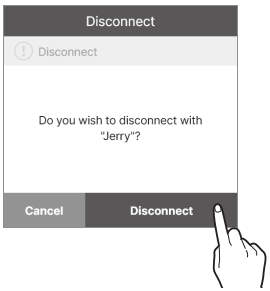
1 Tap ⚙ at the bottom of the home screen.

2 Tap **Care Providers**.

3 On the 'Care Providers' screen, tap 🗑 to the right of the care providers you want to stop sharing data with.



4 On the 'Disconnect' pop-up window, tap **Disconnect**.



10 Maintenance

Learning and following these guidelines for how to take care of CareSens Air will allow you to use it more effectively.

This section will help you to:

- Maintain and take care of the sensor effectively.
- Safely store the sensor.
- Safely dispose of CareSens Air.

Warning

Do not use a damaged or defective sensor. This may lead to infection.

Caution

The sensor has been sterilized with Ethylene Oxide gas (EO) after packaging. Do not clean the product with water or any other solution before use.

Note

This manual only covers the maintenance of the CareSens Air sensor. For how to maintain your smart device, refer to the manufacturer documentation.

10.1 Taking care of the sensor during use

Follow these instructions to take care of the sensor during use.

⚠ Caution
Do not wash the sensor. Using an unsuitable solution could damage the device.

Method	Every day	Before and after use	When needed
Inspecting the sensor	• Make sure that the sensor is secured to the point where it is attached. • Take caution that solid objects smaller than 1.0 mm in diameter do not enter the sensor.	If a skin care product such as sunscreen or insect repellent gets on the sensor, wipe it immediately with a clean cloth.	An alert will occur when the battery begins to run out. Replace the sensor if you receive this alert.

10.2 Storing a sensor

Storing sealed sensor packages properly can keep CareSens Air from malfunctioning.

- Keep sensors sealed (sterilized) until you are ready to attach them.
- Before and after storing a sensor, check the expiration date on the package label.
- Store the sensor package at a temperature of 5–30 °C.
- Store the sensor package at a relative humidity of 15–85 %.

10.3 Disposing of this product

When disposing of a medical device, you must comply with your country's regulations for handling and managing medical waste. Regulations concerning the disposal of the sensor and products that have been in contact with bodily fluids may vary by country.
Contact your place of purchase or customer service for inquiries related to discarding the product.

11 Warranty

i-SENS neither explicitly nor implicitly ensures that its products and services are free from defects in fact or law, (including defects, errors and bugs, infringement of rights, etc. regarding safety, reliability, accuracy, completeness, validity, appropriateness for a particular purpose, security, etc.) and provides no warranty, either implied or otherwise. i-SENS is not obliged to eliminate these defects and provide products or services to users.

i-SENS provides the following limited warranty if problems occur while using this product.

i-SENS guarantees the product's quality during its lifespan which is labeled on the exterior of the CareSens Air package.
However, the quality is not guaranteed in the following cases.

- If damage is caused by the user not following the instructions and cautions listed in the manual
- Accidents, misuse, abuse, negligence, problems due to abnormal physical, electrical, or electromechanical stress
- Equipment whose identification on the sensor package label has been removed or cannot be read
- If damage is caused by using an accessory or separate product not approved by the manufacturer
- If the product is disassembled or assembled by someone not authorised by i-SENS
- If the surface is scratched or damaged through regular use
- Lifespan exceeded

Warranty of replacements

If the sensor is replaced within the warranty period due to a defect from materials or production process, the remaining warranty period is transferred to the replaced sensor, and the replacement's warranty becomes invalid.

Appendix A Frequently Asked Questions

This chapter presents situations that may occur while using CareSens Air and how to deal with them.
If any situation which is not presented in this chapter occurs, or if you experience an issue that you are unable to resolve on your own, contact the authorised distributor.

This section will help you to:

- Identify the causes of problems that occur while using CareSens Air.
- Resolve problems that occur while using CareSens Air.

What should I do if I receive a sensor replacement alert?
The sensor can be used for 15 days, and the sensor replacement alert will occur 5 days before expiration. The sensor is automatically disconnected when it expires. The sensor needs to be replaced in this case. Read 'Disconnecting and removing the sensor' for more information on how to disconnect the sensor.

What should I do if my sensor expires before it is replaced?
A sensor is automatically disconnected when it expires. Remove the sensor from where it is attached and switch to a new sensor.

What should I do if the sensor falls off before expiration?
The sensor cannot be reattached once it falls off. Disconnect the sensor from the CareSens Air app and replace it with a new one. When replacing, refer to the following instructions:

- Attachment Recommendations
  - Disinfect the sensor attachment area with an alcohol swab and allow it to dry completely.
  - After attaching the sensor, press around it with your fingers to secure the adhesive tape.
  - If necessary, you can use the included sensor tape to help prevent the sensor from detaching.

※ The adhesive strength of the CareSens Air sensor tape has been verified through clinical testing. However, please note that the sensor may fall off due to the following external factors:

  - The sensor may detach if it gets caught on clothing while changing. To prevent this, cover the sensor area with your hand.

- If the sensor tape gets wet from activities such as showering or swimming, its adhesive strength may temporarily weaken. Use a towel or tissue to gently press and remove moisture from the tape.
- During sports that involve extensive arm movement, such as golf or baseball, the sensor may detach due to excessive motion. In such cases, apply the included tape or additional medical tape for extra security.

What should I do if the sensor signal is lost?

Check that your smart device's Bluetooth is turned on. If Bluetooth is turned on, refer to 'If the connection between the sensor and the smart device is interrupted'.

My sensor glucose readings do not match the fingertip blood glucose readings.

A BGM (Blood Glucose Meter) measures glucose levels from fingertip blood, while a CGM (Continuous Glucose Monitoring) sensor measures glucose levels from interstitial fluid. Due to the time lag for glucose to reach the interstitial fluid, differences in readings may occur. This difference may be more noticeable during the first couple of days of sensor use. If the sensor readings feel inconsistent with your body's condition, or if needed, you can calibrate them based on your BGM measurement. For more details on sensor calibration, please refer to '6 Calibration'.

What should I do if my sensor glucose reading does not match my physical condition?

Wash your hands thoroughly with water or an alcohol swab, use your glucose meter to obtain a reading by pricking a finger, and compare the result with your physical condition. Consult a medical professional if necessary.

What should I do if I receive a 'Signal Anomaly Detection' notification?

The 'Signal Anomaly Detection' notification appears when the CGM sensor detects a temporary inaccuracy in glucose readings. Below are common causes and recommended actions.

Possible Causes

1. Improper Sensor Attachment
   If the sensor is not properly attached to the skin or is under external pressure, it may not function correctly.
   - Ensure the sensor is securely attached to your skin.
   - Check if any part of the sensor is being pressed or compressed.
2. Interference from Vitamin C Infusion
   Receiving Vitamin C injections or IV drips may cause the sensor to display falsely high readings or trigger errors.
   - If you suspect Vitamin C interference, check your glucose levels using a blood glucose meter.
   - It is recommended to avoid Vitamin C injections while wearing the sensor.

Recommended Actions

If a sensor error is detected, wait up to one hour to see if it resumes normal operation. Until then, using a blood glucose meter to check your glucose levels is the safest approach. If the issue persists or the sensor does not return to normal, please contact customer service.

Once the sensor is attached, the sensor will not separate from the applicator even if you press the release button.

The sensor cannot be used if it doesn't detach properly. Hold the adhesive patch on the sensor and gently remove the sensor from the applicator. If a sensor on an applicator does not detach properly and is not attached in the proper area, the sensor cannot be used. Do not use the sensor, and contact the nearest authorised dealer or customer service center.

What should I do if the place where I attached the sensor is itchy?

Attaching the sensor to the skin can cause slight chafing. The degree of stimulation or itchiness can differ according to environment, individual differences, allergic reactions, etc. If the chafing and itchiness persist even after you change the attachment location, stop use and consult a medical professional.

What should I do if I can't hear the alert?

If you can't hear the alerts on your smart device, check the following factors:

- Check your alert settings on the app.
- Check the permissions and alert volume settings on your smart device.

What should I do if the CareSens Air app doesn’t connect to the sensor or shows a 'Sensor Connection Failed' notification?

What should I do if the CareSens Air app doesn’t connect to the sensor or shows a ‘Sensor Connection Failed’ notification?

- Please check the following:
  Make sure the sensor’s power button is properly pressed. When pressed correctly, you should hear a “click” sound, and the button should move inward.
- Ensure you scanned the barcode on the sensor package label (foil-type). If you entered the information manually via 'Enter Manually', check that you correctly entered the last four digits of the product serial number and the six-digit PIN code from the sensor package label.
- If the sensor was previously connected to the app 'Pasta', it cannot be linked to the CareSens Air app. Please reconnect it to 'Pasta'.
- The issue may be related to your smart device’s system. Restart your device as follows:
  - Android: Go to **Settings** > **Restart** your phone. After turning it off, wait 10–15 seconds before turning it back on.

- iOS: Force close the CareSens Air app and restart it. If the issue persists, restart your phone. After turning it off, wait 10–15 seconds before turning it back on. Additionally, if Background App Refresh is disabled, signal loss may occur. Enable it by going to:
  Settings > **General** > **Background App Refresh** (Wi-Fi/Cellular) > **Enable 'CareSens Air' app**.

How can I terminate a sensor early?
Disconnect the sensor on the app, hold the edge of the adhesive tape, and slowly peel it off. Dispose of the sensor after removing it. Read 'Disconnecting and removing the sensor' for more information on how to disconnect the sensor.

Why is there an empty region on my glucose trends?
When the app is unable to receive sensor glucose readings, the status of the signal icon on the home screen will be displayed as **Signal loss**, and new glucose readings will not be displayed. The sensor takes and sends glucose readings every 5 minutes. Any data that hasn't been sent will be stored for 12 hours. It will be sent automatically when the connection is restored.

Can I go in the water with CareSens Air attached?
CareSens Air has passed a waterproofing test at a depth of 1 m for 24 hours. However, the waterproof performance can change according to the usage environment, and it is best to stick waterproof tape on it for sensor protection and safe use when it will be exposed to water for a long time.

What should I do if the sensor's adhesive strength has weakened?
The sensor's adhesive strength may decrease over time. To help maintain adhesion for as long as possible, please refer to 'What should I do if the sensor falls off before expiration?' in the FAQs for proper attachment and usage guidelines.

Appendix B Technical information

B.1 Device features and characteristics

Electromagnetic compatibility

- This product requires special attention relating to EMC (electromagnetic compatibility) and must be installed and serviced according to the EMC information provided in the manual.
- Using an accessory, sensor, or cable that is not supported by the manufacturer may increase or decrease the system's burst size.
- When the sensor is in use, do not put other equipment close to it. If you are using the sensor in such circumstances, check whether it is operating normally.
- Portable RF communication devices (including peripheral equipment such as antenna cables and external antennas) must be kept at least 30 cm (12 inches) away from all parts of the device. Failure to comply may lead to a decrease in product performance.

The table below includes the manufacturer's declaration and additional information required by IEC 60601-1-2:2014/AMD1:2020 (4.1 Edition).

Testing name	Standard referenced	Part tested	DC main power voltage	Required testing level	Note
Radiated disturbance	CISPR 11:2015 +AMD1:2016 +AMD2:2019	Enclosure	D.C. 3 V	Group 1, Class B	
Electrostatic Discharges (ESD)	IEC 61000-4-2:2008	Enclosure	D.C. 3 V	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air	
Radiated RF electromagnetic Fields	IEC 61000-4-3:2006 + AMD1:2007 + AMD2:2010	Enclosure	D.C. 3 V	10 V/m 80 MHz ~ 2.7 GHz 80 %, AM at 1 kHz RF wireless communication	
Power-frequency Magnetic Field	IEC 61000-4-8:2009	Enclosure	D.C. 3 V	30 A/m	

Testing name	Standard referenced	Part tested	DC main power voltage	Required testing level	Note
Immunity to proximity magnetic fields	IEC 61000-4-39:2017	Enclosure	D.C. 3 V	8 A/m 30 kHz CW Modulation 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	

Safety

IEC 60601-1:2005 + AMD2:2020

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- Protection against electric shock: Internally powered, Type BF applied part
- Mode of operation: Continuous operation
- Not for use in the presence of an oxygen-enriched atmosphere
- Protection against water and particulate matter: IP48

IEC 60601-1-2:2014/AMD1:2020

Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests

- CISPR 11: Group 1, Class B

IEC 60601-1-6:2010 + AMD2:2020

Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 62366-1:2015 + AMD1:2020

Medical equipment – Part 1: Application of usability engineering to medical devices

IEC 60601-1-11:2015 + AMD1:2020

Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Radio regulation compliance

EN 301 489-1

Method of testing common technical EMC for radio equipment

EN 301 489-17

Method of testing EMC for radio equipment of low-output wireless data transmission systems

B.2 Technical specification

Product specification

Parameter	Description
Product Name	CareSens Air
Model No.	CGM-ST-002
Analysis method	Electrochemical method
Enzyme type	GDH-FAD
Measurement range	40–500 mg/dL (2.2–27.8 mmol/L)
Data transfer interval	Once every 5 minutes
Transmission distance	6 meters maximum
Operating conditions	• Temperature: 10–45 °C (The maximum outer surface temperature of the sensor: 48 °C) • Humidity: 10–95 RH % • Pressure: 700–1,060 hPa • Altitude: -382–3,011 m
Storage conditions	• Temperature: 5–30 °C • Humidity: 15–85 RH % • Pressure: 700–1,060 hPa • Altitude: -382–3,011 m
Transport conditions	• Temperature: 5–30 °C • Humidity: 15–85 RH %
Shelf life	12 months
Useful life	Up to 15 days
Sterilization	Ethylene Oxide gas (EO)
Number of uses	Single-use

Parameter	Description
Dimensions (W x L x H)	• Transmitting part: 35.2 x 19.2 x 5.0 mm • Applicator: 51.8 x 49.8 x 73.3 mm
Weight	• Transmitting part: 4.5 ± 0.5 g • Applicator: 74 ± 5 g
Communication method	Bluetooth 4.2
Memory	12 hrs of glucose data
Power supply	One coin battery (CR 1632, 3 V), non-rechargeable
Power consumption	8 mWh
Ingress Protection	IP48: Protected from ingress of dust, protected from submersion in water up to depth of 1m for 24 hours
Packaging specification	• Primary packaging: Tyvek + PET • Secondary packaging: PET + Aluminum sheet

Accuracy Performance

- Clinical Study 2022: The performance of the CareSens Air was evaluated in a controlled clinical study involving 50 participants aged 18 years or older with Type 1 or Type 2 diabetes, using venous glucose measurements as comparison values.
- Clinical Study 2024: The performance of the CareSens Air was evaluated in a controlled clinical study involving 30 participants aged 18 years or older with Type 1 or Type 2 diabetes, using capillary glucose measurements as comparison values.

1) Overall accuracy

MARD (%)	
9.5 % (Clinical Study 2022)	8.7 % (Clinical Study 2024)

2) Accuracy according to the number of days worn

Clinical Study 2022

Number of days worn	MARD (%)
Day 1	11.6 %
Day 2	10.3 %
Day 5	9.4 %
Day 6	9.3 %
Day 10	9.1 %
Day 15	7.7 %

Clinical Study 2024

Number of days worn	MARD (%)
Early (2~5)	9.7 %
Middle (6~10)	7.9 %
End (11~15)	8.5 %

B.3 Cybersecurity

Cybersecurity

- Install an antivirus software on your smart device to prevent malicious programs from accessing your smart device's information.
- If the app and sensor are not connected after scanning the barcode on the sensor package label or manually entering the 6-digit PIN code and 4 digits of the serial number, check if the 6-digit PIN code and 4 digits of the serial number are entered correctly. If the problem persists, contact the Customer Service via the product website caresensair.com.
- If the app connects to the sensor and cannot find a signal, place the sensor and the smart device within 6 meters of unobstructed distance. It may take up to 15 minutes for the connection. If the same problem persists after 15 minutes, force quit the CareSens Air app in the settings app of the smart device and then restart it.
- If you’re logged out and did not log in from another device, reset your password.
- If you have failed to enter your password correctly more than 5 times, reset your password.
- Accounts that have not been logged into for one year will be converted into inactive accounts. If you have switched to an inactive account, email verification is required for log in.
- In the event of a cybersecurity incident related to a smart device, please contact the nearest authorised distributor or the Competent Authority.
- For secure internet access when using your CareSens Air CGM system, please use a cellular data connection, a trusted Wi-Fi network (such as your home or workplace), or a secure connection through a reputable VPN service.
  Avoid using unsecured public Wi-Fi networks, including guest networks in locations such as homes, restaurants, schools, libraries, hotels, airports, or airplanes. These networks may lack proper security measures and could potentially expose your CareSens Air CGM system to cybersecurity risks such as malware or unauthorized access.

Appendix C Glossary

Term	Description
Application	A program developed for user convenience to be used on the operating system of a smart device or a tablet PC.
Applicator	A small tool used for application.
Back	The rear portion of an object
Backing paper	Paper covered with silicone on one or both sides. It is used to protect adhesive surfaces.
BACKUP	To generate additional copies of a file on a location such as a disk in case the file is damaged due to a malfunction.
Bluetooth	A wireless communication technology that allows data to be transmitted over a short distance between wireless communication devices, for example a personal mobile device and electronic office equipment such as a computer or a printer.
Bodily fluid	Refers to blood inside blood vessels or tissues, lymph, and cerebrospinal fluid as a group.
Calibration	The process of providing a continuous glucose monitoring device with a glucose measurement taken from a finger prick. This adjusts the accuracy of the sensor's glucose readings.
Cloud	A system that saves files and information such as documents, photos, music, etc. on a personal online server.
Continuous glucose monitoring system	A system which automatically measures glucose values in a continuous way after a user attaches a sensor to their body. The term can be shortened to CGMS.
CT	Computed tomography. A diagnostic tool in which X-rays or ultrasonic waves are measured from different angles and the images of the reflected internal area are processed by a computer to produce a cross-sectional image. It is a technique used to diagnose various illnesses, including tumors.
Diabetes	A disease which results in a high amount of glucose being mixed with the urine. It occurs when the level of insulin, which is a hormone that controls carbohydrate metabolism, decreases. The frequency and volume of urination increases, water consumption increases due to thirst, and general malaise follows, but appetite improves.

Term	Description
Diameter	A line segment that connects two points on a circle or sphere while passing through its center.
EMC	Electro Magnetic Compatibility, testing for immunity to electro magnetic interference from exterior sources.
Ethylene oxide	One type of cyclic ether. It is oxidized ethylene, a colorless oxide gas. It highly soluble in water, alcohol, and ether, is highly inflammable, and is toxic. It is highly reactive and is used as an ingredient in organic compounds. Its chemical formula is C_2H_4O.
EU	The European Union (an organization formed by 27 countries in the European community under the Maastricht Treaty).
Finger prick	The act of drawing blood for the purpose of diagnosing a disease or performing a transfusion.
Focal	This means many devices are integrated in one semiconductor chip.
Glucose	A type of monosaccharide. It forms white crystals that are sweet and highly soluble in water, and is reducible. It is widely distributed in the biological world, and is consumed as energy by living organisms. Its chemical formula is $C_6H_{12}O_6$. It is also known as glucose.
Blood glucose	Sugar which is carried in the blood. In vertebrates, blood sugar consists mainly of glucose, which is the energy source for the brain and the red blood cells. The level in the blood varies with exercise and meals. BG (blood glucose) can also be referred to as plasma glucose.
Graphical user interface	A display type in which features such as inputs and outputs are displayed in a simple graphical form, making the operation of a device simple and convenient.
GSM	The Global System for Mobile Communications. This is the most widely used personal mobile communication system; a communication standard based on TDMA.
High frequency	A radio wave or electromagnetic wave with a high frequency. This usually refers to waves between 3 and 30MHz in frequency.
Hyperglycemia	A symptom in which glucose concentration in the blood is unusually high. In most cases it is related to diabetes.

Term	Description
Hypoglycemia	A symptom in which glucose concentration in the blood is unusually low. It can be caused by insulin overdose, liver complications, thyroid gland disorders, adrenopathy, pituitary disease, or gastric resection. Symptoms can include hunger, absent-mindedness, and cold sweat. If severe, it could result in holoprosencephaly and coma.
Inflammation	A defensive response that occurs in the body when tissue is damaged. For example, it appears as a symptom in response to an exterior injury, burn, or microbial invasion, and induces hyperemia, edema, fever, and pain in a part of the body.
Insulin	A protein hormone that regulates carbohydrate metabolism. It is secreted by the pancreas. It is used as an allopathic medicine to treat diabetes, as it acts to reduce glucose levels in the body.
Insulin pump	A device that is used to continuously administer insulin 24 hours a day. It continuously administers small dosages of fast-acting insulin, and at the same time adjusts insulin dosage administration to account for meals.
Interstitial fluids	A liquid component that exists in between animal tissue cells and acts as a cell environment. It provides nutrients to cells and removes waste products from them.
IP rating	Ingress protection, a dustproof and waterproof rating regulated by IEC 60529. The first number is a dustproof rating and the second number is a waterproof rating.
Magnetic field	A space in which there is magnetic attraction such as near a magnet or current, or the Earth's surface.
Metal detector	A machine that is used to locate metal objects or determine whether or not an object is metallic.
MRI	Magnetic resonance device (a piece of equipment for chemical analysis that uses magnetic resonance phenomena).
Rating	The rating of an electrical device or any other device is the specified range the device should be used within.
Redness	A symptom in which the skin or mucous membranes swell and become red due to infection. This is caused by enlarging of the capillaries.
RF	Radio frequency; the entire field of equipment design and engineering research concerning wireless communication using high frequencies in the electromagnetic frequency band.

Term	Description
RF communication	Wireless communication
Rooting	The process of acquiring administrator rights on a smart device running the Android operating system.
Sterilization	A process which kills bacteria and other microscopic organisms. This can be done using chemicals, or physically using heat.
Type BF Applied Part	A type BF applied part is classified as a type F applied part, meaning that it is electrically isolated from Earth. This requires a higher protection rating than a type B applied part. This protection rating is designed to protect the user from shock if an unexpected surge from an external power source is connected to the patient and is applied to the patient contact location and the ground.
Water resistance	The property of being resistant to water.
WEEE	Waste Electrical and Electronic Equipment. Regulations regarding obligations for recycling household appliances which have been disposed of. An EU environmental guide which requires consumers to pay recycling fees for disposing of electrical or electronic equipment.
Widget	A collection of features which a user can easily access from the home screen of their smart device, with the most used features in one place.

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