CareSens™ Air
Continuous Glucose Monitoring System

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Safety information

You must read, understand, and strictly comply with the indications, contraindications and warnings listed in this Safety information section 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 healthcare processionals.

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 wait for it to dry 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 other parts 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 removing the safety cap, be careful not to point the applicator towards anyone.
- 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 the 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 healthcare 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 healthcare 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 site 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.
- 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 oedema) or itchiness in some users. If this occurs, remove the adhesive tape and/or sensor immediately and consult a healthcare 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 healthcare professional if you experience any problems.
- Swallowing the sensor could result in choking. Please supervise children so that they do not touch the sensor.
- Blood glucose readings obtained using CareSens Air cannot substitute the care of a healthcare 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 healthcare professionals with diagnosis and treatment.
- Be aware of potential variations in sensor performance, especially during the early phase after sensor attachment.
- If you find that the displayed blood glucose level does not accurately reflect your symptoms, you should immediately use a blood glucose meter to check and make treatment decisions. Take medical action or follow your healthcare professional's instructions.
- 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.
- 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 (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 0.6 mmol/L or higher than 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 make it easily recognisable 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.

⚠ Warning

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.

Risks and benefits

Risks

The risks of using CareSens Air CGM System are:

- Missing your alerts
- Retained sensing part
- Adhesion reactions
- 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 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 and remain under the skin as this did not occur 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 in the user manual before making any treatment decisions.

Benefits

The benefits 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 manage 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 your healthcare professional.

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' in the user manual for more details on events.

Understanding CareSens Air

⚠ Warning

Glucose readings obtained from the CareSens Air CGM System cannot substitute 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 healthcare 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 fluid 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.

Product components

A CareSens Air sensor is designed for single-use only. 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 included 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.

⚠ Warning

- 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 healthcare professional if you experience any problems.

Applicator | Instructions for Use | Sensor tape | CareSens Air app

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.

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.

Note

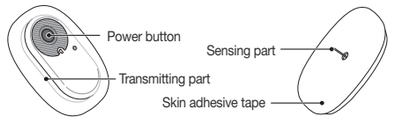
- The applicator is intended for single-use only and cannot be re-used.
- Do not press the Release button until you have removed the safety cap from the applicator and are ready to attach the sensor.

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 an 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 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	Has a built-in battery and transmits the glucose level measured by 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

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 glucose level 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.

Definitions of symbols

The following table lists graphical symbols for electrical equipment in medical practice set by the International Electrotechnical Commission (IEC). 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
	Regulatory compliance mark
	Warning (Contains coin battery)
	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
	Importer
LOT	Batch code
SN	Serial number
	Use-by date

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Pharmaco (NZ) Ltd.
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How to Use

1. Installing the app and registering an account

Please search for CareSens Air on Google Play or App Store and install it and create an account.

Note
Download CareSens Air app
You can download the CareSens Air app by typing the link in your browser or scanning the QR Code.
https://www.caresensair.com/content/download_03

❶ Launch the CareSens Air app on your smart device and tap **Create an account**.

– Enter the email you want to sign up with and tap **Send**. A verification code will be sent to the email address you provided when signing up. Enter the six-digit code to complete the verification.

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.

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

2. Connecting the sensor

Scan the barcode on the package label to connect the sensor with the smart device.

❷ Launch the CareSens Air application on your smart device and log in. Tap **Safety Information** › Read the 'Safety Information' › Tap **Scan Sensor Information** in that order.

❸ Scan the barcode on the package label of the sensor, or manually enter the last 4 digits of the serial number and the 6-digit PIN code.

Note
- Expired sensors cannot be used. Please check the expiration date before use.
- Make sure to enter the correct information indicated on the sensor package label. The sensor will fail to connect if you enter the wrong serial number or PIN code.

❹ Check how to attach the sensor and then tap **Start Pairing**.

3. Attaching the sensor

Attach the sensor to your upper arm and press the power button. Wait until the sensor connection is completed.

❺ Open the CareSens Air sensor package. Take the applicator out of the package and set it on a flat, stable surface.

❻ Hold the applicator and remove the safety cap.

❼ 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.

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

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

❿ Press the power button until it clicks. The button is then recessed inward. Wait until the sensor connection is completed.

- 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.
- 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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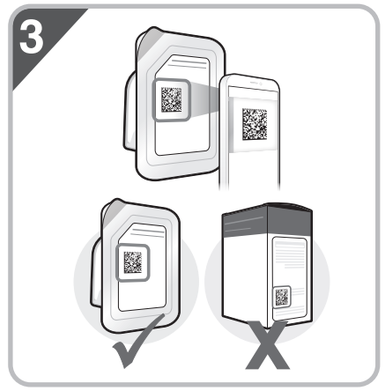

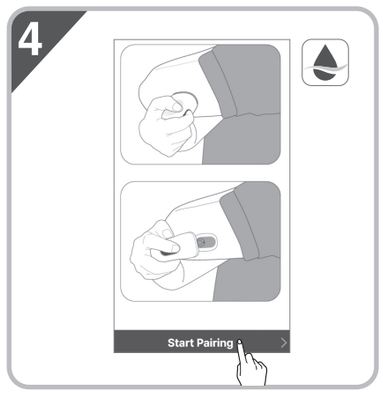

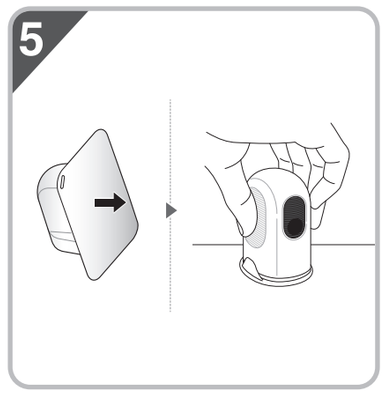

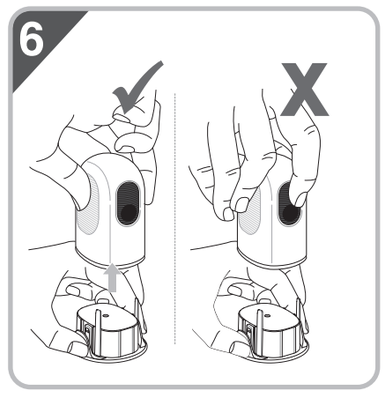

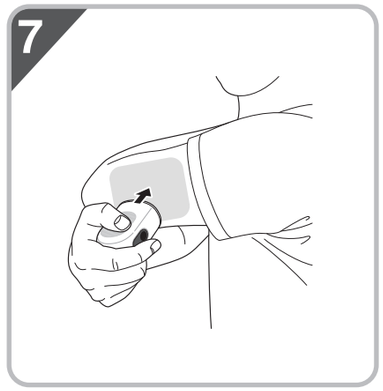

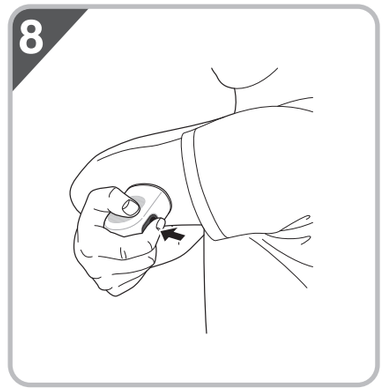

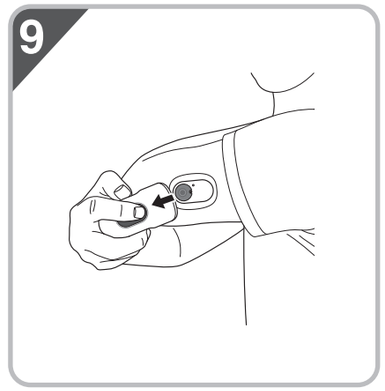

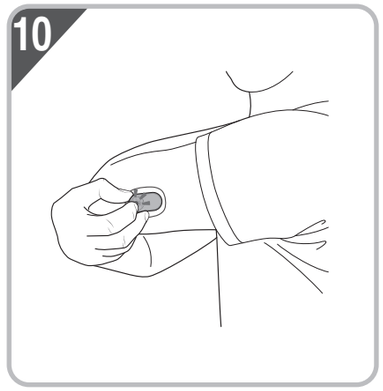

Download Instructions for Use

Please download the CareSens Air User Manual by typing the link in your browser or scanning the QR Code below.
For more troubleshooting information, please contact the nearest authorised distributor.

https://caresensair.com/download