i·sens

***Distributed by*: i-SENS USA, Inc.**
3545 Lomita Blvd., Unit D
Torrance, CA 90505, USA

© 2023 i-SENS, Inc. All rights reserved.

PCGAA-000033 REV A 2023-05

i·sens

User manual

CareSens® Neon

CONTINUOUS GLUCOSE MONITORING SYSTEM

Continuous glucose monitoring system

- Usable for 15 days
- Easily equipped at once
- Slim Design

This manual is intended to help you use CareSens Neon 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.
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. This document is protected by copyright. It is strictly prohibited to copy or alter this manual without prior consent from i-SENS.

Note

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

i·sens

Table of contents

Before use 8

Document conventions 8
Safety Information 11
Risks and Benefits 15

1 Understanding CareSens Neon 17

Intended purpose 17
Significance of use 17
Operating mechanism 18

1.1 Product components 19

Applicator 20
Sensor 21
Smart device 21

1.2 Conditions for use 22

Expiration date 22
Conditions for use and storage 22

2 Installing the CareSens Neon app 23

Recommended smart device specifications 23

2.1 Installing the app on an Android smart device 24

2.2 Installing the app on an iOS smart device 24

3 Using the app 25

3.1 Logging in 26

For first-time users 26
Previously registered users 29
Reset password 30

3.2 Connecting to a sensor 33

Connecting the sensor to Android apps 34
Connecting the sensor to iOS apps 38
Attaching the sensor 41
Configuring your alert settings after connecting to the sensor 45
If the sensor fails to connect 48
If the connection between the sensor and the smart device is interrupted 48
Disconnecting and removing the sensor 49

3.3 Understanding the home screen 51

Basic information 52
Menu bar 53
Glucose data 55
Trend arrows 58
Interpreting trends in glucose data 59
Viewing previous data 61
Alert History 62

3.4 Exploring the app features 63

Running the widget 64
Entering a calibration value 65
Editing and checking your profile 66
Viewing the log book 67
Recording an event 69
Changing your settings 70
Setting app lockout 73
Connecting with a glucose meter 74
Uploading data 77
Updating the app 78
Deleting data 79
See how to use 81
See Help 82
Making an inquiry 83

3.5 Logging out 86

4 Calibration 87
4.1 Measuring a calibration value 88
4.2 Entering a calibration value 89

5 Using events 90
5.1 Checking your event information 90
Viewing the log book 90
5.2 Recording an event 92
5.3 Changing an event 94
Editing an event 94
Deleting an event 97

6 Using alerts 98
6.1 Changing your smart device settings 98
6.2 Initial app alert settings 99
6.3 Checking your alerts 102
Lost signal alert 103
Glucose level alert 104
The 'Rapidly changing' glucose level alert 105
Low battery alert 106
Sensor replacement alert 107
Sensor error 108
6.4 Changing notification settings 109

7 Maintenance 111
7.1 Taking care of the sensor during use 112
7.2 Storing a sealed sensor 112
7.3 Disposal of product 112

8 Warranty 113
Warranty period 113
Warranty exclusions 114
Warranty obligations 114

Appendix A Frequently Asked Questions 115

Appendix B Technical information 118
B.1 Device features and characteristics 118
Electromagnetic compatibility 118
Safety 120
Radio regulation compliance 121
B.2 Product specifications 126
Sensor specifications 126
Applicator specifications 127
B.3 Cybersecurity 128
Cautions regarding cyber threats 128
Security Measures 128

Appendix C Glossary 129

i·sens

Before use

- CareSens Neon is intended for people aged 18 years or older who are diabetic or need glucose level management. It continuously monitors the glucose concentration in interstitial fluid in real time. Continuous Glucose Monitoring provides the concentration of glucose in the blood by measuring the concentration of glucose in interstitial fluid. However, if the glucose concentration in the blood changes, the 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.

Note

- All standards and regulations mentioned are in effect as of the date this manual was issued.
- Some features described in this manual may not be available in some countries.
  Please consult the local representative for region-specific information.
- The screenshots and illustrations in this manual are provided for explanatory purposes. They may differ from the actual appearance.

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.

Notational conventions	Description
'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.

Precautions

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
	Medical device
	Caution
	Do not reuse
	Please refer to the user manual
	Type BF Applied Part
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if the package is damaged
	Sterilized using ethylene oxide
	Degree of protection against ingress of foreign material or water

Safety Information

You must read, understand, and strictly comply with the precautions listed in this chapter before using CareSens Neon.

Contraindications

- Remove the sensor before an 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 should not be used by those who are pregnant or nursing, or under the age of 18.

Warning

- Severe hypoglycemia 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.
- If you use an insulin pump, attach the sensor at least 8 cm away from it.
- If the sensor's 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 symptoms such as 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 notice bruising or severe bleeding at the location where the sensor has been attached, discontinue use and remove the sensor, then consult with a physician or medical professional without delay.
- In the event of slight bleeding when attaching the sensor, an improperly attached sensor, or abnormal measurements, you must remove the sensor and attach a new sensor to a different part of the body.
- 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 skin adhesive tape and/or sensor immediately and consult a physician or medical professional.
- Swallowing the sensor could result in choking. Please supervise the children so that they do not touch the sensor.
- The app data from CareSens Neon may be lost if it is not uploaded to the cloud server.

Warning

- 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.
- 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.
- Blood glucose readings obtained using CareSens Neon 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.
- The user should not make treatment decisions on their own based on the glucose data obtained with this product. Make treatment decisions after consulting with a medical professional.
- Do not use the sensor if the package is damaged or opened. This may lead to infection.
- Keep the desiccant included in the package out of the reach of infants and 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.
- 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.
- After you separate the safety pin from the applicator, be careful not to point it toward any person.
- Do not press the release button on the applicator until you are ready to attach the sensor.
- 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 damaged or defective sensor. This may lead to infection.

Warning

- 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.
- In order to prevent airborne contamination, make sure to attach the sensor immediately after opening the applicator.
- 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.
- Do not use a measurement taken from any other part of the body (palm, forearm, etc.) other than your fingertip for calibration. The result may be different from one taken using a finger prick, and this can affect the accuracy of the sensor glucose readings.
- If the result of the finger prick reading is lower than 40 mg/dL (2.2 mmol/L) or higher than 500 mg/dL (27.8 mmol/L), it cannot be used as a calibration value.
- If a blood glucose level alert occurs, check your glucose level using a glucose meter. If the result is the same, consult with a physician or medical professional.
- Do not remove the safety pin of the applicator until you are ready to attach the sensor. Failure to comply may lead to infection caused by exposure to bacteria.

Caution

- The applicator and the sensor are intended for one-time 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 Neon.
- 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 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 Neon 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 1.2 meter. Please do not submerge the product deeper than 1.2 m or longer than 24 hours.
- You may pass Advanced Imaging Technology (AIT) screening or security checkpoints, including metal detectors, with the CareSens Neon attached. If you are unable to use your smart device at the security checkpoint, measure your blood sugar with a blood sugar meter. Please check the airport security checkpoint before you 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, never close the app after connecting the sensor. It will be disconnected from the sensor.

Risks and Benefits

Risks

The risks of using CareSens Neon are as follows.

- Missing alerts
- Side effects on the skin
- Risks when inserting the sensing part

Missing your alerts

To not miss alerts from CareSens Neon, you should follow i-SENS' recommended settings for smart devices. For more information, refer to Settings > Manual > Using alerts > Smart device settings from the CareSens Neon app. If you want to see helpful information, refer to Recommended smart device specifications, Using alerts, and Frequently Asked Questions.

Adhesion reactions

The skin adhesive tape used with CareSens Neon have passed a biological stability test. The side effects on the skin are slight and do not occur in most people. Some people who participated in clinical studies experienced redness and edema, but these side effects did not lead to serious complications.

Retained sensing part

The sensing part of CareSens Neon did not become disconnected in clinical studies. However, there is a low chance that the sensing part may break or become disconnected and remain under the skin. The sterilized sensing part breaking or becoming disconnected and remaining under the skin will generally not lead to serious complications. If the sensing part breaks or becomes disconnected and remains under the skin, causing symptoms of infection or inflammation, please contact a medical service provider, i-SENS customer service (+82-80-910-0600), or a local i-SENS dealer.

Benefits

The benefits of using CareSens Neon are as follows.

- Preventing hyperglycemia and hypoglycemia with alerts
- Analyzing your glucose trend and pattern for better diabetes management

Tracking trends and patterns

CareSens Neon provides continuous glucose information to detect hyperglycemia and hypoglycemia, analyzes trends and patterns to manage changes in glucose levels, induces better decisions on foods and exercise habits, and can be used when consulting with a medical professional.

Keeping informed

If you have diabetes, it is extremely important to manage your glucose levels in real time. The CareSens Neon app informs you when your glucose level is too high, too low, or changing rapidly, with alerts. You can manage diabetes better with alerts.

1 Understanding CareSens Neon

Intended purpose

The CareSens Neon Continuous Glucose Monitoring System is indicated for continuous monitoring of blood glucose levels via measurement of glucose in the interstitial fluid in patients with diabetes mellitus aged 18 years and older. CareSens Neon System is indicated for use as an adjunctive device to complement blood glucose information obtained from standard home glucose monitoring devices and does not replace it. CareSens Neon 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. CareSens Neon System results should not be used to diagnose diabetes nor provide any medical decisions. CareSens Neon System is intended for use by patients at home and in healthcare facilities.

⚠ Warning

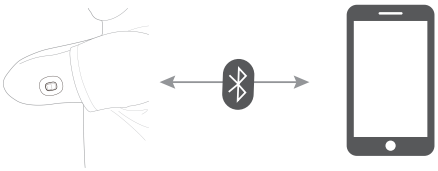
Glucose readings obtained from CareSens Neon cannot be substituted for a professional medical care. They are only intended to provide the patient with data on glucose level changes in order to help with diagnosis and treatment through consultation with a medical professional.

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 Neon 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 provides the concentration of glucose in the blood by measuring the concentration of glucose in interstitial fluid. However, if the glucose concentration in the blood changes, the 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 rear 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 Neon sensor to help with diabetes management.

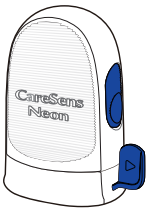
The user can monitor the blood glucose level data received from the sensor in the CareSens Neon app on a smart device. You can also use the app to record information on life events and to input calibration values taken with a glucose meter, which can lead to more effective diabetes management.

1.1 Product components

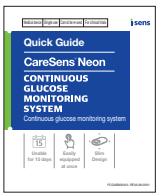
CareSens Neon is only designed for one-time use. Once it has been attached, the sensor cannot be re-used.
The contents of the package are as follows: Make sure that all of the contents are present before opening the package.

⚠ Warning

- Do not use the product if the sensor package is damaged or opened. This may lead to infection.
- Keep the desiccant included in the package out of the reach of infants and 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



Quick Reference Guide

User manual

🔍 Note

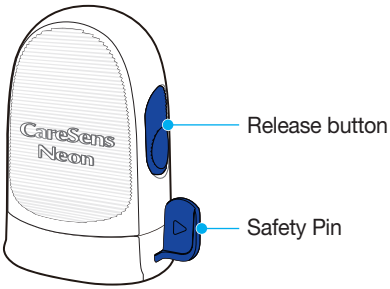
The sensor is inside the applicator.

Applicator

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

Note

- The applicator is intended for one-time use only and cannot be re-used.
- Do not press the Release button until you have removed the applicator's safety pin and are ready to attach the sensor.



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

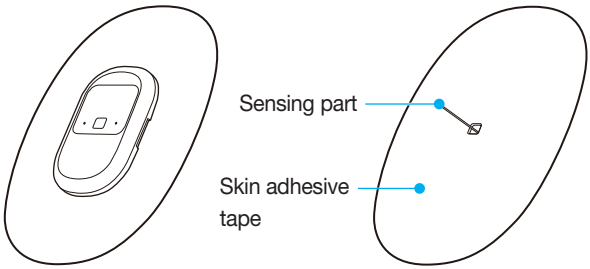
Name	Function
Safety Pin	This prevents the sensor from being released unintentionally.
Release button	When this button is pressed, the sensor is released and attaches to the user's body.

Sensor

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

Note

- The sensor is water resistant. It can be submerged in up to 1.2 meter of water for up to 24 hours.
- Solid foreign substances measuring 1.0 mm or larger cannot enter the sensor.
- The smart device and the sensor must be kept within 10 meters between each other.
  The transfer range of the sensor decreases when it comes into contact with water.
- The battery of the sensor has a life of 15 days. An alert will occur when the battery begins to run out.



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

Name	Function
Skin adhesive tape	Attaches the sensor to the user's skin.
Sensing part	Measures the user's glucose levels.

Smart device

You can use the CareSens Neon 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, refer to 'Connecting the sensor to Android apps' or 'Connecting the sensor to iOS apps'.

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 '7.3 Disposing product' for more information on sensor disposal.

⚠ Caution
Do not use an expired sensor.

Conditions for use and storage

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

Category	While in use	While storing or transporting
Temperature	10–42 °C	5–30 °C
Humidity	10–95 %	15–85 %
Altitude	-382–3011 m	-382–3011 m
Pressure	700–1,060 hPa	700–1,060 hPa

2 Installing the CareSens Neon app

You can use the CareSens Neon 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

Your smart device must meet the following specifications for you to be able to install the app.
The following smart device operating systems are compatible with the CareSens Neon app by their manufacturers.

Note

- Make sure that you connect your sensor to a smart device that meets the recommended requirements. Smart devices with operating systems which have not been verified as compatible by the manufacturer are not guaranteed to operate normally.
- You must check the OS version of 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.
- 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.

Operating system	Version	Manufacturer
Android	Android 8.0 or higher	Samsung, Google
iOS	iOS 13.2 or higher	Apple

2.1 Installing the app on an Android smart device

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

2 Enter "CareSens Neon" into the search bar of the Play Store and tap .

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

4 Wait for installation to be completed and tap **Open**. The CareSens Neon app will launch.

2.2 Installing the app on an iOS smart device

Note

Do not install the app on an iOS smart device that has been jailbroken or an Android smart device that has been rooted.
The app may not function properly.

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

2 In the App Store, tap and enter "CareSens Neon" into the search bar.

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

4 Enter your Apple ID and password.

5 Wait for installation to be completed and tap **Open**. The CareSens Neon app will launch.

3 Using the app

The CareSens Neon app allows users to monitor the glucose readings taken by the sensor on their smart devices. You must be registered in order to log in to the CareSens Neon app. Any data stored in the CareSens Neon app can be uploaded to the cloud server and stored in encrypted form.
In the event that your data is lost, it can be retrieved from the backup data stored on the cloud server.
The glucose change arrows, glucose trends, events, and calibration values available on the app allow you to manage your diabetes more effectively.

This section will help you to:

1. Register for 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.

3.1 Logging in

To use the CareSens Neon 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.

Note

To use the CareSens Neon app, the following permission agreement is required on your smart device:

- Android: Location, Storage, Phone, Notifications, Camera
- iOS: Storage, Phone, Notifications, Camera

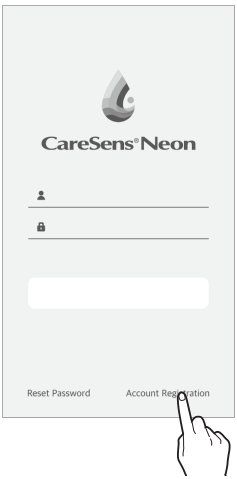
For first-time users

You can register with both the CareSens Neon app and SmartLog at the same time. Follow the steps below:

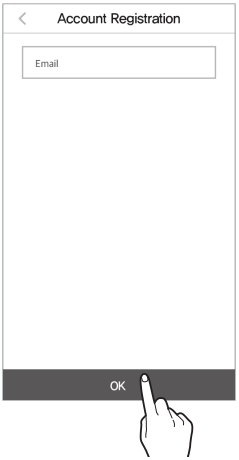
1 Launch the **CareSens Neon** application on your smart device.

CareSens Neon

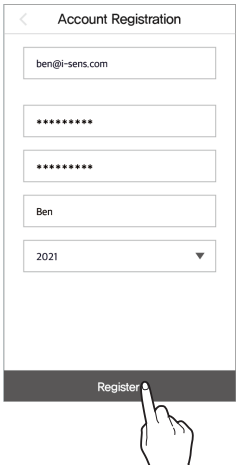
2 Tap **Account Registration** on the login screen.



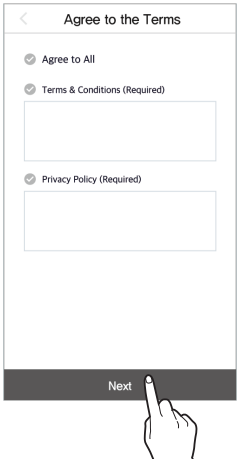
3 On the 'Account registration' screen, enter your email address and tap **OK**.



4 If the email address is available for registration, enter the user information and tap **Register**.



5 Agree to all the terms in the 'Agree to the terms' screen and tap **Next**. A verification code will be sent to the email address you provided when signing up.



6 Enter the 6-digit code in the 'Confirm verification code' screen and tap **Verification**.

Note

- You should enter the code within 10 minutes after the email has been sent. Tap **Resend code** to issue a new code if you fail to enter the code within the time.
- You cannot log in until your email address has been verified.

7 Tap **Log in** on the 'Account registration completed' screen. You will be directed to the app login screen.

Previously registered users

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

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

2 On the starting screen, enter your **Email address** and **Password**, then tap **Log in**.
If you enter a correct email address and password, you will be logged in as a registered user.

3 Take the following steps if you fail to log in:

- If the email does not match, this means your email address has not been registered and you need to register again.
- If the password does not match, tap **Reset password**.
  Refer to 'Reset password' for more information on resetting your password.
- You cannot log in until your email has been verified, even if the email and password you enter are correct.
  Log in again after completing the verification on the 'Verify code' screen.

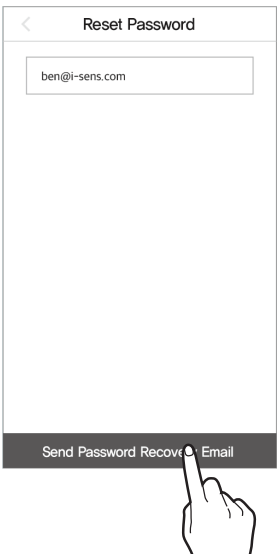
Reset password

Take the following steps if you have forgotten your password for the CareSens Neon app.

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

2 Tap **Reset Password** on the starting screen.

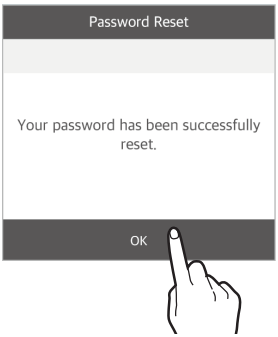
3 Enter the email address on the 'Reset password' screen and tap **Send Password Recovery Email**.
The verification code is sent to the user's email address.



4 Enter the 6-digit code in the 'Confirm verification code' screen and tap **Verification**.

5 On the password recovery page, enter a new password, confirm it, and tap **OK**.

6 Your password has been reset. Log in again.



3.2 Connecting to a sensor

Connect the sensor with the app. Once it is successfully connected, the sensor will be warmed 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 with the app. Configure the alert settings in the app.

2 Sensor warmup will occur.
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

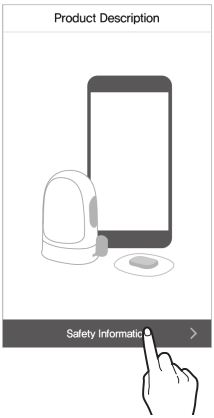
- Once a sensor has been connected, it cannot be connected with another device unless:
  - The same account is used, and
  - When the sensor has not yet expired
- Keep the sensor and the smart device within 10 meters of each other, without any obstacles such as walls or metal objects in between. The 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 apps

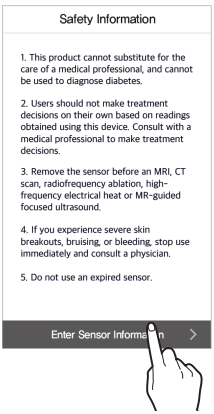
Connect the sensor to the app. Scan the barcode on the sensor package label.

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

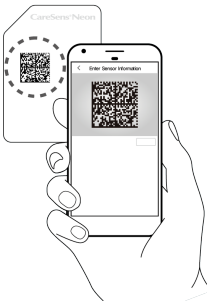
1. Turn on Bluetooth on your smart device.
2. Tap on your smart device and log in.
3. Tap **Safety information** on the 'Product description' screen.



4. Read the information on the 'Safety information' screen, then tap **Enter sensor information**.

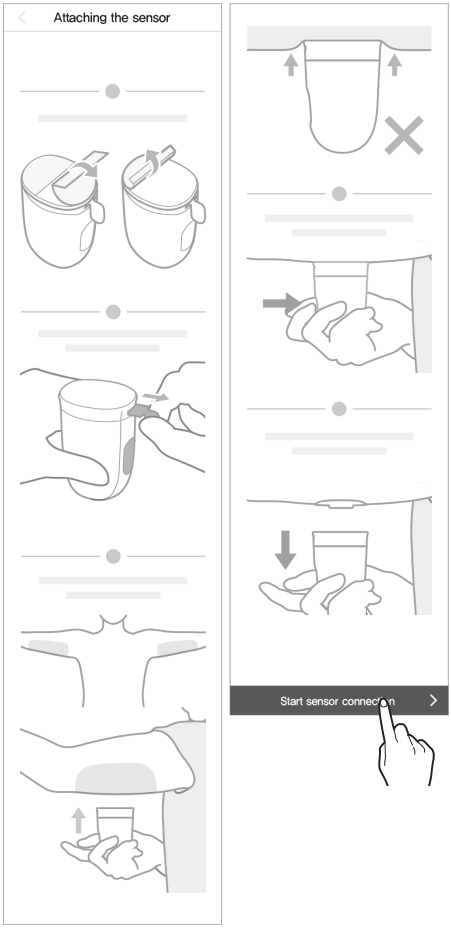


5 On the 'Enter sensor information' screen, scan the datamix barcode on the package label.



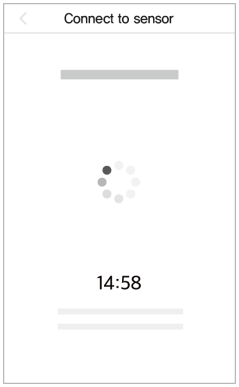
6 Tap **OK** when the sensor information appears.

7 When barcode recognition is completed, it moves to the 'Attaching the sensor' screen. Follow the steps below to attach the sensor on the rear of your upper arm, and tap **Start sensor connection**.



8 Wait until the sensor connection is completed.

- It may take up to 15 minutes for the sensor to connect, depending on the network environment.



Connecting the sensor to iOS apps

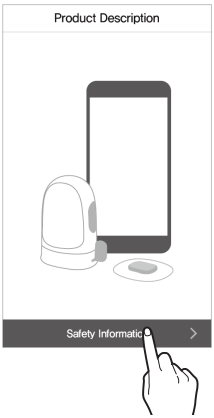
Connect the sensor to the app. Scan the barcode on the sensor package label.

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

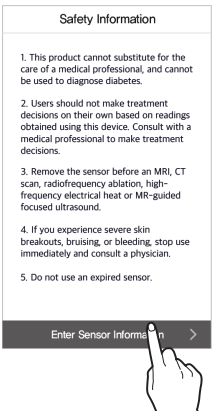
1 Turn on Bluetooth on your smart device.

2 Tap on your smart device and log in.

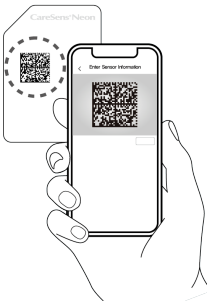
3 Tap **Safety information** on the 'Product description' screen.



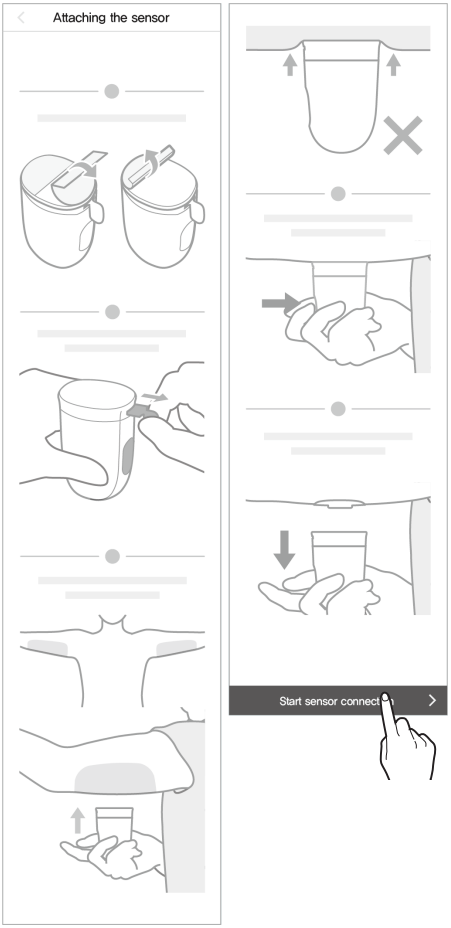
4 Read the information on the 'Safety information' screen, then tap **Enter sensor information**.



5 On the 'Enter sensor information' screen, scan the datamix barcode on the package label.

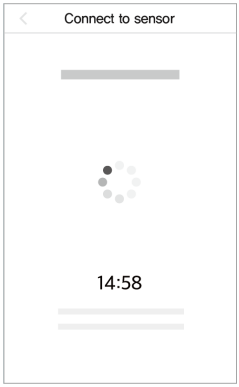


6 When barcode recognition is completed, it moves to the 'Attaching the sensor' screen. Follow the steps below to attach the sensor on the rear of your upper arm, and tap **Start sensor connection**.

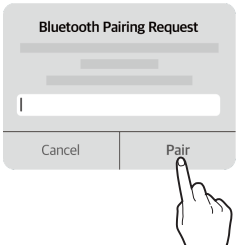


7 Attach the sensor on the rear of your upper arm in the 'Connect to sensor' screen. Wait until the sensor connection is completed.

- Once the barcode is successfully recognized, the manufacture number and PIN code are displayed on the screen.
- It may take up to 15 minutes for the sensor to connect, depending on the network environment.



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



⚠ Warning

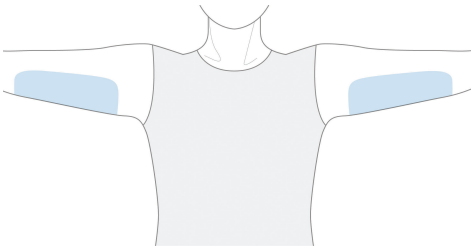
When using iOS, never close the app after connecting the sensor. It will be disconnected from the sensor.

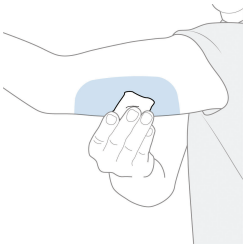
Attaching the sensor

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

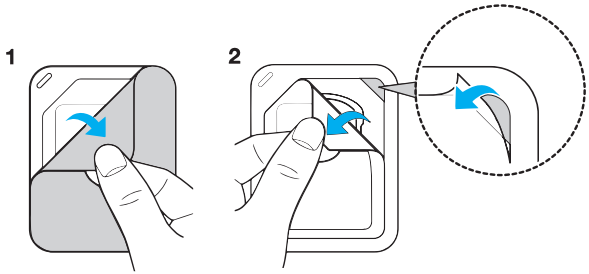
1 Wash your hands with running water and soap and dry them thoroughly.

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





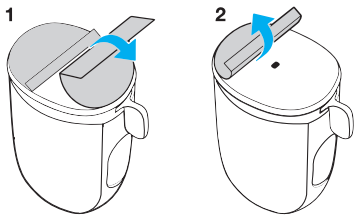
3 Open the package and take out the applicator.

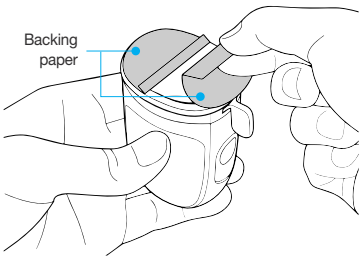


⚠ Caution

- 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.
- In order to prevent airborne contamination, make sure to attach the sensor immediately after opening the applicator.
- 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 pin from the applicator, be careful not to point it toward any person.
- The applicator and the sensor cannot be re-used.

4 Remove the backing paper from the bottom of the applicator.

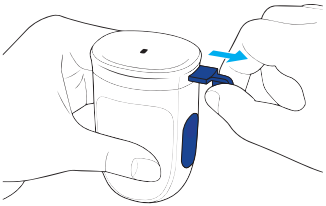




⚠ Caution

When the backing paper is removed, the adhesive patch is exposed. Do not touch or put down the skin adhesive tape on the floor.

5 Hold the middle of the applicator with one hand and remove the safety pin with the other hand.

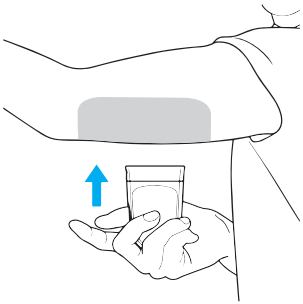


⚠ Caution

Do not put the applicator down on the floor

- when removing the safety pin.
- Be careful not to press the Release button (blue button).

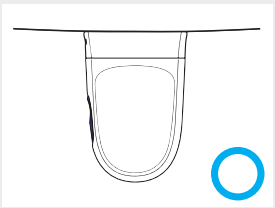
6 Place the applicator on the upper arm.



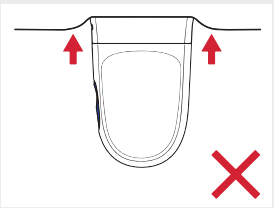
⚠ Caution

The sensor is fixed after attaching, so it must be placed exactly on the area to be attached.

Note

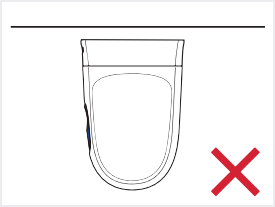


Place the applicator horizontally on the area of attachment and then press the Release button.

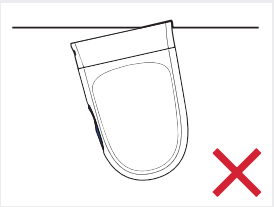


After placing the applicator on the skin, do not press the skin hard before you press the Release button.

Note

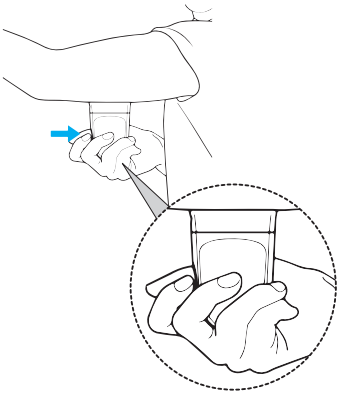


Do not leave any space between the area and the applicator.

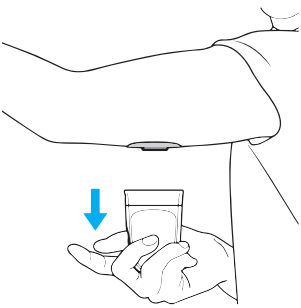


Do not tilt the applicator onto the area.

7 Press the Release button (blue button) on the applicator.



8 Remove the applicator and check if the sensor is properly attached.



⚠ Caution

Do not remove the applicator while the Release button is pressed.

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

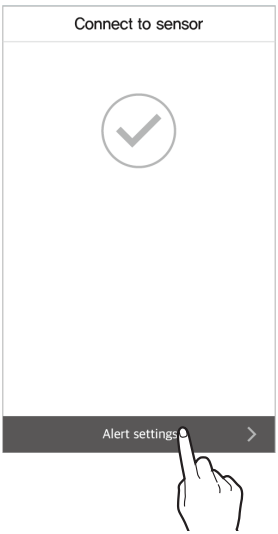
Configuring your alert settings after connecting to the sensor

After the sensor is connected successfully, enter threshold values for very low, low, and high and proceed with setting up your alerts. It is recommended to consult a medical professional to choose the appropriate threshold values for very low, low, and high.

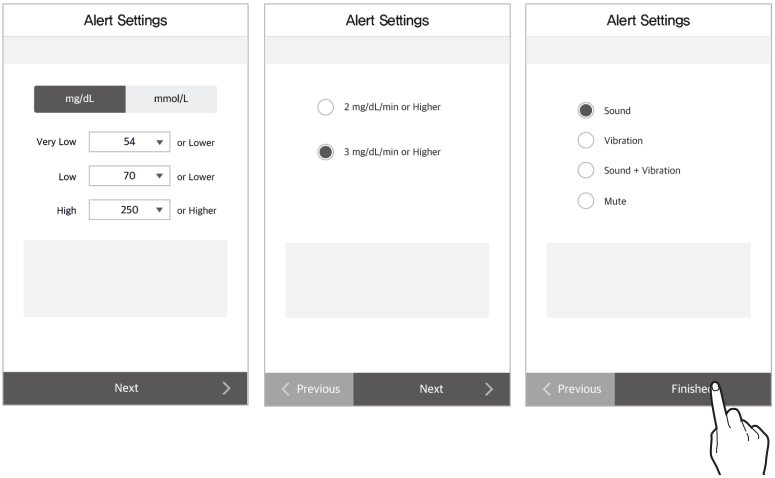
Take the following steps to configure your alert settings after connecting with the sensor.

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

2 Tap **Alert settings** on the 'Connect to sensor' 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, hypoglycemia, hyperglycemia, rapid blood glucose changes, and notification types, then tap **Finished**.



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 stabilize, contact your place of purchase or customer service.

5 Once the sensor is warmed up, the home screen will appear.

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 with a new sensor. Refer to 'Disconnecting and removing the sensor' for more information on how to disconnect the sensor. Refer to 'Connecting the sensor to Android apps' or 'Connecting the sensor to iOS apps' for more information on connecting the sensor.
- If the connection is not secure: The sensor cannot be connected due to an unstable connection. 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 is out of battery
- 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 3 hours. After 3 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.

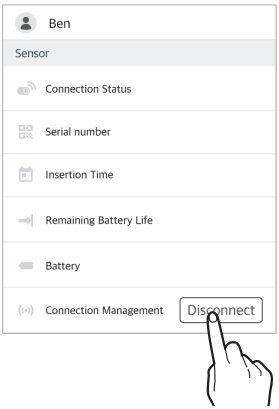
Disconnecting and removing the sensor

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 or low battery. 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.

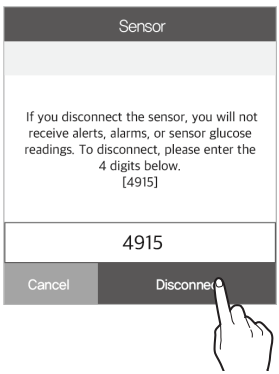
Follow these steps to disconnect from the sensor:

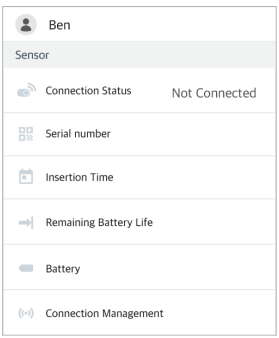
1 Run the app and tap ⚙ at the bottom of the home screen.

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

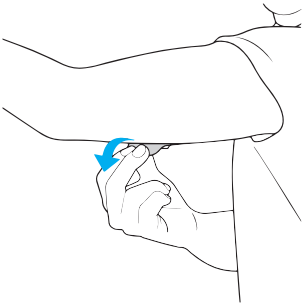


3 Enter the 4-digit code provided in the pop-up window and tap **Disconnect**. Once the sensor is successfully disconnected, the connection status will change to **Not connected**.





4 Remove the sensor 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 Neon app home screen contains the following:

- Basic information: user profile, user name
- Menu bar: Home screen, the log book, and Settings
- Glucose data: sensor connection status, current glucose level, glucose level change arrow, glucose trends, and calibration values

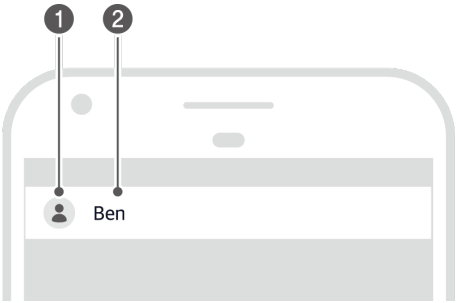
The glucose level and glucose change arrow on the home screen can help you understand your glucose status. You can check the changes in the sensor's glucose levels in the glucose trends. Understanding the content and features of the app will help you use CareSens Neon to manage your diabetes more effectively.

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 levels in the glucose trends.
- Check whether a sensor has been calibrated
- Check the event logs and the details of events

Basic information

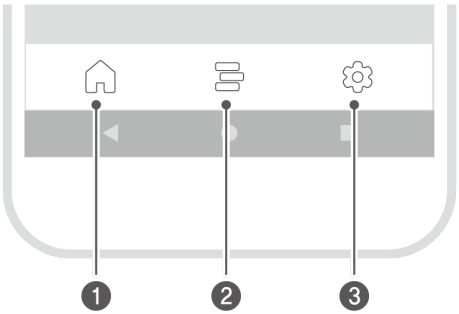
The table below explains the basic information which the CareSens Neon app displays at the top of the Home screen.



Index	Icon	Name	Description
1		Profile picture	The image uploaded to your profile is shown. You can change this image on the 'User information' screen by tapping your nickname.
2	Ben	Nickname	The nickname you entered when you registered is be displayed. It can be changed on the 'User information' screen by tapping it.

Menu bar

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



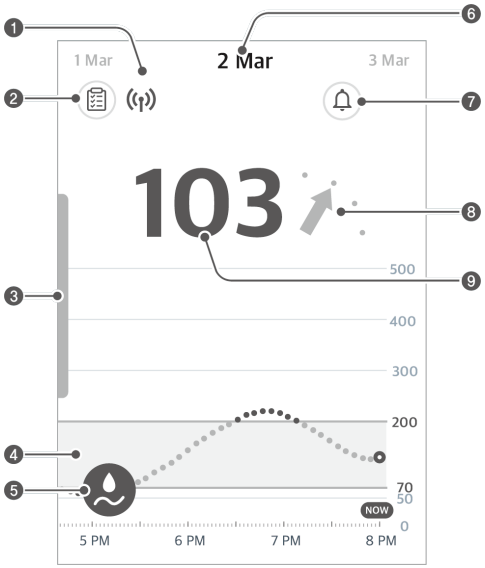
Index	Icon	Name	Description
1		Home	Tap this to go back to the app home screen.
2		Log book	• When you tap this icon, a list of events registered by the user will be displayed. You can add, edit, or delete events. • Refer to '5 Using events' for detailed information on events.

Index	Icon	Name	Description
3		Configuration	• When you tap this icon, you will see a display telling you about the sensor connection status, whether or not the battery is low, the calibration status, alert type, and your glucose alert levels. • All data saved on the app can be uploaded and saved to the cloud server. You can change your settings to automatically upload data, or 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, help center, and app info. • Refer to 'Changing Settings' for more information on changing your settings. • Refer to 'Updating the app' for more information on updating it to the latest version of the app. • You can check the personal 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 personal glucose meter.

Glucose data

The CareSens Neon app displays your current glucose level and the glucose change 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:



Index	Icon	Name	Description
1	((ı))	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 10 minutes. • Gray: The smart device's Bluetooth is turned off.

Index	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, and how much time your level spent within the target glucose level, and the low and high ranges
3		Viewing previous data	When you tap the bar on the left of the screen, 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 value	• If you tap this icon, the calibration input screen will be displayed. Enter a glucose reading taken with a personal glucose meter using a finger prick. Refer to '4 Calibration' for more information on calibration.
6	2 Mar	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		Glucose Alert history	Move to the alert history screen.
8		Glucose trend arrows	The current rate of change in your glucose level compared with the previous measurement is displayed. Each point indicates a glucose reading taken every 1 minutes. Refer to 'Change arrows' for more information on the glucose level change arrow.

Index	Icon	Name	Description
⑨	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 10 minutes • Lo: Lower than 40 mg/dL (2.2 mmol/L) • Hi: Higher than 500 mg/dL (27.8 mmol/L)

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 is increasing or decreasing by less than 1 mg/dL (0.1 mmol/L) per minute, or by less than 5 mg/dL (0.9 mmol/L) every 5 minutes.
	Increasing slowly	The glucose level is increasing by 1 mg/dL (0.1 mmol/L) or higher per minute, or by 5 mg/dL (0.3 mmol/L) every 5 minutes.
	Increasing	The glucose level is increasing by 2 mg/dL (0.1 mmol/L) or higher per minute, or by 10 mg/dL (0.6 mmol/L) every 5 minutes.
	Increasing rapidly	The glucose level is increasing by 3 mg/dL (0.2 mmol/L) or higher per minute, or by 15 mg/dL (0.8 mmol/L) every 5 minutes.
	Decreasing slowly	The glucose level is decreasing by 1 mg/dL (0.1 mmol/L) or higher per minute, or by 5 mg/dL (0.3 mmol/L) every 5 minutes.
	Decreasing	The glucose level is decreasing by 2 mg/dL (0.1 mmol/L) or higher per minute, or by 10 mg/dL (0.6 mmol/L) every 5 minutes.
	Decreasing rapidly	The glucose level is decreasing by 3 mg/dL (0.2 mmol/L) or higher per minute, or by 15 mg/dL (0.8 mmol/L) every 5 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. Refer to 'Change arrows' for more information on the glucose level change 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.

Index	Description
1	This shows that the sensor attached to your body is operating normally. An alert will occur if the sensor goes out of its range.
2	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.

Index	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 change arrow. * means that the glucose level is increasing by 2 mg/dL (0.1 mmol/L) or more per minute, or up to 10 mg/dL (0.6 mmol/L) every 5 minutes. Refer to 'Change arrows' for more information. In this case, the CareSens Neon user and those who use personal glucose meters may take different actions. • With CareSens Neon: 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 change 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 personal 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	The glucose alert levels have been set to 70 mg/dL (3.9 mmol/L) for hypoglycemia and 200 mg/dL (11.1 mmol/L) for hyperglycemia. Check whether your glucose level is staying within the target range.