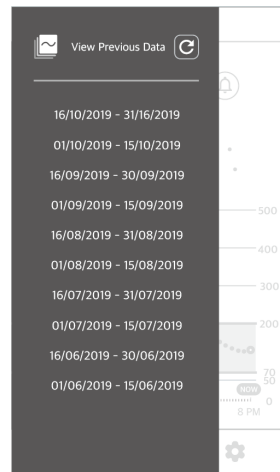
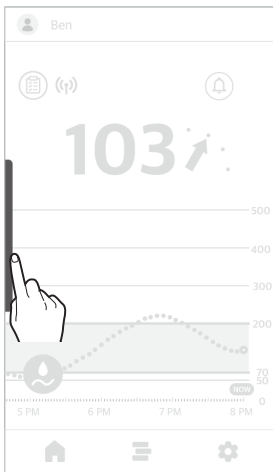


## Viewing previous data

You can click the vertical bar on the left of the app home screen to view earlier data. You can not only view readings from the sensor you are currently using but all the data delivered from any sensor used on your account. The glucose trend screen appears when you tap on the date list.


Take the following steps to view earlier glucose trends:

- 1 Tap the vertical bar on the home screen.




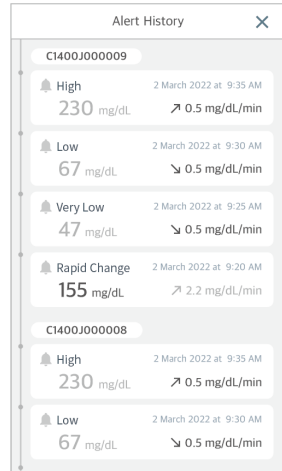
- 2 Tap the date list on the 'View previous data' screen. A detail screen will appear. Tap **X** to go back to the home screen.

## Alert History

Tap  on the upper right corner of the home screen to see the glucose alert history. You can see the history of alert for Very Low, Low, High, and rapid change alerts that occurred while using the sensor.

Follow the steps below to check your glucose alert history.

**1** Tap  in the right top of the home screen.



**2** Tap  to go back to the home screen.

## 3.4 Exploring the app features

You can use various features of the CareSens Neon 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 Neon system can be uploaded and saved on the cloud server.

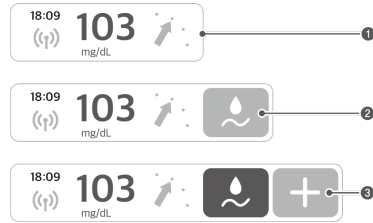
Reading this section will allow you to:

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

## Running the widget



CareSens Neon 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 Neon 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.




Index	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	Tapping  causes the 'Calibration value input' screen to appear.
3	Entering an event	Tapping  causes the 'Enter event' screen to be displayed.

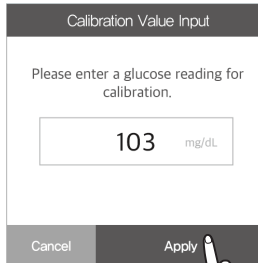
## Entering a calibration value

When you need to enter a calibration value, you should use a personal glucose meter to make a blood glucose reading using a finger prick. Enter this reading as the calibration value for CareSens Neon.

Refer to '[4 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 value input' screen will be displayed.
- 2 Use your personal glucose meter to measure your blood glucose level with a finger prick.
- 3 Enter the finger prick reading within 5 minutes and tap **Apply**.



Calibration Value Input

Please enter a glucose reading for calibration.



103 mg/dL

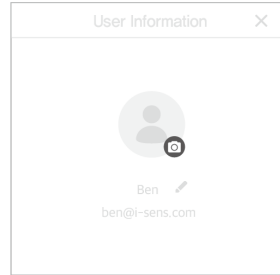
Cancel Apply

## Editing and checking your profile

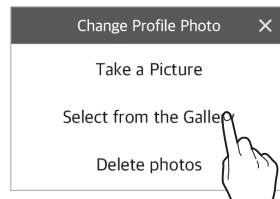
You can view or edit the information in your user profile.



Follow these steps to enter profile information:

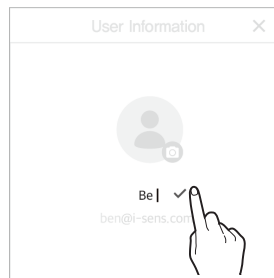
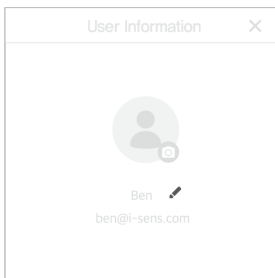
- 1 Tap  at the top of the home screen. The 'User information' screen is displayed.
- 2 Tap  on the 'User information' screen to change your profile photo. The 'Change profile photo' screen will be displayed.



- 3 In the 'Change profile photo' pop-up window, tap **Take a picture** or **Select from the gallery**.





- 4 To change your nickname, tap  on the 'User information' screen. Enter the nickname you would like to use, then tap .

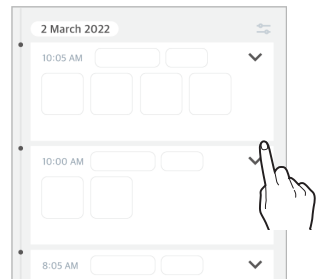


## Viewing the log book

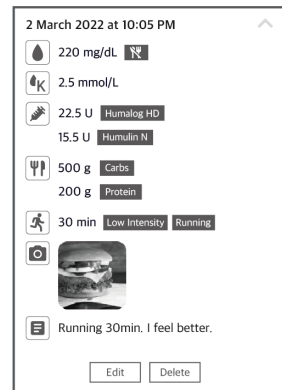
The log book displays all the events registered by the user, beginning with the most recent.




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.
- 2 Tap  on the right side of the event to check the details of the previously entered events.



- The table below explains the icons used on the 'Event details' screen.



Icon	Name	Description
	Glucose level	<p>The value entered by the user or measured using the blood glucometer is displayed as follows at the time the event occurred.</p> <ul style="list-style-type: none"> <li>• : If the entered value indicates a glucose level</li> <li>• : If the entered value indicates a calibration value</li> </ul>



Icon	Name	Description
	Ketone level	The ketone value entered by the user or measured using the ketone meter is displayed at the time the event occurred.
	Insulin	The name of the insulin taken, the dosage, and the time it was taken are displayed. You can enter up to 2 insulin administration records.
	Food	The amount of carbohydrate and protein at the time the event occurred is displayed in grams (g).
	Exercise	The number of minutes spent exercising is displayed, along with the time.
	Picture	Pictures added at the time of event occurrence are displayed.
	Memo	Information about physical state or health issues can be recorded.

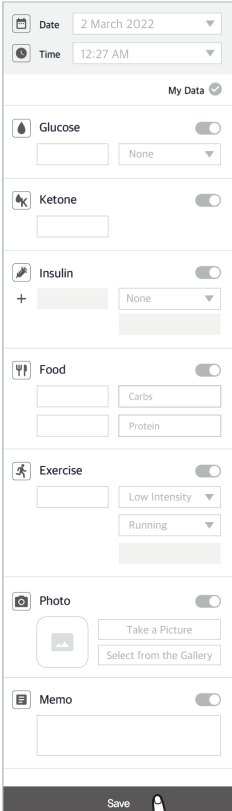


## Recording an event

Activities or situations that may affect your glucose level can be registered as events. Refer '5 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 to open the logbook. Then tap . The 'Enter event' screen will be displayed.
- 2 Enter the event details, including the date and time, on the 'Enter event' screen, then tap **Save**.
  - A maximum of 2 types of insulin can be entered.
  - Glucose level, Ketone level, Insulin, Food, Exercise, Photo and Memo are enabled by default. If you turn off the Enable switch, the input is disabled and the item moves to the bottom.
























The screenshot shows the 'Enter event' screen with the following details:




- Date:** 2 March 2022
- Time:** 12:27 AM
- My Data:**
- Glucose:**  None
- Ketone:**
- Insulin:** +  None
- Food:**  Carbs  Protein
- Exercise:**  Low Intensity  Running
- Photo:**  Take a Picture  Select from the Gallery
- Memo:**
- Save:**

## 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
	Connection status	If a sensor is connected, <b>In use</b> is displayed. If a sensor is not connected, <b>Not connected</b> is displayed.
	Serial number	This is a unique number assigned to the sensor.
	Insertion Time	The date and time when the sensor was first connected are displayed.
	Remaining battery life	The remaining life of the sensor is displayed.
	Battery	The sensor battery status is displayed as <b>Good</b> , <b>Low</b> , or <b>Very low</b> .
	Connection Management	<ul style="list-style-type: none"> <li>Tap <b>Disconnect</b> to disconnect the sensor currently in use.</li> <li>If a sensor is <b>Not connected</b>, <b>New connection</b> is displayed. Refer to '<a href="#">3.2 Connecting the sensor</a>' for more information on how to connect the sensor.</li> </ul>
	Last calibration	The time of the last calibration is displayed.
	Very low	Enter the threshold value for Very low to receive alerts and select the alert method.
	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.

Icon	Name	Description
	Rapidly changing	Enter the threshold value for Rapid changes to receive alerts and select the alert method.
	System	You can set the notifications for calibration, signal loss, sensor expiration, sensor battery, and error notification.
	Voice	You can choose to have your glucose level and alerts read aloud.
	Security	You can set the app lock feature.
	Glucose Meter	Register and connect a personal glucometer with your smart device.
	Last upload	The last time data was uploaded to the app is displayed.
	Upload now	Tap <b>Upload</b> to save data stored in the app on the cloud server.
	Automatic upload	Enable <b>Automatic upload</b> to automatically save all the data stored in the app on the cloud server when connected to a network. Data saved on the cloud server can be accessed via a separate web page.
	Upload when connected to Wi-Fi	Enable <b>Upload when connected to Wi-Fi</b> to upload data on the cloud server only when your smart device is connected to Wi-Fi. Enable <b>Upload when connected to Wi-Fi</b> is available only when <b>Automatic upload</b> is turned on.
	Unit	Choose either mg/dL or mmol/L as a measurement unit.
	Maximum y-axis value on chart	Set the maximum value for the Y axis indicated on the chart.

Icon	Name	Description
	Tutorial	You will be directed to the 'How to use' screen.
	Help	You will be directed to the 'Help' screen.
	App Info	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 ' <a href="#">Updating the app</a> ' 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, Vibration, Sound and Vibration, or Mute**.
  - **Voice:** Choose whether you would like to have your **Glucose level and Alerts** read aloud.
  - **Glucose alert level:** Enter your very low, low and high alert levels.
  - **Rapidly changing:** Choose between **2 mg/dL/min (0.1 mmol/L/min) or higher and 3 mg/dL/min (0.2 mmol/L/min) or higher**.
  - **System:** Set whether to receive alerts for calibration, signal loss, sensor expiration, sensor battery, and error notifications.
  - **Unit:** Select mg/dL or mmol/L as a measurement unit.
  - **Maximum y-axis value on chart:** 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.

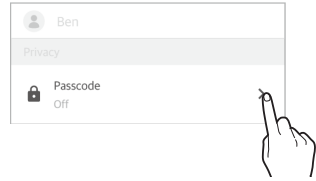
## Setting app lockout

You can set the app lock feature to protect your personal data.

Follow the steps below to set up the app lock feature:

**1** Tap  at the bottom of the home screen. The Settings screen will be displayed.

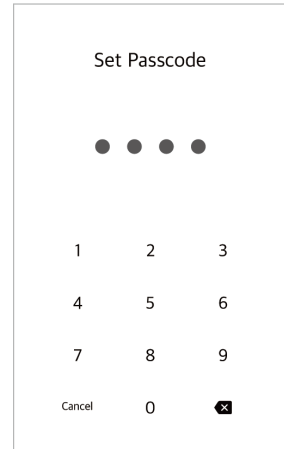
**2** Tap  on the **App Lock**.



**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 a personal glucose meter to the CareSens Neon app and download your glucose meter data.

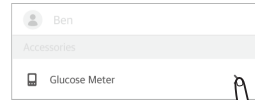
Follow these steps to connect a glucose meter:


### Note

For your personal glucose meter, use a Bluetooth glucose meter from the manufacturer of CareSens Neon.

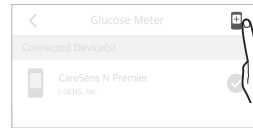
1 Tap  at the bottom of the home screen. The Settings screen will be displayed.

2 Tap  on the **Glucose Meter**.

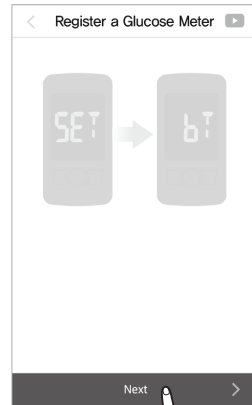



3 Tap  to connect with a new glucometer.

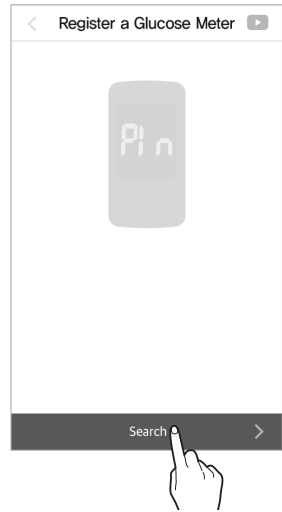
- Turn on your personal glucose meter on and connect using Bluetooth. The method for connecting with Bluetooth may differ depending on the type of glucose meter you use.



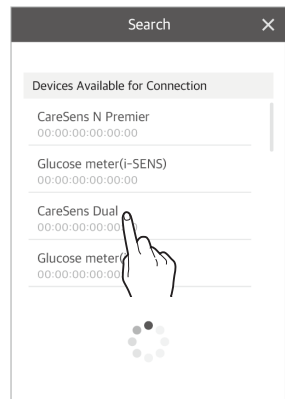
4 Check the glucose meter registration procedure and then tap **Next**.



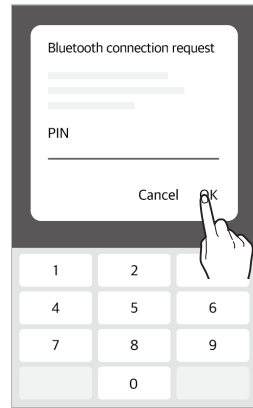
- 5** Tap **Search** to start searching for a glucose meter.
- Tap  for more information on the connection process.



- 6** From the list of connectable devices, tap the glucometer you want to connect to.



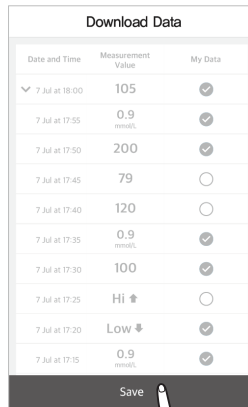
- Enter the PIN code displayed on the glucose meter screen and tap **OK**.



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

**Note**

Uncheck My Data to exclude it from the statistics.





## Uploading data

All the data saved on your smart device by the CareSens Neon app can be saved and used on the cloud server. There are two ways of saving your app data on the cloud server.

- Upload now: Tap **Upload** to upload your data instantly.
- Automatic upload: When you turn on **Automatic upload**, all of your data will be uploaded in real-time whenever you are connected to a network.

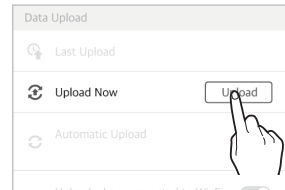
### Note

Automatically uploading your app data is recommended. If you do not enable automatic upload, any smart device data that is not stored on the cloud server could be lost.

Follow the steps below to upload your app data:

**1** Tap  at the bottom of the home screen. The Settings screen will be displayed.

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



**3** If you want your app data to be automatically saved on the cloud server, turn on **Automatic upload**.



- **Upload when connected to Wi-Fi:** Your data will only be uploaded when your smart device is connected to Wi-Fi. **Upload when connected to Wi-Fi** can only be selected if **Automatic upload** is turned on.

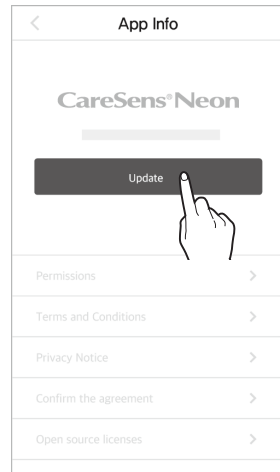
## Updating the app

If a new version of the CareSens Neon app is available and has not been downloaded, it will be shown on the Settings screen.

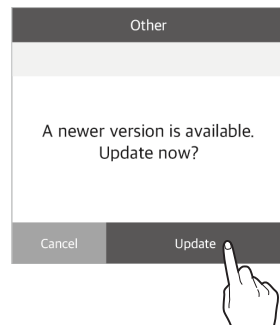
Go to the App Store to download and install the most recent version.

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

- 1 Tap  at the bottom of the home screen.
- 2 On the Settings screen, tap  next to **App info**.
- 3 Tap **Update** in the 'App info' screen. **Update** is enabled only when a new version of the app is available.



- 4 Tap **Update** in the pop-up 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.


## Deleting data

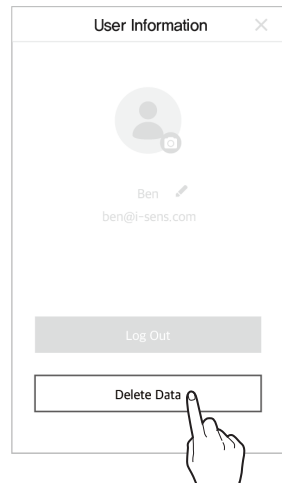
Any data or event records saved on the app can be deleted. Data saved on the cloud server is not deleted.

### Note

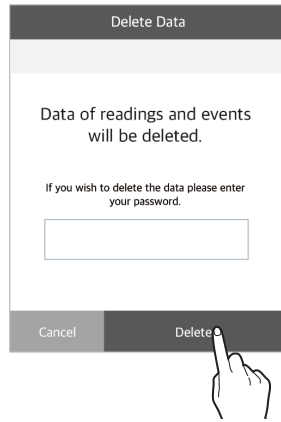
If data is deleted, you cannot restore it unless it is saved on the cloud server. Check your upload status before deleting data.

Follow these steps to delete app data:

- 1 Tap  at the top of the home screen. The 'User information' screen is displayed.
- 2 Tap **Delete data** if you want to delete all your glucose data and event records.





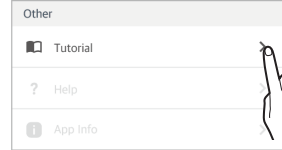
- 3 Enter your password and tap **Delete**. All the glucose data and event records saved on the app will be deleted.



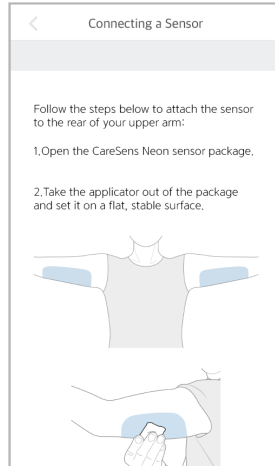
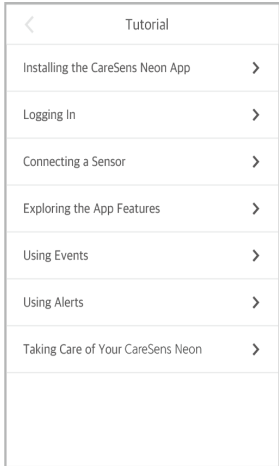
## See how to use

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

- 1 Tap  at the bottom of the home screen.
- 2 On the Settings screen, tap  next to **Tutorial**.

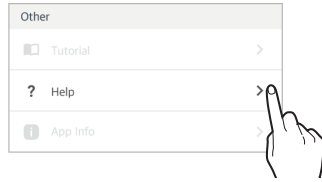


- 3 Tap to check if you have any questions about how to use the device.

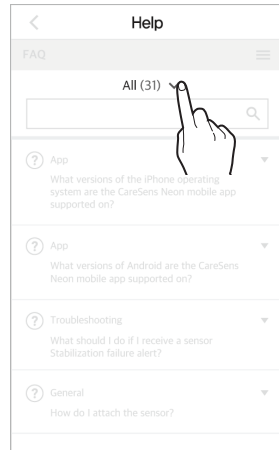


## See Help

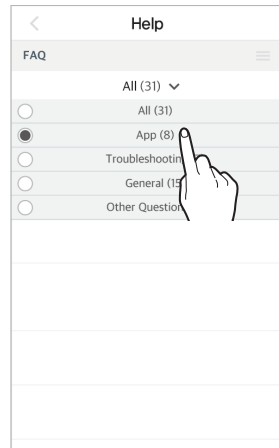
1 Tap > next to **Help** to read frequently asked questions and answers. You will be taken to the 'Help' screen.



2 Tap v on the 'Help' screen to check the Help categories.






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

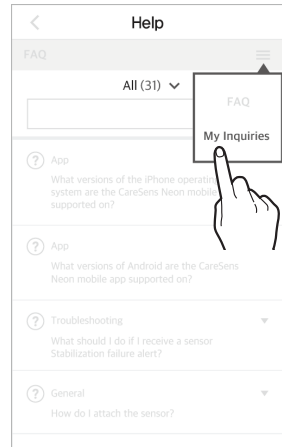
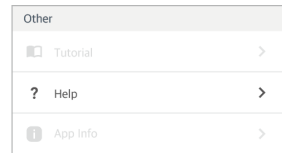


## Making an inquiry

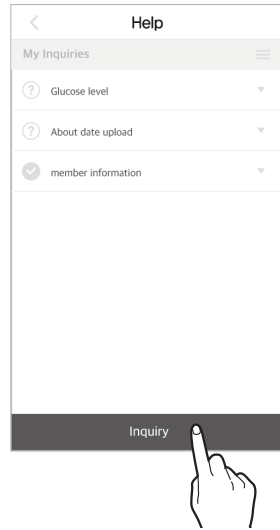
You can use the app to ask questions about CareSens Neon. The manufacturer's customer service representatives will check your inquiry and reply by email.

To view **My inquiries**, or to **Inquiry** provided by the CareSens Neon app, follow these steps:


- 1 Tap  at the bottom of the home screen.
- 2 On the Settings screen, tap  next to **Help**. You will be taken to the 'Help' screen and the FAQ list will be displayed.
- 3 On the 'Help' screen, tap  **My inquiries**. You can see the list of your inquiries.



- 4 Tap **Inquiry** on the 'My Inquiries' screen to make a new inquiry.



- 5 On the 'Inquiry' screen, tap **Finished** after making an inquiry.

- **Email address:** The email address associated with the account is entered automatically and cannot be changed.
- **Model number:** The model of the smart device using the app is entered automatically and cannot be changed.
- **OS version:** The version of the CareSens Neon app installed on the smart device is automatically entered and cannot be changed by the user.
- **App version:** The version of the CareSens Neon app is automatically entered.
- **Title:** Enter the title of the inquiry.
- **Content:** Enter the details of your inquiry.
- **Attachments:**  Tap to attach a product image or screenshot of the app screen related to your inquiry. You can attach up to 4 image files saved on your smart device.
- **Personal information collection and usage agreement:** In order to add an inquiry, you must agree to the collection of your personal information.



**Inquiry** [X]

\* Email Address  
ben@i-sens.com

\* Model Number  
SM-G955N

\* OS Version  
9

\* App Version  
1.0.X

\* Title  
Member information

\* Content  
How do I change member information?

Attachments  
image.png [X] [Pencil icon]

\* Agree to the Collection and Use of Your Personal Information [X]

Finish



**6** Tap **Close** on the pop-up window which confirms receipt of the inquiry.

Help


Your inquiry has been submitted.

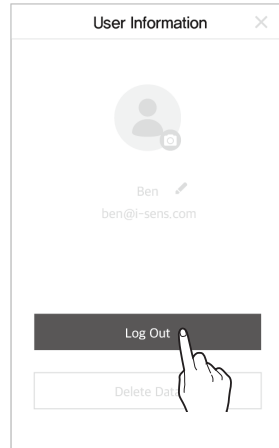
Close



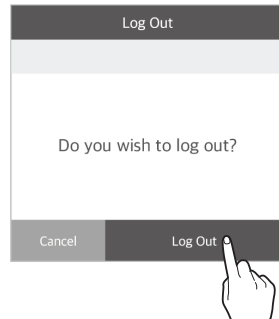
## 3.5 Logging out

Follow these steps to log out of the app:

- 1 Tap  at the top of the home screen. The 'User information' screen is displayed.
- 2 Tap **Log out** on the 'User information' screen to log out.



- 3 Tap **Log out** on the 'Log out' 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.

## 4 Calibration

The sensor measures glucose levels in interstitial fluid and transfers the data to the CareSens Neon app. 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. CareSens Neon can calibrate the sensor by using readings taken by a glucometer 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 CareSens Neon.

### **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**

CareSens Neon does not require calibration. However, if users want, they can enter a calibration value.

## 4.1 Measuring a calibration value

Calibration requires a reading taken using a finger prick. A personal glucose meter is used to measure your glucose level. Refer to '[Connecting 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 using a finger prick, and this can affect the accuracy of 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.

### Note


- If the calibration value is inaccurate, CareSens Neon may fail to provide accurate glucose readings.
- 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.

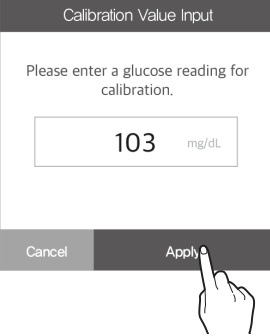
Follow these steps to measure your glucose level from a finger prick using a glucose meter:

- 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 within 5 minutes as the calibration value. Refer to '[4.2 Input Calibration value](#)' for more information on how to input calibration values.

## 4.2 Entering a calibration value

CareSens Neon calibrates the sensor using glucose readings taken within 5 minutes using finger pricks in order to ensure that its readings are accurate.

- Tap  on home screen, enter a calibration value, and tap **Apply**.



Calibration Value Input

Please enter a glucose reading for calibration.

103 mg/dL

Cancel Apply

### Note

A calibration value can be entered after sensor warmup.

# 5 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 Neon 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.

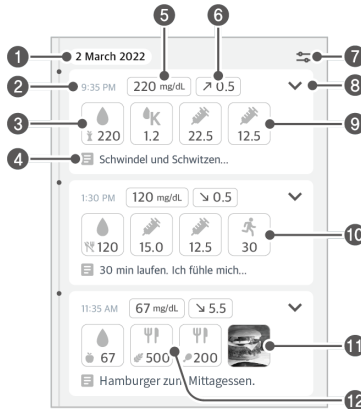
This section will help you to:

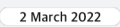











- Record, edit, or delete an event.
- Check the event icon on the CareSens Neon app.
- See the effect of events on your glucose levels.

## 5.1 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 Neon app as shown below: Tap  on the bottom of the home screen to view a list of registered events.





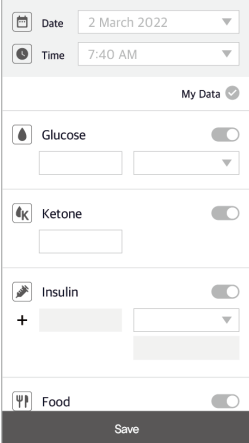
Index	Icon	Name	Description
1		Date	The year, month, and day that the event occurred are displayed.
2		Time	This displays the time that the event occurred.
3		Glucose level	The value entered by the user or measured using a blood glucose meter is displayed at the time the event occurred.
4		Memo	This shows comments relating to the event.
5		Sensor glucose level	The sensor glucose value of the event time is displayed.
6		Sensor changes	The glucose level changes of the event time are displayed.
7		Event filter	The results are filtered by the selected item.
8		View details	Tap this to display the event details.
9		Insulin	This displays the dosage of insulin administered.
10		Exercise	This displays the amount of time exercised.
11		Photo	Displays the photo added to Events.
12		Food	The amount of consumed carbohydrates and protein is expressed in grams.

## 5.2 Recording an event

You can use events to record glucose levels, insulin, diet, exercise, photos, and notes that may affect your diabetes management.

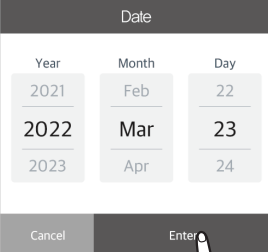
Take the following steps to register an event using the CareSens Neon app:

- 1 Tap  on the menu bar on 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. The 'Enter event' screen will be displayed.

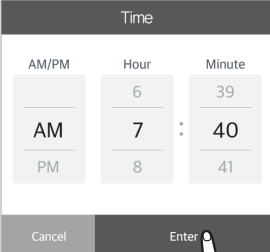


The screenshot shows the 'Enter event' screen. At the top, there are two dropdown menus: 'Date' set to '2 March 2022' and 'Time' set to '7:40 AM'. Below these is a section titled 'My Data' with a checked toggle. Underneath are four rows, each with a toggle switch and an input field: 'Glucose' (toggle on), 'Ketone' (toggle on), 'Insulin' (toggle on, with a '+' sign and a dropdown arrow), and 'Food' (toggle on). A 'Save' button is at the bottom.

- 3 On the 'Enter event' screen, select the date and time of the event and tap **Enter**.



The screenshot shows the 'Date' selection screen. It has three columns: 'Year' with options 2021, 2022, and 2023; 'Month' with options Feb, Mar, and Apr; and 'Day' with options 22, 23, and 24. The '2022' and 'Mar' options are highlighted. At the bottom, there are 'Cancel' and 'Enter' buttons. A hand icon is pointing at the 'Enter' button.



The screenshot shows the 'Time' selection screen. It has three columns: 'AM/PM' with options AM and PM; 'Hour' with options 6, 7, and 8; and 'Minute' with options 39, 40, and 41. The '7' and '40' options are highlighted. At the bottom, there are 'Cancel' and 'Enter' buttons. A hand icon is pointing at the 'Enter' button.



**4** On the same screen, enter the information you want to record into the **Glucose level, Ketone level, Insulin, Food, Exercise, Photo** and/or **Memo** categories. Then tap **Save**.

- All event categories are enabled by default. If you turn off a category you do not want to record information for, it will be shown as disabled by default the next time you record an event.
- **Glucose level:** Please enter a blood glucose reading. The unit selected in the Unit section of the Settings menu is displayed.
- **Ketone level:** Enter the ketone value.
- **Insulin:** Enter a maximum of 2 types of insulin and the doses administered.
- **Food:** Enter the amount of carbohydrates and proteins in grams.
- **Exercise:** Enter the type and duration of the exercise.
- **Photo:** Add photos of what you ate.
- **Memo:** Record your physical condition at the time of the event or any other significant information.





**5** The event has been successfully recorded.

## 5.3 Changing an event



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

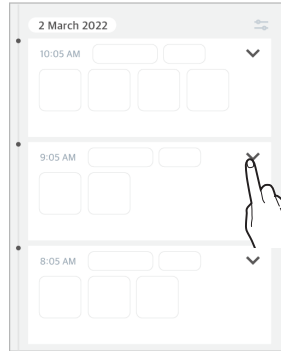
### Editing an event

You can edit the event information you have recorded. If the event includes a blood glucose reading taken with a personal 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. Calibration values and glucose readings entered by a user or taken with a connected glucose meter as part of an event are displayed as shown below:

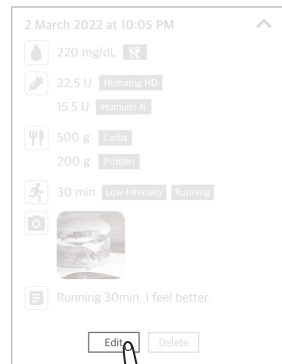
Item	Glucose level icon in events
Calibration value (inactive)	
Blood glucose reading taken with a glucose meter (inactive)	
Blood glucose reading entered by the user	
Ketone values entered by the user	

Follow these steps to edit an event you have recorded:

- 1 Tap  on the menu bar on the home screen.
- 2 On the event list, tap  next to the event you want to edit.



- 3 Tap **Edit** on the 'Event details' screen.



- 4 Tap the category you want to edit and enter your information, and tap **Save**. The event has been successfully edited.



The screenshot shows the 'My Data' section of the i.sens app. At the top, the date is set to '2 March 2022' and the time to '7:40 AM'. Below this, there are several data entry sections, each with a toggle switch and input fields:

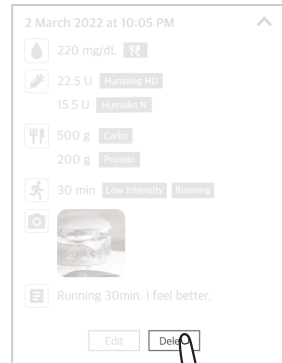
- Glucose:** Value '103', time 'Before Breakfast'. Toggle is on.
- Ketone:** Value '4.1'. Toggle is off.
- Insulin:** Values '+ 22.1' (Humalog HD) and '- 15.5' (Humulin N). Both have 'Manual' options. Toggle is on.
- Food:** Values '500' (Carbs) and '200' (Protein). Toggle is off.
- Exercise:** Value '30', intensity 'Low Intensity', activity 'Running'. Toggle is off.
- Photo:** Options 'Take a Picture' and 'Select from the Gallery'. Toggle is off.
- Memo:** Text 'fresh morning'. Toggle is off.

At the bottom, a dark bar contains a 'Save' button, which is being pointed to by a hand icon.

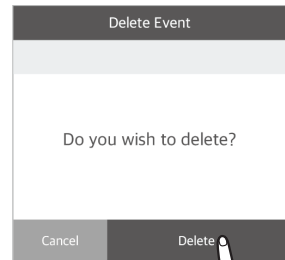
## Deleting an event

Follow these steps to delete an event you have recorded:

- 1 Tap  on the menu bar on the home screen.
- 2 Tap  next to the event detail you want to delete.
- 3 Tap **Delete** on the 'Event details' screen.



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



### Note

Calibration values entered by you and glucose levels measured with a personal glucose meter cannot be deleted.


# 6 Using alerts

If you have diabetes, it is extremely important to manage your glucose levels in real time. The CareSens Neon 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 Neon in real time.


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

## 6.1 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.

Follow these steps to enable the CareSens Neon app to send notifications to your smart device:

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

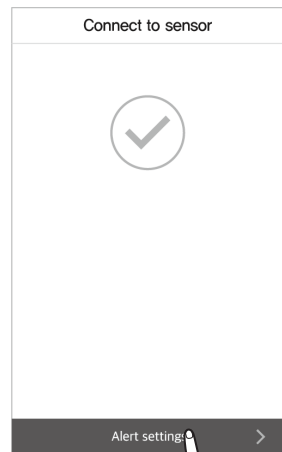
## 6.2 Initial app alert settings

The initial notification settings are made when you connect a new sensor to the CareSens Neon app. You can change your alert settings in the app settings. For more information, please refer to '[Connecting the sensor to Android apps](#)' or '[Connecting the sensor to iOS apps](#)'.

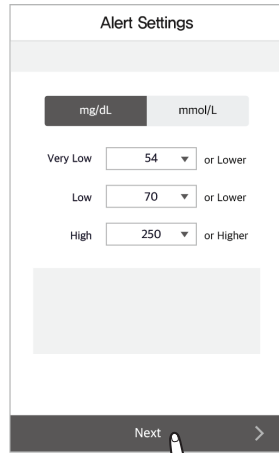
You can set notifications in the CareSens Neon app for glucose levels (very low, low, high) and rapid changes (2 mg/dL/min (0.1 mmol/L/min) or higher and 3 mg/dL/min (0.2 mmol/L/min) or higher).

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

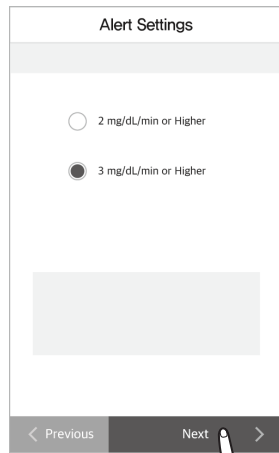
- 1 Use the app to finish connecting the sensor and tap **Alert settings** on the 'Connect to sensor' screen.



- 2 On the 'Alert settings' screen, set the threshold notifications levels for hypoglycemia and hyperglycemia and tap **Next**.

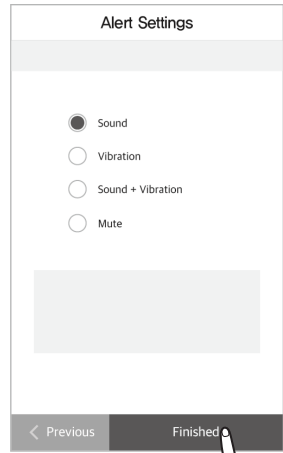


- 3 On the 'Alert settings' screen, set the rapidly changing glucose alert level and tap **Next**.





4 Choose an alert type and tap **Finished**.



## 6.3 Checking your alerts

CareSens Neon uses various notifications 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:

- Lost signal notifications > Blood glucose level alert > Rapidly changing glucose level notifications > Low battery notifications > Sensor replacement notifications

### Note

- If the system notification settings of your smart device and the notification settings of the CareSens Neon App are different, those of the CareSens Neon 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 Neon 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:

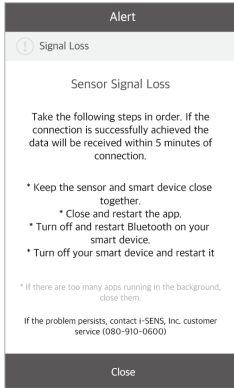
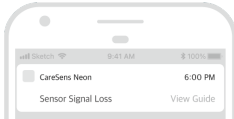
- Tell the difference between the types of notifications sent by the CareSens Neon app
- Understand how the CareSens Neon app delivers notifications to users

## Lost signal alert

The lost signal alert occurs when the connection between the sensor and your smart device is lost for 10 minutes or longer.

- What to do about a Lost signal notifications: Refer to '[If the connection between the sensor and the smart device is interrupted](#)'.
- Change lost signal notifications: Refer to '[6.4 Changing notification settings](#)' for information on how to change your blood glucose level notification settings.


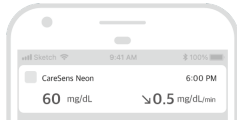
On the following table, you can see the lost signal alert settings and the contents of the messages based on what mode the app is running in.

Situation	Alert type	Screen
With app running	Popup window	
<ul style="list-style-type: none"> <li>• If you are using your smart device after closing the app</li> <li>• If the smart device screen is locked</li> </ul>	Notification	

## Glucose level alert

These alerts occur if your glucose level falls very low, above the hyperglycemia alert level, or below the hypoglycemia alert level you have set. Refer to '[6.4 Changing notification settings](#)' for information on how to change your blood glucose level notification settings.

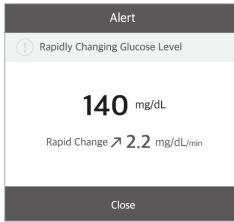
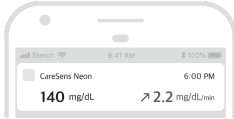
On the following table, you can see the blood glucose level alert settings and the content of messages based on what mode the app is running in.

Situation	Alert type	Screen
With app running	Popup window	
<ul style="list-style-type: none"> <li>• If you are using your smart device after closing the app</li> <li>• If the smart device screen is locked</li> </ul>	Notification	

## The 'Rapidly changing' glucose level alert

The rapid change alert occurs if your glucose level changes more quickly than the set rate. You can select above 2 mg/dL (0.1 mmol/L/min) or above 3 mg/dL/min (0.2 mmol/L/min) as the standard rate for rapidly changing glucose level. Refer to ['6.4 Changing notification settings'](#) for more information on how to change your rapid change notification settings.

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.

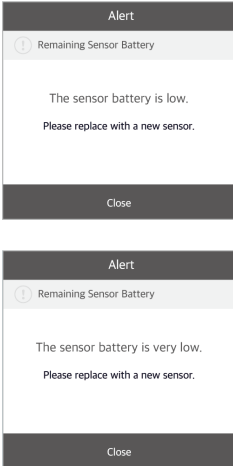
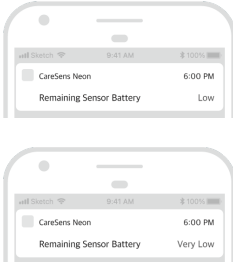
Situation	Alert type	Screen
With app running	Popup window	
<ul style="list-style-type: none"> <li>If you are using your smart device after closing the app</li> <li>If the smart device screen is locked</li> </ul>	Notification	

## Low battery alert

A low battery alert occurs when the sensor battery is low. If the sensor battery is low, replace the sensor with a new one.

- The 'Low' notifications occurs if 1.45 V or less of battery power remains.
- The 'very low' notifications occurs if 1.40 V or less of battery power remains.

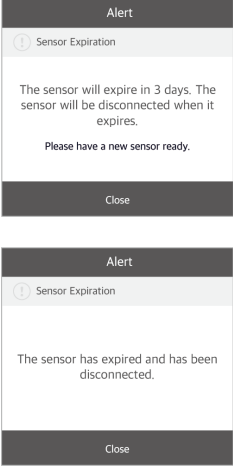
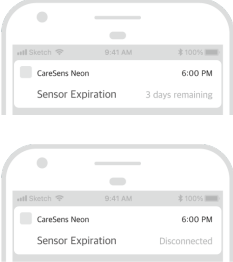
On the following table, you can check the low battery alert settings and the content of messages based on what mode the app is running in.

Situation	Alert type	Screen
<p>With app running</p>	<p>Popup window</p>	
<ul style="list-style-type: none"> <li>• If you are using your smart device after closing the app</li> <li>• If the smart device screen is locked</li> </ul>	<p>Notification</p>	

## 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.

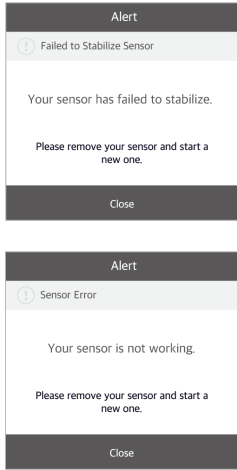
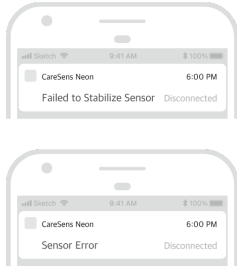
Situation	Alert type	Screen
With app running	Popup window	
<ul style="list-style-type: none"> <li>If you are using your smart device after closing the app</li> <li>If the smart device screen is locked</li> </ul>	Notification	

## Sensor error

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

Depending on whether warmup has been completed, in case of an error, “sensor warmup failure” appears if it has occurred during warmup, or a “sensor error” notification occurs if it has occurred during use after warmup has been completed. When this notification occurs, the app disconnects from the sensor and can no longer be used.

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 window	
<ul style="list-style-type: none"> <li>If you are using your smart device after closing the app</li> <li>If the smart device screen is locked</li> </ul>	Notification	



## 6.4 Changing notification settings


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

- Glucose level alert
- The 'Rapidly changing' glucose level alert
- Lost signal alert
- Voice alert







### Note

Consult with a medical professional to find the best glucose level alert settings for you. A medical professional can help you find the best 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. See the table below:

Alerts	
1	<p><b>Very Low</b></p> <p>54 mg/dL, Sound + Vibration</p>
2	<p><b>Low</b></p> <p>70 mg/dL, Sound + Vibration</p>
3	<p><b>High</b></p> <p>250 mg/dL, Sound + Vibration</p>
4	<p><b>Rapidly Changing</b></p> <p>3 mg/dL/min, Sound + Vibration</p>
5	<p><b>System</b></p>
6	<p><b>Voice</b></p> <p>Do Not Receive</p>

Index	Icon	Name	Description
1		Very low	Set the threshold value to very low. The values entered are displayed on the target range of the glucose trends on the home screen.
2		Low	Set the threshold value for hypoglycemia. The values entered are displayed on the target range of the glucose trends on the home screen.
3		High	Set the threshold value for hyperglycemia. The values entered are displayed on the target range of the glucose trends on the home screen.
4		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.
5		System	You can set the notifications for calibration, signal loss, sensor expiration, sensor battery, and error notification.
6		Voice	You can receive an additional voice alert when a change in glucose concentration is detected or another alert occurs.

# 7 Maintenance

Learning and following these guidelines for how to take care of CareSens Neon 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 Neon.

## **Warning**

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

## **Caution**

The sensor has been sterilized with 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 Neon sensor. For how to maintain your smart device, refer to the manufacturer documentation.

## 7.1 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	<ul style="list-style-type: none"> <li>Make sure that the sensor is stably secured to the point where it is attached.</li> <li>Take caution that solid objects smaller than 1.0 mm in diameter do not enter the sensor.</li> </ul>	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.

## 7.2 Storing a sealed sensor

Storing sealed sensor packages properly can keep CareSens Neon 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 %.

## 7.3 Disposal of product

When disposing of a medical device, you must comply with your countries regulations for handling and managing medical waste. Regulations concerning the disposal of the sensor and of products that have been in contact with bodily fluids may vary by country.

# 8 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 quality during the product lifespan labeled on the exterior of the CareSense Neon package. However, quality is not guaranteed in the following cases, even during the product lifespan:

- If damage is caused by the user not following the instructions and cautions listed in the manual
- 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 authorized by i-SENS
- If the surface is scratched or damaged through regular use
- Lifespan exceeded

## Warranty period

If a material or manufacturing defect is discovered during normal use of the sensor, the following limited warranty is guaranteed for the original purchaser within the warranty period listed below for the period from the shipping date until the corresponding date.

- CareSense Neon Sensor:  
If a replacement is received for the sensor within the warranty period, the remaining warranty period is transferred to the replacement sensor and the warranty of the replacement becomes invalid.

## Warranty exclusions

A warranty is not provided for the following cases in which the user uses the product incorrectly.

- Accidents, misuse, abuse, negligence, abnormal physical, electrical, or electromechanical stress, alteration of product components, or exterior damage
- Equipment with the barcode on the sensor package label has been removed or cannot be read
- If there are scratches and damage to the surface or other exposed areas of the product resulting from normal use
- If there is damage caused by the use of an accessory or separate product that is not provided or approved by CareSens Neon
- If there are flaws or damage resulting from incorrect testing, operation, maintenance, installation, or adjustment
- If the product is disassembled
- If damage is caused by exposure to water outside of the acceptable range specified in the manual

## Warranty obligations

During the warranty period, and at its own discretion, i-SENS will replace a defective CareSens Neon sensor without charging the purchaser. The purchaser needs to put the product in an appropriate box and ship it back to the CareSens Neon customer service department. When returning the product, a receipt showing the date of purchase, the product serial number, the name and address of the seller, or comparable documentation must be included in the box. To get support for the region to ship your CareSens Neon, contact your local i-SENS dealer. After receiving a defective product, i-SENS will replace it immediately.

If i-SENS decides that a warranty exclusion applies to the product, the purchaser must pay for all return shipping costs.

# Appendix A Frequently Asked Questions

This chapter presents situations that may occur while using CareSens Neon 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 nearest authorized dealer.

This section will help you to:

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

## **What should I do if I receive a sensor replacement alert?**

The sensor's lifespan is 15 days, and the sensor replacement alert will occur 5 days before it expires. Disconnect the sensor within 4–5 days after receiving the alert and replace it. Refer to '[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.

## **What should I do if the sensor battery is low?**

A low battery alert occurs when the sensor battery is low. Disconnect the sensor and replace it with a new one. Refer to '[Disconnecting and removing the sensor](#)' for more information on how to disconnect the sensor.

## **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](#)'.



### **What should I do if I lose my smart device?**

If you have automatic upload enabled on the app, all your app data is backed up on the cloud server. In this situation, you can check the data on the website as well.

If automatic upload is disabled, you will be unable to check the data that was on the device you lost unless you backed it up manually. Enable automatic upload in case you lose your device. Refer to '[Uploading data](#)' for more information on how to configure your upload settings.

### **My sensor glucose reading does not match a blood glucose reading I took using a finger prick.**

A glucose meter measures glucose concentration in blood from the tip of the finger, and the sensor measures glucose concentration in interstitial fluids. It may take time for glucose in the blood to reach the interstitial fluid, resulting in a difference in glucose readings.

### **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 personal glucose meter to obtain a reading using a finger prick, and compare the result with your physical condition. Consult a medical professional if necessary.

### **What should I do if the sensor has been discharged, but it does not separate from the applicator?**

The sensor cannot be used if it wasn't attached properly. Hold the skin adhesive tape on the sensor and gently remove the sensor from the applicator. If it cannot be removed, it is a damaged or a defective product. Do not use the sensor, and contact the nearest authorized dealer or customer service center.

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

Continuously attaching sensors to the same location may cause minor skin irritation. Attach the next sensor to a different location. If the same symptoms 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 app can't find a signal when I'm trying to connect with the sensor?

Keep the sensor and the smart device within 10 meters of each other with no obstacles in between them. Connecting may take up to 15 minutes. If the problem persists after 15 minutes, do as follows.

- Android: Go to **Settings** > **Applications** on your smart device and force restart CareSens Neon.
- iOS: Force restart CareSens Neon.

## How can I terminate a sensor early?

Disconnect the sensor, hold the edge of the skin adhesive tape, and slowly peel it off. Dispose of the sensor after removing it. Refer to '[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 lost**, and new glucose readings will not be displayed. The sensor takes and sends glucose readings every 1 minutes. Any data that hasn't been sent will be stored for 3 hours. It will be sent automatically when the connection is restored.

## Can I go in the water with CareSens Neon attached?

CareSens Neon has been tested as waterproof for up to 24 hours at a depth of 1.2 meter. Daily activities within this range will not have an effect on the operation of the sensor. However, the effect on the system of longer periods under water has not been tested.

# 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 (Edition 4.1).

Testing name	Standard referenced	Part tested	DC main power voltage	Required testing level	Note
Radioactivity disturbance	CISPR 11:2015 + AMD1:2016 + AMD2:2019	Enclosure	D.C. 1.5V	Group 1, Class B	
Electrostatic discharge immunity test	IEC 61000-4-2:2008	Enclosure	D.C. 1.5V	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air	
Radiated, RF electromagnetic field	IEC 61000-4-3:2006 + AMD1:2007 + AMD2:2010	Enclosure	D.C. 1.5V	3 V/m 80 MHz–2.7 GHz 80 %, AM at 1 kHz RF wireless communication	

Testing name	Standard referenced	Part tested	DC main power voltage	Required testing level	Note
Power frequency (50/60Hz) magnetic field	IEC 61000-4-8:2009	Enclosure	D.C. 1.5V	30 A/m	
				8 A/m 30 kHz CW Modulation	
Immunity to proximity magnetic fields	IEC 61000-4-39:2017	Enclosure	D.C. 1.5V	65 A/m 134.2 kHz PM 2.1 kHz	
				7.5 A/m 13.56 MHz PM 50 kHz	

### **IEC 60601-1:2005 + AMD1:2012 + AMD2:2020**

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

- Protection against electrical shock: Internally powered, Type BF applied part
- Operating method: 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 + AMD1:2013 + 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 (FCCID:OELCGM-ST-101)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

### Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

### **Part15.21 statement:**

Changes or modifications not expressly approved by the manufacturer (or party responsible) for compliance could void the user's authority to operate the equipment

## Guidance and Manufacturer's Declaration – Electromagnetic Emission

The CGM-ST-101 is intended for use in the electromagnetic environment specified below.

The customer or the user of the CGM-ST-101 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF Emission CISPR 11	Group 1	The CGM-ST-101 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	
Harmonic Emission IEC 61000-3-2	Not applicable	The CGM-ST-101 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuation and flicker IEC 61000-3-3	Not applicable	

## Recommended separation distances between portable and mobile communication equipment and the CGM-ST-101

The CGM-ST-101 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CGM-ST-101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CGM-ST-101 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	IEC 60601-1-2: 2014	
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.


**Note**

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Guidance and manufacturer's declaration - electromagnetic immunity**

The CGM-ST-101 is intended for use in the electromagnetic environment specified below.

The customer or the user of the CGM-ST-101 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 Vrms	$d=2.0 \sqrt{P}$ 80 MHz to 2.7 GHz Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with following symbol: 

**Note**

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CGM-ST-101 is used exceeds the applicable RF compliance level above, the CGM-ST-101 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CGM-ST-101.
- b Over the frequency range 150kHz to 80MHz, field strengths should be less than the compliance level 3V/m.
- c The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

## Guidance and manufacturer's declaration - electromagnetic immunity

The CGM-ST-101 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30cm (12 inches) to any part of the CGM-ST-101. Otherwise, degradation of the performance of this equipment could result.

Immunity test	Band <sup>a</sup>	Service <sup>a</sup>	Modulation	IEC60601 test level	Compliance level
Radioactivity disturbance	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 - 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 - 787 MHz	LTE Band 13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 - 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28V/m



Immunity test	Band <sup>a</sup>	Service <sup>a</sup>	Modulation	IEC60601 test level	Compliance level
Radioactivity disturbance	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28V/m
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28V/m	28V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

### Note

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

- a For some services, only the uplink frequencies are included.
- b The carrier shall be modulated using a 50% duty cycle square wave signal.
- c As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

## B.2 Product specifications

### Sensor specifications

Item	Specifications
Analysis method	Electrochemical method
Enzyme type	GDH-FAD
Measurement range	40–500 mg/dL
Transmission distance	Maximum 10 m (32.8 ft)
Operating conditions	Temperature: 10–42 °C (52–107.6 °F) (Max. measured temperature of the applied part: 42.6 °C (108.6 °F)) Humidity: 10–95 %
Storage and transport conditions	Temperature: 5–30 °C (41–86 °F) Humidity: 15–85 %
Sterilization	Ethylene Oxide (EO)
Number of uses	Single-use
Dimensions (W x L x H)	23.6 x 15.8 x 2.9 mm (0.9 x 0.6 x 0.1 in) (Skin adhesive tape excluded)
Weight	About 1.3 g (0.04 oz) (release paper excluded)
Color	Gray
Power supply	Coin battery (SR716W, 1.55 V) 1 ea
Useful life	Before opening: 12 months after its date of manufacture After opening: 15 days after applying the sensor
Maximum memory	3 hours of glucose data
Operating altitude	-382–3011 m

Item	Specifications
Waterproof protection	IP48
Data transfer interval	Once every 1 minutes
Communication method	Bluetooth 5
Protection against electrical shock	Type BF Applied Part
TX/RX frequency	2.402–2.480 GHz
Maximum Output Power	-3.13 dBm EIRP
Modulation	GFSK
Data Rate	1 Mbps

## Applicator specifications

Item	Specifications
Dimensions (W x L x H)	50.5 x 40.0 x 73.5 mm (1.9 x 1.5 x 2.8 in) (safety pin, sensor excluded)
Weight	About 45 g (1.5 oz) (safety pin, sensor included)
Color	White

## B.3 Cybersecurity

### Cautions regarding cyber threats

- Install a virus protection or antivirus program on your smart device to prevent malicious programs from accessing your smart device's information.
- If you are logged out because your account has been compromised, reset the password.
- If you enter the wrong password more than five times, reset your password.
- If you have not used your account for over 1 year, the account becomes inactive. You will be required to re-authenticate in order to make the account active again.
- In the event of a cyber security incident related to a smart device, contact i-SENS customer service (+82-80-910-0600) or the relevant authority.

### Security Measures

- The CareSens Neon System is designed to transmit data between the transmitter and the designated smart device according to the Bluetooth Low Energy (BLE) protocol. Radio frequency (RF) communications using other protocols, including the Bluetooth classic communication protocol, are not allowed.
- The CareSen Neon application communicates with the CareSens server on a regular basis unless it is disabled. Communications between the CareSens Neon application and the CareSens server are protected by several mechanisms designed to prevent data damage. The JSON Web Token (JWT) authentication and authorization are included. All of these communications take place only in an encrypted data path in the industry standard SSL format.

# Appendix C Glossary

Term	Description
High frequency	A radio wave or electromagnetic wave with a high frequency. This usually refers to waves between 3 and 30MHz in frequency.
Focal	This means many devices are integrated in one semiconductor chip.
Hyperglycemia	A symptom in which glucose concentration in the blood is unusually high. In most cases it is related to diabetes.
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.
Metal detector	A machine that is used to locate metal objects or determine whether or not an object is metallic.
Water resistance	The property of being resistant to water.
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.
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.
Backing paper	Paper covered with silicone on one or both sides. It is used to protect adhesive surfaces.
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.
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.

Term	Description
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.
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.
Ethylene oxide (EO)	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 <sub>2</sub> H <sub>4</sub> O.
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. It may also be referred to as interstitial fluid.
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.
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.
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.
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.
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.

Term	Description
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.
Magnetic field	A space in which there is magnetic attraction such as near a magnet or current, or the Earth's surface.
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.
Rating	The rating of an electrical device or any other device is the specified range the device should be used within.
Diameter	A line segment that connects two points on a circle or sphere while passing through its center.
Finger prick	The act of drawing blood for the purpose of diagnosing a disease or performing a transfusion.
Bodily fluid	Refers to blood inside blood vessels or tissues, lymph, and cerebrospinal fluid as a group.
Cloud	A system that saves files and information such as documents, photos, music, etc. on a personal online server.
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 <sub>6</sub> H <sub>12</sub> O <sub>6</sub> . It is also known as glucose.
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.
Back	The rear portion of an object

Term	Description
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.
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.
EMC	Electro Magnetic Compatibility, testing for immunity to electro magnetic interference from exterior sources.
EU	The European Union (an organization formed by 27 countries in the European community under the Maastricht Treaty).
GSM	The Global System for Mobile Communications. This is the most widely used personal mobile communication system; a communication standard based on TDMA.
IP rating	Ingress protection, a dustproof and waterproof rating regulated by KS C IEC 60529. The first number is a dustproof rating and the second number is a waterproof rating.
MRI	Magnetic resonance device (a piece of equipment for chemical analysis that uses magnetic resonance phenomena).
RF	Radio frequency; the entire field of equipment design and engineering research concerning wireless communication using high frequencies in the electromagnetic frequency band.
RF communication	Wireless communication



Term	Description
RFID	Radio-Frequency Identification uses electromagnetic waves to uniquely identify an ID, and is often referred to as RFID. RFID technology refers to the technology of using electromagnetic waves to process information over a long distance.
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.