# **User manual**

# Sens 365 Web





This user manual is intended to assist with the proper use of the Sens365 web. The Sens365 app connects to the sensor users of the CareSens Air Continuous Monitoring System.

Read this user manual thoroughly and adhere to all precautions before use.



Thoroughly review this user manual before using the Sens365 web.

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# Before use

- 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.
- Check whether the device used to run the software is turned on and connected to a wired/wireless network

#### O Note

- All standards and regulations mentioned are in effect as of the date this
  manual was issued.
- i-SENS, Inc. has carefully prepared the information in this manual to be as accurate as possible.
- However, i-SENS is not responsible for any errors or omissions contained in the manual. i-SENS may change the product described in this manual or any related software applications without notice in order to enhance the product reliability, features, or design.
- This document is protected by copyright. It is strictly prohibited to copy or alter this manual without prior consent from i-SENS.



# **Definitions of symbols**

These symbols not only provide additional information on the product and product use, but also on safety.

Symbol	Description
CE	CE Mark
EC REP	Authorised representative in the European Community/ European Union
MD	Medical device
[]i	Consult instructions for use or consult electronic instructions for use
***	Manufacturer
#	Model number
UDI	Unique device identifier

# **Safety Information**

#### Intended purpose

Sens365 is intended for use by home users and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose data to support effective diabetes management.

#### **Important User Information**

- You must create an i-SENS account to use Sens365.
- Sens365 is a secondary viewer for the CareSens Air Continuous Glucose
  Monitoring System and is not intended to provide treatment decisions or
  to be used as a substitute for professional healthcare advice. Sens365
  does not guarantee the real-time reception of glucose data of CareSens
  Air Continuous Glucose Monitoring System user.
- The warnings and cautions must be read and understood before using Sens365, and they must be strictly adhered to. Sens365 must be used according to the instructions in the user manual.

# Warnings

- Users of CareSens Air Continuous Glucose Monitoring System and their family members and guardians must not make treatment decisions based on the Sens365 glucose data. In addition, Sens365 does not offer any medical advice and must be not used for that purpose. You must consult a medical professional to make a treatment decision.
- Medical institutions and medical professionals must not use only the glucose data provided by Sens365 for treatment decisions or analysis.



#### **Precautions**

- CareSens Air Continuous Glucose Monitoring System user must turn on the share feature in order to send glucose data to his or her care providers (family members, guardians, medical institutions, medical personnel), and if the care providers want to view the shared content, they must download Sens365 and connect with CareSens Air Continuous Glucose Monitoring System user.
- The care providers must be connected to CareSens Air Continuous Glucose Monitoring System user and the care providers' smart devices must be connected to the Internet in order to view the information of CareSens Air Continuous Glucose Monitoring System user through Sens365.
- If the smart device of CareSens Air Continuous Glucose Monitoring System
  user or care provider (family members, guardians, medical institutions,
  medical personnel) is turned off, in airplane mode or not connected to the
  Internet, the glucose data may not be sent or received.
- If care providers (family member, guardian, medical institution, medical personnel) terminate the connection, the content sent by CareSens Air Continuous Glucose Monitoring System user cannot be viewed.

# 1 Understanding the Sens365 web

# **Working Mechanism**

This product is a secondary display software that collects and saves processed glucose data with i-SENS' CareSens Air Continuous Glucose Monitoring System. The system is capable of sending data and displaying information on Android and iOS smart devices. The glucose data collected and processed by the i-SENS' CareSens Air Continuous Glucose Monitoring System can be securely transmitted to care providers (including family members, guardians, medical institutions, and medical personnel) using the Secure Sockets Layer (SSL) encryption protocol.

# 2 Recommended specifications for the Sens365 web

The following operating systems have been verified as compatible by their manufacturers.

# 2.1 Recommended Operating System

#### O Note

Make sure to use an operating system that meets the recommended specifications. Proper functioning of the Sens365 web is not guaranteed for operating systems which have not been verified as being compatible.

Operating System	Resolution	
Google Chrome, Mozilla Firefox, Microsoft Edge, Apple Safari	1280 x 800	

# 3 Using the Sens365 web

You can run the Sens365 web and monitor the glucose readings measured by the connected continuous glucose monitoring system. In order to log in to the Sens365 web, you must create an account.

Using various features offered by the Sens365 web enhances the efficiency of diabetes management.

This section will help you to:

- 1. Register for and log in to the Sens365 web.
- 2. View the sensor user list.
- 3. Manage groups, sensor users, and care providers.
- 4. View the Reports screen and glucose reports.
- 5. Edit basic information and manage i-SENS accounts by changing settings.



# 3.1 Logging in

# **Running the Sens365 web**

- Open your browser and enter the Sens365 web url. URL: https://sens365.com
- 2 The Sens365 web start screen is displayed.



# **Creating an account**

If you do not have a Sens365 account, go to the Create an Account screen of the Log in screen to sign up.

- 1 Click Starting Sens365 on the Sens365 web start screen.
- 2 Click Create an account when the account Log in screen is displayed.



#### O Note

Change the language on the top right as needed.

3 Select your country and language.



4 Verify your email.





5 Agree to the required terms.



6 Enter your password and fill out all your information, then complete the account registration.



# **Resetting the password**

If you forget your password or need to change your password for security reasons, you can reset it.

- 1 Click Starting Sens365 on the Sens365 web start screen.
- Select Forgot your password? when account Log in screen is displayed.



3 Verify your email.





4 Set your new password.



5 Log in to your account with the new password.

# Logging in

If you have a Sens365 account, log in to Sens365 on the Log in screen.

- Click **Starting Sens365** on the Sens365 web start screen.
- 2 Enter your registered email and password when the account Log in screen is displayed.



# Logging out

Click Log Out after selecting the profile on the top right of the screen to log out.



2 You will be redirected to the Sens365 start screen if you logged out properly.



# Selecting the user mode

The user mode selection screen will be displayed when you log in to Sens365 for the first time. (In the user mode selection screen, CareSens Air users should select the Sensor User mode and care provider of CareSens Air should select the Care Provider mode.)

The user mode selection screen will be displayed when you log in to Sens365 web for the first time.



- 2 Select sensor user or care provider according to the use purpose.
- 3 For a sensor user, a report appears on the start screen. For a care provider, the sensor user list is displayed on the start screen.







# 3.2 Viewing the sensor user list

# Viewing the sensor user report from the list

1 If you select Group from the menu on the left, the sensor user list of the selected group is displayed.



If you select the row of a sensor user in the sensor user list, you can view the report on the selected sensor user.





# **Adding favorites**

You can add frequently searched sensor users of the sensor user list to the favorites list.

1 Click the ☆ icon to the left of the desired sensor user from the sensor user list.

The \( \frac{1}{\pi} \) icon changes to yellow when added to favorites.



2 Check the added sensor user in the favorites list.



3 Once a sensor user has been added to the favorites list, clicking on the 
icon again removes them from favorites.

# Adding a dashboard

Sens365 offers a dashboard feature to be able to quickly view the reports of multiple sensor users.

The dashboard can be viewed by clicking on **Dashboard** on the top right of the screen.



2 Select Dashboard add button of the desired user from the sensor user list to add the sensor user to the dashboard.



3 Open the Dashboard and check whether the selected sensor user has been added.



- 4 Click the 🖷 icon to delete the sensor user from the dashboard.
- 5 To clear the dashboard, click the icon and click Clear Waiting List.

#### **⊘** Note

Click the pin icon to pin sensor users in the waiting list.

Sensor users pinned in the waiting list are not deleted from the list.



# 3.3 Managing groups

# **Adding groups**

1 Click the : icon in the menu on the left and select Add Group.



2 Enter the name of the group to add.



3 A group is created with the entered name.



# **Editing group names**

1 To edit the group name, click on the : icon of the group you would like to edit ad select **Group Settings**.



2 Enter a new group name.



3 Check the edited group name.





# **Adding sensor users**

1 To add a new sensor user to the group list, click Add on the top right of the list.



2 Enter the share code of the sensor user to add and click Ok.



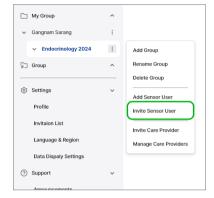
#### **○** Note

The share code can be created in the CareSens Air app used by the sensor user. For more details, check the CareSens Air user manual.

3 If the entered share code is valid, the sensor user is added to the list.

# **Inviting sensor users**

To invite a sensor user to the group, click the icon of the group and select **Invite Sensor User**.



2 Enter the group name to display to the invited sensor user and click Next.

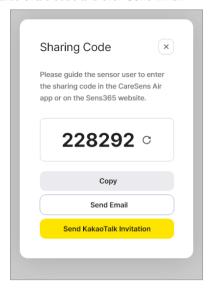


# Note

The entered group name will be visible to the invited sensor user.



3 Check the created share code and click **Send Email**.



4 Enter the email address of the sensor user to invite and click **Send**.



5 An invite email is sent to the provided email address.





When sending via KakaoTalk, enter the phone numbers of the sensor users you wish to invite and click **Send**. A maximum of 10 KakaoTalk messages can be sent at one time.

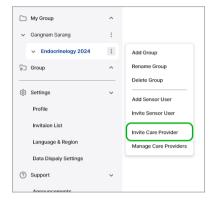


7 A KakaoTalk message will be sent to the phone number you entered.



# **Inviting care providers**

1 To invite care providers to the group, click the icon of the group and select Invite Care Provider.

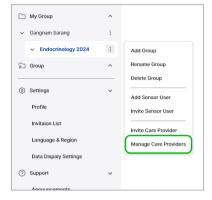


2 Enter the email address of the care provider to invite and click **Send**.



# Managing care providers

1 To manage the care providers of the group, click the icon of the group and select Manage Care Providers.



Select the group to manage from the groups displayed in the group care provider management list.



3 The care providers that belong to the selected group are listed.





4 To change the permissions of the care providers of the group, click the vicon of the care provider permissions and select the permission to change.



### **,**○ Note

There are Admin and Coordinator permissions.

5 To delete a care provider from the group, click the ... icon on the right of the care provider to delete and select **Remove**.

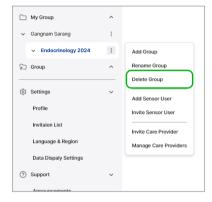


# **Deleting groups**

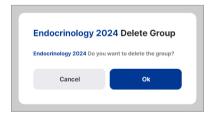
#### **₽** Note

Groups can be deleted if there are no registered sensor users in the group.

To delete a group, click the : icon of the group to delete on the left menu, and select **Delete Group**.



2 Click Ok when the delete confirmation pop-up appears. The selected group will be deleted.





# 3.4 Report

# Viewing reports

- 1 Follow these steps to check the report.

  Sensor user mode: Select the report on the top left menu.

  Care provider mode: Select the row of the desired user from the sensor user list.
- 2 The Report screen is displayed.



#### Note

- In sensor user mode, the overview report screen is displayed first.
- In care provider mode, the AGP screen is displayed first.



3 Each report is composed of the following content.

Report	Content
Overview	The following information for the selected period is provided.  Time in Ranges  Average Glucose  Glucose Management Index (GMI)  Glucose Variability  Standard Deviation  Average Glucose  Insulin  Time CGM Active  Sensor  Min/Max Glucose by Events (fingerstick)  Ketones  GKI  Average Meal per Day  Exercise
AGP	The standard AGP for the selected period is provided.
Comparison	A table and chart is provided to compare glucose levels per period.  Glucose within Target Comparison  Comparison (Glucose Variability, Standard Deviation, Glucose Management Index (GMI), Average Glucose)  Patterns Comparison
Patterns	The daily charts and event information on areas where low glucose, time in ranges, and high glucose have occurred during the selected period are displayed.
Trends	The daily charts and weekly charts for the selected period are provided.



Report	Content
Statistics	The following information for the selected period is provided.
	Time in Ranges
	Average Glucose
	Daily Average Glucose Variability
	Daily Average Sensor Activation Percentage
	Hourly Time in Ranges
	Hourly Average Glucose Value
	Hourly Average Glucose Variability
	Hourly Average Time CGM Active
Events	User events entered during the selected period are provided in a table.

- 4 To save the report, click the 

  icon on the top right. You can select the report and save it as a PDF file.
- 5 To print the report, click the 🗐 icon on the top right. You can select the report and print it.
- 6 To send the report by email, click the ☑ icon on the top right. You can send the report PDF file to a specific email.

# 3.5 Settings

# **Changing profile information**

1 To change basic information, click **Profile** on the top right or on the left menu > Settings menu.



- 2 The basic information that can be edited is as follows:
  - Name
  - · Date of Birth
  - Gender
  - Phone
  - Diabetes Type
- 3 When information is changed, the changed information is saved automatically.



# Managing i-SENS accounts

1 To manage your account, click **Go to Account Settings** on the basic information screen.



2 Select Edit Profile and check the information entered upon creating the account.





# Resetting the password

1 To change your account password, click **Change Password** on the Go to Account Settings screen.



2 Enter the current password then enter the new password.





# Managing connected services

To manage connected services, click Manage Connection Services on the Go to Account Settings screen.



You can check the list of services in use with your current account.



# **Deleting accounts**

1 To delete your account, click **Delete Account** on the Go to Account Settings screen.



When deleting your account, check the notice and click I agree and Ok to complete the process.





### Changing the user mode

1 To change the use mode, click Switch User Mode on the basic information screen.



When the Switch User Mode pop-up is displayed, select the user mode to change to and click **Ok**.



3 The screen layout will be changed according to the selected user mode.

# **Sharing my data**

### **₽** Note

To enter the share code for glucose data sharing, the mode must be set as sensor user.

To share your glucose data with a new care provider, click the left Menu > Settings > Connections. A list of care providers who receive your shared data is displayed.



- To enter the share code, click Connect with Care Provider on the top right.
- 3 Click Ok after entering the share code of the care provider to receive the shared data.



4 If the entered share code is valid, the group is added to the care providers list.

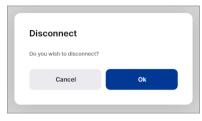


To stop sharing with an existing care provider, click **Disconnect** on the right of the care provider to disconnect.





6 Click **Ok** when the stop sharing confirmation pop-up appears. Sharing will be stopped with the selected care provider.

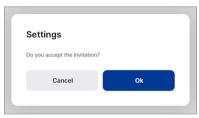


# **Accepting invites**

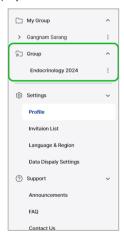
1 If you are invited to a group as a health manager, the invitation information is displayed in **Menu** > **Settings** > **Invitation List**.



- 2 To accept an invite, click Accept.
- 3 Click Ok when the accept confirmation pop-up appears.

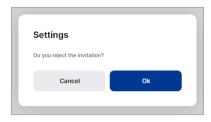


4 The invited group is displayed on the left menu.





- 5 To reject an invite, click Reject.
- 6 Click **Ok** when the refuse confirmation pop-up appears. The invited group is not added to the menu.



# **Changing languages**

- 1 To change the language, select the **Language & Region** in the **Settings** of the left menu.
- 2 Select the desired language on the language selection screen.



### **Setting units**

- To set up units, select **Data Display Settings** under **Settings** on the left menu.
- 2 Select the desired unit of glucose in the unit section when the glucose settings page appears.





### Setting the threshold per diabetes type

- 1 To set the threshold for setting the target diabetes glucose range, select Report > Target Range Settings.
- 2 Set the target glucose per area under the Time in Ranges section when the Target Range Settings page appears.



### Note

- Clicking on Reset resets to the diabetes type threshold.
- Changing the target glucose range settings applies to the Time in Ranges of the sensor user. (AGP, Comparison excluded)
- If a day/night application time change is needed, the Day Start Time and Night Start Time can be set up in the Day & Night Time section.

# Setting up AGP report criteria

- 1 To set the custom range of the AGP report, select Report > AGP Report.
- 2 If you set the report criteria at the top of the screen to user settings, you can change the low or high criteria.



When you click Apply, the AGP report on the screen will be displayed based on the set value.

# Appendix A Frequently Asked Questions

This chapter presents situations that may occur while using CareSens Air and how to deal with them.

If any situation which is not presented in this chapter occurs, or if you experience an issue that you are unable to resolve on your own, contact the authorized distributor.

This section will help you to:

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

### What should I do if I can't connect with a care provider?

Please verify if the sharing code received from the care provider is accurate.

### How do I stop sharing my data?

To stop sharing your data with a care provider, go to Settings > Connections and choose to disconnect.

### How can I share reports?

Reports can be shared through a connection with a care provider in two ways: First, enter the sharing code received from the group you wish to share with at **Settings** > **Connections** > **Enter Sharing Code**. Second, share the sharing code generated in the CareSens Air app.

### How do I check the reports?

Click on the Report menu in the top left corner. If you want to print the report, click on **Download Report**, **Print Report**, or **Send Report** icons in the top right corner of the report screen to view the report in PDF format.

### How do I set up Sens365 in sensor user or care provider mode?

After signing up for Sens365, a mode selection screen will appear during your first login. Select either the sensor user or care provider mode, and Sens365 will operate in that mode. You can later change the user mode in **Profile** section under the **Settings** menu.



### How do I upload my glucose data?

Glucose readings in the CareSens Air app will be automatically uploaded. You can also manually upload data in the CareSens Air app > Settings > Upload Now. However, you can only upload data when you have an internet connection.

### What is the inactive account policy for Sens365?

If a user doesn't use Sens365 for a year, their account will be classified as inactive and their personal information will be securely stored separately. This stored information will be retained for a year and may be discarded if there's no legal requirement to keep it. i-SENS will notify inactive users 30 days before their account becomes inactive and provide information about the stored data. If you don't want your account to become inactive, simply log in before the inactive period. Even if your account becomes inactive, as long as your personal data hasn't been discarded, you can log in, obtain user consent, restore the inactive account, and continue using the service.

# How can I ensure that the data stored in Sens365 is securely protected?

Personal and sensitive information stored in Sens365 is encrypted. During data transmission, the SSL (Secure Sockets Layer) encryption protocol ensures the confidentiality and integrity of the data, protecting it from eavesdropping and alterations.

# How can a care provider view the glucose data uploaded by the sensor user?

The care provider must be connected with the sensor user through their affiliated group to view the glucose data uploaded by the sensor user. There are two methods for this:

- The first method is to click in the group menu where you manage the sensor users. Then select 'Invite Sensor User'. Next, directly provide or email the sharing code of that group to the sensor user. The sensor user then enters the group's sharing code (CareSens Air app > Settings > Care Providers > Connect > Enter Sharing Code). Please note that each group has a unique sharing code, and once assigned, the sharing code does not change. If you want to change it, click the refresh icon next to the sharing code.
- The second method is to click : of the group managing the sensor users, select 'Add Sensor User', and then enter the sharing code created in the CareSens Air app (CareSens Air app > Settings > Care Providers > Connect > Generate Sharing Code) to add the sensor user.



### How do I download the raw glucose data of the sensor user?

You can download the raw glucose data in CSV format by clicking the 'Export Data' icon in the top right corner of the sensor user's report screen.

### How do I compare the glucose data of the sensor user?

Glucose data can be comparaed by setting two periods in the Comparison tab of the sensor user's report screen.

### How can I check the report?

When you click a sensor user within a group, you can view their glucose report. If you want to print the report, click on the **Download Report**, **Print Report**, or **Send Report** icons in the top right corner of the report screen to view the report in PDF format.

### How can I set up as a sensor user or care provider?

After signing up for Sens365, a mode selection screen will appear during your first log in. From this screen, you can choose the sensor user or care provider mode, and Sens365 will run in the selected mode. Later, you can change the user mode under the 'Settings' menu in the 'Profile' section.

### How can I join someone else's group?

The care provider of the group you wish to get invited to can click : next to that group and select 'Invite Care Provider' to send an invitation via email. By clicking the invitation email link, you can accept the invitation and join the group. Additionally, you can accept the invitation from the invitation lists in Settings > Profile. However, the inviting email must match the care provider's Sens365 login account.

### How many sensor users or care providers can be in one group?

There is no limit to the number of sensor users and care providers that can be added to a group.

### Who can I invite to the group?

You can invite sensor users to the group to manage their glucose levels, and you can also invite other care providers to co-manage the sensor users of the group.



### What is the group sharing code and how can I check it?

The group sharing code is a unique code generated for each group to invite and manage sensor users. You can check the sharing code of the group by clicking in the group menu and selecting **Invite Sensor User**. Please note that each group has a unique sharing code, and once assigned, the sharing code does not change. If you want to change it, click the refresh icon next to the sharing code.

### What features are available in the group?

Care providers create groups for organizational and management purposes to effectively manage sensor users. When you first join Sens365, a default group is automatically created under your name. You can change the group name as you wish, create subgroups, and manage sensor users. Additionally, you can invite or add sensor users within the group to check their reports, and you can also invite care providers to the group to co-manage sensor users.

### What is the inactive account policy for Sens365?

If a user doesn't use Sens365 for a year, their account will be classified as inactive and their personal information will be securely stored separately. This stored information will be retained for a year and may be discarded if there's no legal requirement to keep it. i-SENS will notify inactive users 30 days before their account becomes inactive and provide information about the stored data. If you don't want your account to become inactive, simply log in before the inactive period. Even if your account becomes inactive, as long as your personal data hasn't been discarded, you can log in, obtain user consent, restore the inactive account, and continue using the service.

### Is the data of the added sensor user in the group secure?

The data is securely transmitted during the transmission through the SSL (Secure Sockets Layer) encryption protocol, and personal and sensitive information is stored in an encrypted state. Only care providers belonging to the group can access the data of the added sensor users in the group.

#### How do I search for sensor users?

You can search for sensor users by names, notes, and tags included in the list.

### How can I manage or monitor a specific sensor user?

By clicking the favorite icon of a user in the sensor user list, you can set them as a favorite. Then, you can manage them separately in the favorites tab.



#### How can I filter the list of sensor users?

The sensor user list can be viewed by applying the filtering or sorting options provided in the table header of the sensor user list.

#### What is the list of sensor users?

It is a list of sensor users connected for management in the respective group. You can check the real-time glucose information of sensor users in the group.

# Appendix B Technical Information

# **B.1** Performance

Web Browser: HS-FE-01

Product name	Sens365			
Compatible medical devices	Product name: CareSens Air Continuous     Glucose Monitoring System     Model: CGM-ST-002			
Communication environment	Communication protocol: HTTPS			
Operating environment	Recommended browser: Google Chrome,     Mozilla Firefox, Microsoft Edge, Apple Safari     Resolution: 1280 x 800			
Transmitted and reveiced data	Continuous glucose values of a compatible medical device user, user input data (meals, insulin, exercise, etc.)     User data statistics and reports including the glucose of a compatible medical device user			
Key performance	<ul> <li>Care providers (family members, guardians, medical institutions) who use the app can receive shared data by connecting with the user web of a compatible medical device user.</li> <li>Displays statistics for a compatible medical device user's data and saves reports.</li> <li>Displays the continuous glucose values of a compatible medical device user and user input data.</li> </ul>			
Software version	Version: 1.0.x			



# **B.2** Cybersecurity

#### Cautions regarding cyber threats

- Install a virus protection or antivirus program on your smart device, whether a Windows, Mac OS or tablet device, to prevent malicious programs from accessing the device's information.
- If you are unable to receive the glucose data from the sensor users despite
  entering the share code, make sure the six-digit share code was entered
  correctly. If the same issue persists despite entering the correct share code,
  contact our Customer Center (080-910-0900).
- If you are logged out due to another device logging in, change your password if it was not you who attempted to log in.
- 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. If your account has become inactive, you must reactivate it.
- If a cybersecurity incident occurs related to Sens365, contact the nearest authorised distributor and the competent authority.

#### Safety regarding cyber threats

- A token is issued to the user once his or her credentials have been verified as valid.
- For each request, the validity of the token is verified, and then the authentication is processed.
- The SSL communication method is used to send data.
- AES encoding is used to encrypt personal information data and the data is saved to a DB.
- If you enter the wrong password more than five times, you must reset your password.
- If you have not used your account for over 1 year, the account becomes inactive. If your account has become inactive, you must reactivate it.

# i.sens

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