

Sens 365 Web

i-sens



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

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

O Note

Thoroughly review this user manual before using the Sens365 web. Sens365 is a secondary viewer for the CareSens Air CGM 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 CGM System user.

Table of contents

Be	fore us	e	6
		Document conventions	7
		Safety Information	8
1	Under	rstanding the Sens365 web	10
		Working Mechanism	10
2	Recor	mmended specifications for the	
		865 web	11
	2.1	Recommended Operating System	11
3	Using	the Sens365 web	12
	3.1	Logging in	13
		Running the Sens365 web	
		Creating an account	
		Resetting the password	
		Logging in	
		Selecting the user mode	
	3.2	Viewing the sensor user list (Care Provider Mode)	
		Viewing the sensor user report from the list	20
		Adding favorites	21
		Adding a dashboard	
	3.3	Managing groups (Care Provider Mode)	23
		Adding groups	23
		Editing group names	24
		Adding sensor users	25
		Inviting sensor users	26
		Inviting care providers	28
		Managing care providers	29
		Deleting groups	31

3.4	Report	32
	Viewing reports	32
3.5	Settings	
	Changing profile information	35
	Managing i-SENS accounts	36
	Resetting the password	
	Managing connected services	38
	Deleting accounts	39
	Changing the user mode	40
	Sharing my data	41
	Accepting invites	43
	Changing languages	45
	Setting the threshold per diabetes type	46
	Setting up AGP report criteria	47
Appendix	A Frequently Asked Questions	48
Appendix	B Technical Information	53
B.1	Performance	53
B.2	Cybersecurity	

Before use

- This product only makes use of personal information which the user has agreed to allow for collection.
- Contact the manufacturer or visit the website for details of this product.
- Check that 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.



Document conventions

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
EU 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

Indication for use

Sens365 is indicated for continuous monitoring of blood glucose levels via measurement of glucose in the interstitial fluid in persons with diabetes mellitus aged 18 years and older. Sens365 is intended for use by patients, care providers, and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis, and evaluation of historical glucose data from compatible glucose monitoring devices to support effective diabetes management. Sens365 is available as cloud-based web software (Sens365 Web) and as a smart device application (Sens365 App).

Sens365 Web is not intended to provide clinical decisions or to be used as a substitute for professional healthcare advice. Patients should consult a healthcare professional before making any medical interpretation and therapy adjustments based on the information provided by the software. Healthcare professionals should use the information in conjunction with other relevant clinical information available to them.

Sens365 App is a secondary viewer that allows home users and healthcare professionals to remotely view glucose data from users of compatible glucose monitoring devices. The software is intended solely to provide a secondary level of awareness and should not be expected to communicate and display real-time glucose information.

Important User Information

- You must create an i-SENS account to use Sens365.
- Sens365 is a secondary viewer for the CareSens Air CGM 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 realtime reception of glucose data of CareSens Air CGM 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 CGM 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 healthcare professional to make a treatment decision.
- Medical institutions and healthcare professionals should use data provided by Sens365 in conjunction with other clinical information available to them for treatment decisions or analysis.

Precautions

- CareSens Air CGM System users must turn on the share feature in order
 to send glucose data to their care providers (family members, guardians,
 medical institutions, medical personnel). If the care providers want to
 view the shared content, they must download Sens365 and connect with
 CareSens Air CGM System user.
- The care providers' smart devices must be connected to the Internet in order to view the information shared by the CareSens Air CGM System user through Sens365.
- If the smart device of the CareSens Air CGM 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.
- Care providers (family members, guardians, medical institutions, medical personnel) can co-manage the CareSens Air CGM System with the user, however, the sensor user must always be the subject of active glucose management.
- If care providers (family member, guardian, medical institution, medical personnel) terminate the connection, the content sent by CareSens Air CGM System user can no longer 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 CGM System. The system is capable of sending data and displaying information on Android and iOS smart devices. The glucose data collected and processed by i-SENS' CareSens Air CGM 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.

Recommended Browser	Resolution
Google Chrome, Mozilla Firefox, Microsoft Edge, Apple Safari	1280 x 800 px or higher

OS (Operating System)	Version
Windows	10 or later
Mac OS	11 or later

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 'Create an account' screen of the login screen to sign up.

- 1 Click **Get Started** on the Sens365 web start screen.
- 2 Click Create an account when the account login screen is displayed.
 - You may use a social login to sign up for an i-SENS account.
 - To sign up with Social Login, enter your country of residence, and user information, and agree to the required terms and conditions.



O Note

Change the language on the top right as needed.

3 Verify your email address.





4 After accepting the required terms and conditions by ticking the appropriate boxes, click **Ok**.



5 Enter your password and fill out all your information, then click **Ok**. Your account registration will be completed successfully.





Resetting the password

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

- 1 Click **Get Started** on the Sens365 web start screen.
- 2 Click Forgot your password? when account login screen is displayed.



3 Verify your email address.





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 login screen.

- Click **Get Started** on the Sens365 webstie start screen.
- 2 Enter your registered email and password when the account login screen is displayed.
 - If you have signed up with Social Login, keep using the same account that was selected in Social Login.



Logging out

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



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.

- CareSens Air users should select the Sensor User mode.
- Care providers 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.



- Select Sensor User or Care Provider as required.
- 3 For a sensor user, '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 (Care Provider Mode)

Viewing the sensor user report from the list

1 If you select a group on the left, the sensor user list of the selected group will be displayed.



2 If you select 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 ☆ to the left of the desired sensor user from the sensor user list. The ☆ changes to yellow when added to favorites.



Check the added sensor user in the favorites list.



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

Adding a dashboard

Sens365 offers a dashboard feature to enable easy viewing of reports from multiple sensor users.

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



2 From the sensor user list, select the desired user and click Add to Dashboard to add the sensor user to the dashboard.



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



- 4 To delete a sensor user from the dashboard, select the sensor user and click $\widehat{\mathbf{w}}$.
- To clear 'Dashboard', click inext to the group name and Empty Dashboard.

Note

Click $^{\circ}$ to pin sensor users in 'Dashboard'. Sensor users pinned in 'Dashboard' will not be deleted from the list.



3.3 Managing groups (Care Provider Mode)

Adding groups

1 Click in the 'My Group' on the left and click 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 : of the group you would like to edit and click **Group Settings**.



2 Enter a new group name and click Save.



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 sharing code of the sensor user to add and click **Ok**.



O Note

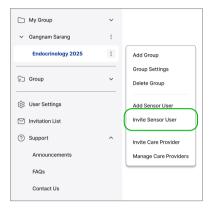
The sharing code can be created in the CareSens Air app used by the sensor user.

For more details, check the CareSens Air user manual.

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

Inviting sensor users

1 To invite a sensor user to the group, click inext to the group name and click invite Sensor User.



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

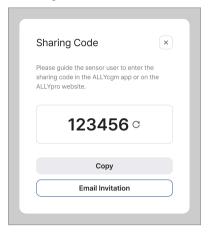




The group name will be visible to the invitee sensor user.



3 Check the created sharing code and click **Email Invitation**.



4 Enter the email address of the sensor user to be invited and click Send. You can send a maximum of 10 emails at once.

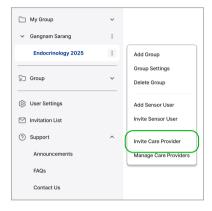


5 An invitation email is sent to the provided email address.

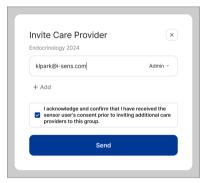


Inviting care providers

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



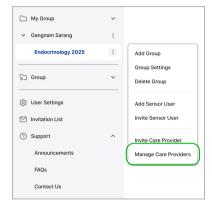
2 Enter the email address of the care provider to be invited and click Send.





Managing care providers

1 To manage the care providers of the group, click : next to the group name and click **Manage Care Providers**.



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



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





4 To change the permissions of the care providers of the group, click ▼ in the Authority field and select the permission to change.



Note

There are 'Admin' and 'Coordinator' permissions. Selecting 'Admin' provides permission to manage groups, healthcare professionals and sensor users. Selecting 'Coordinator' provides permission to manage sensor users only.

5 To delete a care provider from the group, click ... next to the care provider to delete and click Remove.



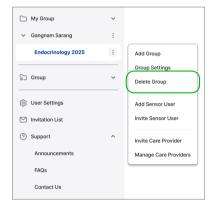


Deleting groups

O Note

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

1 To delete a group, click: next to the name of the group, then click **Delete**Group.



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





3.4 Report

Viewing reports

- Follow these steps to check the report.
 - Sensor User mode: Click 🔀 Report on the top left menu.
 - Care Provider mode: Click the row of the desired user from the sensor user list.
- 2 The 'Report' screen is displayed.



○ Note

- In Sensor User mode, the 'Overview' screen is displayed first.
- In Care Provider mode, the 'AGP (Ambulatory Glucose Profile)' screen is displayed first.



3 Each report comprises of the following content.

Report	Content	
Overview	The following information for the selected period is provided.	
	Time in Ranges	
	Average Glucose	
	Glucose Management Indicator (GMI)	
	Glucose Variability	
	Standard Deviation	
	Daily Average Glucose	
	Insulin	
	Daily Time in Ranges	
	Time CGM Active	
	Device Information	
	Sensor	
	Min/Max Glucose by Events (fingerstick)	
	Ketones	
	GKI (Glucose Ketone Index)	
	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 Indicator (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
	Average Glucose Variability
	Average Time CGM Active
	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

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

 on the top right. You can send the report PDF file to a specific email.



3.5 Settings

Changing profile information

To change basic information, click the profile at the top right or User Settings on the left.



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

Managing i-SENS accounts

1 To manage your account, click **Go to i-SENS Account Settings** on the personal information screen.



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







Resetting the password

To change your account password, click **Change Password** on the account settings screen.



2 Enter the current password then enter the new password.



Managing connected services

1 To manage connected services, click **Manage Connection Services** on the 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 account settings screen.



When deleting your account, ensure that you read 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 personal 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

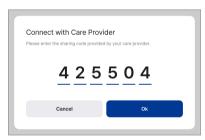
O Note

You can enter the sharing code for glucose data sharing in 'Sensor User' mode.

1 To share your glucose data with a new care provider, click **Connections**. A list of care providers who receive your shared data is displayed.



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



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





5 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.



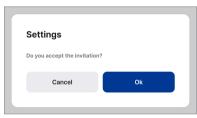


Accepting invites

1 If you are invited to a group as a health manager, the invitation is displayed in 'Invitation List'.



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

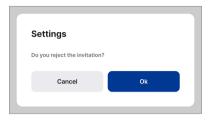


4 The invited group is displayed on the left.





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





Changing languages

- 1 To change the language, click at the bottom right of the screen.
- 2 Select the desired language on the language selection screen.



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Setting the threshold per diabetes type

- To set the threshold for setting the target diabetes glucose range, click Target Range Settings at the top of 'Report' screen.
- 2 Set the target glucose per area on the 'Target Range Settings' screen.



Note

- Clicking on the 'Reset' button resets the target range to the default values.
- Changing the target glucose range settings applies to the Time in Ranges of the sensor user. (AGP, Comparison excluded)
- 3 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, click **AGP** on the 'Report' screen.
- 2 If you set the report criteria at the top of the screen to user settings, you can change the low or high criteria.



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

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Appendix A Frequently Asked Questions

This section presents situations that may occur while using Sens365 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 the Sens365 web.
- Resolve problems that occur while using the Sens365 web.

Dashboard

Care Provider

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 🚖 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.

General

Sensor User

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 dormant account policy for Sens365?

If a user does not use Sens365 for a year, their account will be classified as dormant and their personal information will be securely stored separately. This stored information will be retained for a year and may be discarded if there is no legal requirement to retain it. i-SENS will notify dormant users 30 days before their account becomes dormant and provide information about the stored data. If you do not want your account to become dormant, simply log in before the dormancy period. Even if your account becomes dormant, as long as your personal data has not been discarded, you can log in, obtain user consent, restore the dormant 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.

Care Provider

What is the dormant account policy for Sens365?

If a user does not use Sens365 for a year, their account will be classified as dormant and their personal information will be securely stored separately. This stored information will be retained for a year and may be discarded if there is no legal requirement to retain it. i-SENS will notify dormant users 30 days before their account becomes dormant and provide information about the stored data. If you do not want your account to become dormant, simply log in before the dormancy period. Even if your account becomes dormant, as long as your personal data has not been discarded, you can log in, obtain user consent, restore the dormant 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.

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Group

Care Provider

How can I join someone else's group?

A care provider of the group you wish to join can send you an email invitation by clicking the icon next to the group name and selecting **Invite Care Provider**. By clicking inext to 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 invitation 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 C 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 sign up for 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.



Mode

Sensor User

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.

Care Provider

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.

Reports

Sensor User

How can I share reports?

Reports can be shared with a care provider in two ways:

- Enter the sharing code provided by your care provider at Settings > Connections > Connect New Sensor User.
- Share the sharing code generated in the CareSens Air app (CareSens Air app > Settings > Care Providers > Connect > Generate Sharing Code) with the care provider.

How do I view the reports?

Click on the Report menu in the top left corner. If you want to print the report, click on $\, \underline{\,}\, \downarrow \,$, $\, \underline{\,}\, = \,$, or $\, \underline{\,}\, \subseteq \,$ in the top right corner of the report screen to view the report in PDF format.

Care Provider

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

You can download the raw glucose data in CSV format by clicking **1** 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 compared by setting two periods in the Comparison tab of the sensor user's report screen.

How can I view 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 \ddots , $\ensuremath{\boxdot}$, or $\ensuremath{\boxtimes}$ in the top right corner of the report screen to view the report in PDF format.

Data Sharing

Sensor User

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.

Care Provider

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 click 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 next to the sharing code.
- The second method is to click of the group managing the sensor users, click
 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.

Appendix B Technical Information

B.1 Performance

Web Browser: HS-FE-01

Product name	Sens365			
Compatible medical devices	Product name: CareSens Air CGM System Model: CGM-ST-002			
Communication environment	Communication protocol: HTTPS			
Operating environment	 Recommended browser: Google Chrome, Mozilla Firefox, Microsoft Edge, Apple Safari OS(Operating System) Version: Windows 10 or later, Mac OS 11 or later Resolution: 1280 x 800 px or higher 			
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	 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. Displays statistics for a compatible medical device user's data and saves reports. Displays the continuous glucose values of a compatible medical device user and user input data. 			
Software version	Version: 1.1.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 information in your smart device.
- 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 your authorised i-SENS distributor.
- 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, you must reset your password.
- If you have not used your account for over 1 year, the account becomes inactive, and must be reactivated.
- If a cybersecurity incident occurs relating to Sens365, contact the nearest authorised i-SENS 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 (Data Base).
- 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, and must be reactivated.

isens

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