

User manual

Sens 365 Web



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.

 **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

Before use	6
Document conventions	7
Safety information	9
1 Understanding the Sens365 web	11
Working mechanism.....	11
2 Recommended specifications for the Sens365 web.....	12
2.1 Recommended operating system	12
3 Using Sens365 web (General users).....	13
3.1 Running Sens365 web	14
3.2 Understanding the home screen	15
3.3 Viewing reports.....	17
Overview	18
AGP	21
Comparison	22
Patterns.....	23
Trends.....	24
Statistics	25
Events	26
3.4 Settings.....	27
Changing profile information.....	27
Managing i-SENS accounts.....	28
Managing care providers	29
3.5 Connecting the receiver	30
Connecting the receiver to PC.....	30
Understanding the receiver screen.....	31
Exploring receiver functions.....	33

4 Using Sens365 web (Healthcare professionals)34

4.1 Switching to professional account	35
Healthcare professional authentication	35
4.2 Understanding the professional screen.....	37
4.3 Understanding the group screen	38
4.4 Managing groups	39
Adding groups	39
Inviting sensor users.....	39
Inviting care providers	39
4.5 Viewing the sensor user report	40
4.6 Selecting receiver users	41

Appendix A Inactive account policy42

Sens365 inactive account policy	42
Data protection of sensor users.....	42

Appendix B Technical information43

B.1 Performance	43
B.2 Cybersecurity.....	44

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.

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.
- Images are representational and are provided for illustrative purposes only. Actual device screens and appearances may differ from those shown in this manual.

Document conventions

Notational conventions

This manual uses the following notational conventions to aid in understanding its content.

Notational conventions	Description
Boldface	Boldface is used to display elements of the graphic user interface, including menus and directories.
' '	Single quotation marks are used to indicate pages, portals, and screens from the graphical user interface.
'Cross-references'	'Cross references' are used to refer to different sections of this document.
Visual aids	Visual aids in the form of graphics, illustrations, or screen captures are used to help the reader understand the text.
Tables	Tables are used to present large amounts of data in an easy-to-read format.

Supplementary descriptions and explanations

You can refer to these for information about exceptions and limitations.

Note

This indicates reference situations to note which can provide helpful information or help you avoid danger when using the product.

Safety messages

This manual uses the following types of safety messages to alert the user of situations in which they need to take precautions when using the product:

Warning

This marks a potential danger that could result in serious injury or death if not avoided.

Caution

This marks a situation that could result in minor injury or property damage if not avoided.

Definitions of symbols

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

Symbol	Description
	CE Mark
	Authorised representative in the European Community/ European Union
	Medical device
	Consult instructions for use or consult electronic instructions for use
	Manufacturer
	Model number
	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 real-time 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 not be used for that purpose. You must consult a medical 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 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). 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 the 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

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 Sens365 web (General users)

You can run Sens365 web and monitor the glucose readings measured by the CareSens Air app or receiver. In order to log in to Sens365 web, you must create an account.

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

This section will help you to:

1. Launch and log in to Sens365 web.
2. View and understand glucose reports.
3. Share your glucose data with care providers and professionals.
4. Connect a receiver to view your data.
5. Edit personal information and manage i-SENS accounts by changing settings.

3.1 Running Sens365 web

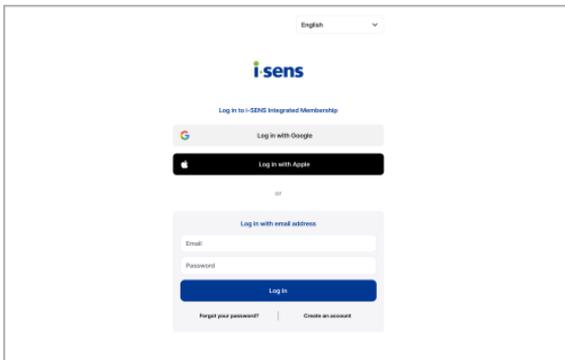
1 Open your browser and enter the Sens365 web URL.

URL: <https://sens365.com>

Click **Get Started** to access Sens365 web.

2 Log in with your i-SENS account.

- If you do not have an account, please create an account. Click **Create an account** and complete registration by verifying your email, agreeing to the required terms and conditions, entering your country of residence, and user information.
- Even if you choose Social Login, you can sign up with an i-SENS account. In this case, please select the same Social Login when logging in.
- If you forget your password or need to change it, you can reset it by clicking **Forgot your password?**.

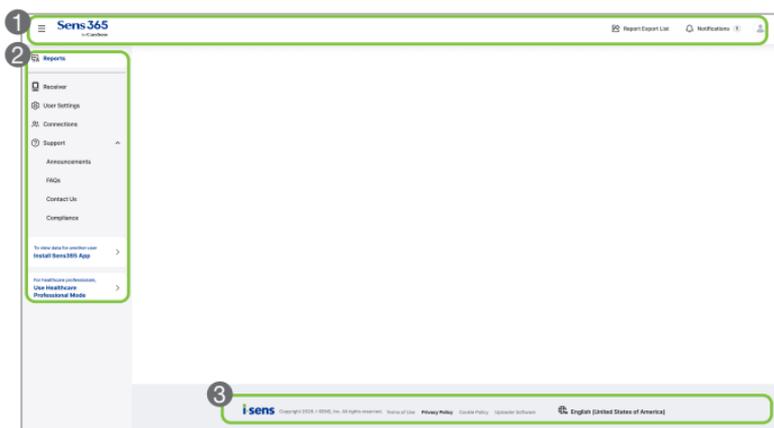


Note

Change the language on the top right as needed.

3.2 Understanding the home screen

The following table describes the basic information displayed when you enter the Sens365 web home screen after logging in.



No.	Name	Description
1	Top Area	<ul style="list-style-type: none"> • Sens365 Home Shortcut: Moves to Sens365 Home. • Report Export List: Add and manage reports in the export list. • Notifications: Check notification logs, such as invitation lists and announcements. • Profile: View profile information and change personal information.
2	Left Menu	<ul style="list-style-type: none"> • Reports: Analyze glucose data recorded over a certain period and check your glucose status through reports. • Receiver: Connect a receiver to upload glucose data. • User Settings: View profile information and change personal information. • Connections: Manage the list of connected care providers. • Support: View information such as Announcements, FAQs, Contact Us, and Compliance. • Shortcut Banner: Install the Sens365 app or complete healthcare professional authentication.

No.	Name	Description
3	Bottom Area	<ul style="list-style-type: none">• i-SENS Website Shortcut• Terms of Use• Privacy Policy• Cookie Policy• Uploader Software• Language Settings

3.3 Viewing reports

- 1 Click  **Reports** on the top left menu to access the report screen.
- 2 Use the icons at the top of the report to perform the following functions.

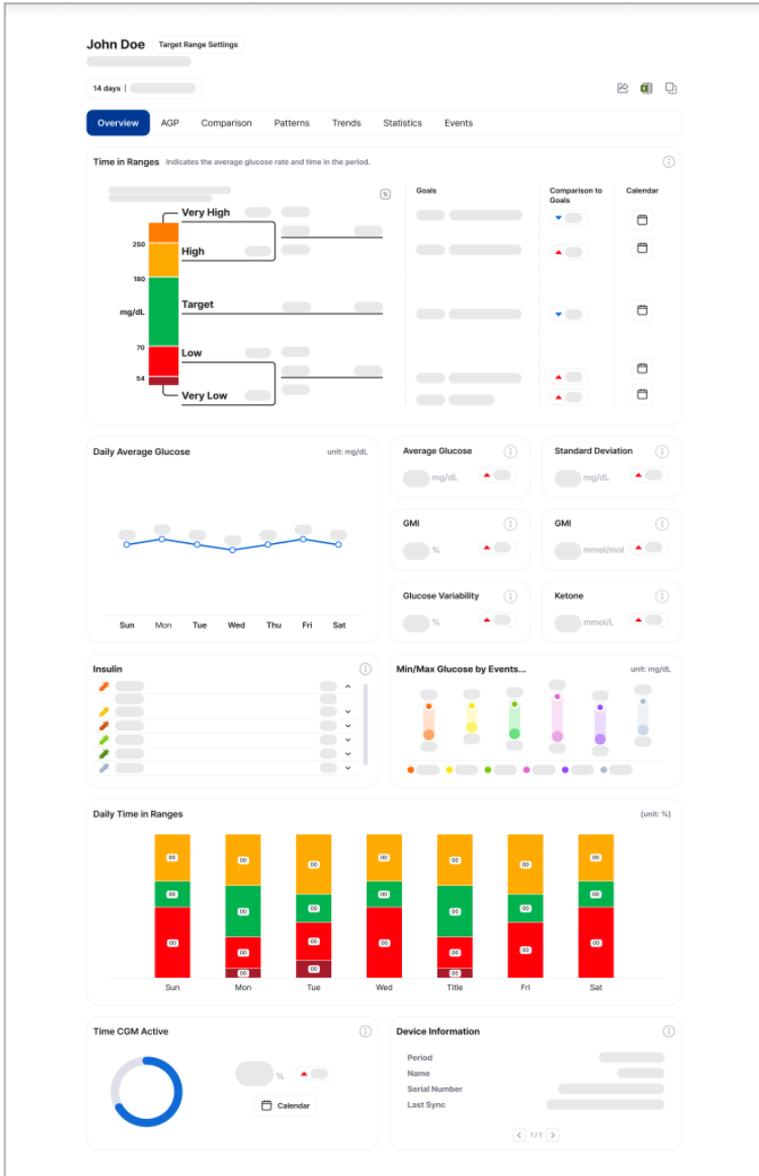


No.	Name	Description
1	Target Range Settings	Change the target glucose range displayed in the report.
2	Period	Change the report viewing period.
3		Copy the AGP report as text.
4		Save, print, or transmit the report content.
5		Export the report content to Excel.

- 3 On this page, click the following reports to view the related information.
 - Overview, AGP, Comparison, Patterns, Trends, Statistics, Events

Overview

The following glucose metrics and key information such as insulin and sensor data for the selected period is provided.

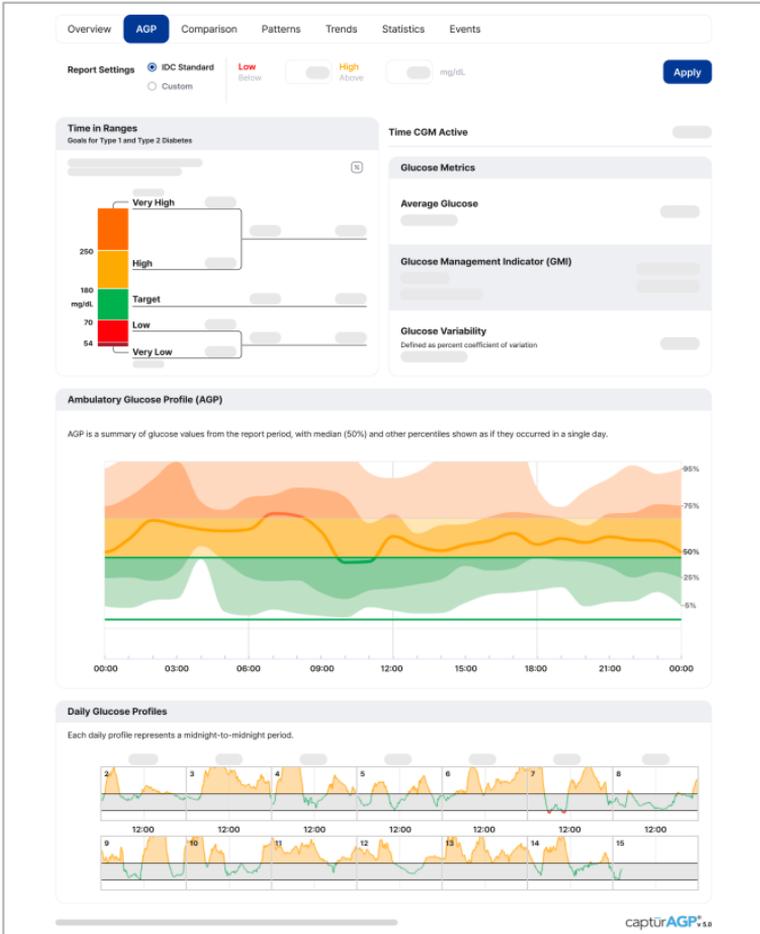


Name	Description
Time in Ranges	<p>Indicates the percentage of time glucose was within each glucose range during the selected period.</p> <ul style="list-style-type: none"> • Target: Indicates the percentage of time glucose levels remained within the target glucose range. • Low / Very Low: Indicates the percentage of time glucose values were lower than or much lower than the target range. • High / Very High: Indicates the percentage of time glucose values were higher than or much higher than the target range.
Daily Average Glucose	Provides average glucose values for the selected period by day of the week.
Average Glucose	The average glucose value for the selected period.
Standard Deviation (SD)	A numerical value showing how far the measured glucose levels deviate from the average. A lower value indicates that glucose is maintained within a consistent range.
Glucose Management Indicator (GMI)	Provides an estimated glycated hemoglobin (A1C) level based on the average glucose value for the selected period.
Glucose Variability	A percentage (%) calculated by dividing the standard deviation by the average glucose, representing the degree of variation in measured glucose during the selected period.
Ketone	The average ketone value for the selected period.
Insulin	Displays the total daily dose of insulin administered by type.
Min/Max Glucose by Events (Fingerstick)	Displays the minimum and maximum glucose by Events within data measured with a personal blood glucose meter.
Daily Time in Ranges	Displays the percentage of Time in Ranges by day of the week.
Time CGM Active	The percentage of time that the CGM data was collected divided by the entire time of the report.
Device Information	Displays information on the sensor worn during the corresponding period.

Name	Description
Glucose Ketone Index (GKI)	Refers to the ratio of glucose levels to ketone levels during the selected period. This index is used to monitor health conditions related to diabetes, ketogenic diets, etc.
Daily Average Meal	Indicates the average daily intake by nutrient for the selected period.
Daily Average Exercise	Indicates the daily average exercise time for the selected period by exercise intensity.

AGP

The ambulatory glucose profile (AGP) is a report that summarizes glucose data collected over a specific period to show glucose changes throughout the day. You can view the standard AGP report for the selected period.

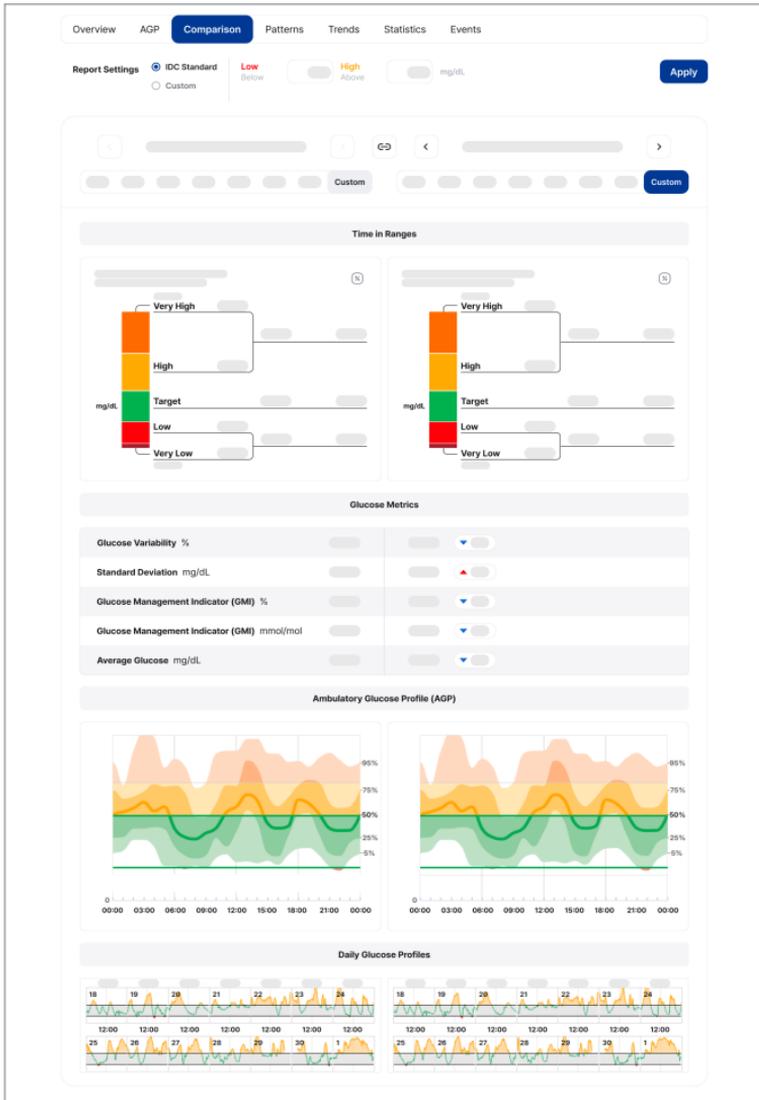


Name	Description
Report Settings	Low/high thresholds can be set to IDC (International Diabetes Center) standards or user settings.
Ambulatory Glucose Profile (AGP)	Glucose values collected during the viewing period are summarized into a 24-hour profile, displaying the median (50%) and percentile ranges.
Daily Glucose Profiles	Represent a midnight-to-midnight period.

Comparison

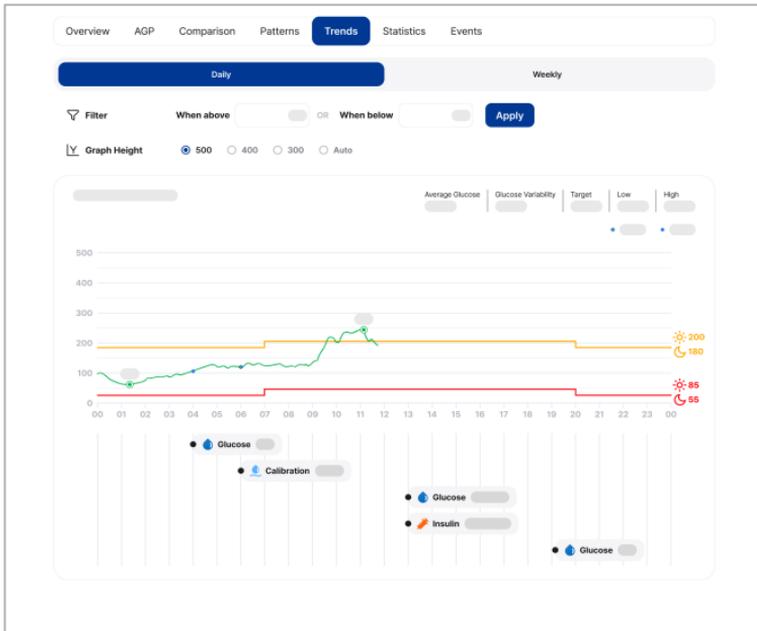
Charts for two periods are displayed side by side to allow comparison of AGP reports by period.

- Time in Ranges Comparison
- Glucose Metrics Comparison (Glucose Variability, SD, GMI, Average Glucose)
- Ambulatory Glucose Profile (AGP) Comparison



Trends

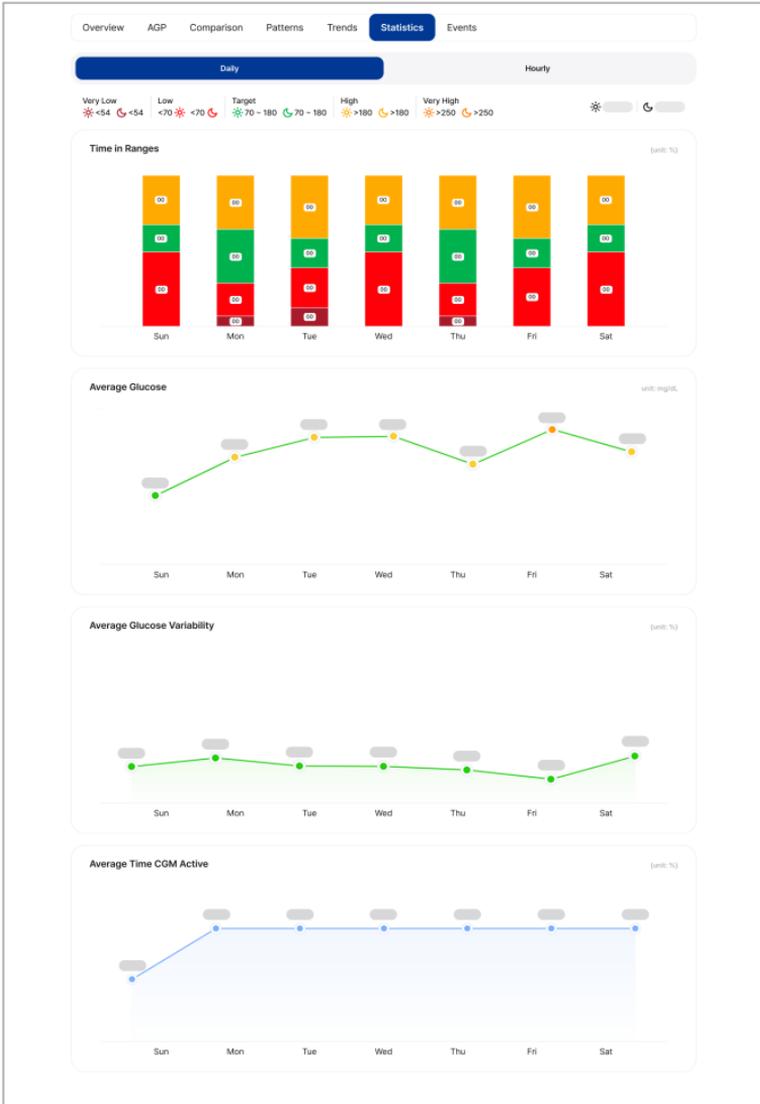
You can view daily and weekly trends for the selected period. Event information is also displayed.



Statistics

The following information for the selected period is provided by day and hour:

- Time in Ranges
- Average Glucose
- Average Glucose Variability
- Average Time CGM Active



Events

User events entered during the selected period are displayed by date, and you can filter to view specific events.

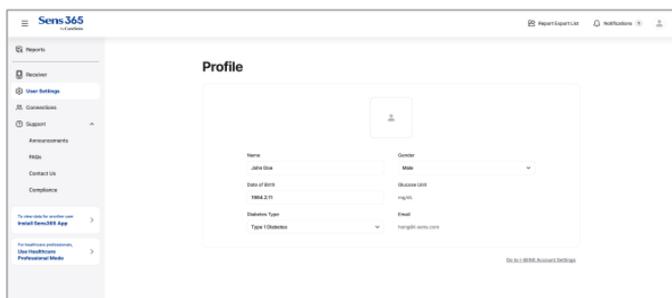
The screenshot displays the 'Events' tab in the Sens365 web interface. At the top, there is a navigation menu with tabs for Overview, AGP, Comparison, Patterns, Trends, Statistics, and Events (which is currently selected). A 'Filter' button is located in the top right corner. The main content area shows a vertical timeline of events. Each event is represented by a horizontal bar with a circular icon on the left and a text label. The events are as follows:

- Medication (Pill icon)
- Medication (Pill icon)
- Glucose (Water drop icon)
- Insulin (Insulin syringe icon)
- Medication (Pill icon)
- Exercise (Person running icon)
- Medication (Pill icon)
- Glucose (Water drop icon)
- Medication (Pill icon)
- Meal (Fork and knife icon)
- Medication (Pill icon)
- Medication (Pill icon)
- Meal (Fork and knife icon)
- Meal (Fork and knife icon)
- Glucose (Water drop icon)
- Medication (Pill icon)
- Glucose (Water drop icon)

3.4 Settings

Changing profile information

- 1 To change personal information, click the profile at the top right or **User Settings** on the left menu.



The screenshot shows the Sens365 web interface. On the left is a navigation menu with options: Reports, Receiver, User Settings (highlighted), Connections, Support, and Assessments. The main content area is titled "Profile" and contains a form with the following fields:

Name	Gender
Johu Doe	Male
Date of Birth	Wishes List
1994-2-10	mg@cs
Diabetes Type	Email
Type 1 Diabetes	john@cs.com

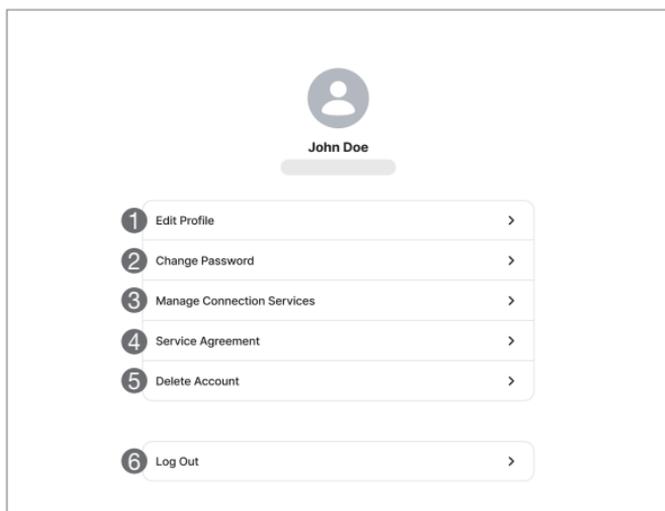
At the bottom right of the form, it says "By: 11-2016, Account: 1000000".

- 2 The personal information that can be edited is as follows:

- Name
- Gender
- Date of Birth
- Diabetes Type

Managing i-SENS accounts

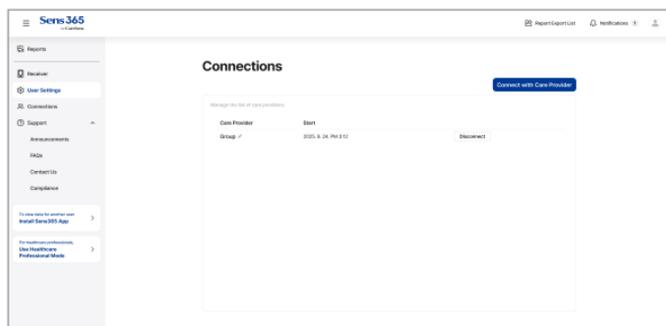
To manage your account, click **Go to i-SENS Account Settings** on the 'Profile' screen.



No.	Name	Description
1	Edit Profile	View and update information entered during registration.
2	Change Password	Change your password to a new one.
3	Manage Connection Services	View and disconnect services linked to the current account.
4	Service Agreement	Review the terms of use and policies.
5	Delete Account	When you delete your account, all information, including glucose data, will be deleted.
6	Log Out	Log out of the i-SENS account and services.

Managing care providers

You can share your data with a care provider by connecting with them. If you wish to stop sharing data, you can disconnect the care provider to stop data sharing.



Connecting care provider

- 1 Clicking **Connections** displays a list of care providers who are receiving your shared data.
- 2 To connect a new care provider, click **Connect with Care Provider**.
- 3 Enter the Sharing Code of the care provider who will receive the data and click **Ok**.
- 4 After entering the Sharing Code, you must consent to data provision to connect with the care provider. Please agree to the relevant items.
- 5 If the entered Sharing Code is valid, a group will be added to the care provider list.

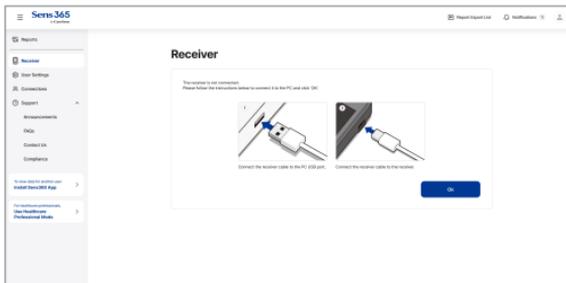
Disconnecting care provider

- 1 To disconnect a previously connected care provider, click **Disconnect**.
- 2 When the sharing disconnection confirmation pop-up appears, click **Ok**. Sharing with the corresponding care provider will be disconnected.

3.5 Connecting the receiver

Connecting the receiver to PC

- 1 To connect Sens365 with the CareSens Air Receiver, select **Receiver** from the left menu.
 - For non-logged-in users, click **Uploader Software** at the bottom of the Sens365 web page.
(Non-logged-in users can only use the receiver software update feature.)
- 2 If the uploader software is not installed on your PC, follow the on-screen instructions to install the software compatible with your OS. Once installation is complete, click **Refresh** on the right.
- 3 If the CareSens Air Receiver is not connected to the PC, connect the CareSens Air Receiver to the PC according to the on-screen instructions. When the connection is complete, click **Ok** at the bottom right.

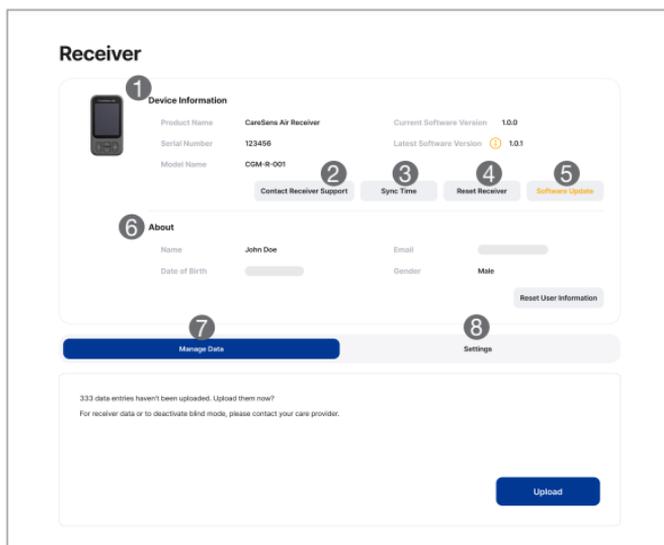


Note

Product availability may vary by country.

Understanding the receiver screen

The following table describes the screen displayed when the CareSens Air Receiver is connected to a PC and the uploader software is installed.



No.	Name	Description
1	Device Information	Displays connected receiver information such as product name, serial number, model name, and software version.
2	Contact Receiver Support	Make an inquiry if you have problems or questions while using the receiver. When making an inquiry, you can also transmit the log data of the connected receiver.
3	Sync Time	Synchronizes the Receiver time with the PC time.
4	Reset Receiver	Resets the connected Receiver.
5	Software Update	<ul style="list-style-type: none"> Updates the Receiver software to the latest version. The button is activated if the software of the connected Receiver is not the latest version.
6	About	Displays the designated user information.
7	Manage Data	Uploads the data stored in the Receiver to Sens365 web.

No.	Name	Description
8	Settings	Check and modify general settings (language, date format, time format, etc.) and notification settings.

Exploring receiver functions

Uploading receiver data

- 1 Check the user information of the connected receiver on the 'Receiver' screen. If no user is designated, click **Select User** to designate a user.
 - For professionals, please refer to '4.6 Selecting receiver users'.
- 2 Click **Manage Data** tab.
 - In the **Manage Data** tab, the number of data records stored on the CareSens Air Receiver is displayed.
- 3 Click **Upload** at the bottom of the screen to upload the CareSens Air Receiver data to Sens365 web.

Note

The **Manage Data** tab is visible only to logged-in users.

Contact receiver support

- 1 If you have problems or questions while using the receiver, click **Contact Receiver Support**.
 - The button is displayed only when a user is selected for the receiver.
- 2 After writing the subject and content, please check **Send Log Data** for customer support.
 - Transmission of receiver log data is only available through **Contact Receiver Support**.
- 3 Click the **Send** at the bottom of the pop-up to submit your inquiry.

4 Using Sens365 web (Healthcare professionals)

Healthcare professionals can monitor glucose data shared by sensor users through Sens365 web. To switch to a professional account on Sens365 web, healthcare professional authentication is required. After authentication, the following features enable safer and more efficient data management.

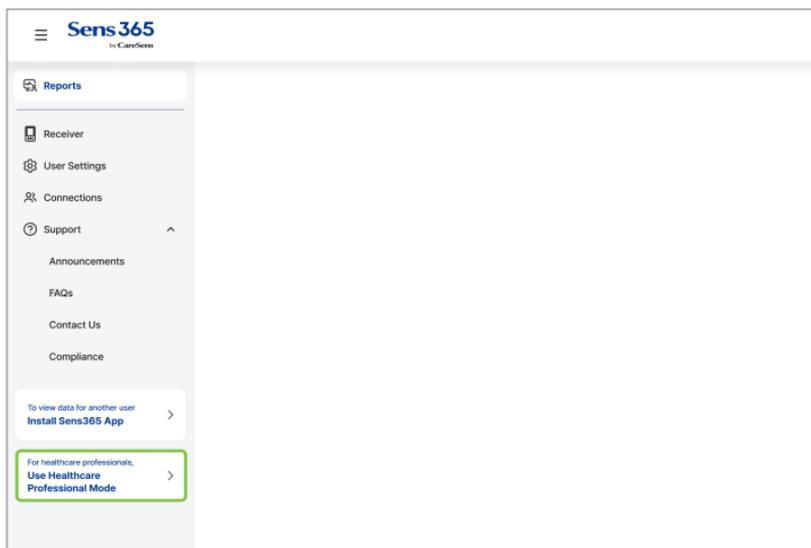
This chapter will help you to:

1. View the list of connected sensor users and their reports.
2. Manage sensor user and care provider groups.

4.1 Switching to professional account

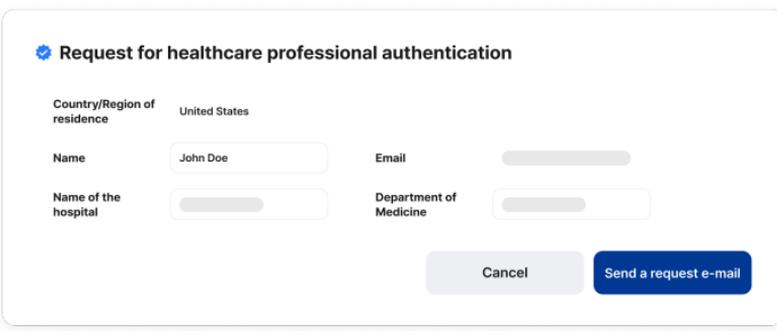
Healthcare professional authentication

- 1 After logging in, click the healthcare professional mode banner at the bottom of the left menu.



- 2 When the **Request for healthcare professional authentication** pop-up appears, enter your name, hospital name, and department.

- 3 After entering the information, click **Send a request e-mail** to request authentication.



The screenshot shows a web form titled "Request for healthcare professional authentication" with a blue checkmark icon. The form contains the following fields and buttons:

- Country/Region of residence:** A dropdown menu with "United States" selected.
- Name:** A text input field containing "John Doe".
- Email:** A text input field that is currently empty.
- Name of the hospital:** A text input field that is currently empty.
- Department of Medicine:** A text input field that is currently empty.
- Buttons:** A "Cancel" button (light gray) and a "Send a request e-mail" button (dark blue).

- 4 Once the request is approved, an authentication completion email and notification will be sent.
- 5 After authentication, reconnect to Sens365 web or click **Use now** in the authentication completion notification to switch to a professional account.

4.2 Understanding the professional screen

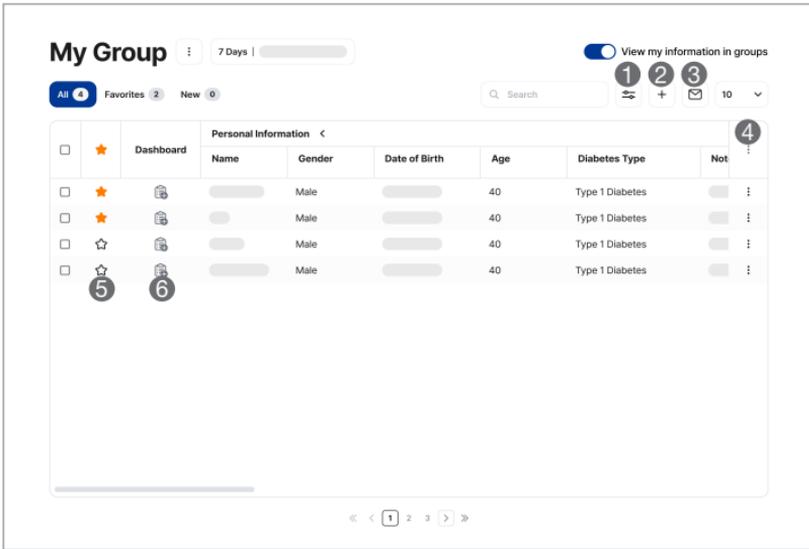
The following table describes the basic information displayed when you enter the Sens365 web home screen after logging in.



No.	Name	Description
1	Top Area	<ul style="list-style-type: none"> • Sens365 Home Shortcut: Moves to Sens365 Home. • Report Export List: Add and manage reports in the export list. • Dashboard: Manage patients by adding them to the dashboard. • Notifications: Check notification logs, such as invitation lists and announcements. • Profile: View profile information and change personal information.
2	Left Menu	<ul style="list-style-type: none"> • My Group: Manage groups and check the list of connected sensor users in each group. • Receiver: Connect a receiver to upload glucose data. • User Settings: View profile information and change basic settings. • Invitation List: View the list of invitations to other groups as a care provider. • Support: View information such as Announcements, FAQs, Contact Us, and Compliance.

4.3 Understanding the group screen

Selecting a group from the left menu displays the list of sensor users connected to that group.



No.	Icon	Description
1		Apply filters to the list.
2		Add a sensor user using a received sharing code.
3		Invite sensor users by providing a group sharing code.
4		Edit the information displayed in the list.
5		Add sensor users to your Favorites. View all favorited users in the Favorites tab.
6		Add sensor users to the Dashboard. View the list of added users by clicking Dashboard in the top area.

4.4 Managing groups

Adding groups

- 1 Click  in the group list on the left menu and select **Add Group**.
- 2 Enter the name of the group to add.
- 3 A group is created with the entered name.

Inviting sensor users

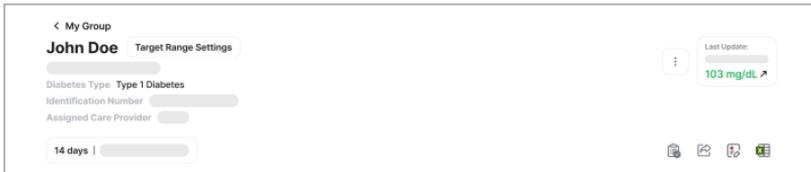
- 1 To invite a sensor user to the group, click  on the right of the group name, and select **Invite Sensor User**.
- 2 If the **Invite Sensor User** pop-up appears, enter the group name to display to the invited sensor user, then click **Next**.
- 3 Check the created sharing code and click **Email Invitation**.
- 4 For email invitation, enter the email address of the sensor user to invite and click **Send**. You can send a maximum of 10 emails at once.

Inviting care providers

- 1 To invite care providers to the group, click  of the group and select **Invite Care Provider**.
- 2 When the **Invite Care Provider** pop-up appears, enter the Sens365 account email of the care provider to be invited and select their permissions.
- 3 Review the precautions at the bottom of the **Invite Care Provider** pop-up and click **Invite**.

4.5 Viewing the sensor user report

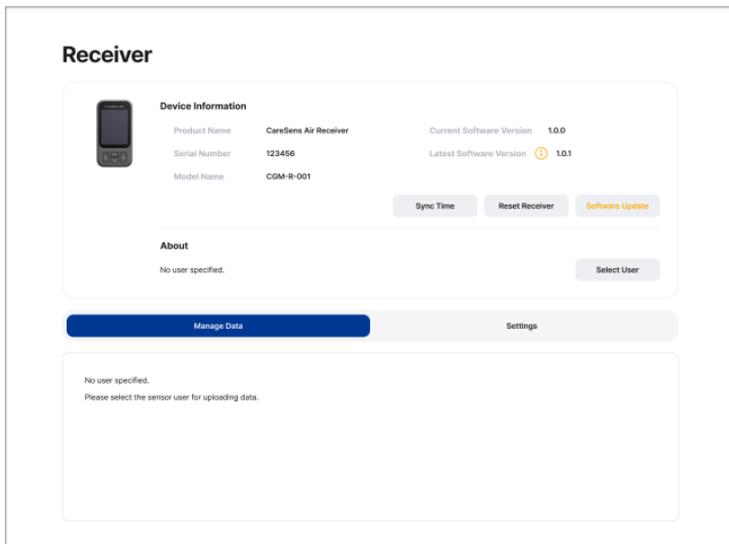
- 1 If you select a sensor user in the group, you can view the report for the selected sensor user.



- 2 You can view the user's information such as Date of Birth, Gender, Diabetes Type, Identification Number, and Assigned Care Provider.
- 3 You can check the latest glucose value information from the sensor connected to the user.
- 4 Click  to issue a prescription for the report.
- 5 For detailed information on viewing reports, refer to '[3.3 Viewing reports](#)'.

4.6 Selecting receiver users

To manage receiver data, a user must be designated.



- 1 Click **Select User** on the 'Receiver' screen.
Refer to '[3.5 Connecting the receiver](#)' for instructions on how to connect the receiver.
- 2 When the pop-up appears, you can select a user eligible for selection for receiver from the sensor users connected within the group.

Appendix A Inactive account policy

Sens365 inactive account policy

Sens365 converts users who have not used the service for 1 year into inactive accounts. During this process, personal information is stored separately and securely protected. Separately stored personal information is retained for 1 year and may be destroyed unless otherwise required by law.

i-SENS provides information about the scheduled inactivation date and the items of personal information being stored separately to members scheduled for inactivation, using methods such as email, at least 30 days before the conversion.

If you do not want your account to be converted to inactive status, log in to the service before the conversion. Also, if your personal information has not yet been destroyed after conversion to an inactive account, you can log in, provide consent, restore your inactive account, and continue using the service as usual.

Data protection of sensor users

- Personal and sensitive information stored in Sens365 is encrypted. During data transmission, the secure sockets layer (SSL) encryption protocol ensures the confidentiality and integrity of the data, protecting it from eavesdropping and alterations.
- Access to the data of a sensor user added to a group is restricted so that only care providers belonging to that group can view it.

Appendix B Technical information

B.1 Performance

Web Browser: HS-FE-01

Product name	Sens365
Compatible medical devices	CareSens Air Continuous Glucose Monitoring System
Communication environment	Communication protocol: HTTPS
Operating environment	<ul style="list-style-type: none"> 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 received data	<ul style="list-style-type: none"> 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 style="list-style-type: none"> 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 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 Customer Service via the product website, caresensair.com.
- 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.
- For secure internet access when using your Sens365, please use a trusted Wi-Fi network (such as your home or workplace), or a secure connection through a reputable VPN service.

Avoid using unsecured public Wi-Fi networks, including guest networks in locations such as homes, restaurants, schools, libraries, hotels, airports, or airplanes. These networks may lack proper security measures and could potentially expose your Sens365 to cybersecurity risks such as malware or unauthorized access.

Safety regarding cyber threats

- A token is issued to the user once their 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.

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PCGAA-000200 REV0 2026-03

