

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. Not following the instructions, cautions, and warnings of the Sens365 web may result in missing the detection of severe hypoglycemia or hyperglycemia, or making incorrect treatment decisions.

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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.
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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
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.
- Care providers (family members, guardians, medical institutions, medical
 personnel) must not manage the glucose of CareSens Air Continuous
 Glucose Monitoring System users. The CareSens Air Continuous Glucose
 Monitoring System user must be the subject of glucose management, and
 must not depend on care providers (family members, guardians, medical
 institutions, medical personnel) to take necessary actions.
- 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.

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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	

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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.
 - Even if you choose to use a simple login process, you can sign up with an i-SENS account.
 - To sign up using a simple login process, enter your country of residence, language and user information, and agree to the required terms and conditions.



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.
- 2 Click 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.

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Logging in

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

- 1 Click **Starting Sens365** on the Sens365 web start screen.
- 2 Enter your registered email and password when the account Log in screen is displayed.
 - If you have signed up with Social Login, Keep using the same account that was selected in Social Login.



Logging out

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 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 (Care Provider Mode)

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 ☆ to the left of the desired sensor user from the sensor user list. The ☆ 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 ★ 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 Click Dashboard add of the desired user from the sensor user list to add the sensor user to the dashboard.



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



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

O Note

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



3.3 Managing groups (Care Provider Mode)

Adding groups

1 Click : in the menu 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.



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**.



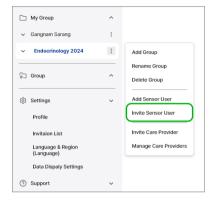
○ Note

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.

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 : of the group and click Invite Sensor User.



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

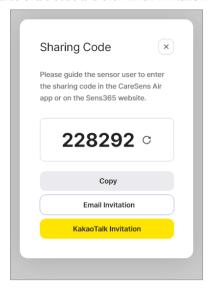


Note

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



3 Check the created share code and click Email Invitation.



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.

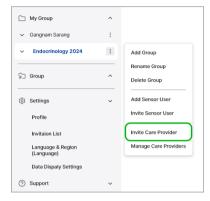


7 A KakaoTalk message will be sent to the phone number you entered.



Inviting care providers

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



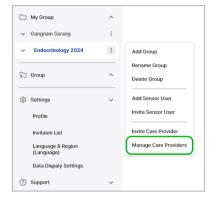
2 Enter the email address of the care provider to invite and click **Send**.



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Managing care providers

To manage the care providers of the group, click of the group and click 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 ▼ 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 ••• on the right of the care provider to delete and click **Remove**.

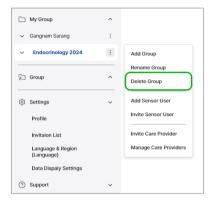


Deleting groups

₽ Note

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

To delete a group, click : of the group to delete on the left menu, and click **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: 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' 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 Indicator (GMI)
	Glucose Variability
	Standard Deviation
	Daily Average Glucose
	• Insulin
	Daily Time in Ranges
	Time CGM Active
	Device Information
	Sensor Min (May Chappe by Frants (fingerstick))
	Min/Max Glucose by Events (fingerstick) Ketones
	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
Companion	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.
- 6 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

1 To change basic information, click **Settings** > **Profile**.



- 2 The basic information that can be edited is as follows:
 - Name
 - Date of Birth
 - Gender
 - Phone
 - Diabetes Type
- 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 Click 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.



2 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 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.





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.

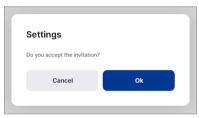


Accepting invites

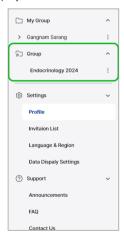
1 If you are invited to a group as a health manager, the invitation information is displayed in **Menu** > **Settings** > **Invitation List**.



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

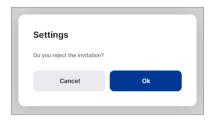


4 The invited group is displayed on the left menu.





- 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, click **Settings** > **Data Display Settings**.
- 2 Select the desired language on the language selection screen.



Setting units

- 1 To set up units, click Settings > Data Display Settings.
- 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, click Report > Target Range Settings.
- 2 Set the target glucose per area 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, click **Report** > **AGP**.
- 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.

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 doesn't 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's no legal requirement to keep it. i-SENS will notify dormant users 30 days before their account becomes dormant and provide information about the stored data. If you don't 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 hasn't 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 doesn't 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's no legal requirement to keep it. i-SENS will notify dormant users 30 days before their account becomes dormant and provide information about the stored data. If you don't 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 hasn't 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.



Group

Care Provider

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 click **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 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 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.

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 through a connection 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 check the reports?

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 街 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 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 \checkmark , \boxminus , or \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 sclick 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 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	 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: 1.0.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.

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