CE 0344

Syai Health Technology Pte. Ltd.

Syai Tag Continuous Glucose Monitoring System(CGMS)

INSTRUCTIONS FOR USE

Model: X1

Version B/0
Issue date: 18 June, 2025

CONTENTS

Please note: the illustrations, diagrams, and other forms of materials within the document serve to depict the operational processes and the current state of the software's user interface, etc. Please refer to the actual usage for the up-to-date details as the standard.

1. Welcome Onboard: Discovering Your Syai Tag CGMS

Thank you for your trust in Syai Health products. We hope to present you with the best experience and service with our Syai Tag Continuous Glucose Monitoring System (Syai Tag CGMS).

1.1 Product Introduction

The Syai Tag CGMS automatically tracks your glucose levels and trends by measuring your interstitial fluid glucose in real time with a 1-minute interval, continuously for 14 days. You may comprehensively understand how your glucose changes over time, which will assist you and the healthcare professional in making more informed decisions about balancing your food, physical activity, and medicine intake for the most optimal glucose management results.

1.2 Key Features and Benefits

Key Features of Syai Tag CGMS:

- **Smaller, lighter, and thinner:** The Syai Tag Monitor is Φ20 (average) mm*3.6mm in size, smaller than a quarter and weighs only 1.2 grams.
- **Integrated design for ease of use:** The Syai Tag Monitor has an integrated design of Sensor and Transmitter and requires no assembly, making it easier to use.
- **Factory calibration:** The Syai Tag Monitor adopts factory calibration technology and does not need fingerstick calibration during use.
- **Pin-point accuracy:** The Syai Tag device is clinically proven to have a Mean Absolute Relative Difference (MARD) value of 8.106%.
- **Real-time readings and stable software:** The Syai Tag Monitor measures and transmits real-time readings every minute and stores up to 14 days of glucose data even when data transmission is blocked.
- **Multiple alert methods:** Glucose alerts and signal loss alerts will be delivered to you through ringtones or vibration notifications, following the settings in the Syai Tag app, desktop widgets, and system notifications to ensure that the user receives important information promptly.
- **Standardized Glucose Report:** The Syai Tag CGMS offers a comprehensive glucose report for your personalized analysis in-app.

Clinical benefits:

Complications resulting from diabetes mellitus (including, but not limited to, diabetic retinopathy and diabetic nephropathy) are well documented [Textbook of Diabetes, Volumes 1&2, Pickup and Williams 1999]. Self-monitoring of blood glucose (SMBG) by patients has revolutionized the management of diabetes [ADA Position Statement. Test of glycaemia in diabetes. Diabetes Care.2003;26 (Suppl1) S106-108.]. Using glucose monitoring devices, patients with diabetes can work to achieve and maintain specific glycaemic goals. Given the results of the Diabetes Control and Complications Trial (DCCT) [Diabetes Control and Complications Trial Research: the effect of

intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. New Engl J Med. 1993; 329:977-986] and other studies, there is broad consensus on the health benefits of normal or near-normal blood glucose levels and the importance, especially in insulin-treated patients, of glucose monitoring devices in treatment efforts designed to achieve these glycaemic goals. Based principally on the DCCT results, experts recommend that most individuals with diabetes should attempt to achieve and maintain blood glucose levels as close to normal as is safely possible. Most patients with diabetes, especially insulin-treated patients, can achieve this goal only by using glucose monitoring devices.

The Syai Tag CGMS can provide real-time glucose monitoring and store the readings automatically, providing users with real-time glucose readings, glucose trends and glucose fluctuation characteristics as well as alert information such as high/low glucose alerts which can strongly help diabetes patients with diabetes management, and especially alerting patients by hypoglycemia and hyperglycemia events, so that clinical or medical intervention can be provided in time to prevent the progression and deterioration of the disorder of glycemia and the complication accompanied.

1.3 Product Kit

Each Syai Tag CGMS product kit contains:

- A Syai Tag Device - including an Applicator and a Monitor

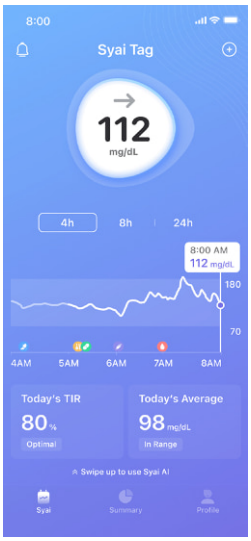
To be used in conjunction with a Syai Tag mobile application.

The Syai Tag Device

The Syai Tag Device comprises a 14-day wearable Monitor and a fully disposable Applicator. Use the Applicator to apply the Monitor to your body.

The Mobile Application

The Syai Tag Mobile Application displays all your glucose information, statistics, and alerts. It also allows you to edit all the settings and capture the corresponding glycemic events.



1.4 Contact Information

Legal Manufacturer: Syai Health Technology Pte. Ltd.

Address: 112 ROBINSON ROAD #03-01 ROBINSON 112 SINGAPORE

Postal Code: 068902

Contact information: 0065-6396736

After-service provider: Local Importer

Lay operators or responsible organizations should contact the local importer or the EU representative, respectively:

- For assistance if needed, in setting up or operating the Syai Tag CGMS.
- To report unexpected operation issues or events.

EU authorised representative: Luxus Lebenswelt GmbH

Address: Kochstr.1, 47877, Willich, Germany

Telephone: 0049-1715605732

SRN: DE-AR-000005110

2. Important Safety Information

Before using the Syai Tag CGMS, please ensure that you have fully read and familiarized yourself with the Instructions for Use. Failure to follow the instructions may result in pain, harm, or affect the system's performance. For any questions about the use of this product, please consult medical staff or contact the Syai Health support team or the local importer.

To keep you and the product safe during your use of the system, this chapter provides safety information, including indications, contraindications (avoidance circumstances), precautions, and warnings as follows:

1. Indications for use: to define the suitable user group.
2. Contraindications: to make you aware of certain circumstances under which use of the product should be avoided and, if not avoided, may cause harm to yourself or damage the product.
3. Precautions: to remind you of the specific situations in which your attention is needed during use to prevent any minor or moderate harm to you or damage to the product.
4. Warnings: to remind you of any severe or life-threatening environment that needs to be avoided when using the product, as well as the corresponding consequences and the way to avoid danger.

Upon unpacking the product, check whether the product is intact. If any parts are missing or damaged, please get in touch with the importer as indicated on the package.

2.1 Indications for use

The Syai Continuous Glucose Monitoring System is intended for adults (18 and above) with diabetes mellitus who need to monitor their glucose levels. The system is indicated for measuring interstitial fluid glucose levels in intended adult users and can provide users with real-time glucose readings, glucose trend and fluctuation characteristics, and alert information such as high/low glucose alerts. It is intended to supplement blood glucose testing, allowing better management of diabetes for individuals, helping individuals make decisions about medication, diet, and exercise, and improving the quality of life for individuals with diabetes. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Syai Continuous Glucose Monitoring System is intended for single-patient use.

The system is intended to be deployed with the support of qualified healthcare providers where applicable, you may also refer to Chapter 15.3 for other requirements before you apply your Monitor.

2.2 Contraindications

The following principles should be followed for the use of the Syai Tag CGMS:

1.Patients with allergic skin should use the product with caution.

2.Patients prone to skin ulcers are prohibited from using the product.

3.Patients suffering from bodily fluid-borne diseases should consult the doctor before any use.

4.Patients with insufficient self-care abilities should use the product only when supervised by a caregiver who is at least 18 years of age.

5.Patients who lack good visual and auditory abilities to recognize and respond to alerts should use the product only when supervised by a caregiver who is at least 18 years of age.

It is advisable to seek prompt assistance from your healthcare providers if you experience any discomfort or suspect that the Monitor readings do not align with your symptoms.

2.3 Precautions

1. Please use the Syai Tag Device according to the Instructions for Use; otherwise, damage to the device may be caused.
2. Do not expose the Monitor to magnetic resonance imaging (MRI) equipment, X-ray equipment, computed tomography (CT) equipment, intensity modulated radiation therapy (IMRT) equipment, or any other equipment that generates strong magnetic fields or ionizing radiation.
3. The product is for single-use only, and cannot be shared with others (the device in use).
4. Do not freeze this product.
5. Do not expose this product to direct sunlight or high temperatures.
6. Do not apply the Monitor onto sites that may be frequently rubbed by clothing, have scars, or are with frequent movement.
7. Store the product in a cool and dry place before opening. Do not open the package with wet hands.
8. Do not use household cleaners, chemicals, solvents, bleachers, washing pads, or sharp tools to clean the Monitor. Clean the Monitor surface with a small amount of rubbing alcohol.
9. Restart the Syai Tag Mobile Application each time after restarting your mobile phone.
10. Evaluation of the performance of the system, when used with other implantable medical devices (i.e., pacemaker) , has not been conducted.
11. The Monitor's performance may be affected by the disease states and/or medications administered to critically ill patients. Therefore, glucose measurements from the Monitor may not be accurate when used for critical care monitoring.
12. Do not wear the Monitor for more than 14 days because no readings will be available after 14 days.
13. Taking ascorbic acid (vitamin C), salicylic acid (pain relievers such as aspirin and some skin care products), methyldopa (for high blood pressure treatment), or tolbutamide (for diabetic treatment), acetaminophen (paracetamol) may affect the accuracy of glucose values measured by the Monitor.
14. Do not change or modify the Syai Tag Device. Changing or modifying the Syai Tag Device can result in improper insertion, pain, or injury.
15. Do not use products beyond the valid period.

16. Connect to a trusted WI-FI network with your smartphone. Avoid connecting to public WI-FI networks, such as guest networks in other's homes, restaurants, schools, libraries, hotels, airports, aeroplanes, etc., as these networks are not secure and connect to this kind of WI-FI does not need passwords to connect, connect to it could result in exposing your phone to the malware. In smart device settings, turn on the screen auto-lock and use a strong password.
17. The Syai Tag CGMS is IP28 rated; the Monitor/Sensor is protected by a sterile barrier, and the sterile barrier will be breached after opening the packaging of the Syai Tag Device; the Syai Tag Device must be used immediately after opening.
18. Do not operate the device near heat sources (e.g., fireplaces, radiant heaters) where temperatures may exceed the maximum operating limit.
19. The clinical study of Syai Tag CGMS does not gather sufficient clinical data among diabetes patients who have experienced severe hypoglycemia within six months. If you have experienced severe hypoglycemia in the last six months, please consult a healthcare professional before use if deemed necessary.
20. Please make sure that small children or pets cannot pull the Monitor from your arm when wearing the Monitor.

2.4 Warnings

1. Do not use the Monitor if the packaging has been damaged or opened.
2. Do not use the damaged or broken Monitor for fear of any potential electrical safety hazards or electric shock injuries as a result of failures.
3. Avoid applying the Monitor on the same site repeatedly; inserting the Monitor into the same site may cause scarring or skin irritation.
4. Children must not handle the Syai Tag Device without direct adult supervision. The device contains small components that present a choking hazard.
5. Always seek professional medical help when suffering from infection or inflammatory symptoms, swelling, or pain at the insertion site.
6. Do not disregard symptoms potentially indicative of hyperglycemia or hypoglycemia. If you have symptoms that do not match well with the Monitor’s glucose readings and alerts, or suspect that your readings and alerts may be inaccurate, always check your blood glucose by conducting a finger-stick test using a blood glucose meter.
7. After the 30-minute warm-up period, the Monitor and your body need to adjust to each other. It's recommended to conduct fingerstick tests as the primary reference and seek HCP advice for diabetes treatment decisions, especially during the first day after the Monitor application.
8. The Syai Tag Device must not be used outside its specified operating environment. Use outside this environment may result in inaccurate glucose readings.
9. The application of the Monitor on the skin might induce discomfort and potential bleeding. If bleeding persists after application with notifications in-app prompts for a removal, please delicately remove the Monitor and consider applying a new one to an alternate site.

10. To reduce potential interference when activating the Monitor, you may stay away from other users during the activation.
11. Predict alerts remind you of the risk of high or low glucose levels, only for reference. Do not make treatment decisions based on the predictive alerts. If your symptoms do not match your Monitor readings, you may seek timely help from your HCP.
12. If your Monitor is damaged, please contact your local distributor's customer service using the details on the packaging.

2.5 RF Communication

The Syai Tag CGMS will generate, use, and radiate RF energy and may cause harmful interference to radio communications. So, interference may be inevitable in a particular usage environment. If the Monitor does cause interference to radio or television reception, you are advised to mitigate the interference by moving the Monitor farther away from the disturbed reception.

The Monitor uses RF energy only for internal communication with the smart device. Therefore, its RF emissions are very low and are not likely to interfere with nearby electronic equipment.

Communication between your Monitor and your smart device may be blocked if any other common consumer electronic devices work at the same frequency band as the Monitor. However, such interference will not cause any inaccurate data or any damage to your device.

The RF communication distance between the Monitor and the smart device is up to 10 meters (33 feet).

2.6 Waterproof Performance

When worn during showering, bathing, or swimming, the Monitor is waterproof. However, hot water may shorten the service life of the monitoring device.

It is strongly suggested that the Monitor should be dried with a clean towel when it is out of water.

Note: The Monitor cannot communicate properly while immersed in water since the Bluetooth signal is weakened in water. Do not expose the product to water over 1.5 meters (4.92 feet) deep or for more than 30 minutes.

2.7 Waste Disposal

This product should be disposed of according to all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to interstitial fluids.

You may contact your local distributor/importer for further information on the appropriate disposal of system components.

3.Introduction to Syai Tag CGMS

3.1 Name and Model

Name: Continuous Glucose Monitoring System
Model: X1

3.2 Working Principle

The Syai Tag CGMS uses the electrochemical sensor to monitor glucose levels in interstitial fluid. Based on the electrochemical reaction principle, the glucose in subcutaneous interstitial fluid is oxidized by glucose oxidase on the Sensor, and the electrons generated in the redox reaction are transferred to the metal electrode, thereby generating current. The current intensity is proportional to the glucose content in the interstitial fluid. The Sensor is in touch with the subcutaneous interstitial fluid, collects the electrochemical signal, and outputs the analogue signal. The Transmitter, fixated on the user's skin surface by an adhesive bandage, receives the analog signal of the Sensor, converts it into a digital signal through the analog front end, and transmits it to the mobile App through Bluetooth (radio frequency). The App receives the signal and displays readings of the glucose level on the mobile App interface for users to read.

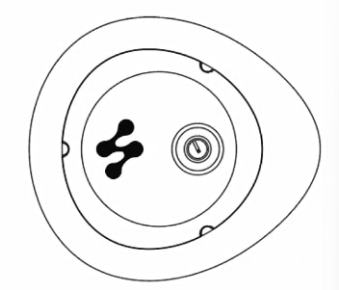
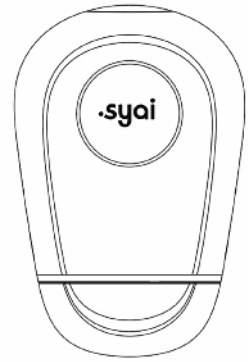
Based on the monitoring graph, the patient's daily maximum and minimum glucose values and the pattern of glucose fluctuations can be analyzed. Based on real-time readings of glucose values, the App also provides the patient with a high and low glucose alert function. Users may also read information on the orientation and rate of change of glucose trends.

The Syai Tag CGMS adopts factory calibration technology and does not need fingerstick calibration during use.

3.3 Scope of Application and Function

The Syai Tag CGMS is intended for adults (aged 18 and above) with diabetes mellitus who need to monitor their glucose levels. The critical function of Syai Tag CGMS is real-time glucose monitoring. The system is indicated for measuring interstitial fluid glucose levels in intended adult users and can provide users with real-time glucose readings, glucose trend and fluctuation characteristics, and alert information such as high/low glucose alerts. The results measured by the product should not be used as the basis for determining or adjusting the treatment regimens for patients with diabetes. The system is intended for single-patient use.

3.4 Composition

Syai Tag Continuous Glucose Monitoring System		
Device (Hardware)		Mobile App (Software)
Monitor, including: Sensor Transmitter	Applicator, including: Guide needle	Release version number: V1.1.61.252433
		

The Syai Tag CGMS consists of two main components, the Syai Tag Device and the Syai Tag app. The Syai Tag Device is composed of a 14-day wearable Monitor and a fully disposable Applicator. During the continuous monitoring session, the application will alert users to hypoglycemia and hyperglycemia events. The Syai Tag application will present Monitor readings and trend graphs with other corresponding analytics.

4. Using Your Monitor

Bluetooth activation: To ensure an optimal experience with your Monitor, a mobile phone with the operating system of Android 8.0 or higher and iOS 13.0 or higher is required. The Monitor has built-in hall effect parts for simplified activation.

To prepare yourself for the device application, the following items are required:

- Soap or alcohol wipe
- A smart device (with Bluetooth function and camera modules.)
- A trusted network (cellular data or Wi-Fi)

4.1 Set Up Your Smart Device

Internet access is required during the entire setup.

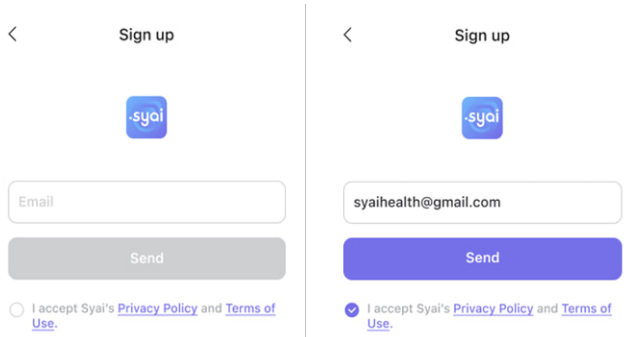
Get started:

- Download the Syai Tag app:
  - Option 1: On the exterior of the product packaging, there are 2 QR codes for downloading the application and the IFU. Scan the corresponding QR code to view the download page (make sure your device is connected to a stable network before scanning).

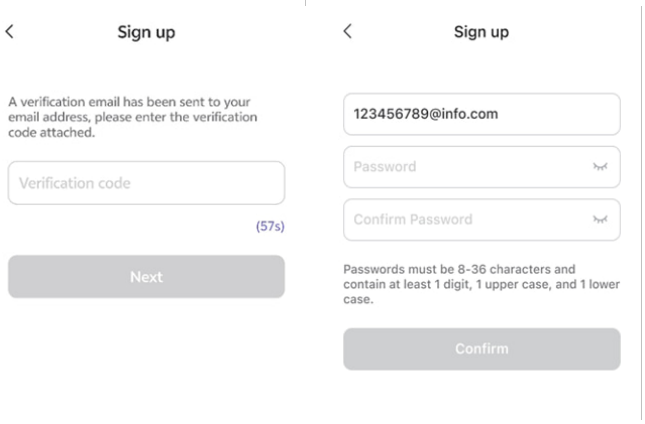
  - Option 2: Search for "Syai Tag" in the App Store or the Google Play Store. Then follow the steps to install it.

- Sign up for an account:
  - Open the Syai Tag Mobile App, tap "Sign Up".

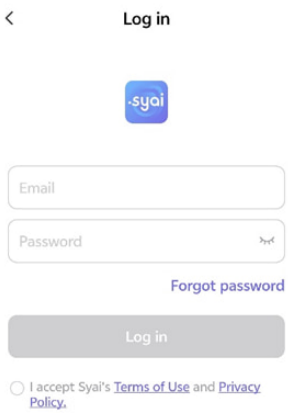
  - Enter an email address as your App account, and tap "Send". You will receive a verification code in your email.



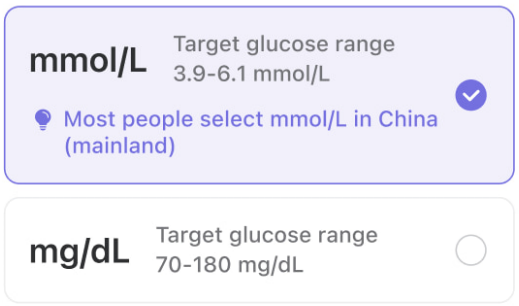
  - Enter the verification code received, tap "Next," and set up a password for your account.

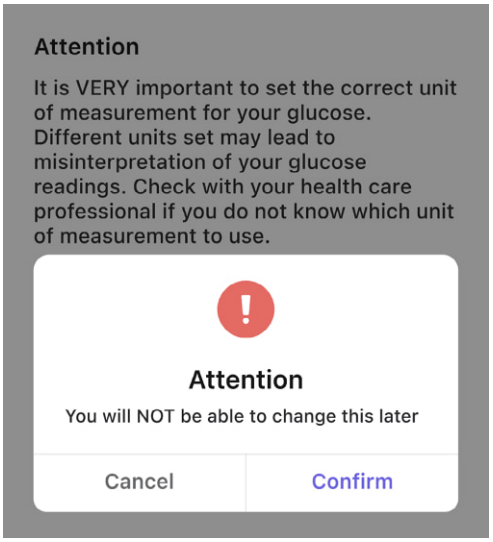


- **Log in to the app:**
  - Tap the “Syai Tag” app icon on your mobile device to launch the application.
  - Log in to your Syai Tag App using the account details you have registered with.



- **Set up your app:**
  - Select the unit of measurement (mg/dL or mmol/L) to be utilized in the App and your glucose report, and confirm your selection. If you are not sure, check with your Health Care Professional (HCP).



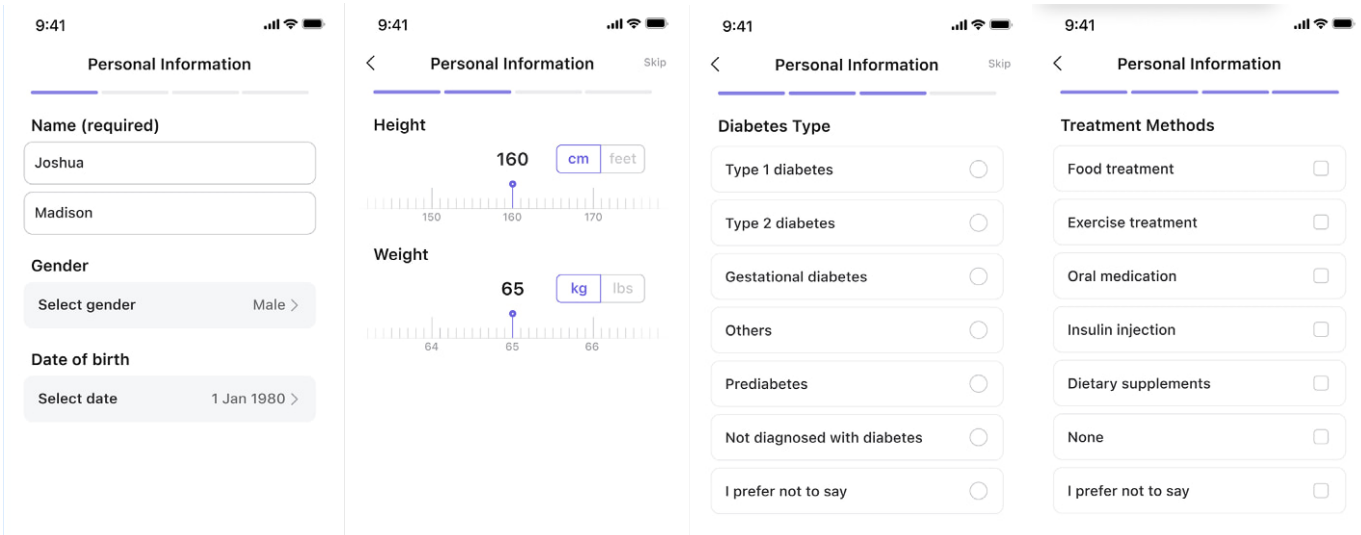


⚠ **CAUTION**: It is VERY important to select the right unit of measurement for an optimal user experience. The wrong unit selected here may lead to misinterpretation of your glucose data. Check with your healthcare professional for which unit to pick if you are unsure.

Once confirmed, it cannot be changed unless a new account is registered.

Follow the steps on the screen to set up your Syai Tag App, including:

- **Enable Bluetooth:** Bluetooth function is necessary to connect your Monitor.
- **Enable Location Services:** Bluetooth and Location must be on for Syai Tag to work. It pairs the Monitor with the App.
- **Allow Notifications:** Enable notifications to get all your Alerts.
- **Personal Information:** Essential information for personalised glucose management.



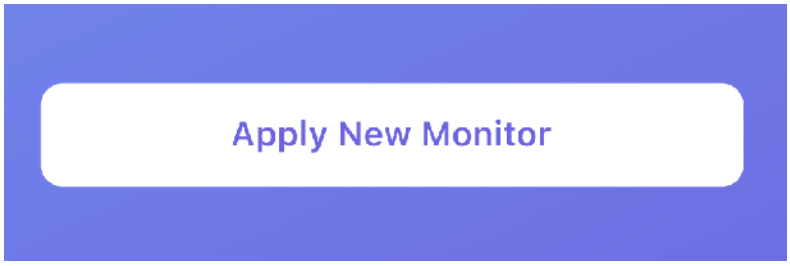
After entering the personal information, you will be directed to the home page. When you are ready to apply the Monitor, tap "Apply New Monitor". Follow the graphic instructions in the App, or go to the next chapter of this "Instructions for Use", to apply the Monitor correctly.

4.2 Applying Your Monitor

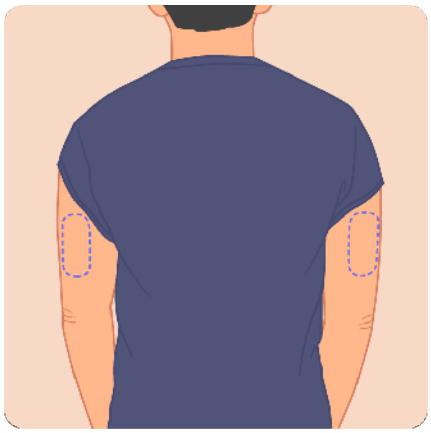
Before applying, you may open the product package and check whether the device is intact first.

First-time user: After setting up your Syai Tag App, tap "Apply New Monitor" on the screen. The Instructions for Use will be shown before the application.

Replacement with New Monitor: Make sure the previous Monitor has ended its session and been removed, then tap "Apply New Monitor" on the Syai Tag App's dashboard.



- **Step 1: Choose the back of your upper arm as the application site.**



Note: For optimal monitor performance, please select a site:

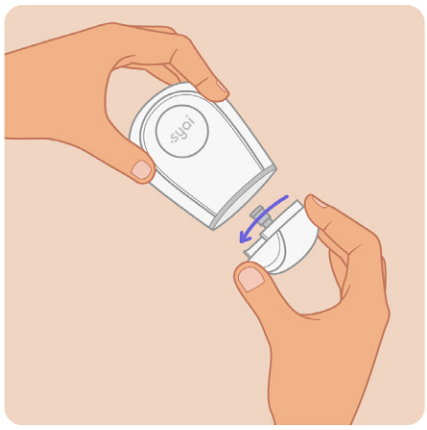
- Without scars, moles, stretch marks, or lumps.
- Avoid bony areas and irritated skin.
- Generally stays flat during your normal daily activities, avoiding any bending or folding.
- At least 2.5 cm (1 inch) away from an insulin injection site.
- Select a different site from the one most recently used to prevent discomfort or skin irritation.
- Consider shaving the area to ensure a snug fit.

- **Step 2: Clean the application site and wait for the skin to dry before proceeding to the next step.**

Note: The application site MUST be sufficiently clean and dry to make the Monitor adhere securely to the skin.

- Clean the skin using soap and wait to dry before sanitizing the application site with alcohol pads. Allow the site to air-dry before proceeding.

- **Step 3: Rotate open the bottom cover of the Applicator.**



Caution:

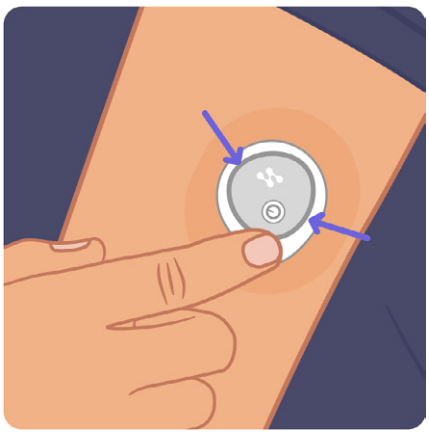
- Do NOT use if the Applicator is opened or damaged before use. The needle is sterile unless the Applicator has been opened or damaged.
- Do NOT put the cover back on as it may damage the Monitor.
- Do NOT touch inside the Applicator as it contains a needle.
- Do NOT apply it if the expiry date has passed.

- **Step 4: Place the Applicator over your arm, press the grey launch button on the top, and gently pull away the Applicator. The Monitor should now be attached to the skin.**

Note:

- Hold the Applicator flat against your arm and make sure the bottom edge is fully adhered to the skin, or application failure may occur.
- Before removing the Applicator, keep holding the Applicator against your arm for a few seconds. This can help the adhesive stick to your skin.
- Applying the Monitor may cause bleeding. If bleeding occurs,
  - Wipe away the blood with a cotton swab.
  - If necessary, use a cotton swab to press on the small opening on the Monitor or apply ice packs to help stop the bleeding.
  - Remove the Monitor and apply a new one at a different site only if bleeding does not stop.

- **Step 5: Gently press the tape around the edge of the Monitor to attach it firmly to the skin.**

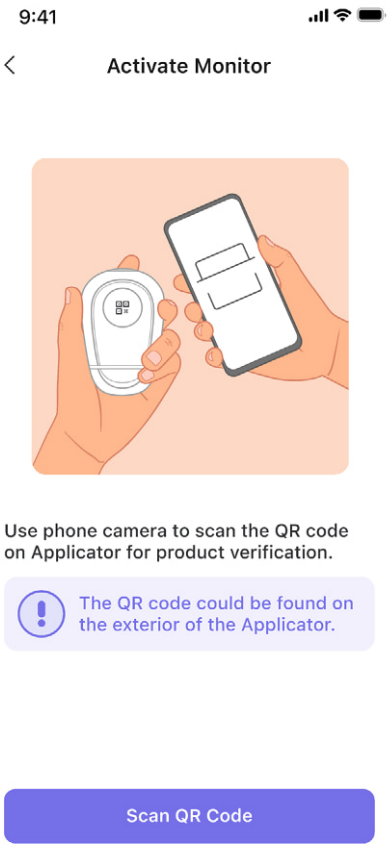


Note:

- Discard the used Applicator following local guidelines for disposal of blood and bodily fluid contact parts.

4.3 Starting Your Monitor

- **Step 1: Tap the "Scan QR Code" button on your phone screen.**



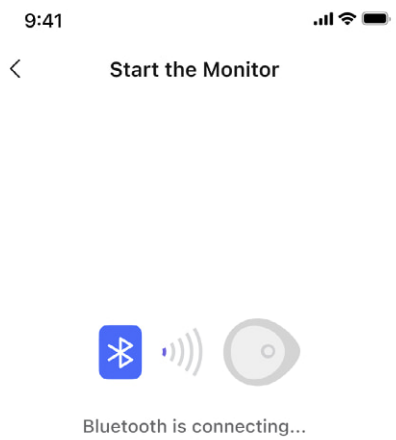
Note:
The QR code can be found on the exterior of the Applicator.

- **Step 2: Scan the QR code for the Monitor verification.**

Note:

Please ensure to scan the correct QR code. Please follow the on-screen instructions after the scan to proceed until you get to Step 3.

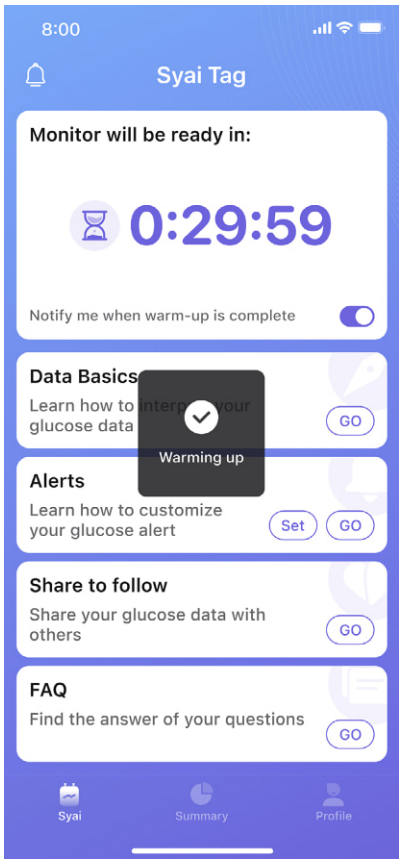
- **Step 3: Bluetooth activation.**



You may hear or feel the beeps or vibrations. The Monitor will start connecting to the phone via Bluetooth. The Bluetooth connection will be done in seconds. Then, you will be automatically directed to the warm-up page.

Note:
Try exiting the app and scanning the QR code again to activate the Monitor. This may help with activation failure.

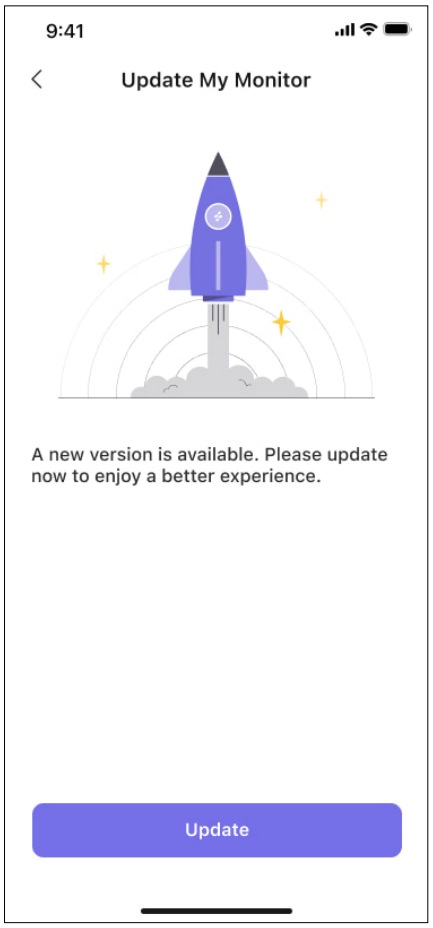
- **Step 4: Warm-up period.**



After the Monitor is applied correctly and connected to the mobile App, a 30-minute warm-up period is required before the glucose data can be displayed.

Getting an upgrade message?

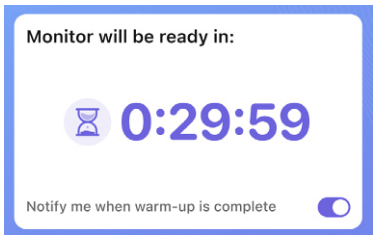
A better product experience is our constant pursuit, and you may receive an upgrade prompt during the Monitor activation process. It doesn't happen very often. Once it happens, just follow the instructions to upgrade and check out our newest updates.



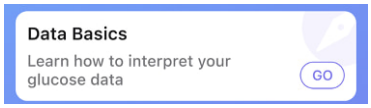
4.4 Explore more during the warm-up

The Monitor warm-up time is 30 minutes. During this period, you can learn more about using the Syai Tag CGMS, including data interpretation, alert settings, glucose data sharing, and FAQs!

> Warning: After the 30-minute warm-up period, the Monitor and your body need to adjust to each other. Use your BG meter to make diabetes treatment decisions during the first hour of wearing a new Monitor.

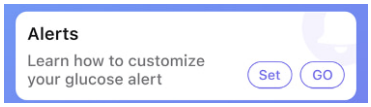


- You will receive a notification when the warm-up period is finished. This notification is turned on by default.
- You can turn off this notification manually.

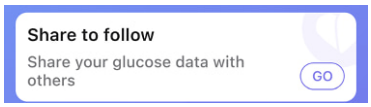


Learn how to interpret your glucose data:

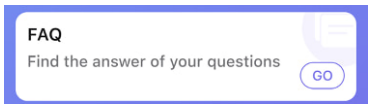
- Glucose trend arrow.
- Data color inside the cards of the graph (you might refer to Chapter 5.2 for more info).
- Daily Graph.
- Multi-day Graph.
- Glucose Fluctuation.



- GO: Learn how to customize your glucose alert.
- Set: Jump to the Alerts settings page to personalize your Alerts.



Jump to the Profile page for the Home & Doctor Care features.

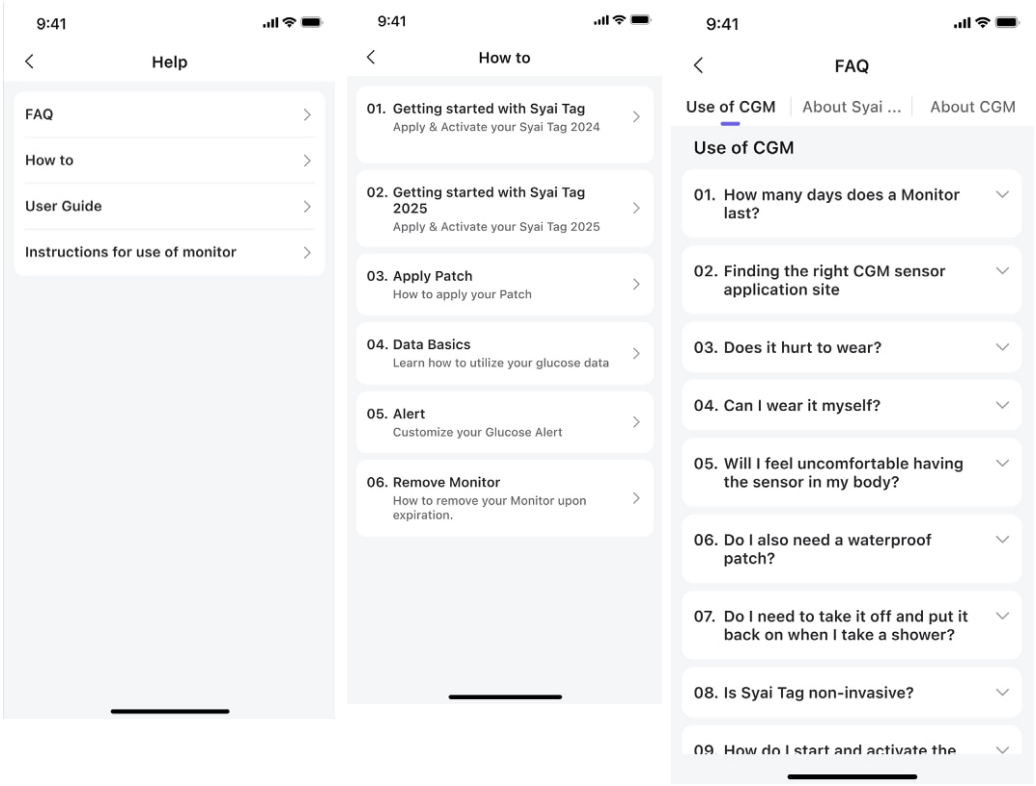


Find the answers to your questions, including:

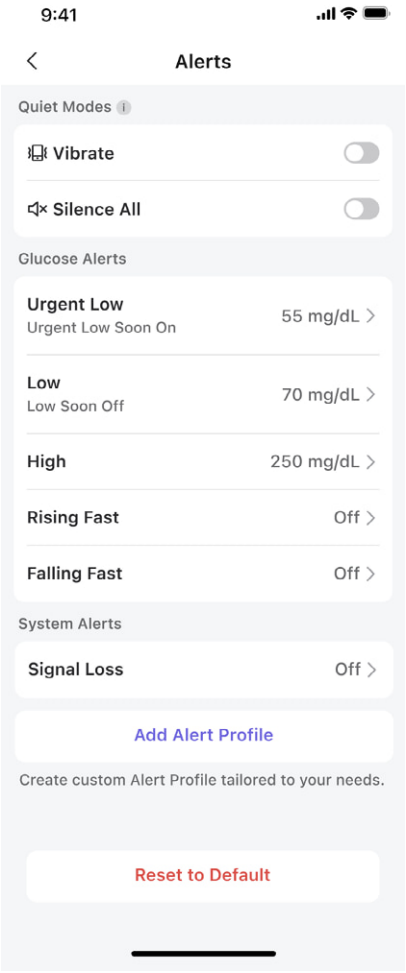
- Use of the Syai Tag CGMS.
- About the Syai Tag App.
- About the Syai Tag CGMS.

You can always access all these instructions or settings pages again in-app at any time.

- Profile>Settings>Help:

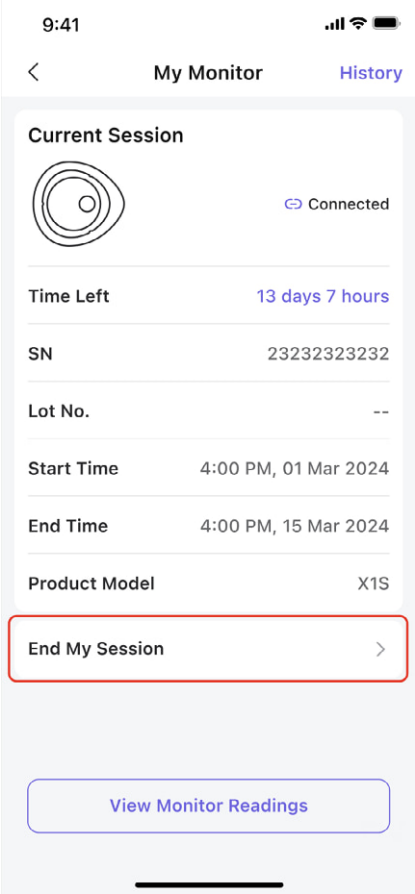


- • Profile>Settings>Alerts (please refer to Chapter 7 for the alert system guides):



4.5 Removing Your Monitor

When your Monitor has been worn for 14 days, or after tapping the "End My Session" button, the Monitor will be terminated. Make sure all data has been uploaded before disposal, and you can do this by following the instructions prompted in-app.



Gently lift a corner of the adhesive on the edge of the Monitor. Slowly remove the Monitor.

Note:

- Any remaining adhesive residue on the skin can be removed with warmt, soapy water.
- Discard the used Monitor following local guidelines for the disposal of parts that have been in contact with body fluids.

Replace your Monitor immediately if the following occurs:

- There's irritation or discomfort at the application site.
- The Syai Tag App reports a severe problem with the current Monitor and indicates removal.
- The Monitor filament tip has been fully detached from the application site.

Taking action early can prevent more risky events.

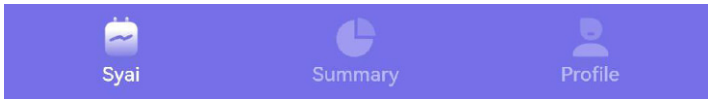
⚠ If your glucose readings do not align with how you feel, first check the Monitor for dislodgement or looseness. Should the Monitor filament be out of your skin or loose, immediately remove the current Monitor and apply a new one.

5. App Insights: Navigating Real-Time Data and Analysis

The Syai Tag App can monitor your glucose data at any time, render daily monitoring charts based on your cyclic glucose changes, and generate glucose analysis reports. When the Monitor is properly applied and continuously connected to the Syai Tag app successfully via Bluetooth, the app will provide you with high/low glucose alerts to monitor your glucose at any time, anywhere.

5.1 Quick Guide to Navigating the App Interface

Syai Tag App contains three functional pages: Dashboard, Summary, and Profile.



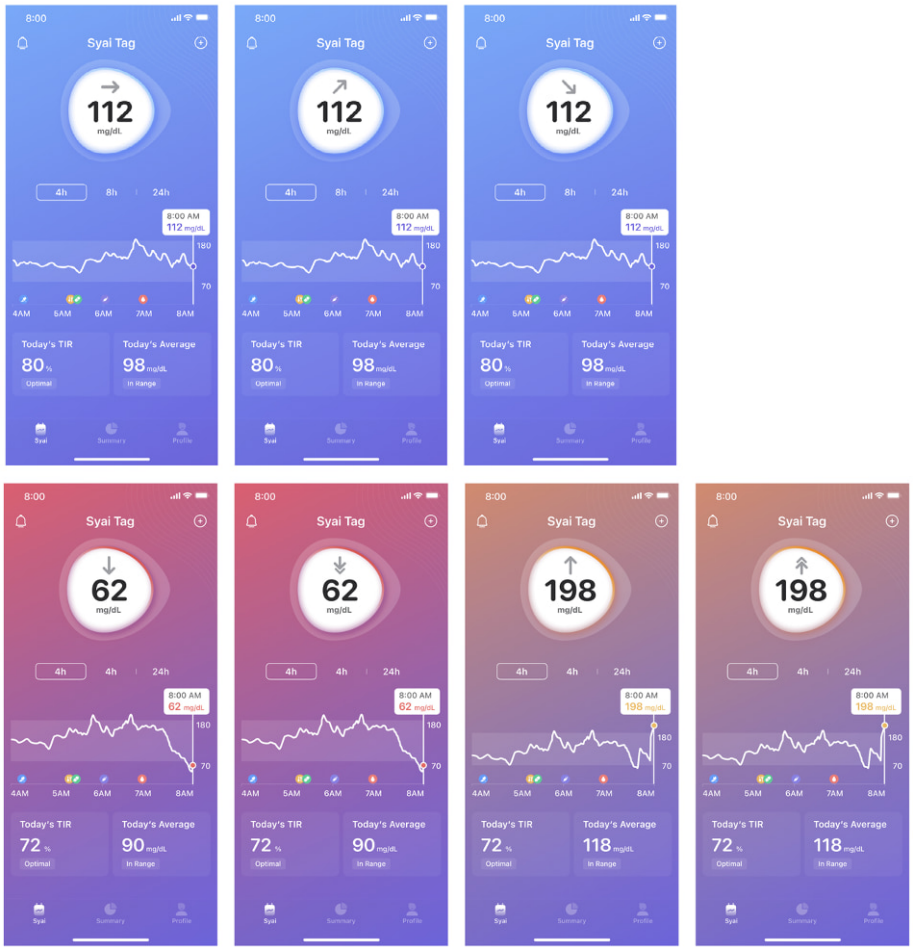
- Dashboard: you can access real-time readings and glucose trends, view 4h/8h/24h glucose curves, use the Syai AI features, etc.
- Summary: you can review and analyze historical data, with rich data analysis dimensions and metrics involved.
- Profile: you could explore the Syai Health Ecosystem for the extensive connectivity, check your Monitor status, invite caregivers and HCPs to follow, view glucose reports, and modify system settings, etc.

5.2 Interpreting Real-Time Glucose Levels

The Syai Tag device real-time monitoring page is displayed when you tap on the Syai Tag App icon on your phone's screen. You can check glucose readings, glucose target-reaching status, glucose trend graph, and glucose data synchronization timestamps.

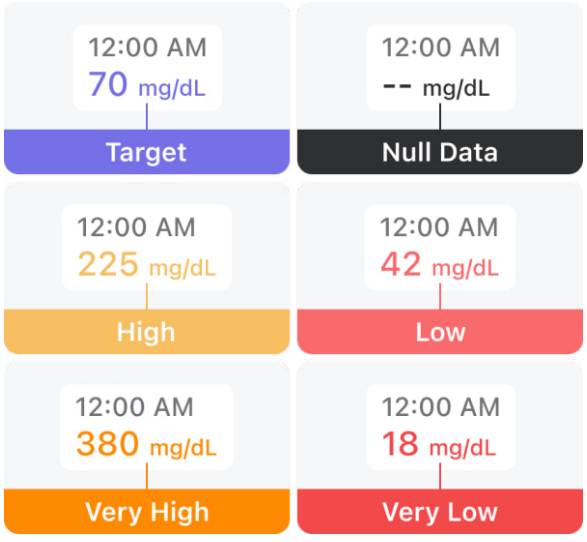
The whole page includes the current glucose level, a glucose trend arrow, a glucose graph, and a glucose card on the graph.

- Current Glucose: Readings are automatically updated every minute. A background with a color spectrum is used, indicating high or low glucose readings.



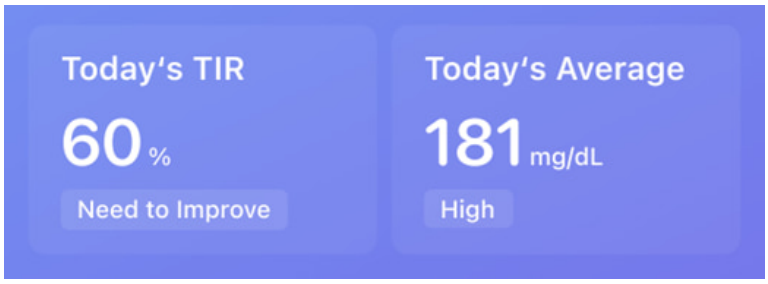
- Trend Arrow: Indicating your current glucose trend.

⇈	Rapidly rising	The reading is rising at a chosen warning rate (please refer to Chapter 7 for the warning thresholds) for a set period
↑	Rising fast	The change in glucose is greater than 2 mg/dL or 0.11 mmol/L per minute
↗	Gradually rising	The change in glucose varies in the range of 1-2 mg/dL or 0.06-0.11mmol/L per minute
→	Steady	The change in glucose is less than 1mg/dL or 0.06 mmol/L per minute
↘	Gradually falling	The change in glucose varies in the range of 1-2mg/dL or 0.06-0.11 mmol/L per minute
↓	Falling fast	The change in glucose is greater than 2mg/dL or 0.11mmol/L per minute
⇊	Rapidly falling	The reading falls at a chosen warning rate (please refer to Chapter 7 for the warning rates) for a set period



- Glucose Graph: Show your glucose readings in the past 4 hours, 8 hours, or 24 hours.
- Glucose Card: Displays the time and glucose level at the corresponding point on the glucose graph.
  - When the label stays on the right side of the graph, it displays the current glucose level and the time stamp.
  - The data is shown in different colors depending on whether your glucose level is within your target range or not.

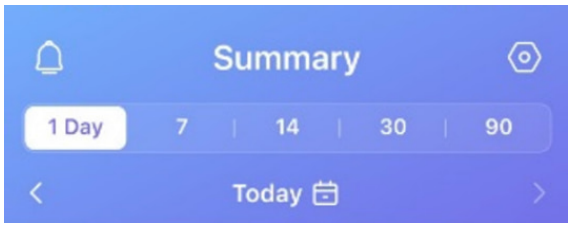
- Below the glucose graph are Today's TIR and Today's Average.



5.3 Utilizing Graphs and Historical Data for Better Insights

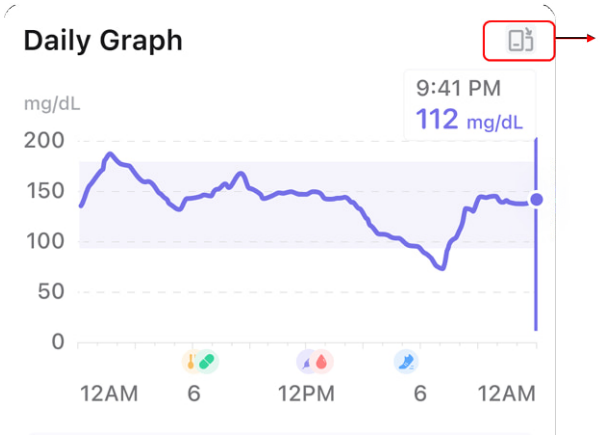
You can explore more glucose insights in the Summary page.

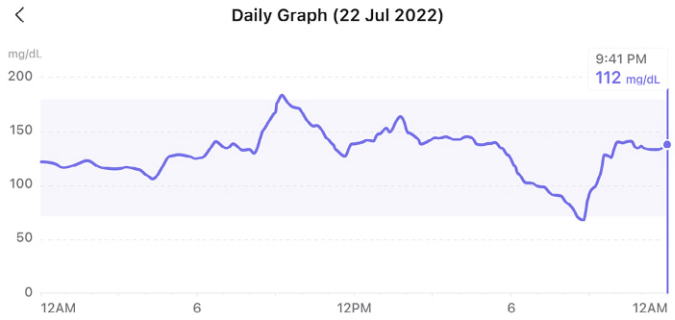
Tap the top bar to switch between different time ranges (1, 7, 14, 30, and 90 days) and view the glucose analytics accordingly, including your TIR, daily graph (for a single day only), metric insights, glycaemic events distribution graph, average glucose levels, multi-day graph, and the AGP graph.



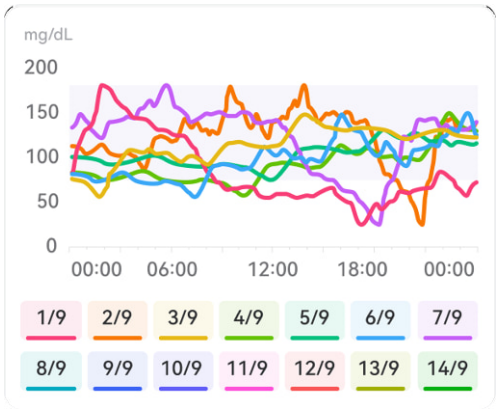
- TIR: Time in Range shows the percentage of time your glucose reading was above, below, or within your target range during the monitoring period, providing a more complete picture of your level of glucose control. You could also tap the different color-shaded sectors of the TIR ring to view more analytics correspondingly.

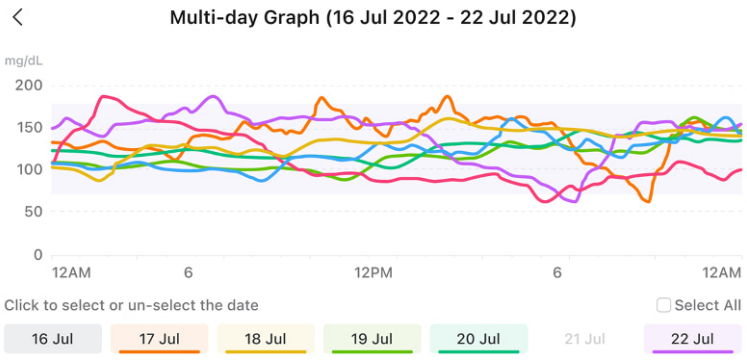
- The Daily Graph is plotted with your real-time readings from the Monitor for the selected day, reflecting your glucose pattern accordingly. Tap the 'Rotate/Horizontal View' button in the upper right corner to rotate the display horizontally.



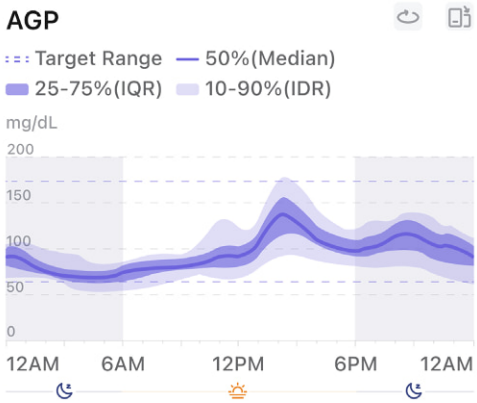


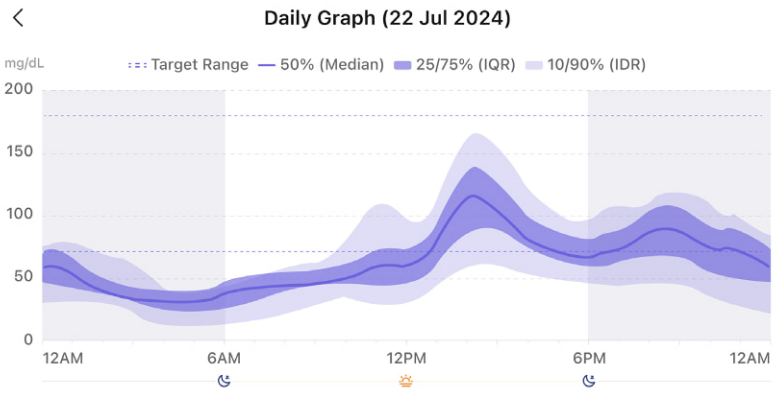
- The Multi-day Graph plots all the glucose curves for a date range of your choice, with each curve representing each day's glucose variation, and you can select the curve you wish to view by tapping on the date marker below the graph. It can also be expanded to a horizontal full-screen display.





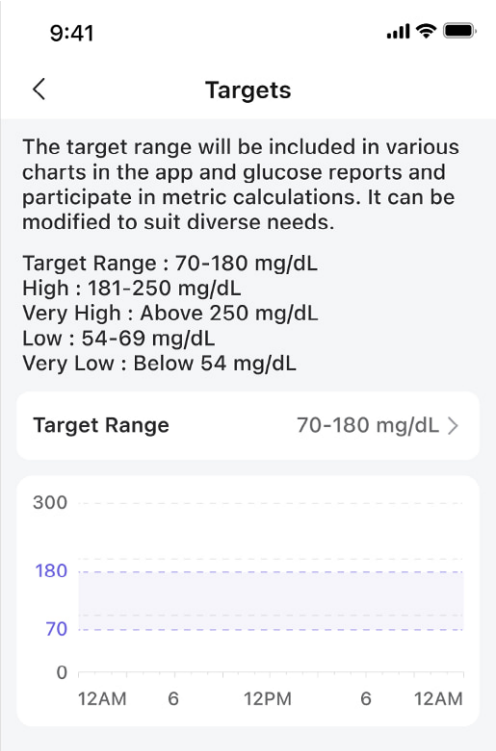
- The AGP graph is a comprehensive graph showing the 10th, 25th, 50th (median), 75th, and 90th percentiles of glucose readings. This helps in visualizing glucose trends and understanding glucose variability for the reporting period. The graph card is also flipable and can be extended to a horizontal display with the buttons at the top right corner.





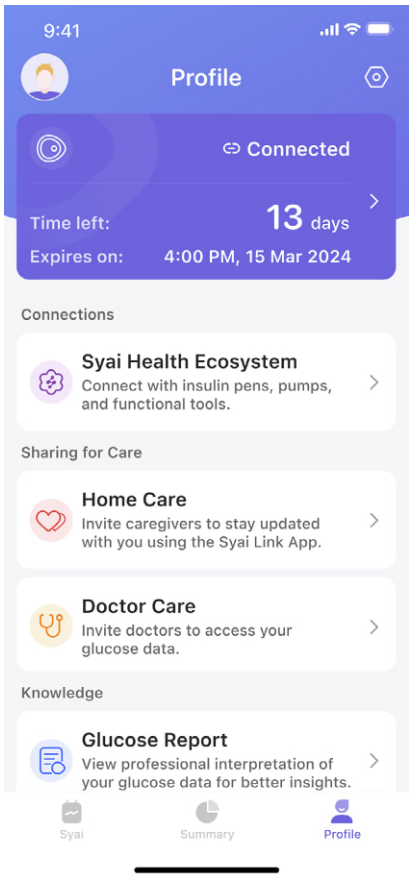
5.4 Target Glucose Range

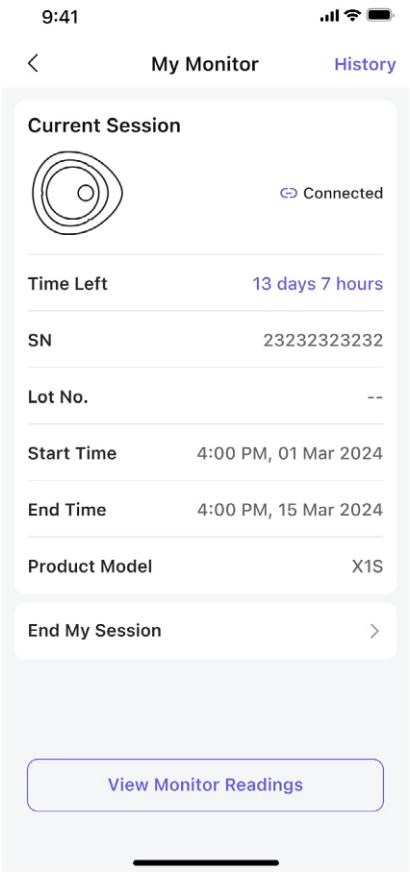
Your target glucose range will be shown and utilized to calculate relevant glucose data, such as Time in Range (TIR) and so forth. The default glucose target in the Syai Tag App is set between 70-180 mg/dL or 3.9-10.0 mmol/L and can be altered to suit diverse usage scenarios.



5.5 Profile

Go to "Syai Tag App - Profile", and tap the purple device card under the page title to view details of the Monitor in use, including remaining time for the session, SN, etc.

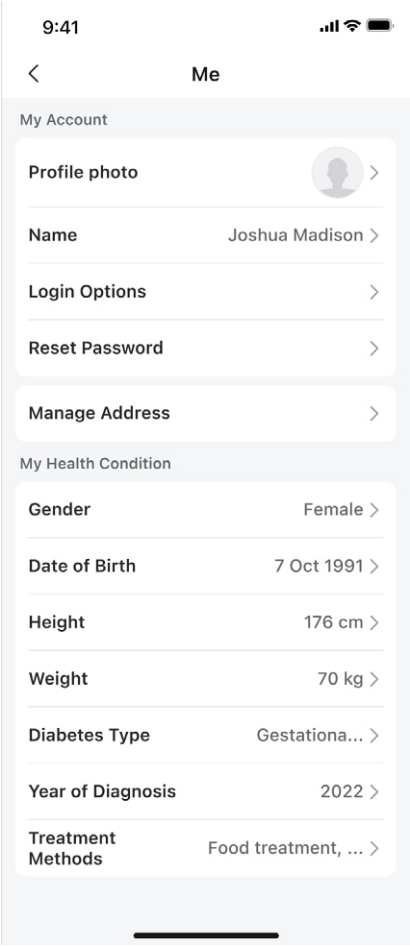




End Monitoring Session: Go to "Syai Tag App - Profile", and tap the purple device card under the page title, then tap "End My Session" to manually terminate the current monitoring session of the device if needed. Ending the session means that the device cannot be activated again and the remaining session period will also be unavailable if any.

5.5.1 Personal Information

Tap the avatar on the upper left on the "Profile" page to view personal information, including nickname, date of birth, gender, height, and other details.

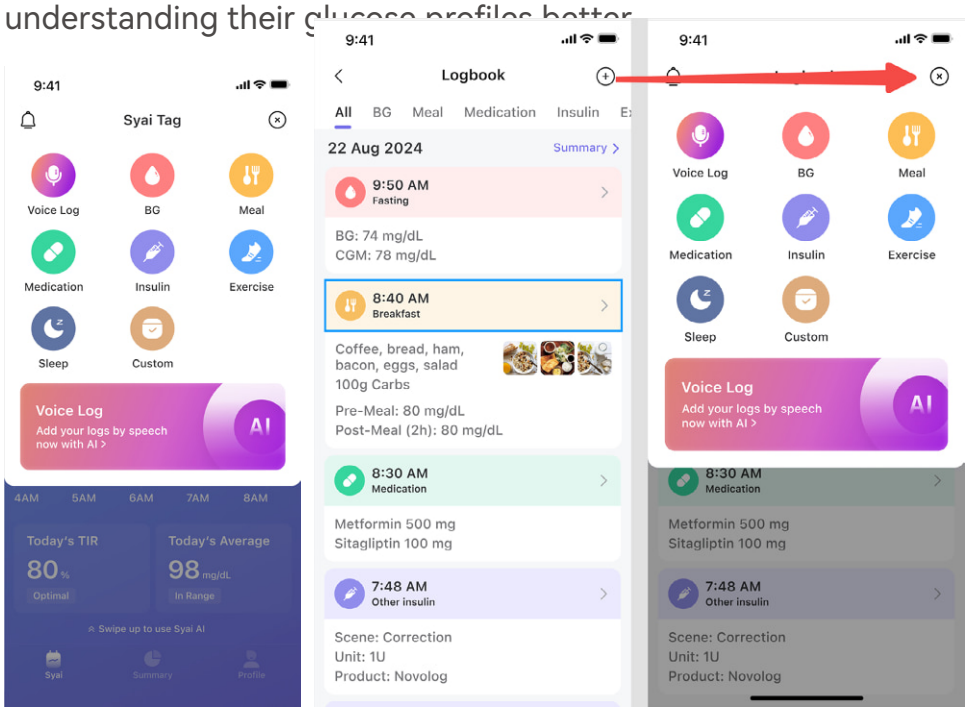


As mentioned, the user must log in to access the real-time Monitor readings, glucose analytics/reports, data-sharing features, and such. The application will only utilize information from the current account. A stable network (Wi-Fi or cellular data) is recommended when using the application to ensure a smooth experience with data syncing, notifications, etc.

6. Advanced Features

6.1 Lifestyle Tracking and Analysis

You can tap "+" on the Syai Tag page of the application or go to "Home screen - Profile - Logbook" to record an event such as daily meals, medications, exercises, insulin injections, or BG test results. Event logs will assist both users and other stakeholders in analyzing and understanding their glucose profiles better.



- **Log a new event**
  - **Log a meal**

    Tap "+" > "Meal", select the correct time and the meal type, enter the carbs amount, and upload pictures if needed, tap "Save" to save the changes.
  - **Log a medication**

    Tap "+" > "Medication", you could log the medication name, dosage, time, etc., and tap "Save" to finish logging.
  - **Log an exercise**

    Tap "+" > "Exercise", you could log the start time of the exercise, the specific type of the exercise (such as 'hiking' and such), duration and calories burned, then tap "Save" to finish logging.
  - **Log an insulin injection**

    Tap "+" > "Insulin". You could log the injection time with details like the insulin type, unit, product name and the intervention scene (such as a meal bolus) and tap "Save" to finish logging.
  - **Log an BG result**

    Tap "+" > "BG", you will be asked for camera access to scan your BG meter to automatically log your BG measurement, but you could also tap the BG section to manually input the

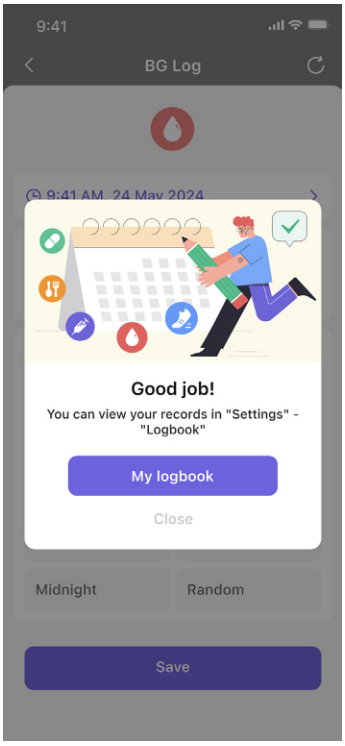
result with the scenario set (such as a random BG, or an after-meal one, etc.), and tap "Save" to finish logging.

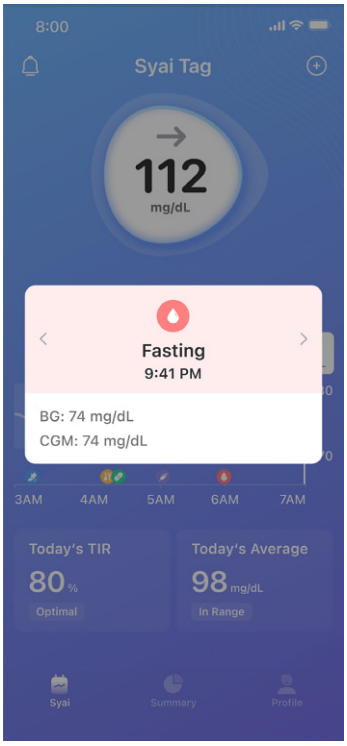
- **Log your sleep**

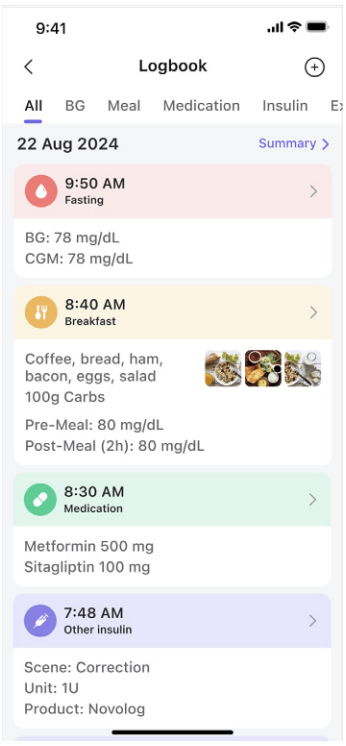
  Tap "+" and tap the "Sleep" icon to track your sleep too. You could log the time that you fell asleep and woke up.

*The AI logging feature is also available where you could log events by speech, the auto-recognition will convert the relevant content to different types of the event logs, you will be prompted to edit & save them in-app.

- **View log history**
  - You could tap “My Logbook” in the pop-up window upon log saving to view all the logs.
  - Tap the icon below the home screen trend graph to view the specific event log details, and tap the arrows (“<” and “>”) on either side of the card to switch between the logs.
  - Tap the gear icon on the top right of the “Profile” page and tap “Logbook” to view all the logs.
- **Edit/delete an event log**
  - You could tap any history log, then on the top right corner of the log, there's a "Delete" button to delete the corresponding log; the log will be deleted permanently.
  - Tap any log in the log history, then you can edit the details as needed, and then tap "Save" to save the edited logs.





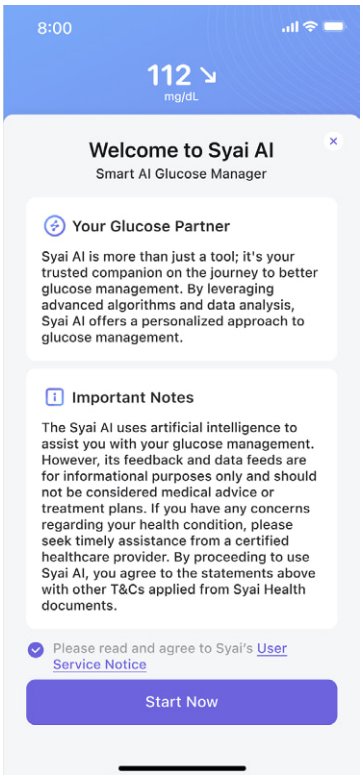


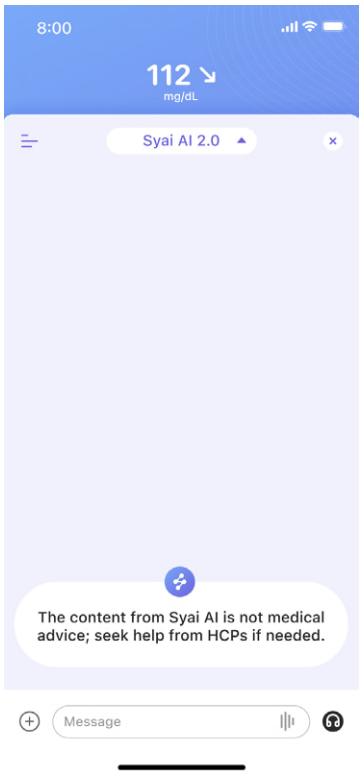
6.2 Explore Your AI Glucose Buddy: Tailored Management with Your Syai Tag

The Syai Tag App has an LLM-driven AI expert that responds to users' inquiries 24/7. The AI expert constantly learns from users' inquiries and responds with personalized responses to serve patients' needs.

You could swipe up at the application homescreen then lift to enter the Syai AI feature (Make sure the device is connected to a trusted Wi-Fi network beforehand and the "Syai AI" option is enabled in the Settings page.)

By default, the option would be enabled. Please check your settings if the portal is not responding.





7. Glucose Alert & Notification Settings

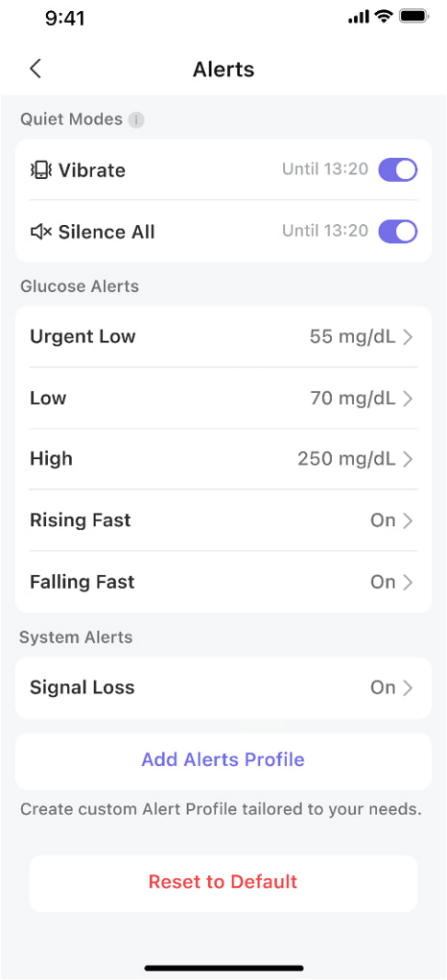
⚠ WARNING: You must allow notifications for your Syai Tag App during the initial setup. Do not turn off notifications for the App in your mobile device settings. If you turn off notifications, you will not receive any Alerts and risk glycaemic events.

Your Alerts help you keep your glucose within the range you set. You'll receive an alert when your glucose is out of the preset alert range, at or below 55 mg/dL or 3.1 mmol/L. There are also more settings on the "Alerts" page. Please refer to the chapter below. For alert level configuration, you can check with your doctor to see what is right for your alert range and customize the settings in the App.

7.1 Glucose Alerts Settings

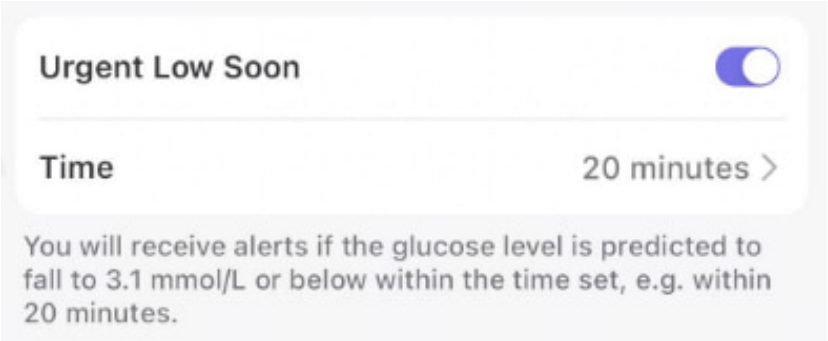
The Syai Tag App has a set of Alert settings where you could get to adjust how every functional alert will behave for different usage scenarios.

- In the "Syai Tag App – Profile". Tap the Settings icon, then tap 'Alerts'.

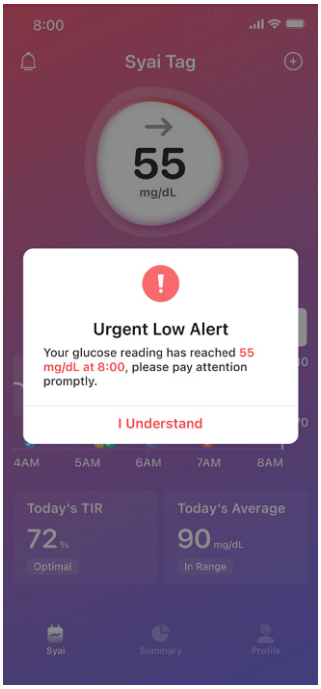


- Under the 'Quiet Modes' section, you can set how all alerts will notify you with preset modes. This will not override your system notification settings, but the 'Alert Sound' settings within each unique alert (Glucose Alerts + System Alerts below) will be affected. Please exercise caution and carefully read through the description first, so you won't miss out on crucial alerts.
  - Vibrate: All alerts will only vibrate with no sound. You could set a duration or manually turn it on & off based on the conditions. (For safety purposes, Urgent Low and Signal Loss alerts will vibrate for the first time still. If no actions were taken for the first time, they will sound on the next time.)
  - Silence All: When Silence All is on, all alerts will not sound or vibrate, including Urgent and Signal Loss alerts. The maximum duration for this mode is 6 hours.
  - When 'Silence All' mode is on, there will be a floating reminder on the home screen/ dashboard page as shown below, which also acts as a shortcut to edit the settings if needed:

- Reset to Default: Doing so will delete your alternative alert profile and reset all alert settings to default. Please exercise caution before resetting.
- • Predictive Alerts (sub-setting with the alert name + soon): Under the 'Glucose Alerts' section, for Urgent Low and Low alerts, you could set a timeframe for the Urgent Low/ Low soon events, then the Syai Tag App will alert you if your glucose is predicted to be at or below your threshold set in the set time.

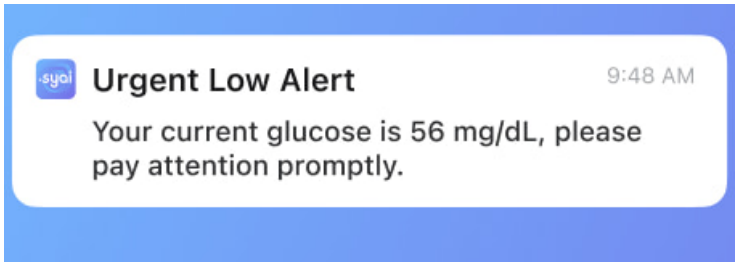


7.1.1 Urgent Low Alerts



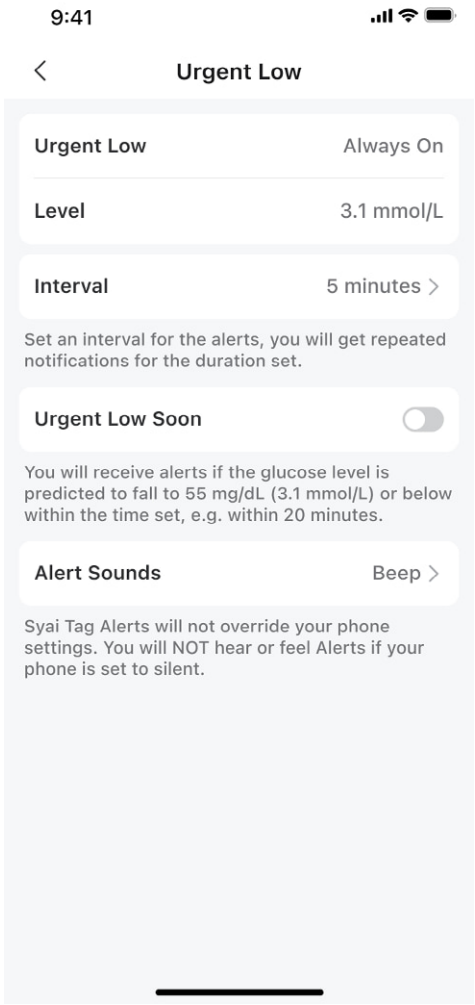
Trigger conditions:

Alerts you when your Monitor reading falls to or below 55 mg/dL (3.1 mmol/L).

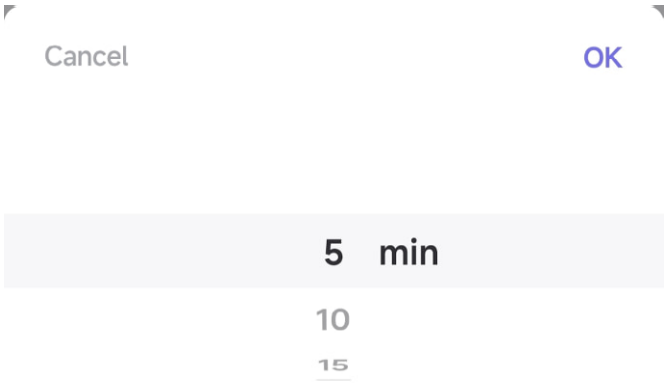


How to find the relative settings:

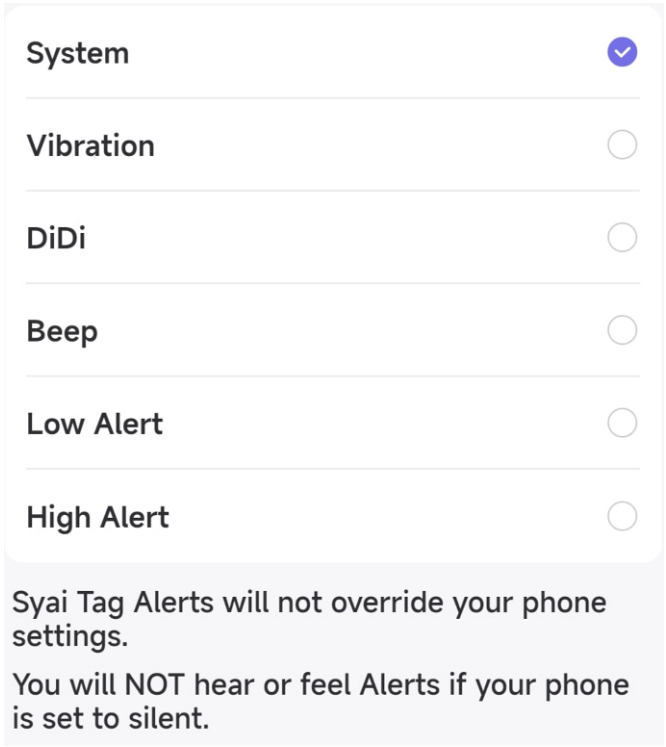
From the application home screen, go to "Profile> Settings > Alerts > Urgent Low".



a. The Urgent Low Alert cannot be turned off, and the warning level also can't be modified.
b. Interval: You will get repeated alert notifications for the interval set.



c. Alert Sounds: You can set how the system will alert you. There are a variety of ringtones to choose from.

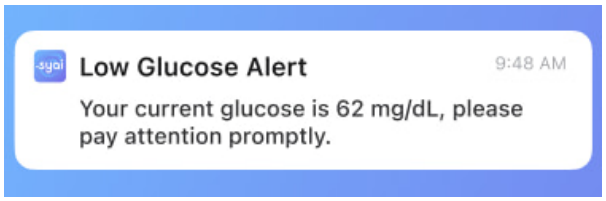


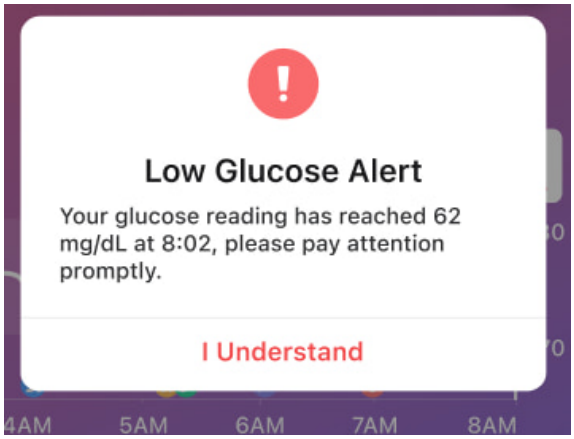
⚠ WARNING: Although the Alert system has been tested in clinical settings, if you have symptoms that do not match well with the Alert notifications, or corresponding Alerts are not triggered when there are hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, you could conduct fingerstick tests with a BG meter as additional references and seek advice from your HCP if needed.

7.1.2 Low Alert

Trigger conditions:

Alerts you when your Monitor readings are at or below the glucose alert range set.



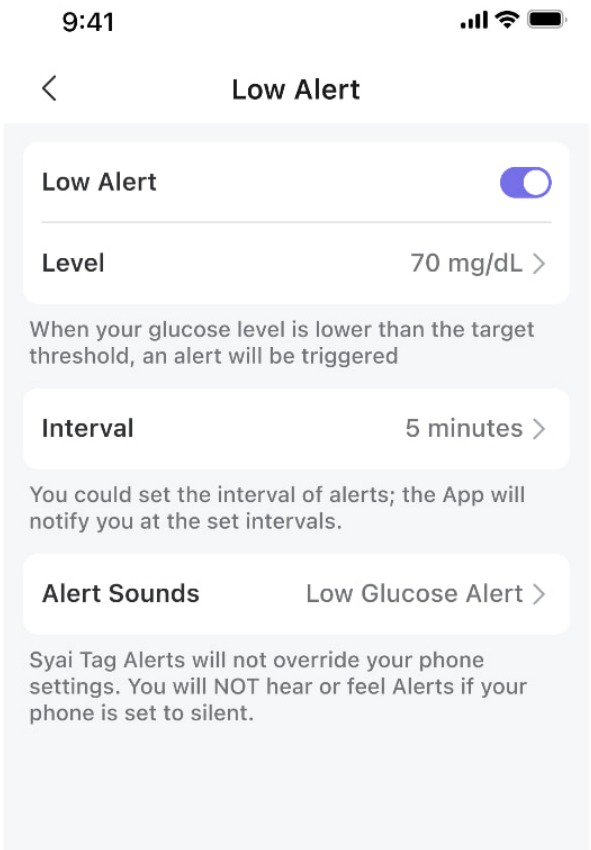


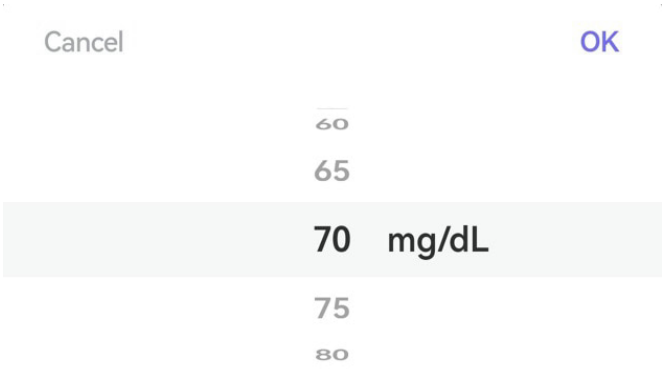
How to find the relative settings:

Go to "Profile > Settings > Alerts > Low Alert".

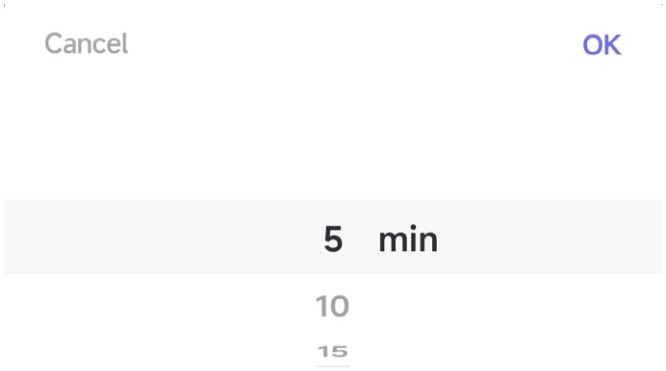
a. Low Alert: Tap the button switch at the top to turn on/off the Low Alert;

b. Level: You can modify the alert threshold to remind you when glucose is lower than the set value;

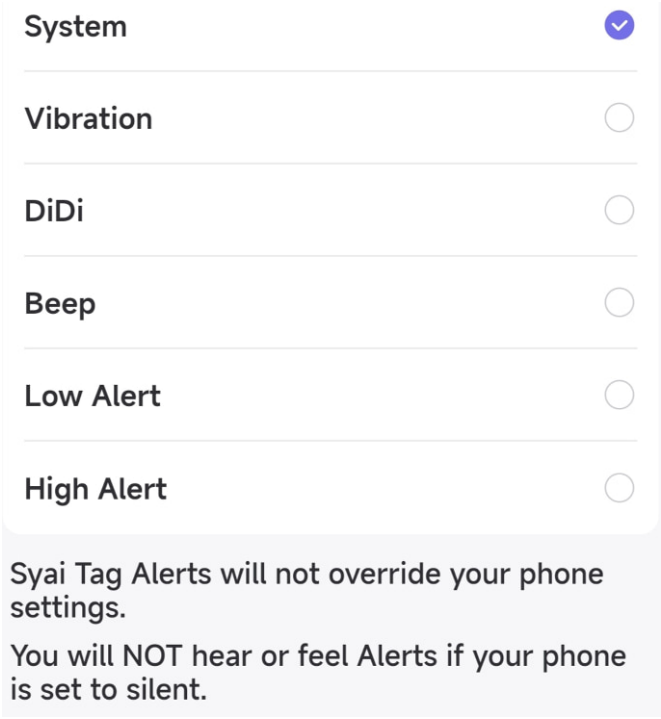




c. Interval: You can set the alert interval. When you have a prolonged period of low glucose, the application will alert you based on the interval you set.



d. Alert Sounds: In Alert Sounds, you can choose a vibration and ringtone. There are a variety of ringtones to choose from.

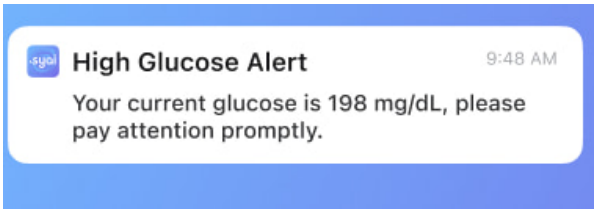


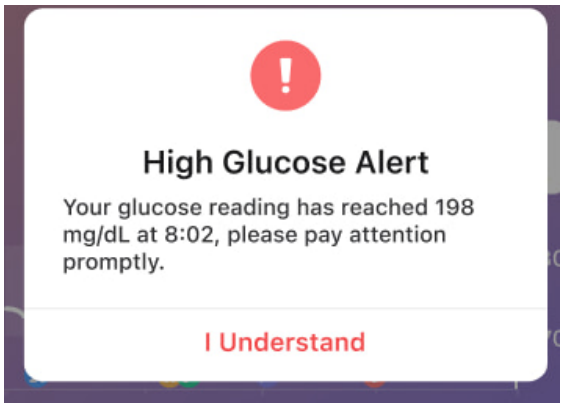
⚠ WARNING: Although the Alert system has been tested in clinical settings, if you have symptoms that do not match well with the Alert notifications, or corresponding Alerts are not triggered when there are hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, you could conduct fingerstick tests with a BG meter as additional references and seek advice from your HCP if needed.

7.1.3 High alert

Trigger conditions

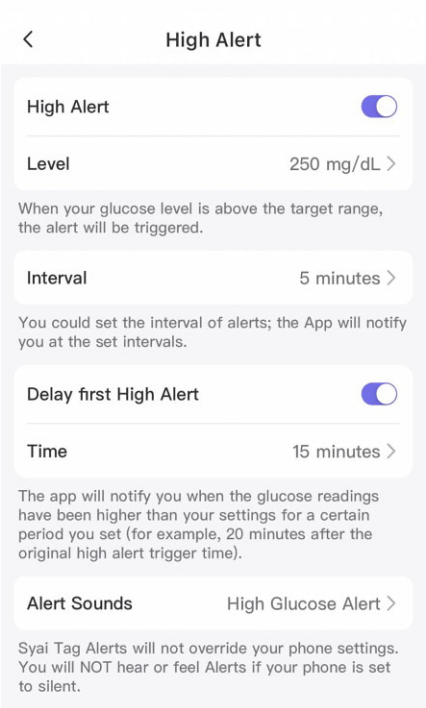
Alerts you when your Monitor readings are at or above the set glucose alert range.





How to find the relative settings:

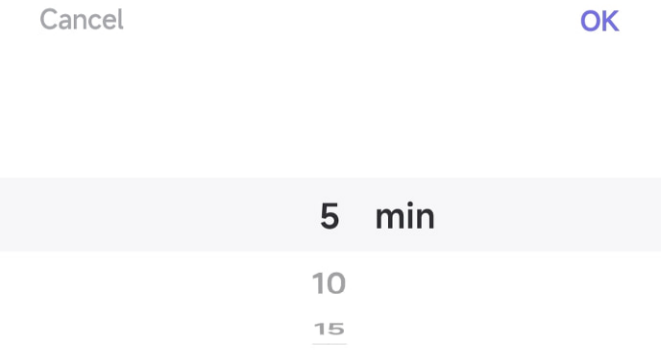
App Settings Path: Profile > Settings > Alerts > High Alert.



a. High Alert: You can switch on/off the High Alert with the toggles.

b. Level: The Alert level can be changed; the App will notify you when the glucose readings are higher than the settings.

c. Interval: You could set the interval of alerts. When there's a relatively long period of high glucose events ongoing, the app will notify you at set intervals.

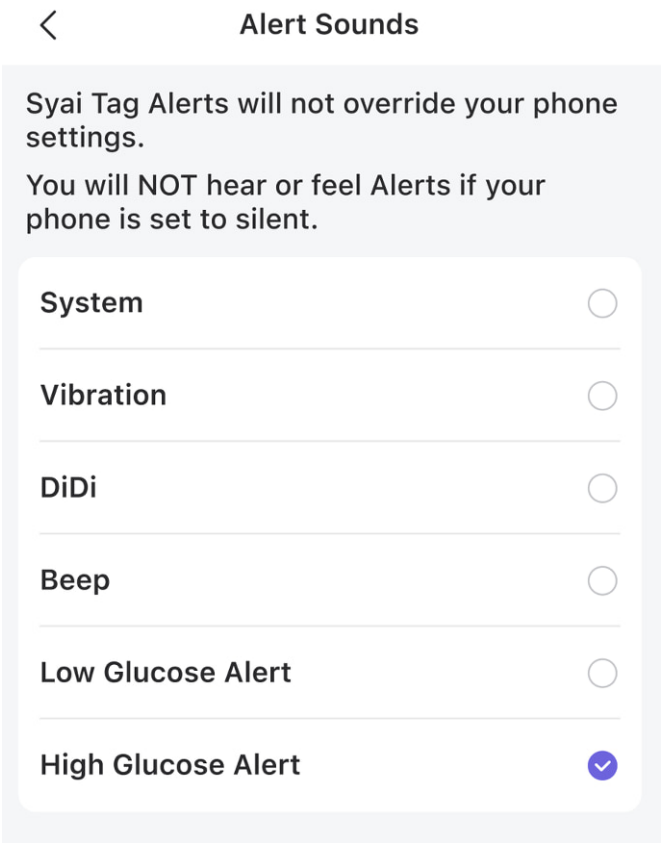


d. Delay First High Glucose Alert:

You can manually delay your first High Alert for a certain period. If your glucose level remains in the high alert range, alert notifications will resume.

For example, the app will set off alerts 20 minutes after the first high event.

e. Alert Sounds: You can choose a vibration or ringtone in Alert Sounds.

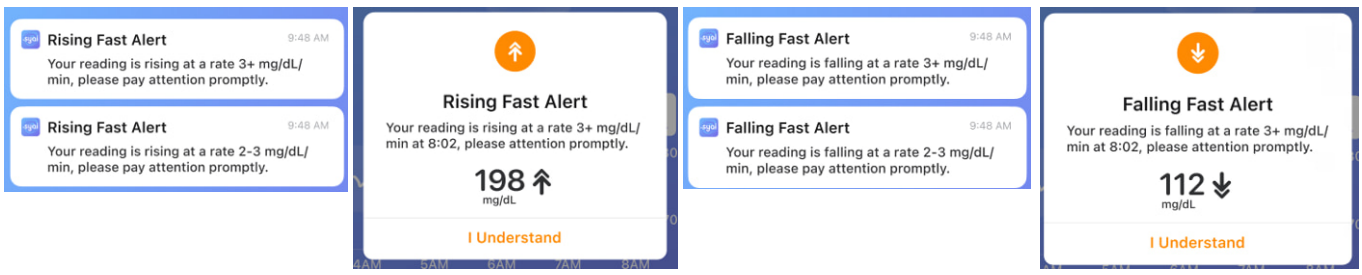


⚠ WARNING: Although the Alert system has been tested in clinical settings, if you have symptoms that do not match well with the Alert notifications, or corresponding Alerts are not triggered when there are hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, you could conduct fingerstick tests with a BG meter as additional references and seek advice from your HCP if needed.

7.1.4 Rising Fast & Falling Fast Alerts

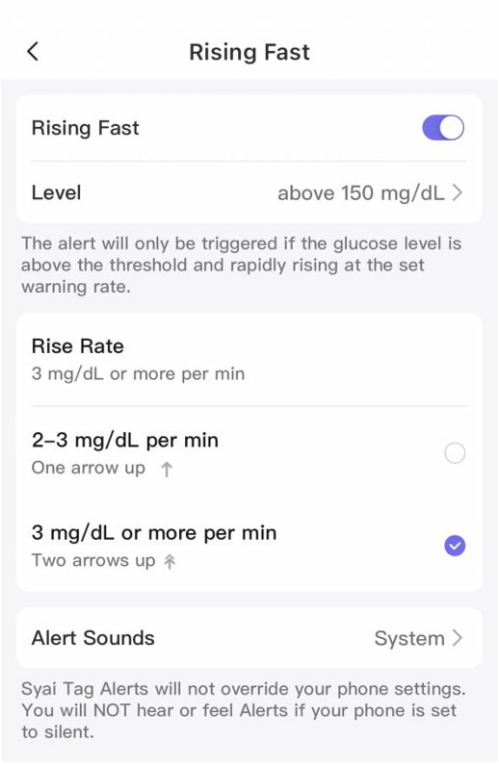
Trigger Conditions:

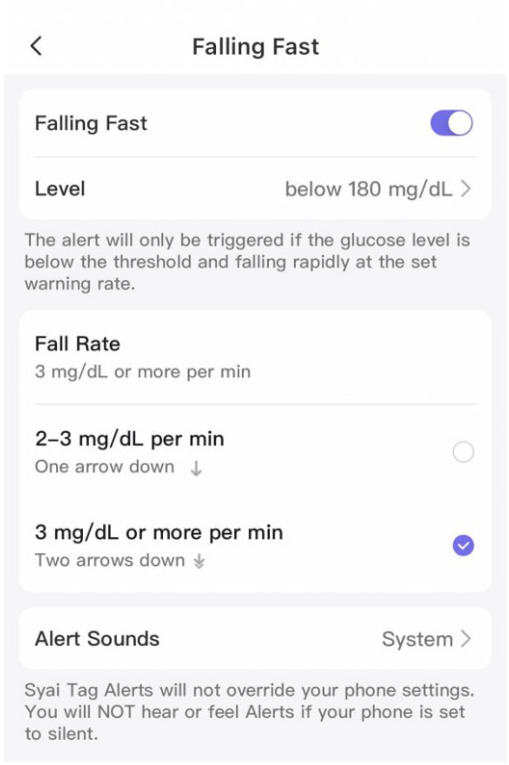
These two alerts are designed to aid in crucial situations when glucose levels change fast above or below the set levels at the warning rate selected.



How to find the relative settings:

Go to "Profile > Settings > Alerts > Rising Fast/Falling Fast"

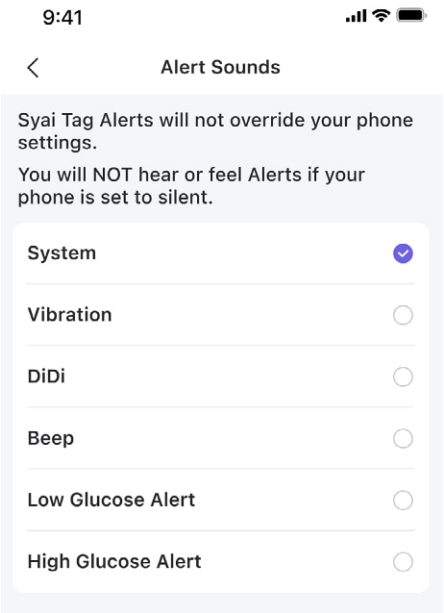




a. You could tap the toggle on the right side to turn the specific alert on/off.

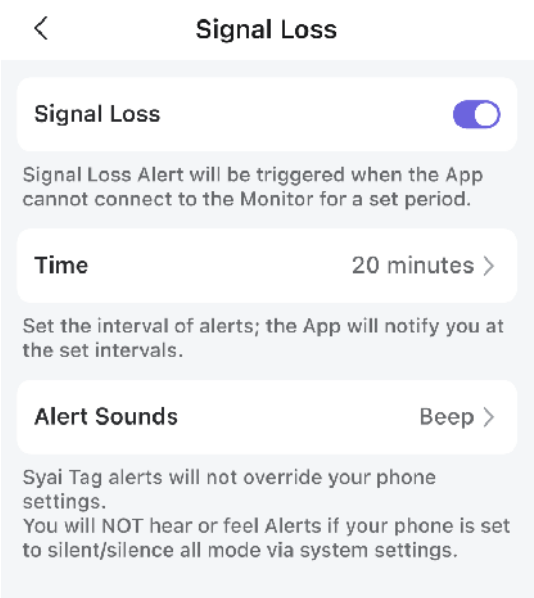
b. Rise/Fall Rate: You could set the warning rate; if the glucose is above/below the set level and rapidly rising/falling at or over the set rate, you will receive alerts via system notifications and in-app.

c. Alert Sounds: You can choose a vibration or ringtone in Alert Sounds. There are a variety of ringtones to choose from.



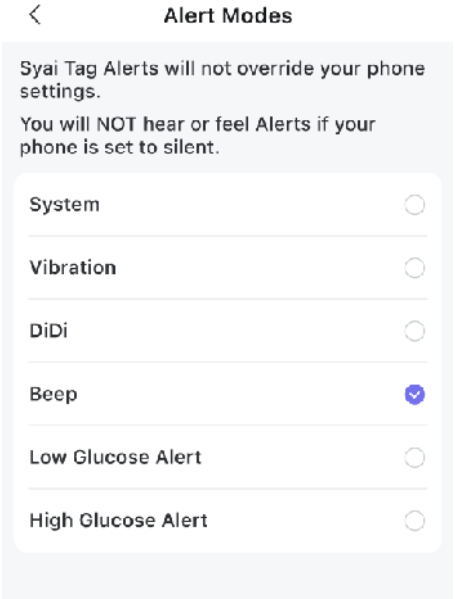
7.1.5 Signal Loss Alert Settings

The application will notify you when there are issues with the Monitor connection to the app, and network connectivity problems that incur data delay.



a. Time: You will only be notified when the Signal Loss event lasts for more than the time threshold set.

b. Alert Sounds: You can choose a vibration and ringtone in Alert Sounds.

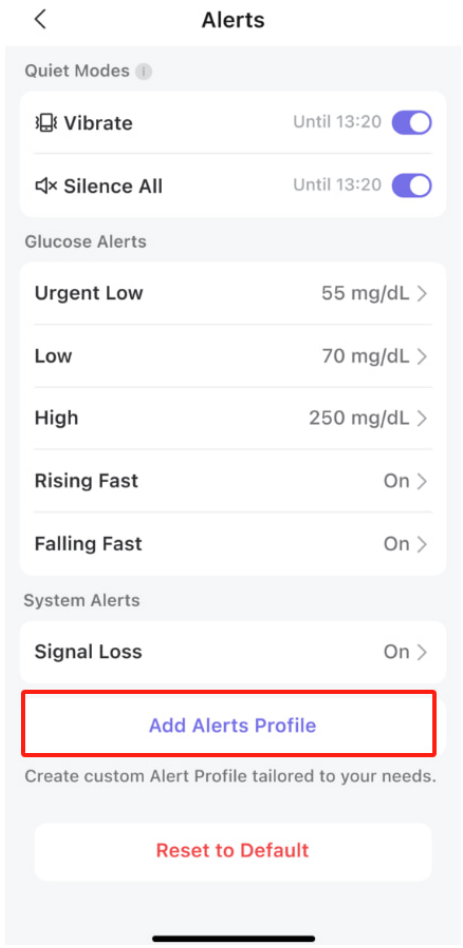


7.2 Customizable Alert Profile

You can set another Alert Profile to customize how Alerts will behave for other usage scenarios, such as meetings.

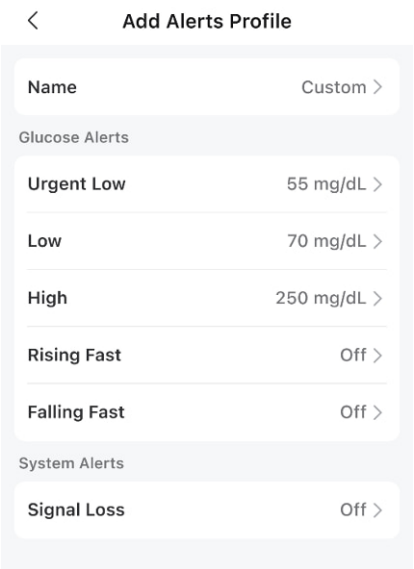
How to find the relative settings:

Go to "Profile > Settings > Alerts > Add Alerts Profile"



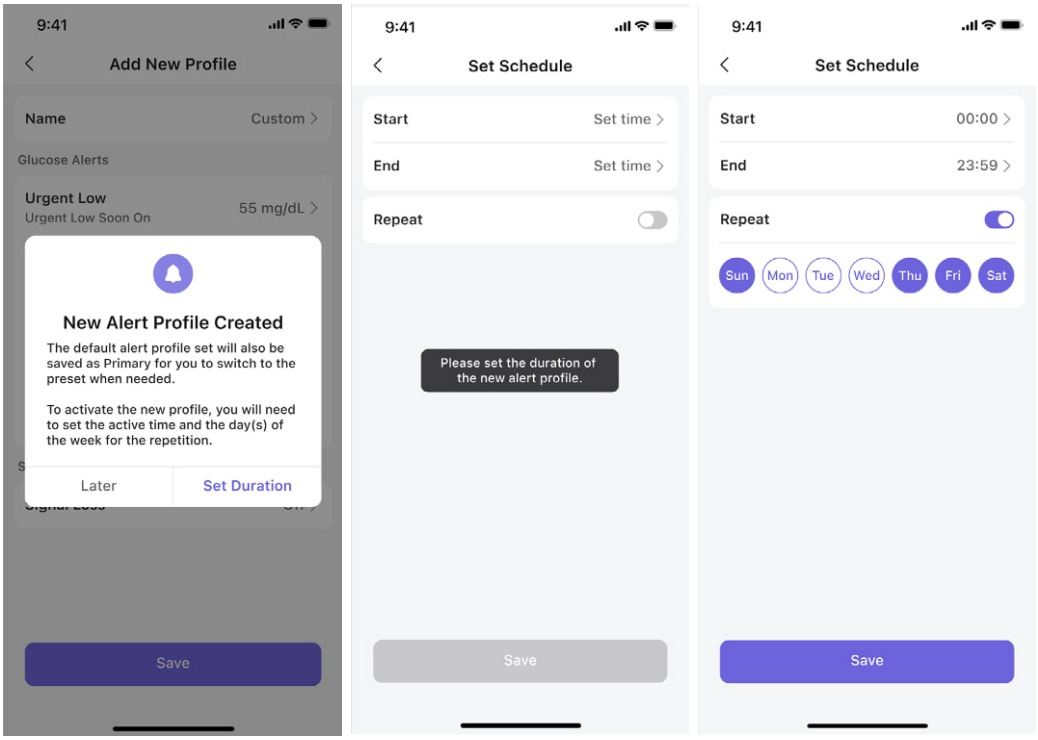
7.2.1 Change settings for the custom profile

Following the "Add Alerts Profile" action, a new profile settings page will be presented, as illustrated below:

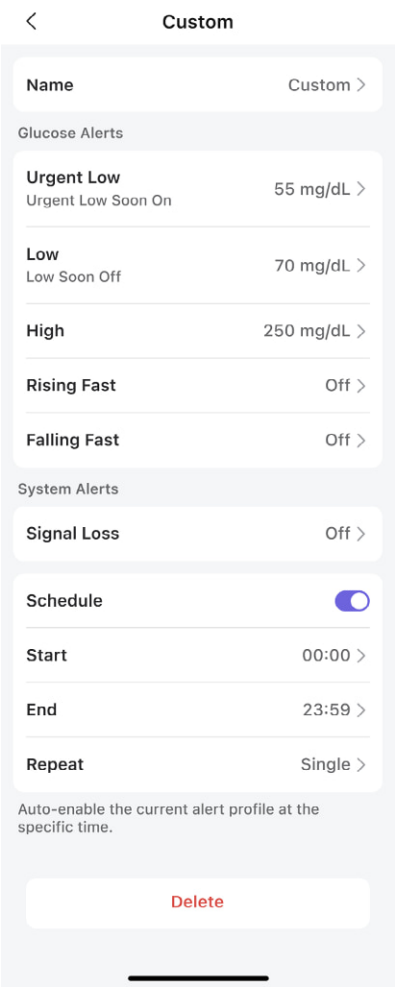


You can:

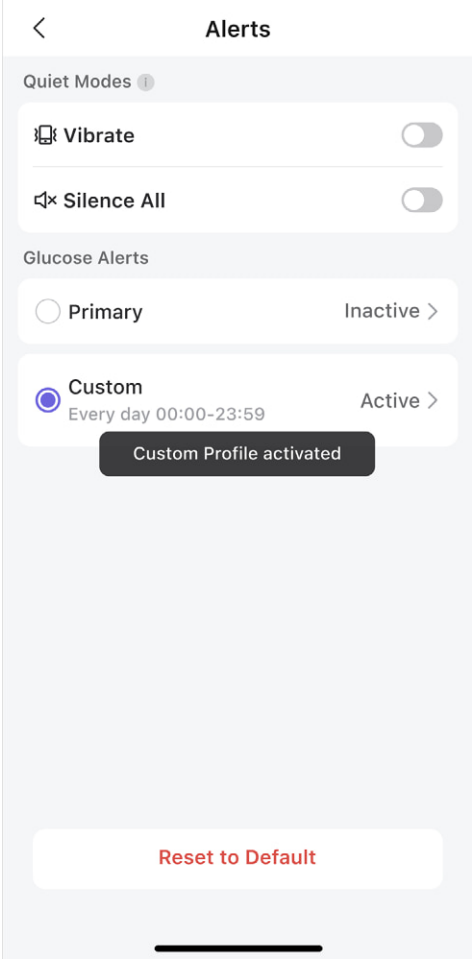
1. Name the profile as you wish to differentiate it from the default profile, such as "Meeting."
2. Change the settings for different Glucose/System event alerts; please refer to **Chapter 7.1** for more info and exercise caution before saving changes, so you won't miss out on crucial alerts.
3. Set a timetable for the new profile after setting up the Glucose Alerts, for the active time period within a day, and the repetition regarding days in the week (recurring).



If the "Repeat" is not turned on, then the effective duration of the profile will not be applied to another day of the week. The repeat option will display "Never" since no days in a week are selected.



Notes: The default profile (Glucose Alerts + System Alerts) will be saved as "Primary" for you to switch between custom and system default settings as needed. Hence, there will be only TWO alert profiles in total after the new profile has been added.



7.3 System Notifications and Alerts

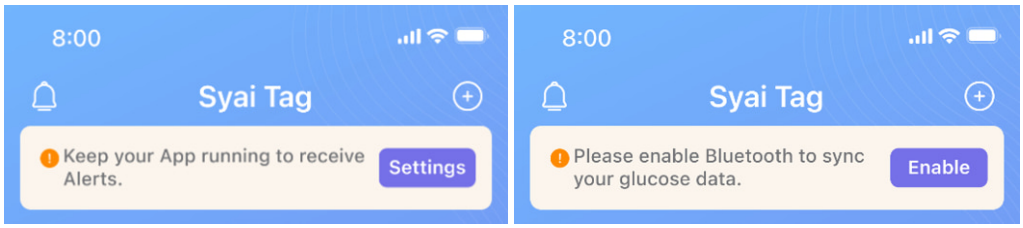
As mentioned in Chapter 7.1, the notification changes made to Syai Tag Alerts won't override the phone's system settings, and you won't hear or feel the glucose alerts if the phone is set to 'Silent/Silence All' or other similar settings in the operating system.

7.3.1 System Alerts

7.3.1.1 Signal Loss Alert

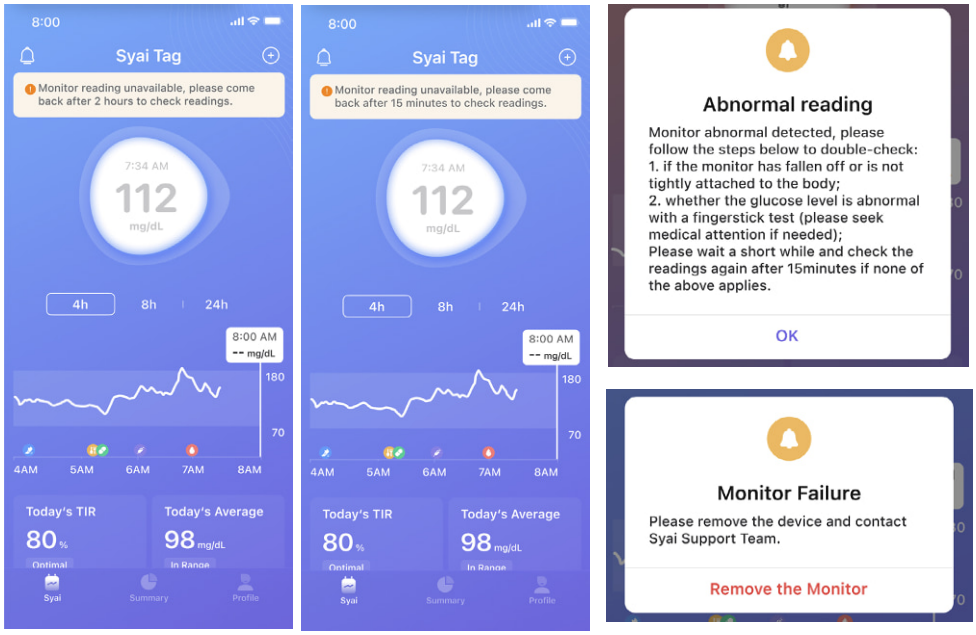
The application will notify you when there are issues with the Monitor connection to the app, and network connectivity problems that incur data delay.

You can refer to Chapter 7.1.5 for how to set the interval and alert sounds.



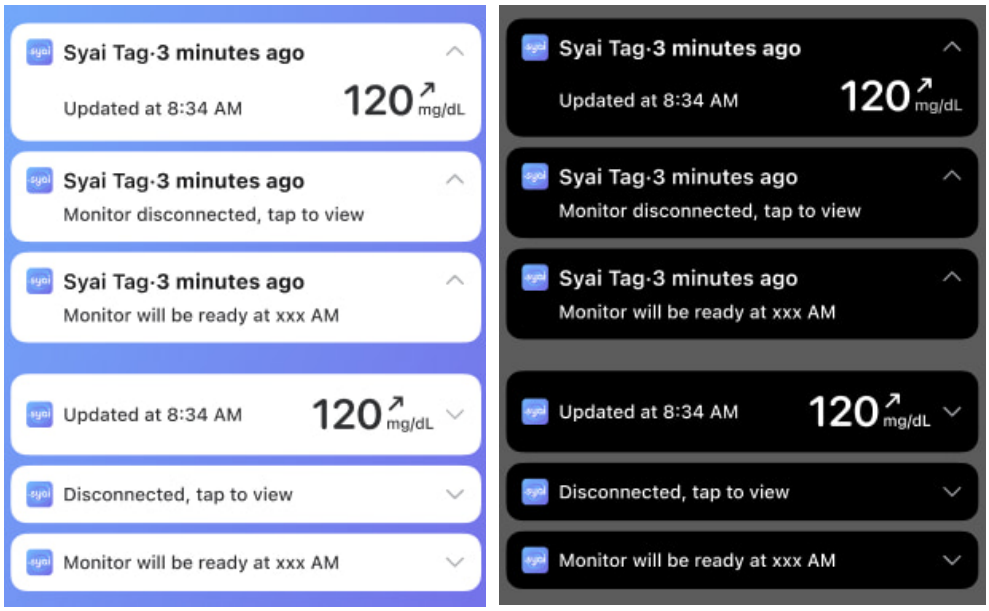
7.3.1.2 Monitor expiring soon alert

7.3.1.3 Alerts when the Monitor is not working properly



7.3.2 System Notifications (Android)

The resident system notification window includes the trend arrow, real-time reading and data update timestamp. The notification content will also change correspondingly with the Monitor status.



7.3.3 Mobile Homescreen Widget

7.4 Alerts on Smartwatch

You can wear a smartwatch to see alerts and feel their vibrations when the alerts are triggered. You may refer to "Syai Tag app - Profile - Connect with Watch" to see the compatible models with connection guides accordingly.

Please make sure that your smartwatch stays connected with your phone & corresponding apps to sync the notifications, or there will be unsynchronized alerts or delays.

⚠ **Important:**

- Make sure notifications are sent to both your phone and watch in your smart device settings (you may check the associated third-party applications when applicable).
- Don't disable or block notifications from the Syai Tag App and the associated applications for smart devices.

8. Living With Your Syai Tag CGMS

8.1 Bathing, Showering, and Swimming

The Syai Tag Monitor has an Ingress Protection rating of IP28. It is safe to wear during bathing, showering, or swimming. Do NOT take your Monitor deeper than 1.5 meters (4.92 ft) or immerse it longer than 30 minutes in water. Please note that hot water may shorten the service life of the monitoring device.

It is strongly suggested that the Monitor should be dried with a clean towel when it is out of water.

Note: The Monitor cannot communicate properly while immersed in water since the Bluetooth signal is weakened in water.

8.2 Sleeping

You can always set up a second Alert profile to sleep uninterruptedly by turning off any alerts that aren't essential for you except for hypoglycemia events.

8.3 Exercising

Intense exercises can cause your Monitor to loosen due to sweat, heat or muscle movements around the Monitor. If this happens, you may receive inaccurate readings that do not reflect the exact glucose status. Therefore, it is essential to follow the instructions to select an appropriate application site.

8.4 Travelling by Air

Prepare for airport security checks and screening procedures for your air travel. Review the airport website and travel updates before your trip.

At Security check point

- You can wear your Monitor when going through walk-through metal detectors and Advanced Imaging Technology (AIT) body scanners, as the Monitor can be exposed to common electrostatic discharge (ESD) and electromagnetic interference (EMI).
- However, the Monitor should not be exposed to X-rays or millimeter radio waves (sometimes used in full-body scanners). The effects of these scanners have not been evaluated, and the exposure may damage the Monitor or cause inaccurate results. To avoid removing your Monitor, you may request another type of screening. If you choose to go through a full-body scanner, you must remove your Monitor.
- Alternatively, you can ask for a hand-wanding or a full-body pat-down and visual inspection. Ask for a visual inspection of any part of the Syai Tag Device in the baggage scanning machine.

On the plane

Always follow instructions from the airplane crew while on the plane. You can continue to get glucose readings and alerts after switching your phone to airplane mode by turning Bluetooth on.

Note: Timezone changes may affect the glucose graphs and other statistics; please be aware.

8.5 Storage and Transportation

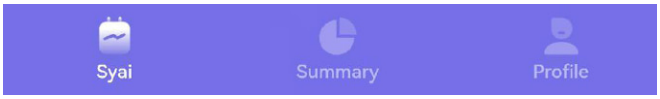
The product should be stored at 2℃ ~ 30℃ and with a humidity level of 10% ~ 85% RH, with no condensation allowed. The product is fragile and shall be kept away from any moisture or freezing.

9. Glucose Reports in Syai Tag APP

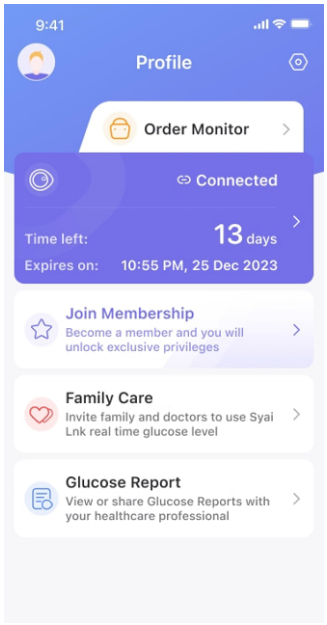
⚠ The software does not offer any medical advice and should not be construed as such. Users are strongly advised to consult a qualified healthcare professional before making any medical interpretations or adjustments to therapy based on the information provided within the software.

9.1 Where to Find

1. Tap "Profile" at the bottom of the application.



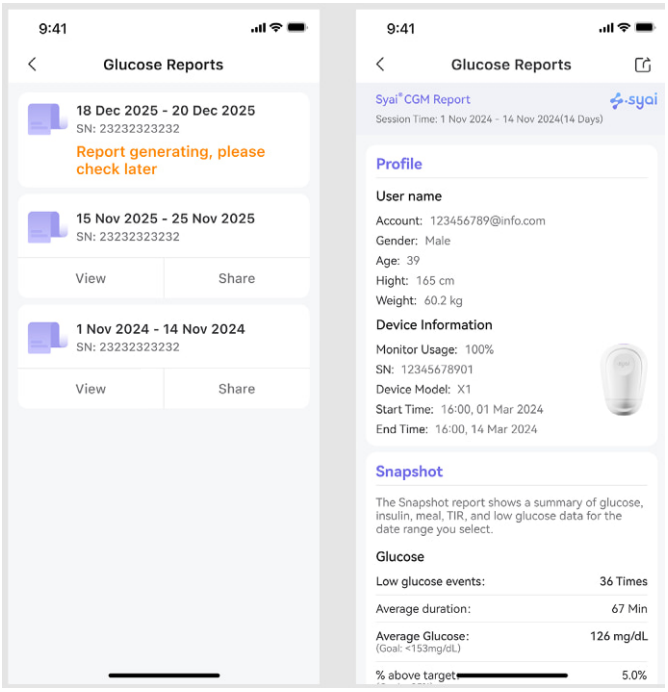
2. Tap "Glucose Report," and you can find all the available glucose reports.



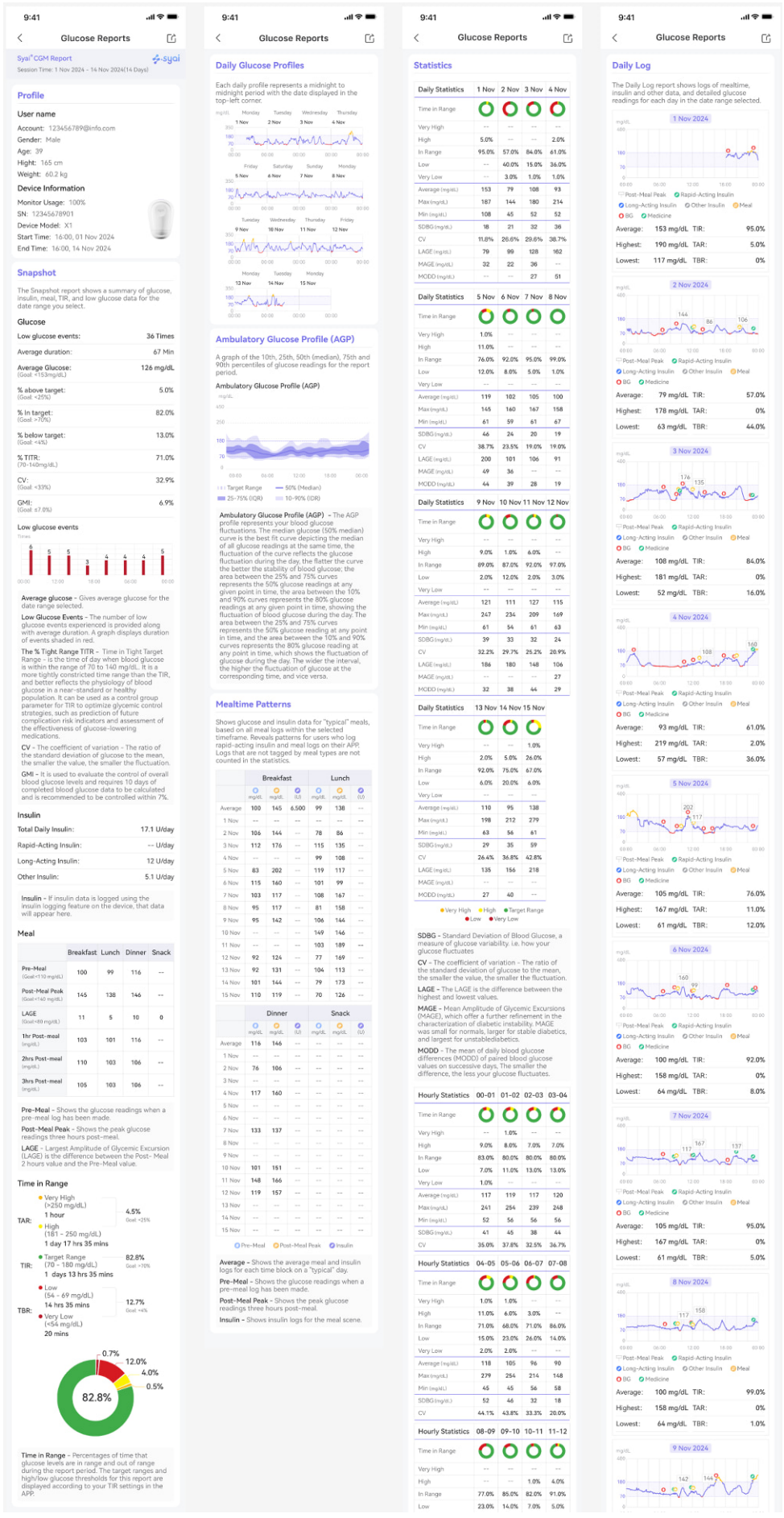
9.2 How to Download

1. Tap the Glucose Report that you wish todownload to enter the report browser.

2. Tap to download/share the glucose report as needed.



9.3 Report Overview



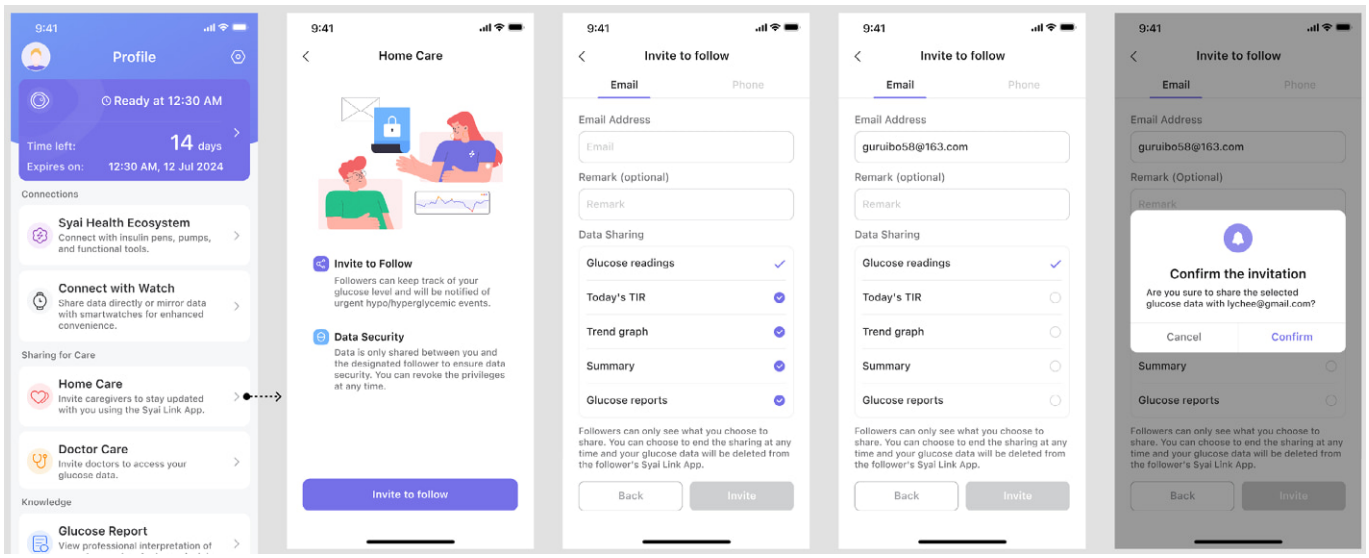
10. App Connections

10.1 Share and Follow

10.1.1 Share your glucose data with caregivers

Invite the caregiver to follow your glucose data via an email address in the Syai Tag App (the corresponding caregiver could accept the invitation with the registered Syai Link account via the mobile app "Syai Link", but the email address should be the same as the registered account):

Go to "Profile > Home Care", enter the account (email/phone number) that you want to share with, and modify the visibility for the selected account.



An email will be sent to the email address. The caregiver can follow the instructions in the email to download the Syai Link App, register with the same address, and start following you.

Maximum number of caregivers:

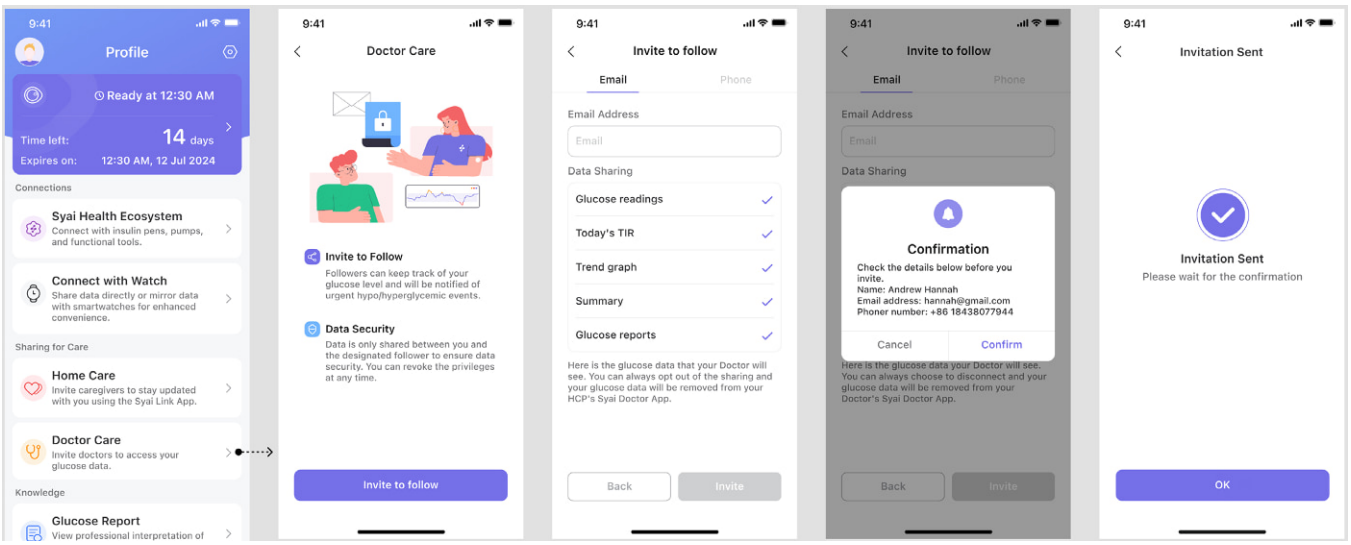
Up to 15 caregivers can be invited by each Syai Tag account.

Note: Invited caregivers will receive corresponding emails for the invitation. They need to download the Syai Link App and use the same email address to register accounts to proceed with invitations.

10.1.2 Share Glucose Data with Your HCP

Invite your HCP to follow your glucose data via an email address in the Syai Tag App (the doctor could accept the invitation with the registered Syai Doctor account via the Syai Doctor web portal or the mobile app "Syai Doctor") :

Go to "Profile > Doctor Care", enter the email address of your HCP and confirm his/her details.

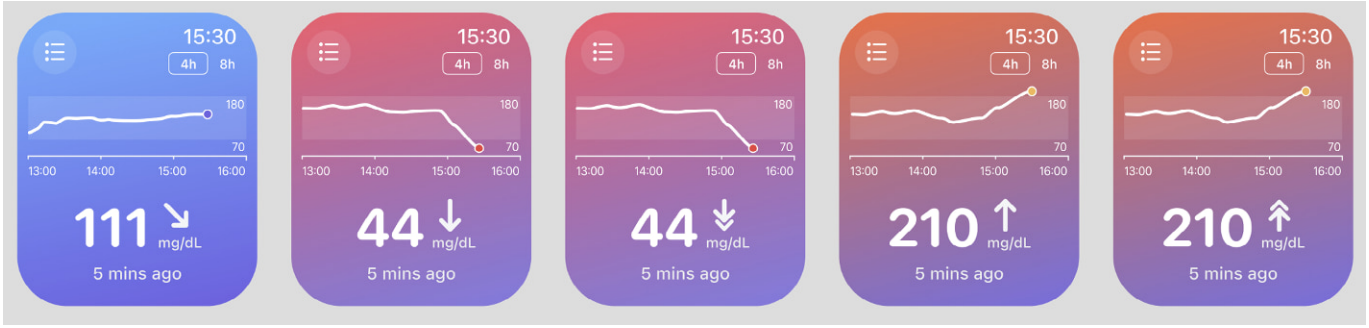


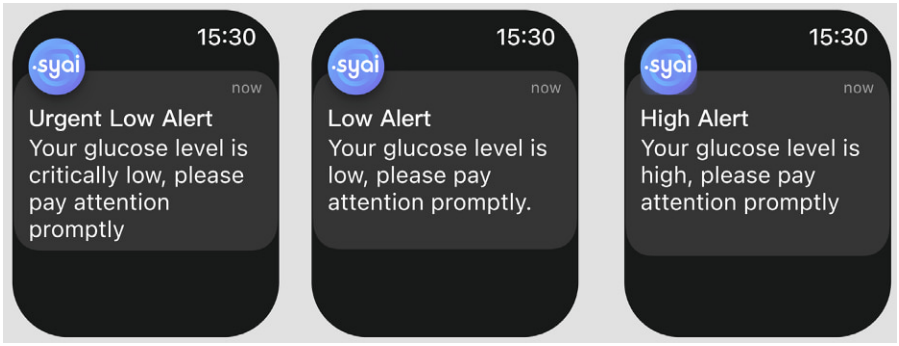
Maximum number of caregivers:

Up to 5 doctor accounts can be invited for each Syai Tag account.

10.2 Smartwatch

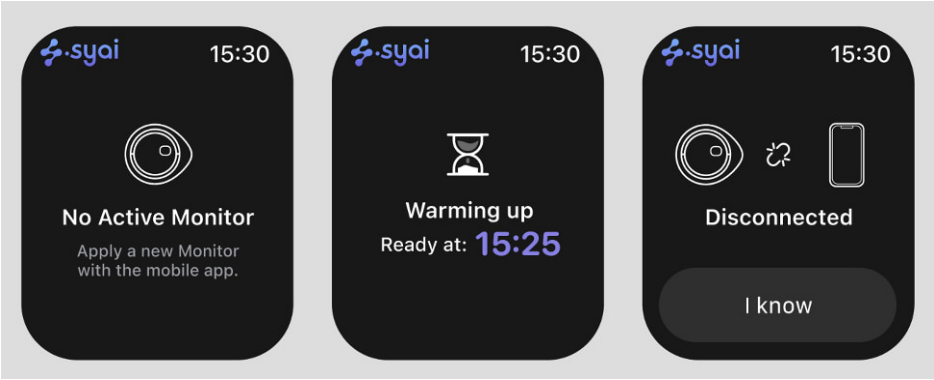
The Syai Tag watch application shows your glucose readings, trend arrow and the glucose pattern graph, similar to your mobile application.





You could refer to Chapter 5.2 for trend arrow interpretations.

Besides, the app will also utilize system notifications for event alerts, such as Urgent Low/ Low/High alerts, etc. You could also acknowledge them by tapping the notifications.



Besides, the Monitor status will also be displayed in the watch app, such as "No Active Monitor"/"Warming Up"/"Disconnected".

The glucose data from the Syai Tag App will be synced/forwarded to specific apps, and then mirrored to the watches. Compatible third-party smartwatches are listed below:

Apple

Models: Apple Watch models that are running WatchOS 9.0+

How to install the app:

1. Search "Syai Tag" on the watch App Store and download it.

2. Search "Syai Tag" on the App Store of the paired iPhone and download it, and the app will be synced to your watch.

Garmin

Models: Garmin Forerunner series, Fenix series, MARQ Adventurer, and more series with the Connect IQ Store.

To install the app, search "Syai Tag" in the CIQ store and download it.

*Note: Please take care that the 'Compatible Models' list within the CIQ store download page of the Syai Tag app is provided by the store; the actual compatibility may vary.

Samsung

Models: Samsung Galaxy Watch series, Galaxy Watch Active series and others with Google Wear OS*

How to install the app: Search "Syai Tag" in the Google Play Store and download it.

*Please refer to the actual model for feature availability.

Google

Models: Google Pixel Watch 2

To install the app, search "Syai Tag" in the Google Play Store and download it.
*The compatible watch models are extracted from internal lab tests; please refer to the actual usage scenario as the standard. Specific watch models may vary by region or country

due to regulations.

10.2.1 Be Aware of Your Smartwatch Connection

Using a smartwatch with your Syai Tag App may impact how you get readings.

- Your smartwatch may:
  1. Communicate with your phone, not the Monitor.
  2. Connect directly with your Monitor, not the phone instead.
- You won't get glucose readings on your watch if the "watch-Monitor" or "watch-phone app-Monitor" connection is interrupted.
- Make sure you understand how you get notifications when a watch is connected.
- In your smart device settings, ensure notifications are enabled for your phone and watch.
- Don't disable or block notifications from the Syai Tag App.
- There may be a brief delay before your watch app shows the latest information due to various reasons, such as network delay, etc.

11. Termination of Glucose Monitoring (Monitor Removal or Replacement)

You can terminate glucose monitoring under different circumstances while using a Monitor.

The Syai Tag App will display the remaining service time of your Monitor on the homepage. You may purchase or replace the device in advance according to the remaining service time to monitor your glucose changes continuously.

11.1 Normal Termination of Glucose Monitoring

- The Syai Tag Monitor is designed to be worn for 14 days (336h per monitoring session), after which the wearing session should be stopped, and no more glucose data will be measured and recorded in any form.
- After the Monitor is terminated, you can gently lift a corner of the adhesive bandage from the skin and tear off the Monitor slowly.
- Safely discard the Monitor.

11.2 Terminate Your Monitoring Session in Advance

To terminate the Syai Tag Monitor in use before the 14-day designated session ends, please refer to Chapter 4.5 for the operation of removing the Monitor.

Note: You may terminate glucose monitoring in advance under any one of the following circumstances:

- The Monitor is not in the designated service lifespan.
- The Monitor or the Adhesive bandage falls off.
- The Monitor has friction with other items causing pain or displacement.
- The Monitor is not located at the recommended site (see Chapter 4.2).
- The Monitor is located at any site that has failed to be cleaned or dried in advance.

12. Troubleshooting

12.1 Problems at the Sensor Application Site

- **The Monitor is not sticking to your skin**
  - The applied area MUST be sufficiently clean and dry to make the monitor adhere securely to the skin.
    - Clean the skin using soap and wait to dry before wiping the area with alcohol pads.
    - Make sure it is fully dry before proceeding next! Allow the site to air-dry.
    - Make sure the device is not rubbing against clothes, folds, and other objects.

⚠ **Friendly Reminders**

- In case of sweaty skin, please use non-moisturizing, fragrance-free soap to fully clean the wearing area and dry it fully before wearing the Monitor.
- AVOID excessive hair between your Monitor and the skin at the intended application site. Consider shaving the application area if necessary.

- Before pulling away the Applicator to finish the application, keep holding the Applicator against your arm for a few seconds. This can help the adhesive stick to your skin and relatively reduce the risk of failed injection.

⚠ **Daily Do's and Don'ts**

- Be careful not to catch your Monitor on objects such as doorways, car doors, seatbelts, and furniture edges.
- When dressing or undressing, be careful not to catch your undergarments on the Monitor.
- After a shower or swim, take extra care when towelling off to avoid catching or pulling off your Monitor.
- For contact sports and heavy exercise, select a sensor site on the back of your upper arm rather than the abdomen to minimize the risk of the Monitor being knocked off.
- Give your Monitor room to breathe by wearing loose-fitting clothing and lightweight materials.
- Try not to play with, pull, or touch the Monitor while wearing it.

- **Skin irritation at the Monitor application site**

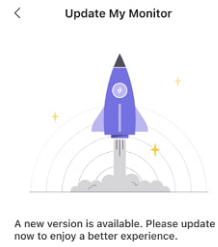
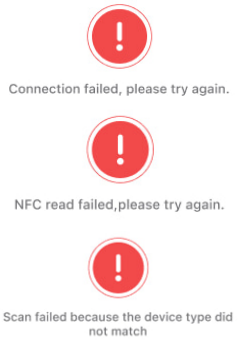
  The adhesive is verified in compliance with rigurous standards itself and from renowned suppliers worldwide, the irritation might be caused by sweating or poor ventilation. Please closely monitor the condition of your skin in the affected area. If necessary, we recommend removal and seeking medical attention promptly. If you have a significant skin allergy after device application, please contact your healthcare professionals to identify the best solution.

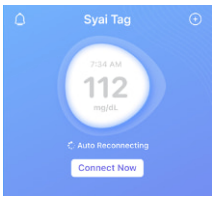
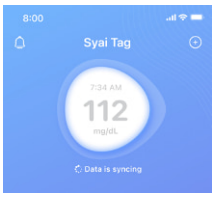
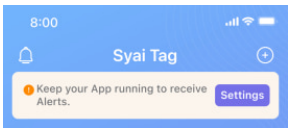
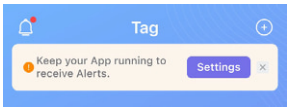
⚠ IMPORTANT

1. Patients with allergic skin should use the product with caution.
2. Patients prone to skin ulcers are prohibited from using the product.

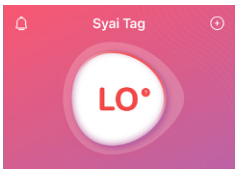
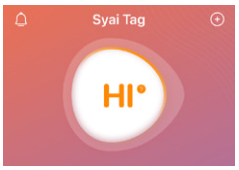
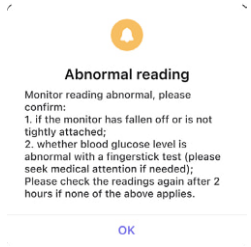
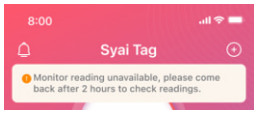
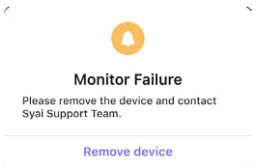
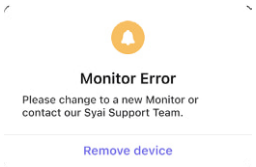
12.2 Problems Starting Your Monitor or Receiving Monitor Readings

Sometimes the screen shows a prompt. You can follow the instructions below to deal with it and contact customer service if necessary.

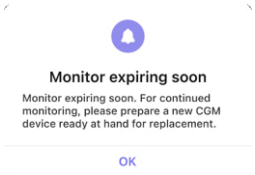
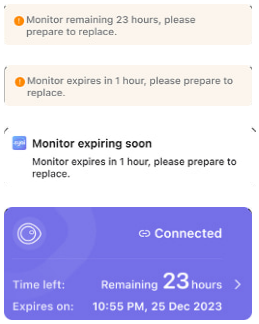
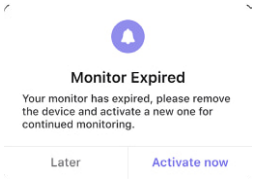
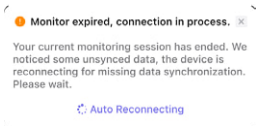
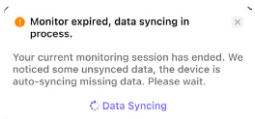
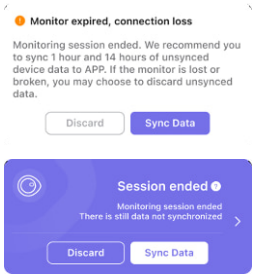
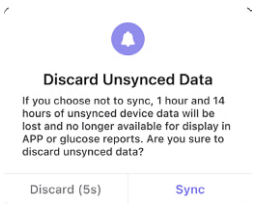
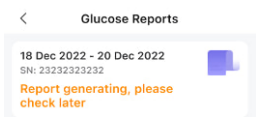
What You See	What It Could Mean	What To Do
	Updates that will offer a better experience are now available. It doesn't happen very often. It may appear while activating the Monitor.	Once it appears, simply follow the instructions to upgrade.
	This connection has failed.	Rescan the Monitor.

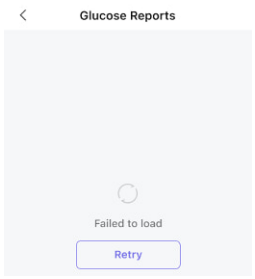
	You have a new message.	Tap the icon to check the message in time.
 	The Monitor is disconnected. When you open the App, it will automatically reconnect and sync the data.	Please check if Bluetooth and the internet work normally. Wait for auto-reconnect and sync data.
	Your phone's Bluetooth function is turned off and the Monitor is disconnected.	Turn on your phone's Bluetooth, reconnect the Monitor and wait for an updated reading.
	The Syai Tag App may be closed in the background of your mobile phone, leaving the Monitor disconnected, and data not updating timely, even missing glucose alerts.	Tap Settings and follow the prompts. This will help to keep your App running to receive Alerts.

12.3 Abnormal Readings

What You See	What It Could Mean	What To Do
	Your current glucose reading is below 36mg/dL (2.0mmol/L).	Check your blood glucose by conducting a finger-stick test using a blood glucose meter and intervene promptly to correct any hypoglycaemia.
	Your current glucose reading is above 450mg/dL (25.0mmol/L).	Check your blood glucose by conducting a finger-stick test using a blood glucose meter and intervene promptly to correct any hyperglycaemia.
	Abnormal reading has been measured, alerting you to check if the Monitor is wearing properly.	Check if the Monitor is wearing properly. • If the Monitor is properly attached to the skin, check the finger blood to confirm the blood glucose condition. • If the Monitor is loose or has fallen off, please replace it with a new one and contact the Syai Support Team.
	Monitor reading is unavailable for 2 hours as it is temporarily abnormal.	Check your blood glucose by conducting a finger-stick test using a blood glucose meter, and check Monitor reading again after 2 hours.
	The monitor has failed and is no longer in service.	Remove the device and contact Syai Support Team.
	The monitor is error and is no longer in service.	Remove the device and contact Syai Support Team.

12.4 Monitor Expiring or Expired

Screen Display Content	What It May Mean	What To Do
	The monitor will expire in 24 hours.	Tap OK and prepare a new CGM device ready at hand for replacement.
	The monitor will expire soon.	Prepare a new Syai Tag Device ready at hand for replacement.
	Your monitor has expired.	Remove the Syai Tag Device and activate a new one for continued monitoring.
	The Monitor has expired and stopped monitoring. The Monitor is auto-reconnecting with your phone to synchronize the rest of the data.	Waiting for Monitor to reconnect.
	Monitor connected, synchronising data.	Waiting for data synchronisation complete.
	The Monitor has expired and is out of connection. Some data remains in the Monitor and a re-connection is needed to synchronize with the Syai Tag App.	Tap "Sync Data" immediately.
	Check if you are giving up synchronized data. If the sync is aborted, unsynced data will be lost and no longer available for display in the App or glucose reports.	It is recommended to tap Sync immediately. If the monitor is lost or unable to connect, you may choose to discard unsynced data.
	Glucose Report is generating and is unavailable now.	Try again in 10 minutes.

	Glucose Report failed to load.	Confirm mobile networking status and Retry.
App crashes or freezes	Smart device system crash.	Restart the Syai Tag App, or reboot the smart device, or go to the App Store and upgrade the app to the latest version.
Skin allergy after device implantation	Clothes, folds and other objects in the installation part rub against each other.	
	The user is allergic to the material of the product.	Contact your HCP.
Device start-up failed	The device is not properly installed due to improper operation.	Check the Instructions for Use of the Monitor or contact customer service.
	Check if the device is outside the specified temperature range.	Relocate the Monitor to the specified operating temperature (5°C (41°F) - 40°C (104°F)) and turn it on again.
	Another situation occurs.	Contact customer service.

For more troubleshooting information, visit the Guide Center section on the Syai Health website (https://www.syai.com/customer-care/guide-centre) or contact your local distributor.

12.5 Accuracy

CGM readings vs. BG meter values?

CGM glucose readings are from interstitial fluid in tissue rather than blood drops as the BG meter values. Also, they hold different time concepts. The readings of the CGM will have a lag time since the blood drops will be affected first by sugar intake, then the interstitial fluid. The lag is considered to be from a few minutes to upwards of 20 minutes, with individual differences.

12.6 Report of serious incident

Report any serious incident with your Syai Tag CGMS to Syai Health Technology Pte. Ltd., and the competent authority of the European Member State in which you live.

Name: Syai Health Technology Pte. Ltd.

Address: 112 ROBINSON ROAD #03-01 ROBINSON 112 SINGAPORE

Contact information: 0065-6396736 Email: info@syai.com

13. Information on Clinical Trials

Note: Please consult your healthcare team on how to use the information in this chapter.

Clinical Trial Overview

This product has been evaluated through prospective, multicenter, single-arm clinical trials. The subjects included both type I and type II diabetic patients, and the product was worn on the back of the upper arm for a period of 14 days. For the enrolled subjects, the accuracy of the continuous glucose monitoring system was evaluated according to the gold standard venous blood glucose (analyzed via the EKF Biosen C-Line Glucose Analyzer). In the clinical trials, both the efficacy and the safety of the continuous glucose monitoring system were evaluated during wear.

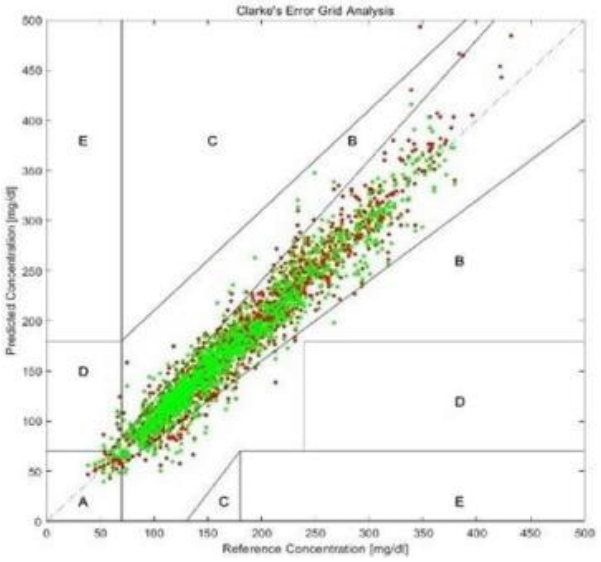
The system performance accuracy indicators and results of the entire data range are as follows:

Types of Indicators	Evaluation Indicators	Clinical Trial Results
Primary evaluation indicators	20/20% concurrence with the control reference value	93.3%
	Proportion of measurement points falling in the A+B region of the Clarke error grid analysis	99.6%
	Proportion of measurement points falling in the A+B region of the Consensus error grid analysis	99.8%
	Mean Absolute Relative Error Value (MARD%)	8.106%±3.869%

Secondary evaluation	Correct Alert Rate	The success rate of high glucose alert was 95.8%; the success rate of low glucose alert was 84.1%. The success rate of high glucose detection was 95.7%; the success rate of low glucose detection was 88.0%.
	The Sensor Stability	The 20/20% concurrence rate was higher than 90% for all time staging except for the late stage (day 14) where the 20/20% The concordance rate was 86.8%. The mean MARD values for the anterior (day 1), anterior-intermediate (days 2-5), intermediate (days 6-9), middle-late (days 10-13), and late (day 14) phases were 8.591% ± 4.191%, 6.716% ± 2.852%, 8.525% ± 3.450%, 8.166% ± 3.930%, and 10.506% ± 6.564%, respectively.
Security evaluation indicators	Repeatability of the Sensor	The mean value of the mean absolute difference (PARD) for primary/secondary sensor pairs was 0.065 ± 0.085.
	Product Ease of Use	The total score of the questionnaire totalled 90 points, and the average of the total score was 86.0±7.27, suggesting positive feedback from the users on the product's ease of use.
	Sensor Life	The primary/secondary sensors survived a median of 14 days of wear, with a cumulative overall failure rate of 11.6%.
	Adverse Events	A total of 5 (6.9%) participants experienced 6 adverse events. All adverse events were positively unrelated to the device.
	Device Defects	No device defects were found during the trials.

Clarke Error Grid

FAS analysis showed that the proportion of the points falling into zones A and B was 99.6%, with the lower limit of the 95% bilateral CI of 99.3%, which was higher than the target value of 90%. The results of the PPS analysis were the same as FAS. The proportions falling into zones A, B, and D were 94.7%, 4.9%, and 0.4%, respectively. No measurement point fell into zones C and E.



Comparison of Monitor readings and EKF reference

Glucose	Mean Absolute Relative Difference (%)
≤4.4mmol/L or 79mg/dL	9.881
4.4-11.1mmol/L or 79-200mg/dL	8.165
＞11mmol/L or 200 mg/dL	7.932

Monitor performance relative to the EKF venous reference at different glucose levels

	Day 1	Day 6-9	Day 10-13	Day 14
Within ±20mg/dL and within ±20% of reference	92.5%	92.9%	94.0%	86.8%
Mean Absolute Relative Difference (%)	8.591	8.525	8.166	10.506

Note: The performance of the Monitor is significantly better during the first 13 days of use and the results of the Monitor show deviations on the last day. It is recommended to consult your healthcare team if you find the CGM readings on the last day do not match well with your symptoms.

Skin Irritation: No skin irritation or bleeding was reported during the study.

13.1 Clinical Performance Description of High/Low Glucose Alert Function

This product has a high and low glucose alert function. Users can customize the upper and lower limits of the target glucose range according to their own conditions. When the glucose is higher than the upper limit of the target range or lower than the lower limit of the target range, the Syai Tag app will issue an alert to the user.

The performance of the high and low glucose alert function has been evaluated through clinical trials. In the clinical trial, the value for the low glucose alert was set to 4.4 mmol/L or 79 mg/dL, and the value for the high glucose alert was set to 11.1 mmol/L or 200 mg/dL. The performance evaluation of high and low glucose alerts included the success rate and failure rate of high and low glucose alerts (i.e., sensitivity), and the detection success rate and failure rate (i.e., specificity). The relevant definitions in clinical trials are as follows:

1. Low glucose alert success rate and failure rate (i.e., sensitivity). The success rate of a low glucose alert is the number of times the continuous glucose monitoring system successfully prompts a low glucose alert within the first 15 minutes and the next 30 minutes when the EKF measurement value is lower than the alert threshold. Proportion. The low glucose alert failure rate is the proportion of the continuous glucose monitoring system that did not prompt a low glucose alert during the above period.
2. Low glucose detection success rate and failure rate (i.e., specificity). The success rate of low glucose detection is the proportion of EKF that also detects low glucose within 30 minutes before and after the continuous glucose monitoring system prompts a continuous low glucose event. The low glucose detection failure rate is the proportion of EKF that does not detect low glucose within 30 minutes before and after the continuous glucose monitoring system prompts a low glucose event.
3. High glucose alert success rate and failure rate (i.e., sensitivity). The high glucose alert success rate is the number of times the continuous glucose monitoring system successfully prompts a high glucose alert within the first 15 minutes and the next 30 minutes when the EKF measurement value is higher than the alert threshold. Proportion. The high glucose alert failure rate is the proportion of continuous glucose monitoring systems that did not prompt a high glucose alert during the above period.
4. High glucose detection success rate and failure rate (i.e., specificity). High glucose detection success rate is the proportion of EKF also detecting high glucose within 30 minutes before and after the continuous glucose monitoring system prompts a high glucose event. The high glucose detection failure rate is the proportion of EKF that does not detect high glucose within 30 minutes before and after the continuous glucose monitoring system prompts a high glucose event.

The clinical performance test results of this product's high and low glucose alerts are summarized as follows:

Hypoglycemia alert success rate and loss Failure rate (i.e., sensitivity)		Success and loss of hypoglycemia detection Failure rate (i.e., specificity)		Hyperglycemia alert success rate and loss Failure rate (i.e., sensitivity)		Success and loss of hyperglycemia detection Failure rate (i.e., specificity)	
Success rate	Failure rate	Success rate	Failure rate	Success rate	Failure rate	Success rate	Failure rate
84.1%	15.9%	88.0%	12.0%	95.8%	4.2%	95.7%	4.3%

Note:

1. The high/low glucose alert function is only used to prompt the user to measure glucose with fingertip blood using a BG meter and is not used as a basis for deciding and adjusting treatment plans.

2. The performance of the product's high/low glucose alert functions has been evaluated through clinical trials. The alert thresholds for high/low glucose are initially set to Glucose >11.1mmol/L or 200mg/dL will prompt a high glucose alert, and glucose <4.4mmol/L or 79mg/dL will prompt a low glucose alert. The high/low glucose alert thresholds in clinical trials are only recommended values for subjects in clinical trials. Users can customize the high/low glucose alert thresholds according to their glucose conditions.

3. In the clinical trial of this product, in the subgroups with glucose <3.9mmol/L or 70mg/dL and <4.4mmol/L or 79mg/dL, the proportion of measurement points falling in the A+B area of the Clarke error grid analysis was less than 90%. In case of a hypoglycemia event, it is advised to use a BGM to test fingertip glucose for confirmation.

4. Sensor glucose value is based on interstitial fluid glucose level, which may be different from glucose level (finger), especially when glucose changes rapidly. If your glucose reading does not match your symptoms or expectations, please use a BGM to perform a glucose test to check the glucose reading measured by the system.

14. Warranty

14.1 Syai Tag Monitor Limited Warranty

To the fullest extent permitted by applicable law, your Syai Tag CGMS comes without any warranty by Syai Health. For claims, device replacements, or concerns regarding batch quality, etc., please contact the authorized distributor in your region.

Your Syai Tag CGMS does not contain any user-serviceable parts and requires no routine maintenance by the user. Any attempt to service or repair the device yourself will void the warranty if applicable. Please contact your local distributor for any device-related issues.

15. Technical Information

15.1 System Specifications

15.1.1 Compliance

The Syai Tag CGMS shall meet the requirements of the following regulatory documents:

ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer.

MDR 2017/745 Medical Device Regulation.

15.1.2 Software Operating Environment

	Android	IOS
Operating system	Android 8.0 or above	IOS 13.0 or above
CPU	Main frequency not lower than 1.4 GHz	Main frequency not lower than 1.4 GHz
Memory	No less than 3 GB	No less than 2 GB
Storage	No less than 10 GB	
Bluetooth	Bluetooth 4.2 or above	
Network bandwidth	No less than 5 Mbps	
Screen size	No less than 5.0 inches	No less than 4.7 inches
Screen resolution	No less than 1280*720	No less than 1334*750
Screen maximum brightness	No less than 150 cd/m(2)	
Effective radiated power	≤20dBm (EIRP)	
Ambient light	With functions including ambient light detection, display brightness correction, automatic screen brightness adjustment and manual adjustment	
Battery capacity	No less than 3,000 mAh	No less than 1,810 mAh

15.1.3 Monitor Specification

Glucose concentration detection range	36~450 mg/dL or 2~25 mmol/L
Guide needle size (total length)	20 mm ± 2 mm
Insertion depth of Guide needle	8.5 mm ± 0.5 mm
Insertion depth of the Monitor	5 mm ± 0.5 mm
Monitor power supply	One lithium battery (3V)
Monitor service life	14 days
Monitor memory	Storage of data for up to 14 days
Operating temperature	5~40 ℃, no freezing
Operating relative humidity	10 %~85 % RH, no condensation
Storage and shipping temperature range	2~30 ℃, no freezing Notice: Even if the Syai Tag CGMS is stored at the minimum storage temperature or maximum storage temperature, there is no need to warm up the device to be ready for intended use when the ambient temperature is 20℃. However, for your comfort and the best performance of the device, we recommend you rest the device for about 10 minutes and let the device temperature restore to room temperature before use if stored in a minimum storage temperature.
Storage and shipping relative humidity	10 %~85 % RH, no condensation
Atmospheric pressure	70~106 kPa
Initiation time	30 min
Wireless transmission distance	10 m
Protection level	IP28 rated
Monitor sterilization method	Sterilized using irradiation

15.2 Device Performance Summary

15.2.1 Accuracy

The Syai Tag CGMS allows continuous monitoring of glucose levels in interstitial fluid and generates real-time glucose readings, glucose trends, and glucose fluctuation characteristics. It has good accuracy and stability; the MARD (Mean absolute relative difference) of the Continuous Glucose Monitoring System is 8.106%.

15.2.2 Performance Efficiency

Under the software running environment described in these Instructions for Use, new glucose data will be displayed every minute in the "Dashboard" page of the Syai Tag App.

15.2.3 Monitor Safety Features

Classification by type of protection against electric shock	Internal power supply device
Classification by degree of protection against electric shock	Type BF applied Part, attached part on the arm that directly contacts the human body
Classification by degree of protection against harmful ingress of water	IP28
Classification by degree of safety of Application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not intended for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Classification by operation mode	Continuously operating
Rated voltage and frequency	Powered by a one-time lithium battery, DC 3V
Input power	N/A
Whether this device has applied parts for protection against the defibrillation discharge effect	No
Whether this device has signal output or input parts	N/A
Permanently installed equipment or non-permanently installed equipment	Non-permanently installed equipment

15.3 Requirements of the intended user

1. Education
• Be able to read and understand the content in the user manual (primary school and above)
b) Knowledge
• minimum: read and understand
• can distinguish body parts
• understands hygiene
• no upper limits
c) Language understanding:
• official language of the target market
d) Experience
• no special experience needed
e) Permissible impairments:
• Visual shall be able to correct to log MAR 0 or 6-6 (20-20)
• Disabled parts have no affect with the use of the device.
f) Gender
• no restriction
g) Cultural background
• no restriction
h) Weight range
• no restriction

i) Health condition

・There is no special requirement on health condition of patient, but the other requirements mentioned above must be met.

Requirements on environment:

The Syai Continuous Glucose Monitoring System (CGMS) is intended for use within standard healthcare environments and does not necessitate specialized infrastructure. While the device's protection rating should be considered in specific contexts, such as athletic activities and aquatic environments, it is strongly advised to ensure the device is dried after exposure to water, similar to precautions taken during physical exertion. Given the integration of mobile applications, compatible smart devices and a stable internet connection are prerequisites for ensuring continuous data accessibility. In instances where wireless network connectivity is required, the utilization of private WiFi networks is recommended over public alternatives to maintain data security and reliability.

You may refer to Chapter 4.1, "Set Up Your Smart Device," and Chapter 4.2, "Applying Your Monitor," for the operating principle.

15.4 Installation and Maintenance

15.4.1 Software Installation

1. For iOS system: You can download the Syai Tag App from the Apple App Store..
2. For Android system: You can download the Syai Tag App from the Google Play Store.

Note: Alternatively, you can also scan the Syai Tag App QR code on the packaging box to download the Syai Tag App.

3. Do not install the Syai Tag App on a jailbroken (Apple) or rooted (Android) smart device.
4. Do not install apps on your smartphone that is running the Syai Tag App from untrusted sources. These Apps may contain malware that may impact the use of the Syai Tag App. Install apps only from trusted sources like the Apple store. If you don’t know what an App is, do not install it, regardless of the source. Doing so may put you at risk of unintentionally installing malware which could prevent the Syai Tag App from functioning as intended on your smartphone; in this case, the monitored glucose may be inaccurate and lose its value for reference.
5. You are required to create a password when you register your Syai Tag App. The password should consist of 8-32 characters, including at least one digit, one capital letter and one lowercase letter. Please do not use simple passwords to prevent unauthorized access.
6. To prevent unauthorized access, please keep your App login information safe and do not share/lend/borrow it to others.
7. You are responsible for properly securing and managing your smartphone. If you suspect an adverse cybersecurity event related to the Syai Tag App, contact Customer Service.

15.4.2 Software Uninstalling

By pressing the icon "Syai Tag" Mobile App of your smart device, you will have the "Uninstall" option displayed next to the icon. Then, you can tap the "Uninstall" option to uninstall the software. In addition, the software can also be uninstalled in the "Settings" – "App Management" of the smart device.

15.4.3 Maintenance and Support

Syai Health Technology Pte, Ltd. provides technical maintenance support for the Syai Tag CGMS software.

If you need to upgrade and maintain the software, Syai Health Technology Pte. Ltd. will assign qualified technical personnel to maintain the software version that can be maintained as designated by the company. The company reserves the right to interpret related issues.

Syai Health Technology Pte. Ltd. will maintain this product through software updates.

15.5 Information Security

The Monitor is engineered to exclusively receive radio frequency (RF) communications from a recognized and paired compatible display device. Before the display device accepts information from the Monitor, the two devices must be successfully paired. The compatible display device guarantees data security through proprietary methods and maintains data integrity through error-checking processes, including cyclic redundancy checks.

15.6 Security Measures

Monitor-App Connection Security:

The Monitor and App establish a secure Bluetooth connection via a verified login-activation process, preventing unauthorized device access. Data transmission utilizes a proprietary encrypted format, safeguarding against interception. Standard BLE & GATT protocols allow multiple users in proximity. If the connection is lost, only the authenticated App, logged into the same Syai Tag account that activated the Monitor, can re-establish it.

In-App Communication Security:

Secure Sockets Layer (SSL) protocol protects in-app (smartphone to cloud) communications, preventing interference and interception. Transmitted data is secured by a proprietary encrypted format and memory map, with the App verifying data integrity. Standard SSL protocols support multiple users in close range. Should the connection drop, only the authenticated App, logged into the same Syai Tag account that activated the Monitor, can reconnect.

Login Security:

Incorrect login attempts trigger an invalid credential alert or may incur temporary account suspensions accordingly. Failed login attempts, like glucose data, are uploaded and archived within the application.

15.6.1 Secure network deployment and servicing

1. Login Attempt

(a) Incorrect username or password: If the wrong username or password is given, then the prompt window informs the user of this error. After 5 failed attempts, the account will be blocked for 1 hour. After 1 hour, the user can retry logging in with this account again.

(b) Log in to another smart device: The Syai Tag App does not have an auto-logout function. If an account is already logged in on one smart device, but the user still tries to log in with this account on another smart device, and the information given is correct, the login attempt will still be successful. The Syai Tag App on the original smart device will inform the user that this account is automatically logged out because of a new login on another smart device.

2. Log files

All operations on the app are located and stored on the server (Ali Cloud). The server is not open to the user. The log files will not be deleted unless the user deletes the account. After that, the log files and information related to this account will be deleted and cannot be recovered.

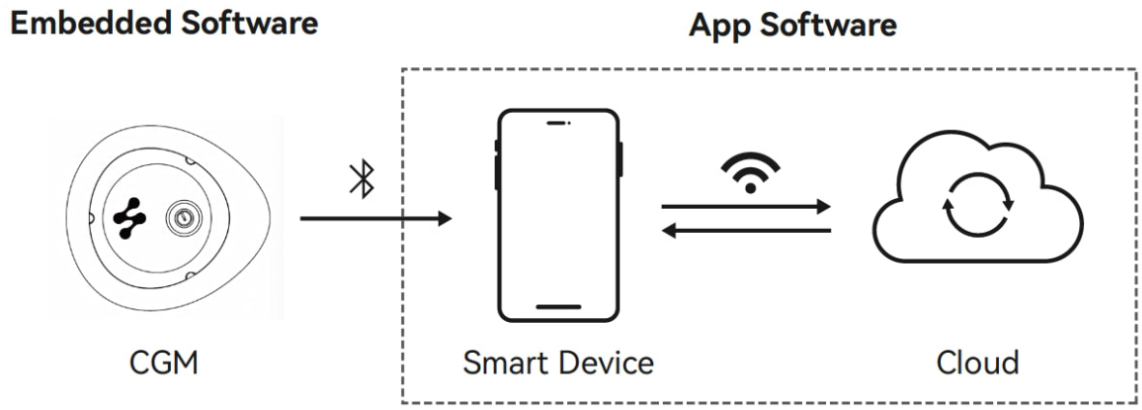
3. 3.Retention and recovery of device configuration

The user information and operational activities, as well as glucose information, are bound to the registered account. As long as this account is still available, the user can access all historical information related to it.

15.7 Data communication and backup

15.7.1 Data communication

There exists a data communication link between the monitor and the application, as well as between the application and the cloud. The transmission path and method are shown in this picture:



The embedded software has two ports:

Port 1: The port is based on GATT service and characteristics. It's mainly used to send glucose information to the Syai Tag App.

Port 2: The port is based on the NDEF Forum data format, which is used to send the MAC address of the Transmitter to the Syai Tag App.

The part of the Syai Tag App of the smart device has 4 ports:

Port 1: The port is based on GATT service and characteristics. It's mainly used to receive glucose information from Embedded Software.

Port 2: Standard HTTPS port, is used to send glucose information to the Cloud end.

Port 3: Standard HTTPS port, is used to receive processed glucose information from the Cloud end.

Port 4: The port is based on the NDEF Forum data format, which is used to receive the MAC address of the Transmitter.

The part of the Syai Tag App of Cloud has 2 ports:

Port 1: Standard HTTPS port, is used to send glucose information to the Syai Tag App.

Port 2: Standard HTTPS port, is used to receive processed glucose information from the Syai Tag App.

15.7.2 Data Backup

The Monitor, Syai Tag App, and cloud can store glucose data. The information about data backup refers to this table:

Location	Description
Monitor	The Monitor can store up to 14 days of glucose data. In normal conditions, the Monitor will transfer glucose data to the Syai Tag App. If the Monitor is disconnected from the Syai Tag App, the stored data in the Monitor during this time will be automatically transferred to the Syai Tag App after reconnection. If cybersecurity has been compromised, the glucose information storage of the Monitor will not be affected. And after the cybersecurity problem is solved, and the connection between the authenticated App which logs in to the same Syai Tag App account that activates the Monitor and the Monitor is recovered, the Transmitter will send the stored information during this period to the Syai Tag App.
Syai Tag App	The Syai Tag App can store all the glucose data. If the connection internal Syai Tag App is interrupted, the stored data in the part of the smart device during this time will be automatically transferred to the Cloud end after reconnection.

15.8 Basic Electromagnetic Compatibility Performance

Syai CGMS provides real-time monitoring of glucose.

15.9 Circuit diagrams and Components List

No maintenance or repair is required, so circuit diagrams and component lists are not provided in this Instructions for Use.

15.10 Product Serial Number/Lot Number, Manufacture Date and Service Life

15.10.1 Product Serial Number/Lot Number, Manufacture Date

Please refer to the packaging label.

15.10.2 Service Life

Service life: 14 days

Sterilization validity: The sterilization package is valid for 1.5 years.

15.11 Interfering substance risks

The interference effect of all possible interference substances shown below were analyzed:

NO.	Substance name
1	Ascorbic acid
2	Acetaminophen
3	Ibuprofen
4	Acetylsalicylic acid
5	Salicylic acid
6	Siklos
7	L-DOPA
8	Gentisic acid
9	EDTA
10	Heparin
11	Pralidoxime iodide
12	Fluvoxamine
13	Glyburide
14	Repaglinide
15	Metformin
16	Acarbose
17	Rosiglitazone
18	Sitagliptin

19	Dopamine
20	Tolazamide
21	Methyldopa
22	Tolbutamide
23	Triglycerides
24	Icodextrin
25	Uric Acid
26	Cholesterol
27	Creatinine
28	Bilirubin
29	Cholesterol
30	Glutathione
31	Haemoglobin
32	Galactose
33	Maltose
34	Xylose
35	Sorbitol
36	Xylitol
37	Isomalt

Based on the test results:

Xylitol is a pentahydroxy sugar-alcohol that exists in very low quantities in fruits and vegetables (e.g., plums, strawberries, cauliflower, and pumpkin). The presence of xylitol in the interstitial fluid higher than 0.06 mg/dL will cause Syai Tag CGMS Monitor readings to be lower than actual glucose levels, which could result in missed hypoglycemia alerts or errors in diabetes management. Consult your doctors about the intake of xylitol when you use Syai Tag CGMS.

Maltose is extensively used in food processing, alcohol production, different oligosaccharides and glucosides, pharmaceuticals, and the production of fine chemicals. The presence of maltose in the interstitial fluid higher than 107 mg/L will cause Syai Tag Sensor glucose readings to be higher than actual glucose levels, which could result in missed hypoglycemia alerts or errors in diabetes management. Consult your doctor about the intake of maltose when you use Syai Tag CGMS.

Syai Tag CGMS has undergone anti-interference tests at interferent concentrations higher than the maximum physiologic or therapeutic plasma concentration in the human body. The level of sensor accuracy depends on the level of xylose and maltose in the body. We recommend that users consult a doctor when they intake such substances in large quantities and always check blood glucose meter readings if in doubt.

Also, in commercially available CGMS products on the market, ascorbic acid and acetaminophen have been commonly identified by Abbott Freestyle Libre 2 and Dexcom G6/7 as interfering substances. The Syai Tag CGMS has demonstrated comparatively good anti-interference performance for these two interferents. Nevertheless, it is still recommended for patients to consult doctors if they are taking a high concentration of these substances and to seek professional advice.

16. Electromagnetic Compatibility

16.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Syai Tag CGMS is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR11	Group 1	The Syai Tag CGMS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

16.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Syai Tag CGMS is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge IEC61000-4-2	±8 kV contact ± 2, 4, 8, 15 kV air	±8 kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ bursts IEC61000-4-4	±2 kV 100kHz repetition frequency	N/A	The requirement does not apply to this battery-powered device.
Surges IEC61000-4-5	Line-to-line: ±0.5 kV, ±1 kV Line-to-ground: ±0.5 kV, ±1 kV, ±2 kV	N/A	The requirement does not apply to this battery-powered device.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% UT; 0.5 cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycles	N/A	The requirement does not apply to this battery-powered device.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30 A/m, 50Hz or 60 Hz	30 A/m, 50Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the table below	Compliance with the tested levels	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise, degradation of the System could result.
Note: UT is the a.c. mains voltage prior to application of the test level.			

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in various locations where the System may be used.

Frequency (MHz)	Band (MHz)	Level (V/m)	Modulation	Test Mode	Antenna Polarization	EUT Face	Result / Observations
385	380-390	27	Pulse Modulation 18Hz	Working mode & Standby mode	Horizontal & Vertical	Front Rear Left Right Top Bottom	A
450	430-470	28					
710	704-787	9	Pulse Modulation 217Hz				
745							
780							
810	800-960	28	Pulse Modulation 18Hz				
870							
930							
1720	1700-1990	28	Pulse Modulation 217Hz				
1845							
1970							
2450	2400-2570	28					
5240	5100-5800	9					
5500							
5785							

Guidance and manufacturer's declaration – electromagnetic immunity

The Syai Tag CGMS is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC61000-4-3	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Syai Tag CGMS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 x √P d=1.2 x √P 80MHz~800MHz d=2.3 x √P 800MHz~6.0GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)a. Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveyb., should be less than the compliance level in each frequency rangec.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. The compliance level of the ISM frequency band between 150 kHz and 80 MHz and the frequency range between 80 MHz and 2.5 GHz is used to reduce the possibility of interference caused by mobile/portable communication devices being accidentally brought into the patient area. To this end, an additional factor of 10/3 is used to calculate the recommended separation distance for transmitters in these frequency ranges.

b. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Syai Tag CGMS is used exceeds the applicable RF compliance level above, the Syai Tag CGMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Syai Tag CGMS.

c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

16.3 Radio Regulations Compliance

Recommended Isolation Distances for Portable and Mobile RF Communication Equipment and the Syai Tag CGMS

The Syai Tag CGMS is intended for use in electromagnetic loop mirrors where radio frequency radiation disturbances are controlled. The purchaser or user of the Syai Tag CGMS can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (Transmitters) and the Syai Tag CGMS as recommended below, based on the maximum output power of the communication equipment.

Transmitter power rating (W)	**Safety distance (m) according to the power of the transmitter**		
	150 kHz–80 MHz d=1.2 x √P	80 MHz–800 MHz d=1.2 x √P	800MHz–2.5 GHz d=2.3 x √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the Transmitter not listed in the table above, the recommended isolation distance d, in meters (m), can use the formula in the corresponding Transmitter frequency column, where P is the Transmitter's maximum rated output power in watts (W) as provided by the Transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the formula for the higher frequency band should be used.

NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

16.4 Warnings

Except for Monitors sold by the manufacturer of the equipment or system as spare parts for internal components, the use of unspecified accessories and Monitors may result in increased emissions or reduced immunity of the equipment or system.

Equipment or systems should not be used close to or stacked with other equipment, and if they must be used adjacent or stacked, they should be observed to verify that they function properly in the configuration in which they are used.

Active medical devices are subject to special EMC precautions and must therefore be installed and used under these guidelines.

Portable and mobile communication radio frequency equipment may affect the use of medical electrical equipment.

Even if other equipment complies with the emission requirements of the corresponding national standards, the equipment or system may still be interfered with by other equipment.

16. Packaging Symbols

CE	CE Mark
	Caution
	Follow Instructions for Use
	Do not use if package is damaged and consult the instructions for use
	Non-ionizing electromagnetic radiation
	Single use only. Do not re-use.
	MR Unsafe: The device presents a projectile hazard.
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
STERILE R	Sterilized using irradiation
	Do Not Throw in the Trash Can
	Date of manufacture
SN	Serial number
	Use-by date
	Type BF applied part
	Manufacturer
LOT	Batch code

EC REP	Authorized representative in the European Community
MD	Medical device
UDI	Unique device identifier
	Importer
IP28	Submersible: Waterproof to 1.5 meters (4.92 feet) for up to 30 minutes
Lithium battery 3V	Including 3V lithium battery
#	Model number
	Single sterile barrier system with protective packaging outside

18.Glossary

Glucose reading	It refers to the glucose results measured with the glucose meter or from the CGM device.
Continuous Glucose Monitoring System	Continuous Glucose Monitoring system (CGMS) refers to the technology used to indirectly reflect the glucose level by monitoring the glucose concentration in the subcutaneous interstitial fluid with a Sensor. It can provide continuous, comprehensive and reliable glucose information throughout the day to enable the user to understand the trend of glucose fluctuations and discover any hidden hyperglycemia and hypoglycemia that are not easily detected by traditional monitoring methods.
Continuous Glucose Monitoring Device	An all-in-one design comprises a Monitor and an Applicator. It refers to a medical device used to measure glucose concentration in the interstitial fluid.
Monitor	Comprises a Sensor and a Transmitter which are collectively referred to as the "Monitor". Users can directly use the Monitor without performing any assembly tasks. The Monitor fits on the surface of the skin and needs to be replaced every 14 days. During this period, it monitors the user’s glucose level in real-time.
Mobile device	It includes smartphones, tablets, smartwatches and any other electronic devices that can connect wirelessly to a network via Wi-Fi, Bluetooth, or cellular data connections (2G, 3G, 4G, 5G, etc.).
Mobile App	App refers to mobile applications designed to run on smart devices. The Syai Tag App is used with the Syai Tag CGMS Device for continuous monitoring of glucose.
Note	To explain nouns and paragraphs.
Warning	To inform you of any potential hazards.