USER GUIDE

Model: X1

Version A/2
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CONTENTS

1. Welcome onboard: Discovering your Syai Tag

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

1.1 Product Introduction

Syai® Tag CGM System can automatically track your glucose levels, also called blood sugar levels, in real-time with a 5-minute interval, continuously for 14 days. You may obtain a very comprehensive understanding of how your glucose changes over time, which will assist you and healthcare professionals in making more informed decisions about how to balance 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 CGM System:

- **Smaller, lighter, and thinner:** Syai Tag Monitor is smaller than a quarter and weighs only 1.6 grams.
- **Integrated design and ease of use:** Syai Tag has an integrated design of sensor and transmitter and requires no assembly, making it easier to use.
- **Factory calibration:** No need for fingerpick calibration. Factory calibration algorithm and deep learning algorithms to improve accuracy and forecasting capabilities.
- **High accuracy:** Syai Tag is clinically proven to have a Mean Absolute Relative Difference value of 8.106%.
- **Real-time readings and stable software:** Syai generates real-time readings every 5 minutes and stores up to 14 days of glucose data even when data transmission is blocked.
- **Multiple alert methods:** Glucose Alerts and Monitor Connection Status can reach you through mobile phone ringing or vibration, notifications within Syai Tag app, desktop widgets, system notifications, and smartwatches to ensure that the user receives important information timely.
- **In-app Glucose Report:** Syai offers comprehensive blood glucose report for more personalized analysis.
- **Share and follow:** You can easily share glucose data with family, friends, and your doctors.

Clinical benefits:

Complications as a result of 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 glycemic 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 on 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.

Syai® Continuous Glucose Monitoring System can provide real-time glucose monitoring and store the reading 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 Components

Each Syai Tag product contains:

- A CGM Device - including an Applicator and a Monitor
- A Patch - Assist in keeping the Monitor on your body

To be used in conjunction with a Syai Tag mobile application

The Syai CGM Device

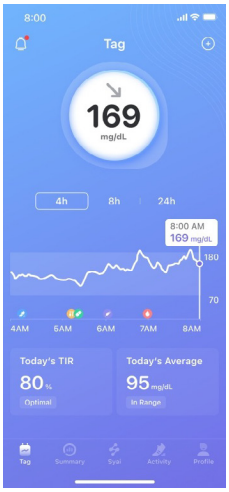
The Syai CGM device is composed of a 14-day wearable Monitor and a fully disposable Applicator. Use the Applicator to apply the Monitor to your body.

The Patch

A patch comes with each device, please use it whenever you feel the Monitor is no longer firmly attached 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 events.



1.4 Contact Information

Name of manufacturer:Syai Health Technology Pte., Ltd.

Address: #03-01 112 Robinson SINGAPORE 068902

Factory address: Room 210, floor 2, building 3, yard 58, Jinghai fifth road, Beijing Economic Technological Development Zone, Beijing, PEOPLE'S REPUBLIC OF CHINA.

Manufacture's contact information: 0086-400-0860-509

After-service provider: Syai Health Technology Pte., Ltd.

Lay operators or responsible organizations should contact Syai Health Technology Pte., Ltd. through the before-mentioned contact address or the after-mentioned EU agent contact address:

- For assistance if needed, in setting up or operating the Syai(®)device.
- To report unexpected operation or events.

EU Agent Information

Agent name: Luxus Lebenswelt GmbH

Agent address: Kochstr.1, 47877, Willich, Germany

Tel: 0049-1715605732

SRN: DE-AR-000005110

2. Important Safety Information

Before using the Syai® CGM System, please ensure that you have fully read and familiarized yourself with this Instructions for Use. Any failure to follow the instructions may result in pain or harm or may even affect the performance of the system. For any questions about the use of this product, please consult medical staff or contact the Syai® support team or the local distributor of Syai®.

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

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

Upon unpacking the product, check whether the product is intact. If any parts are missing or damaged, please contact the Syai® support team at 400-9039-130.

2.1 Indications for use

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 individuals for better management of diabetes, helping individuals make decisions about medication, diet and exercise, and improving 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 use by individuals.

2.2 Contraindications

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

01. Patients with allergic skin should use the product with caution.
02. Patients prone to skin ulcers are prohibited from using the product.
03. Patients suffering from bodily fluid-borne diseases should consult the doctor before any use.
04. Patients with insufficient self-care abilities should use the product only when supervised

by a caregiver who is at least 18 years of age.

05. 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.

2.3 Precautions

01. Please use the device according to the Instructions for Use, otherwise damage to the device may be caused.
02. 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.
03. Do not reuse this single-use product or share it with others.
04. Do not freeze this product.
05. Do not expose this product to direct sunlight or high temperatures.
06. Do not apply the Monitor onto sites that may be frequently rubbed by clothing, have scars, or with frequent movement.
07. Store the product in a cool and dry place before opening. Do not open the package with wet hands.
08. 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 is allowed.
09. Restart the "Syai®" Mobile App each time after restarting your mobile phone.
10. Evaluation on performance of the system when used with other implantable medical devices (i.e. pacemaker) has not been conducted.
11. It is unclear that to what extent the diseases suffered by critically ill patients, or their used drugs, will affect the performance of the Monitor. Hence, glucose readings of the Monitor may be inaccurate when used to monitor the critically ill patients.
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 Sensor.
14. Do not change or modify the device. Changing or modifying the device can result in improper insertion, pain, or injury.
15. Do not use products beyond the valid period.
16. Connect 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, airplanes, etc., as these networks are not secure and connect to this kind of WI-FI do not need a password to connection, connect to it could result in exposing your phone to the malware. In smart device settings, turn on screen auto-lock and use a

strong password

17. The dust-proof and waterproof class of Syai(®) is IP28, the Sensor is protected by a sterile barrier, and the sterile barrier will be breached after opening the device; the device must be used immediately after the device is opened.
18. Do not use the device near a heat source like a fireplace or radiant heater, in which environment the temperature could be over the maximum operating temperature.
19. Please make sure that small children or pets cannot pull the Monitor from your arm when wearing the Monitor.

2.4 Warnings

01. Do not use the Syai Tag if the packaging has been damaged or opened.
02. 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.
03. Avoid apply the Monitor on the same site repeatedly, inserting the Monitor into the same site may cause scarring or skin irritation.
04. Never allow children to hold the device without adult supervision. The device includes small parts that may pose a choking hazard.
05. Always seek professional medical help when suffering infection or inflammatory symptoms, swelling or pain, at the insertion site.
06. Do not ignore symptoms that may be caused by 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.
07. Do not use the device outside of the intended use environment. Use the device outside of the intended use environment may cause inaccurate glucose reading.
08. Contact customer service at 400-9039-130 if your Monitor is damaged.

2.5 RF Communication

The Syai(®) Continuous Glucose Monitor 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 suggested to mitigate the interference by moving the Monitor farther away from the disturbed reception.

The Monitor uses RF energy only for its internal communication with the smart device. Therefore, its RF emissions are very low and are not likely to cause any interference in 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 with the Monitor. However, such interference will not cause any inaccurate data or any damage to your device.

The RF communication distance between the glucose 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.

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

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

2.7 Waste Disposal

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

Contact Customer Service for further information on the appropriate disposal of system components.

3.Using Your Monitor

To use your Monitor successfully, an **NFC-enabled** cell phone with Android 5.0 or higher and iOS 13.0 or higher is required.

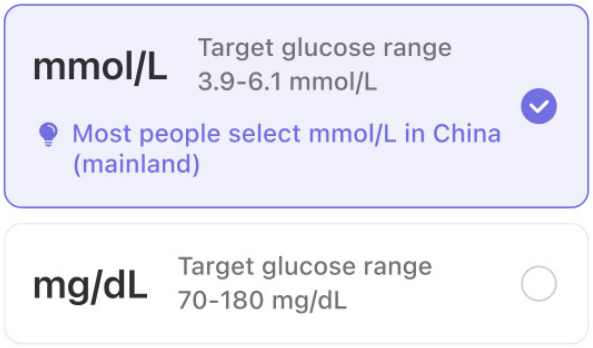
3.1 Set up your smartphone

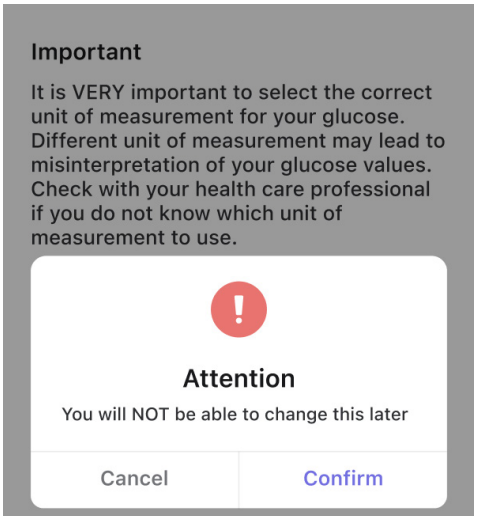
Internet access is required during the entire setup.

- **Install the application:**
  - Download your **Syai Tag** app:
    - Option 1: Open the lid of the outer packaging, two QR codes can be seen on the top of the can seal, scan the corresponding QR code to download the APP.

    - Option 2: Search for “Syai Tag” in your mobile device’s app store. Then follow the steps to install it.

- **Log in the app:**
  - Tap syai on your mobile device to launch the App.
  - Follow the steps on the screen to sign up.
  - Login your Syai Tag App.
- **Set up your app:**
  - Select the unit of measurement and confirm. If you are not sure, check with your doctor.





It is VERY important to select the right unit of measurement for your glucose. The wrong unit of measurement may lead to misinterpretation of your glucose values. Check with your healthcare professional if you do not know which unit of measurement to use.

Once you have confirmed this option, it cannot be changed.

- Follow the steps on the screen to set up your Syai Tag App, including:
- **Enable Bluetooth:** Bluetooth function is necessary to connect your Monitor.• Follow the steps on the screen to set up your Syai Tag App, including:
- **Enable Bluetooth and Location:** 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.• Follow the steps on the screen to set up your Syai Tag App, including:
- **Enable NFC:** NFC is necessary for activating your Monitor.
- **My Health Condition:** Essential information for personalized glucose management.

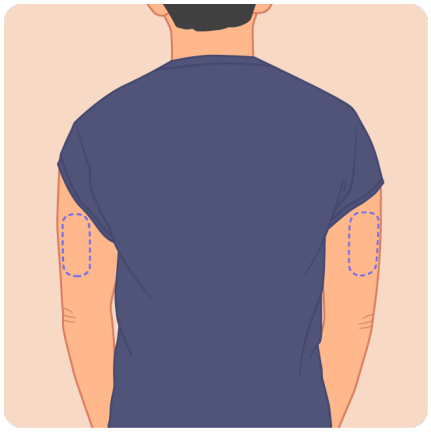
- When you have reached the Apply new Monitor screen, go to the next page of this User Guide for Applying Your Monitor.

3.2 Applying Your Monitor

First time user: After you set up your Syai Tag app, tap Apply new Monitor on the screen.

Replacement with new sensor: Make sure that the previous monitor has stopped monitoring, tap Apply new Monitor on the Syai page or the Profile page.

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



Note: For best monitor performance, Select a site:

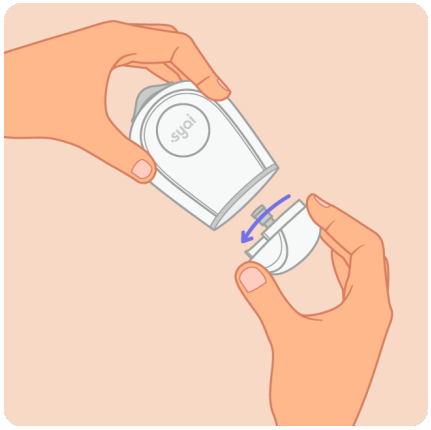
- Without scars, moles, lumps, or tattoos
- Avoid bony areas and irritated skin
- Generally stays flat during your normal daily activities
- At least 25 cm (1 inch) away from an insulin injection site
- Not the one most recently used, to prevent discomfort or skin irritation

- **Step 2: Clean the application site with alcohol pads 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.

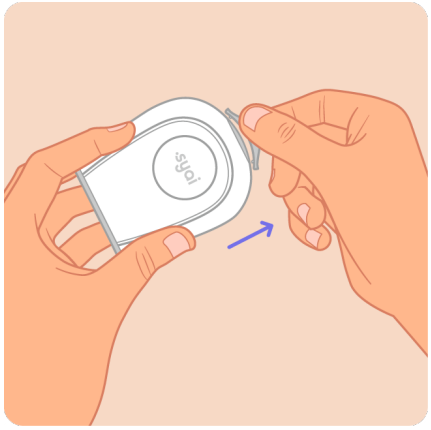
- **Step 3: Rotate open the bottom cover of the Applicator.**



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 use if past the expiry date.

- **Step 4: Remove the safety cap on the top of the Applicator.**



Caution:

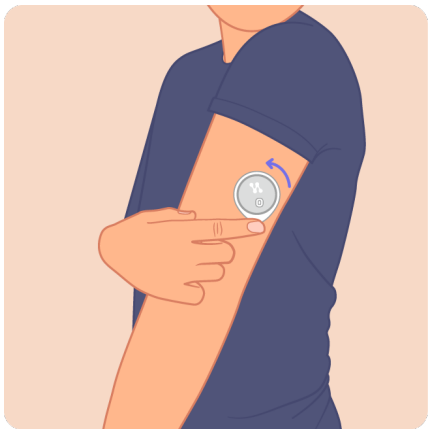
- DO NOT touch the button under the safety cap yet to prevent launching the Monitor unintentionally.

- **Step 5: Place the Applicator over your arm, press the gray 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 6: Gently press the tape around the edge of the Monitor to attach it firmly to the skin.**

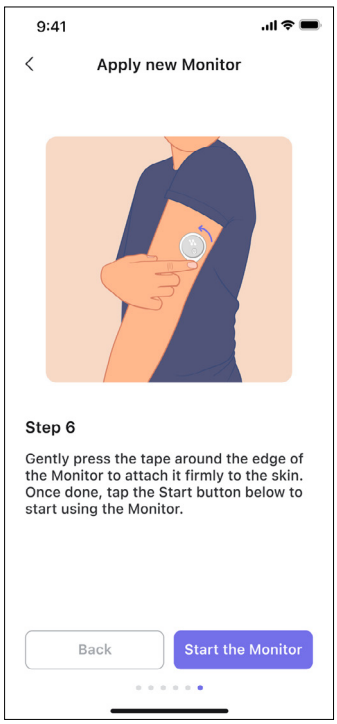


Note:

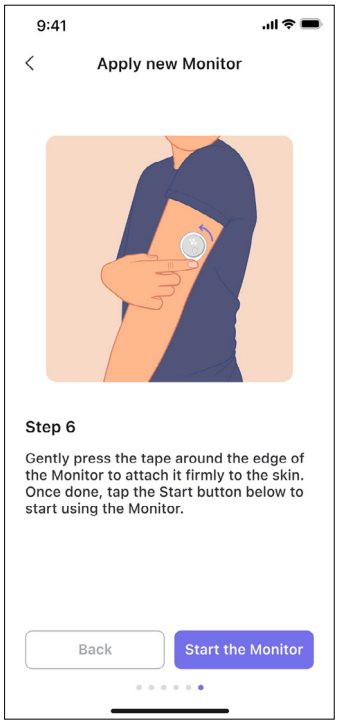
- Discard used applicators following local guidelines for disposal of blood contact parts.

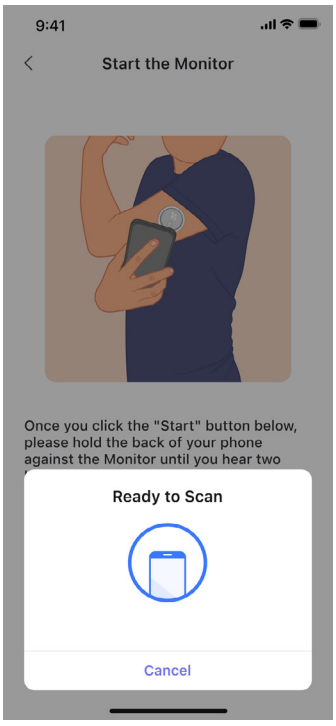
3.3 Starting Your Monitor

- **Step 1:** After successfully applying your Monitor, tap the **Start the Monitor** button on your phone screen.



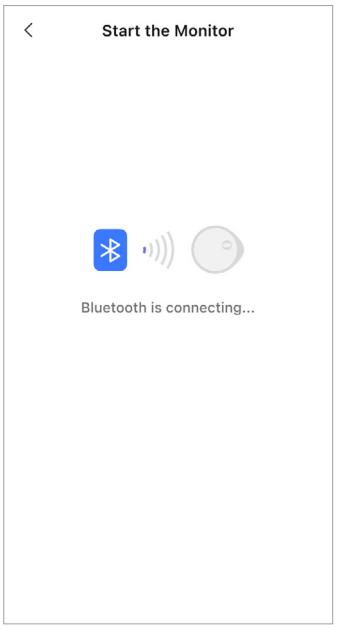
- **Step 2: Activate your Monitor:**
  - Tap the Start button
  - Ready to Scan pops up on your phone's screen.
  - Hold the back of your phone against the Monitor until you hear a beep sound or sense vibrations.

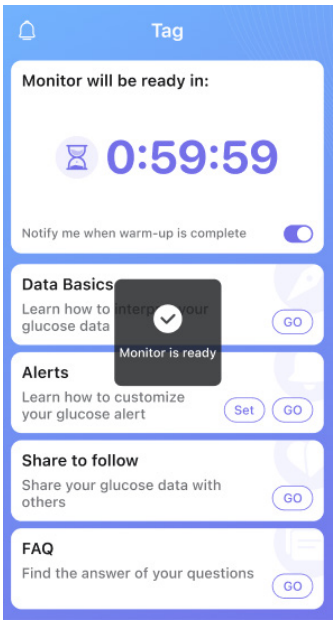




- **Note:**
  - You may need to move the phone to make sure the phone's NFC antenna is close to the Monitor.• Ready to Scan pops up on your phone's screen.
  - Different cell phones may beep and vibrate differently, perhaps once or twice.

- **Step 3: Connect your Monitor:**
  - After the beep or vibrations, the Monitor will start connecting to the phone via Bluetooth.
  - Bluetooth connection will be done in seconds.
  - You will reach the countdown page. The "Monitor is ready" status indicator will show up for a few seconds.



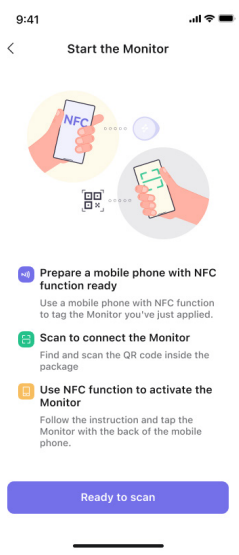


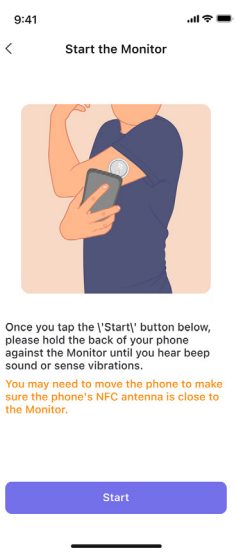
- **Note:**
  - Connection failure may occur, rescanning the Monitor always helps.

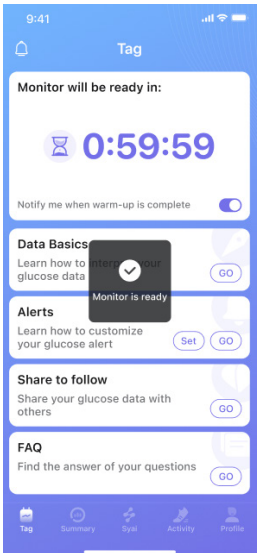
No NFC function on the phone?

Prepare a mobile phone with NFC function ready.

- Use the phone with the NFC function to tap the Monitor you've just applied.
- Scan the QR code inside the package using the cell phone camera intended for connection with the Monitor.
- Use the NFC function to activate the Monitor. Refer to the "Activate your Monitor" section of this chapter for details.
- After your Monitor has been successfully activated by NFC, it connects via Bluetooth to the non-NFC phone that has scanned the QR code as mentioned above, and the phone's screen goes to the "Bluetooth is connecting" page.
- Bluetooth connection will be done in seconds. You will reach the countdown page.

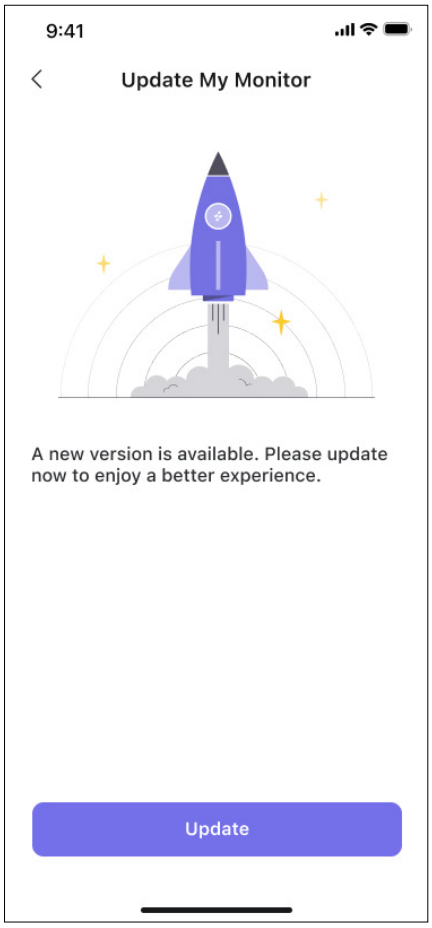






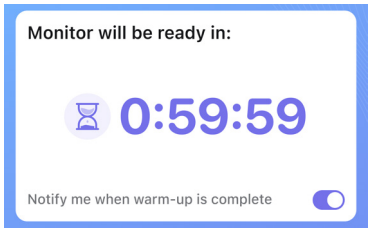
Getting an upgrade alert?

- 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.

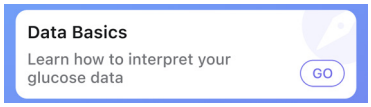


3.4 Do something during the warm-up

Monitor warm-up time is 60 minutes. During this period, you can learn more about using the Syai Tag CGM system, including data interpretation, alert settings, glucose data sharing, and FAQs!

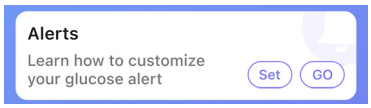


- You will receive a notification when the warm-up period is finished. This notification is turned on by default.



Go to learn how to interpret your glucose data:

- Glucose trend arrow
- Data color inside the bubble of the graph
- Daily Graph
- Multi-day Graph
- Glucose Fluctuation



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

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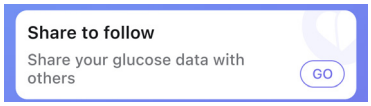
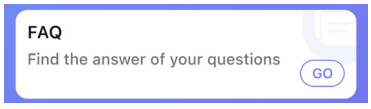


Jump to the function page of Family Care.

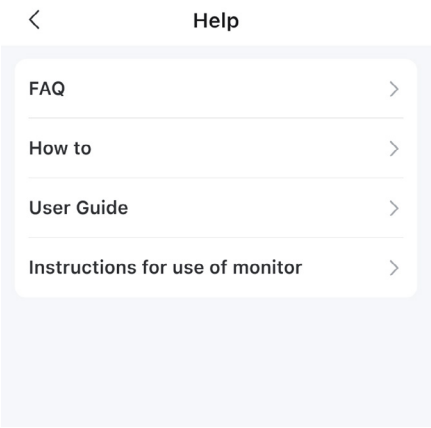


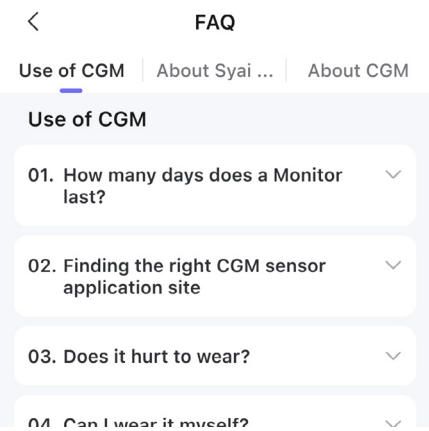
Find the answers to your questions, including:

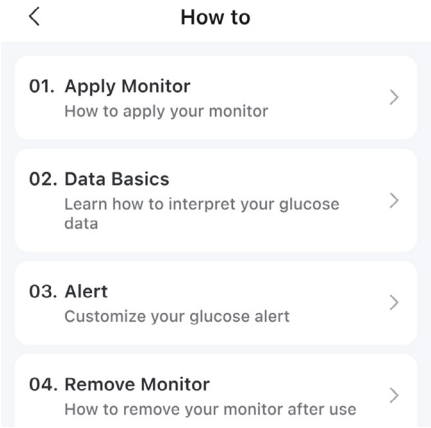
- Use of Syai Tag CGM
- About Syai Tag App
- About CGM

You can access all these instructions or settings pages again in the App at any time you want if you don't have time to do this now.

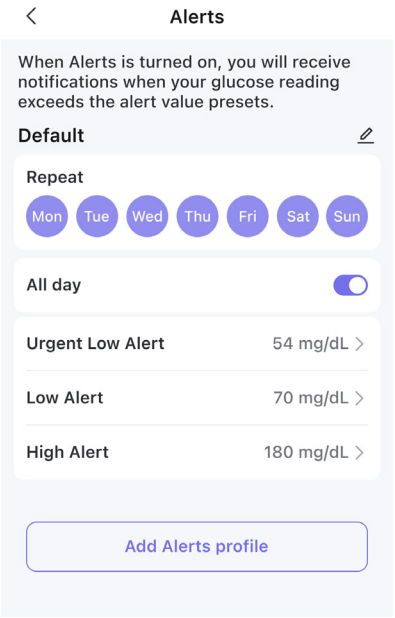
- Profile>Settings>Help:







- Profile>Settings>Alerts:



3.5 Removing Your Monitor

When your Monitor has been worn for 14 days, or after tapping the "End my session" button, the Monitor will stop working. Make sure all data has been uploaded and you can do this by following the instructions prompted.

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 warm soapy water or isopropyl alcohol.
- Discard the used Monitor following local guidelines for the disposal of parts that have been in contact with body fluids.

Replacing Your Monitor within 14 days if:

- Notice any irritation or discomfort at the application site.
- Syai Tag app reports a problem with the Monitor currently in use.
- Monitor tip has come out of your skin, or is coming loose.

Taking action early can prevent more risky events.

⚠ If the glucose readings from the Monitor do NOT seem to match with how you feel, check to make sure that your Monitor has not come loose. If the Monitor tip has come out of your skin, or is coming loose, remove the Monitor and apply a new one.

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

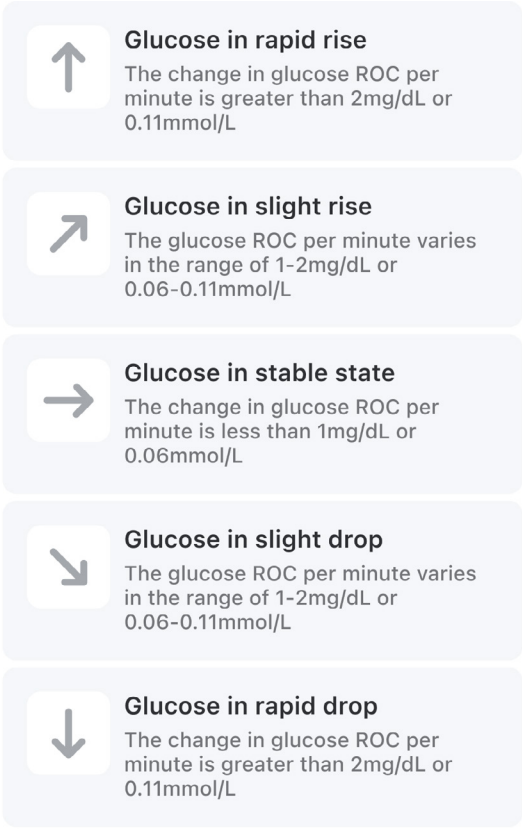
4.1 Quick Guide to Navigating the App Interface

Syai Tag APP contains three functional pages: Syai real-time monitoring page, Summary page and your Profile.

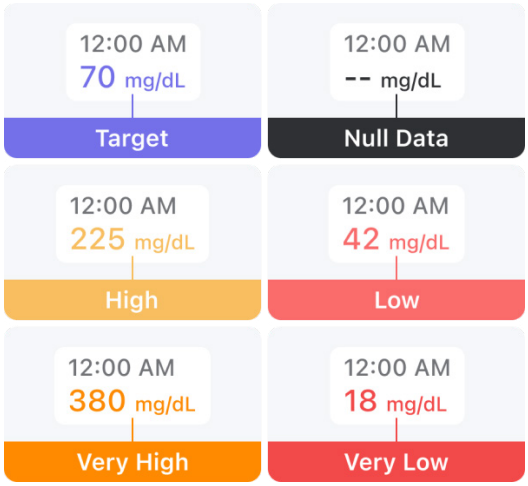
- Syai real-time monitoring page: display real-time readings and glucose trends, view 4h/8h/24h glucose curves.
- Summary page: review and analyze historical data, with rich data analysis dimensions.
- Profile: check device status, invite friends and family/doctor to follow, view glucose report, set glucose target and glucose alert, etc.

4.2 Interpreting Real-Time Glucose Levels

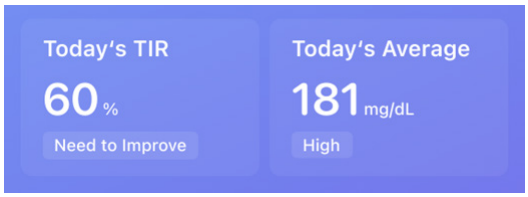
Syai real-time monitoring page is displayed when you tap on the Syai Tag app icon on your phone's screen. You can check glucose readings here. Your Readings include your Current Glucose, Glucose Trend Arrow, Glucose Graph, and a Glucose Bubble on the graph.



- Current Glucose: Readings are automatically updated every 5 minutes.
- Glucose Trend Arrow: Indicating which way your glucose is going.



- Glucose Graph: Show your glucose readings in the past 4 hours, 8 hours, or 24 hours.
- Glucose Bubble: Displays the time and glucose level at the corresponding point on the glucose graph.
  - When the label stays at the right end of the graph, it displays the current glucose level and the time stamp.
  - The data is shown in different colours 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.

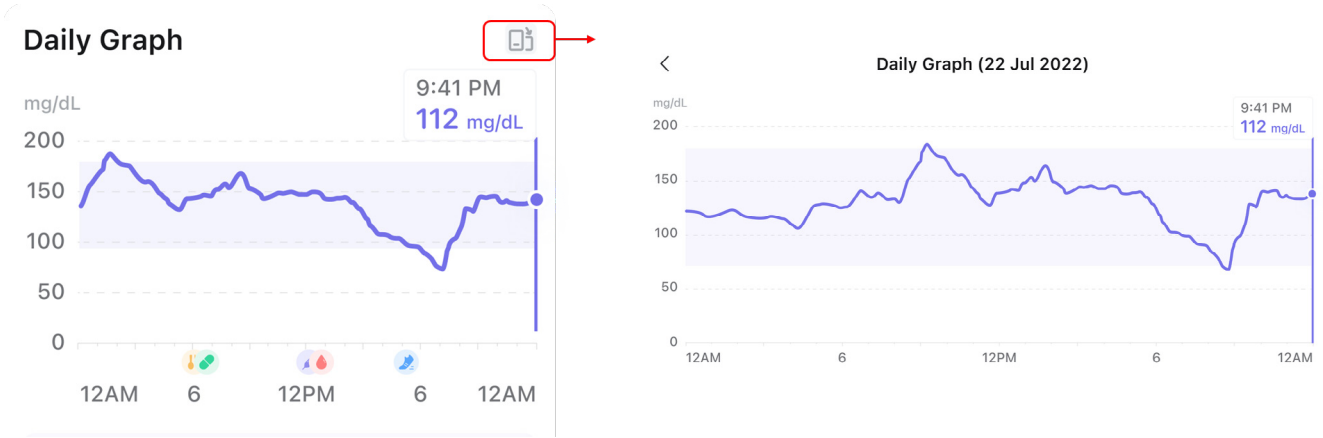
⚠ WARNING: Although the Alert function has been tested in clinical settings, if you have symptoms that do not match well with the Alert information, or Alerts are not triggered when you experience hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, check your glucose by conducting a finger-stick test using a BGM and consult your healthcare provider for professional advice.

4.3 Utilizing Graphs and Historical Data for Better Insights

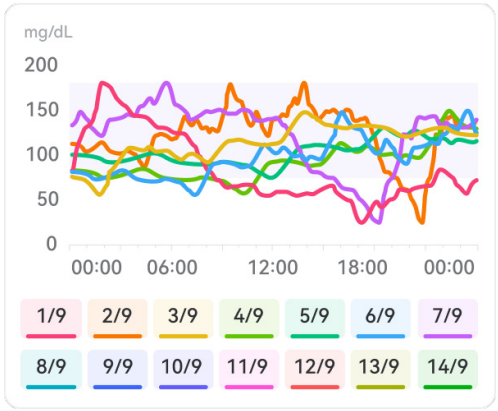
You can explore more data analysis insights by clicking on the summary button. You can see daily data, 7-day data, 14-day data, 30-day data, and 90-day data. The analysis dimension includes TIR, single day glucose curve, multi-day glucose curve, AGP map, high and low glucose event distribution, and multi-metric insights.

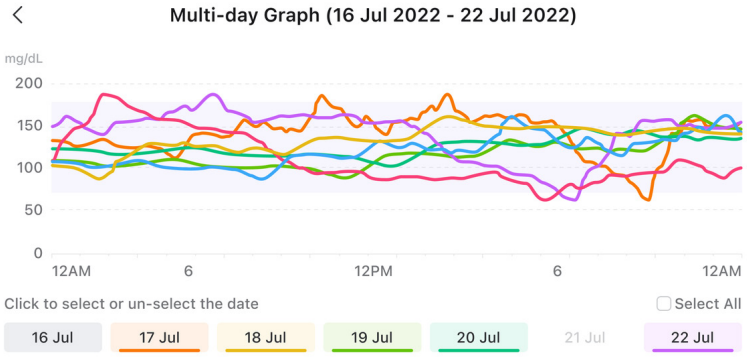
- TIR: Time in Range shows the percentage of time your glucose reading was above, below, or within your target range during the monitoring period, providing a more complete picture of your level of glucose control. Tap on the rings to see more specific analyses!

- The Daily Graph plots the glucose curve for the day you choose, reflecting the change in your glucose for that day and the time interval within your target range. Click on the horizontal button in the upper right corner of the daily curve, the curve will be expanded to a horizontal full-screen display for your convenience.

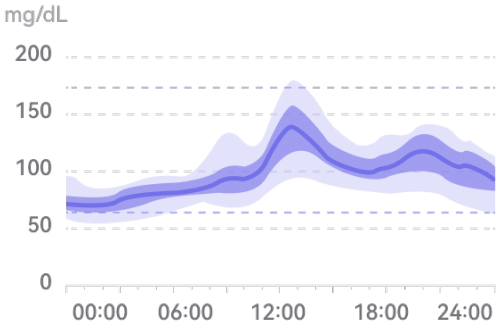


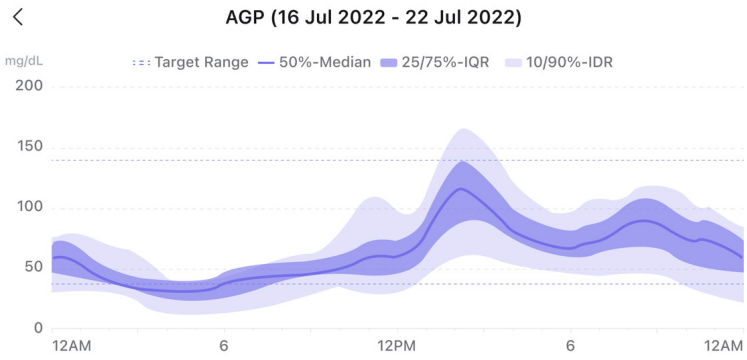
- The Multi-day Graph plots all the glucose curves for a date range of your choice, with each curve representing each day's glucose variation, and you can select the curve you wish to view by tapping on the date marker below the graph. It also can be expanded to a horizontal full-screen display.





- The AGP represents your glucose fluctuations. It also can be expanded to a horizontal full-screen display.



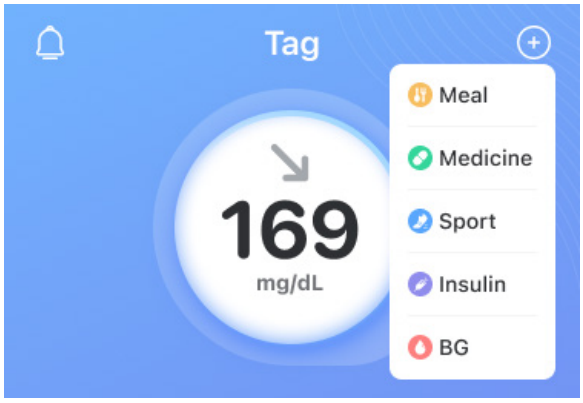


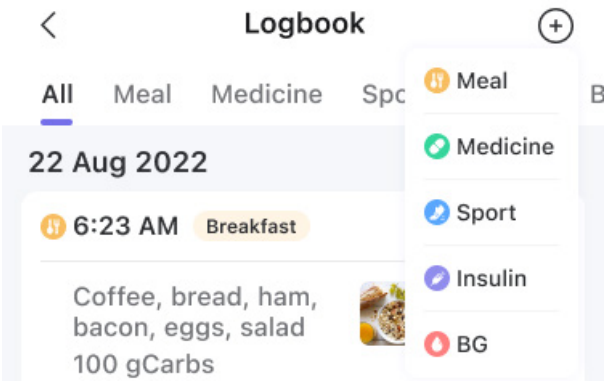
Can't keep track of it all at once? Any time you click on each data card, it will flip to show a detailed explanation of the parameter's data analysis insights. We provide recommendations and analysis based on the statistical performance of these metrics.

5. Advanced Features

5.1 Lifestyle Tracking and Analysis

You can tap + on the Syai page of the app or in the Logbook to record an event such as: Having a meal, Taking Medicine, Doing Exercise, Insulin Injections, or BG measurements. Based on these records, blood glucose data can be analyzed more specifically.





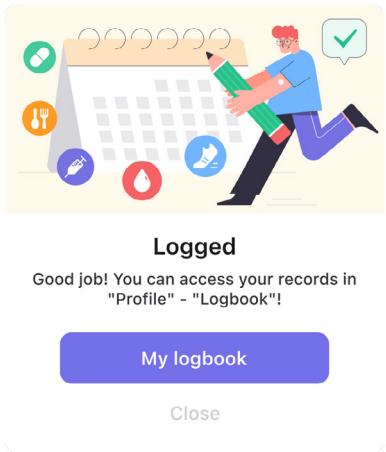
- **Log a new event**
  - **Log a Meal**

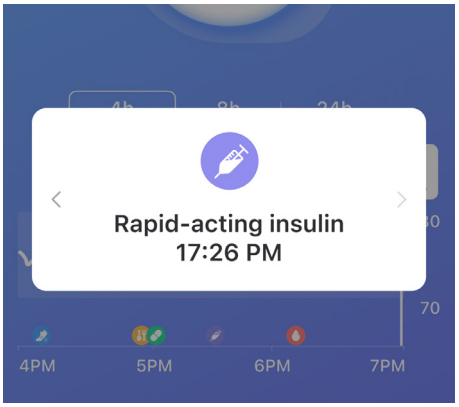
  Click "+", select Meal, check meal time and meal type, enter carb grams, and optionally upload food photos if needed, and click Done.
  - **Log a Medication**

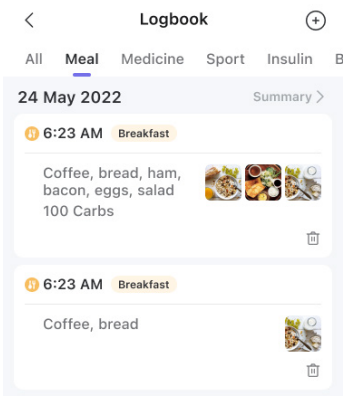
  Click "+", select Medicine, check the time of medication, upload a photo of the medicine, and click Done.
  - **Log an Exercise**

  Click "+", select Sports, check the start time of the sports activity, select the type of sports, enter the number of minutes and calories consumed, and click Done.
  - **Log an Insulin Injection**

  Click "+", select Insulin, check injection time, select insulin type, enter the number of insulin units, and click Done.
- **View Log History**
  - Tap on My Logbook in the "Submission Confirmed" window.
  - – Tap the icon below the graph to view log details at that moment, and tap the arrows "<" ">" on either side of the card can switch the display.
  - – Go Profile>Settings>Logbook







5.2 Explore Your AI Glucose Buddy: Tailored Management at Your Syai Tag

Syai Tag app is equipped with a ChatGPT-driven AI expert who responds to users' inquiries 24/7. The AI expert constantly learns from users' inquiries and outputs more and more personalized responses to serve patients' needs.

Tap the droplet shape with Current Glucose Reading to enter the AI Interactive Interface.(Make sure the device is connected to a trusted Wi-Fi network beforehand and "Syai Ai" option is enabled in the app setting page.)

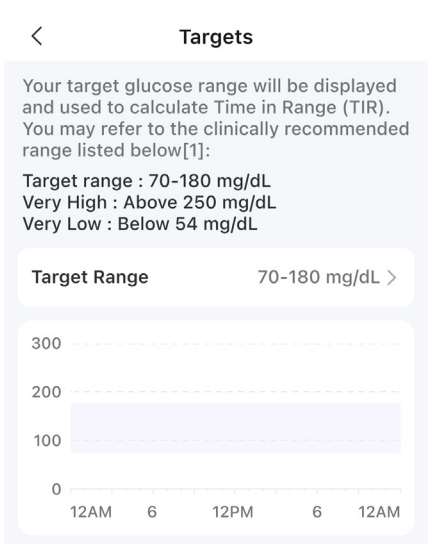
--By default, the option would be enabled. Please check the setting again if the feature is not present after tapping.

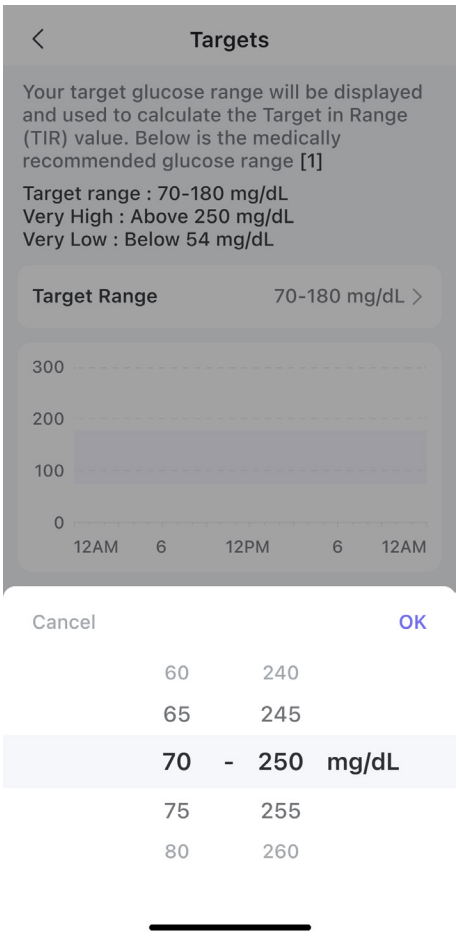
6. Set Your Glucose Target

Your target glucose range will be displayed and used to calculate Time in Range (TIR). Glucose Target is 3.9–10.0 mmol/L or 70–180 mg/dL by default in Syai Tag. 3.9–10.0 mmol/L or 70–180 mg/dL is the international consensus for the recommended target range. This target is recommended for most diabetes patients.
You can also customize your glucose target range to make the range more tailored to your needs.

> ⚠ It is VERY IMPORTANT to set the correct target glucose range. If you want to customize your target blood glucose range, make sure you discuss this with your doctor and always follow their advice.

Go to: Profile>Settings>Targets





7. Alerts

⚠ WARNING: You must allow notifications for your Syai Tag app during 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.

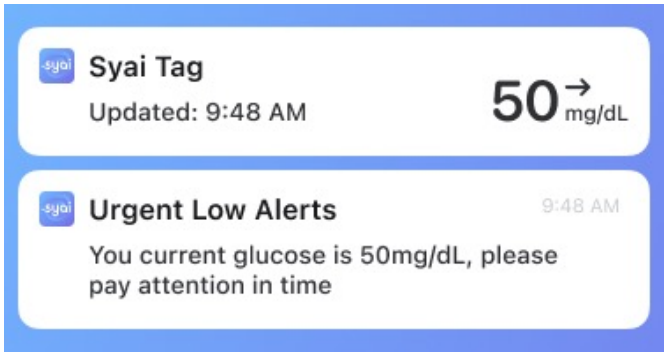
Your alerts help you keep your glucose within the range you set. You'll receive an alert when your glucose is out of the set alert range, at or below 60 mg/dL or 3.3 mmol/L. You can check with your doctor to see what is right for your alert range and customize the settings in the App.

7.1 Types of Glucose Alerts

7.1.1 Urgent Low Alerts

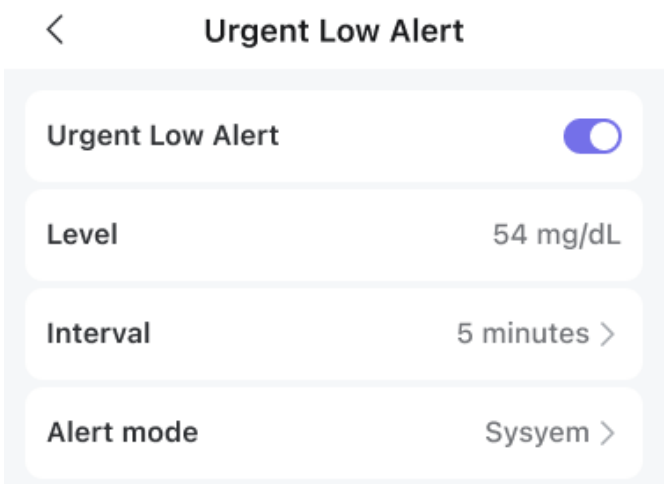
How alerts are triggered

Alerts you when your Monitor reads 60 mg/dL or 3.3 mmol/L or less.



How to set it up

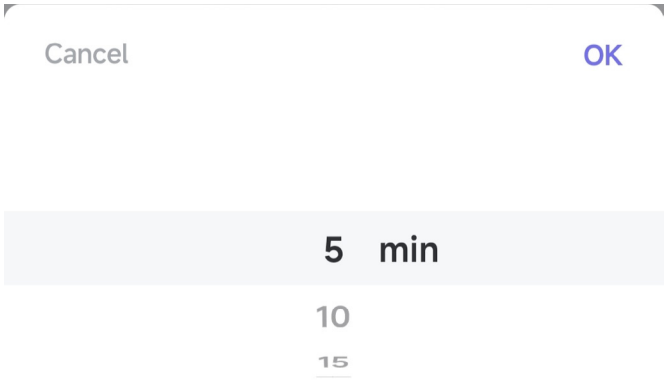
App Settings Path: Profile>Settings>Alerts>Urgent Low Alert.



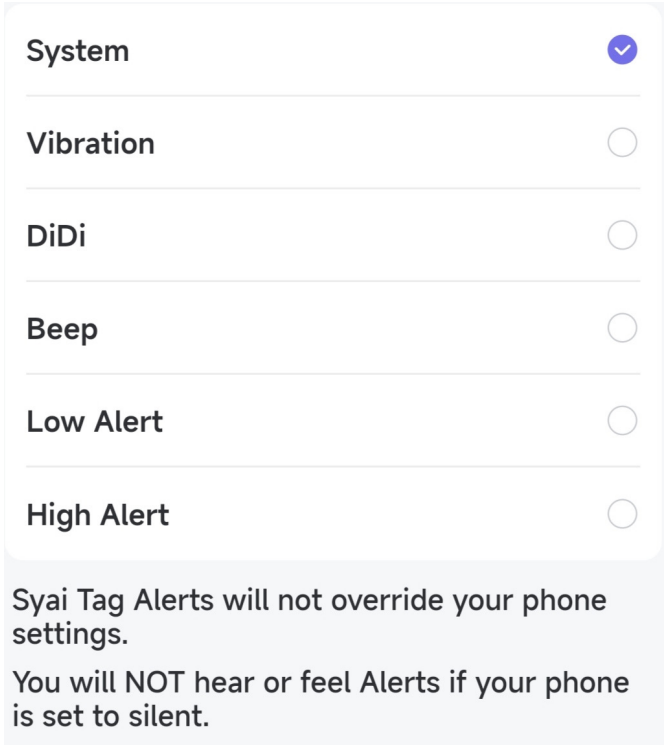
a. Urgent Low Alerts: Tap the button switch at the top to turn on/off the emergency low alert;

b. Level: Emergency hypoglycemia is 3.0 mmol/L or 54 mg/dL by default, which can not be changed, and reminds you when it is lower than the default value;

c. Interval: You can set the reminder interval. When you have prolonged emergency hypoglycemia, we will alert you based on the interval you set;



d. Alert mode: You can set the reminder mode, select vibration and ringtone, and there are a variety of ringtones to choose from.

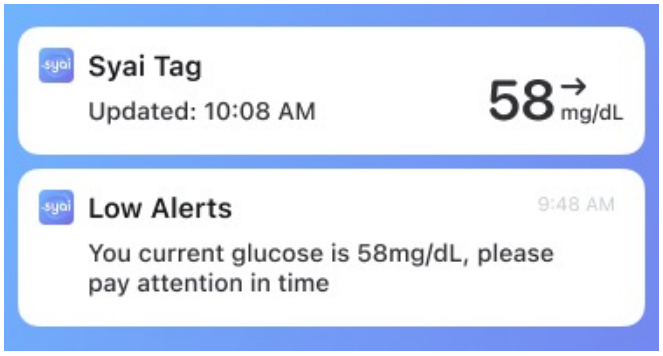


⚠ WARNING: Although the Alert function has been tested in clinical settings, if you have symptoms that do not match well with the Alert information, or Alerts are not triggered when you experience hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, check your glucose by conducting a finger-stick test using a BGM and consult your healthcare provider for professional advice.

7.1.2 Low Alert

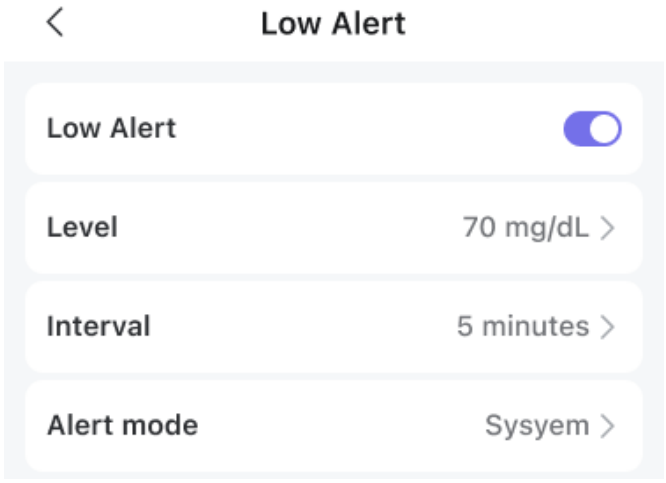
How alerts are triggered

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



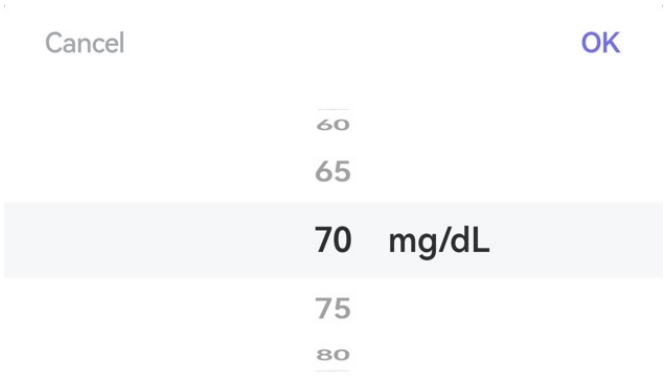
How to set it up

App Settings Path: Profile>Settings>Alerts>Low Alerts.

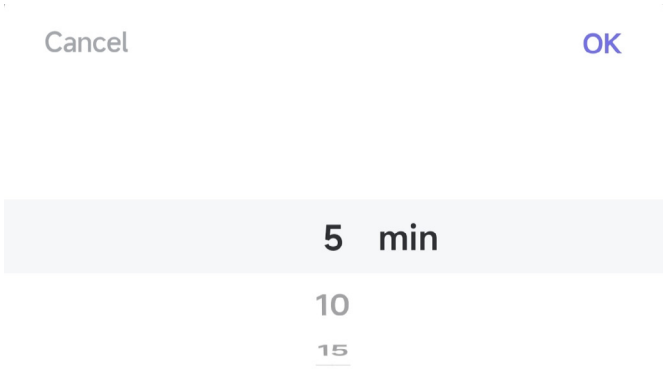


a. Low Alert: Tap the button switch at the top to turn on/off the low alert;

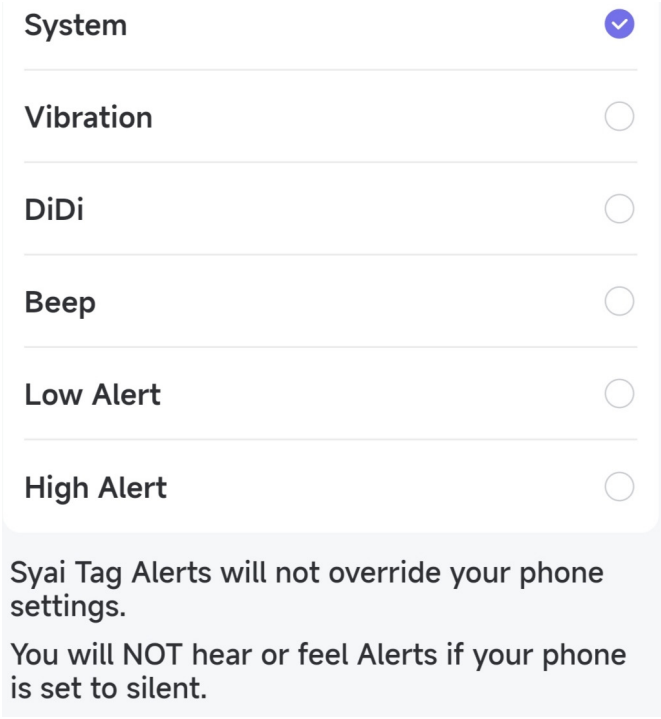
b. Level: You can modify the reminder value to remind you when the glucose is lower than the set value;



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



d. Alert mode: You can set the reminder mode, select vibration and ringtone, and there are a variety of ringtones to choose from.

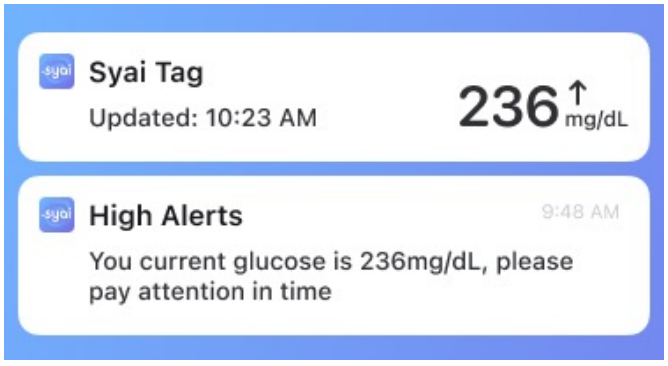


⚠ WARNING: Although the Alert function has been tested in clinical settings, if you have symptoms that do not match well with the Alert information, or Alerts are not triggered when you experience hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, check your glucose by conducting a finger-stick test using a BGM and consult your healthcare provider for professional advice.

7.1.3 High alert

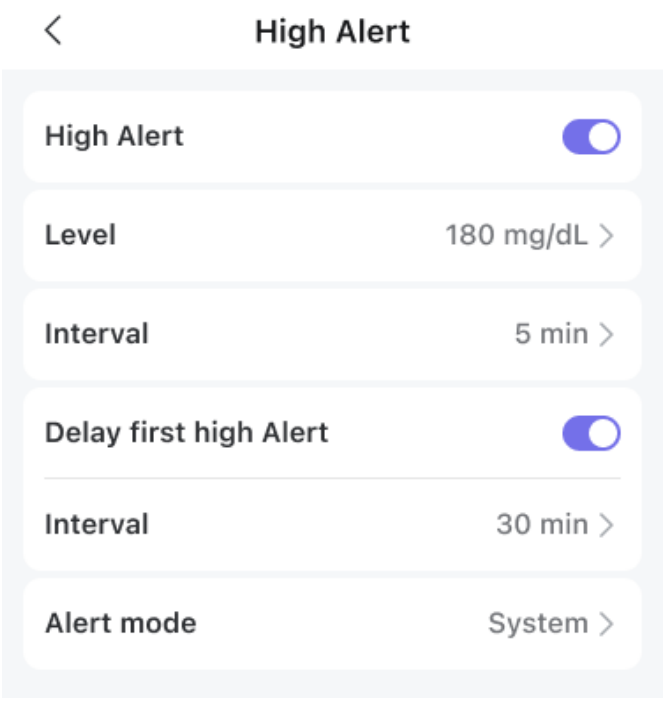
Trigger conditions

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



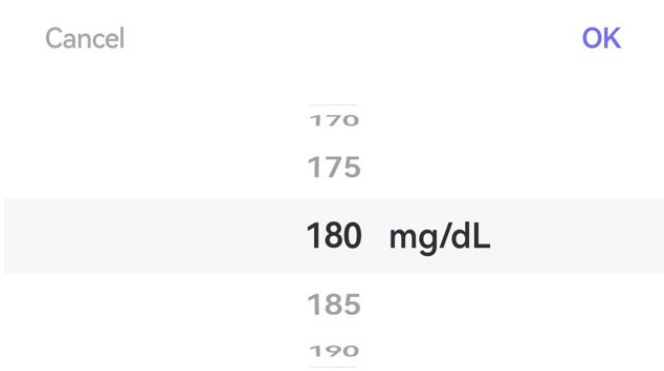
How to set it up

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

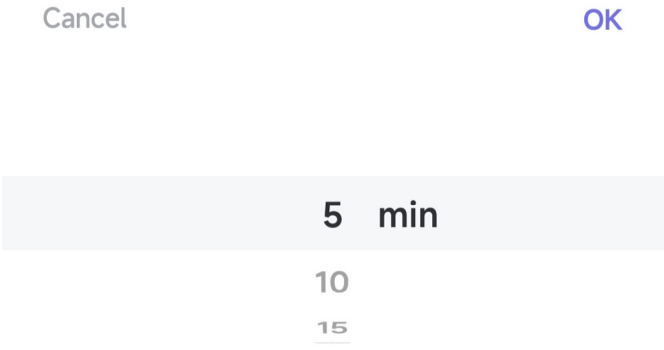


a. High Alert: Tap the button switch at the top to turn on/off the high alert;

b. Level: You can modify the reminder value to remind you when the glucose is higher than the set value;

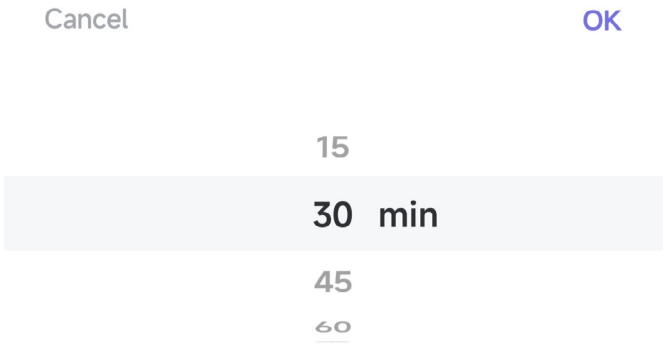


c. Interval: You can set the reminder interval. When you have a long period of high glucose, we will remind you according to the interval you set;

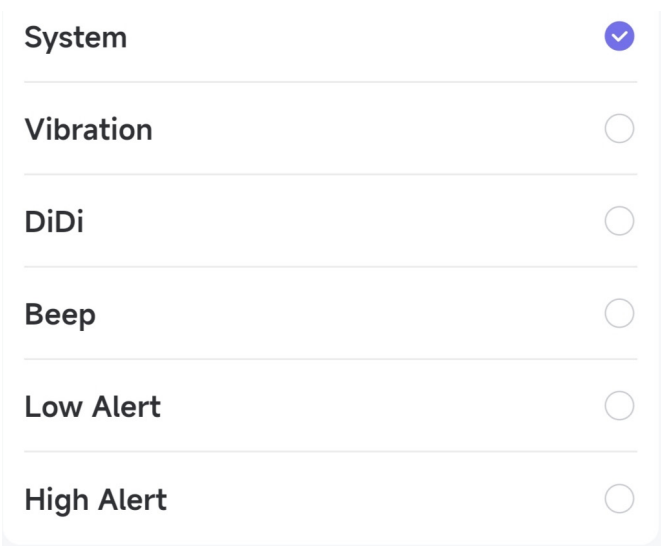


d. Delay First High Glucose Alert: Turn on the first high glucose delay reminder, and remind you after the glucose is higher than or equal to the glucose value you set for a period of time, you can choose the length of time.

If you set the Interval for High Alert to 30 minutes, you won't receive the first reminder until 30 minutes after your glucose reaches the high glucose setting;



e. Alert mode: You can set the reminder mode, select vibration and ringtone, and there are a variety of ringtones to choose from.

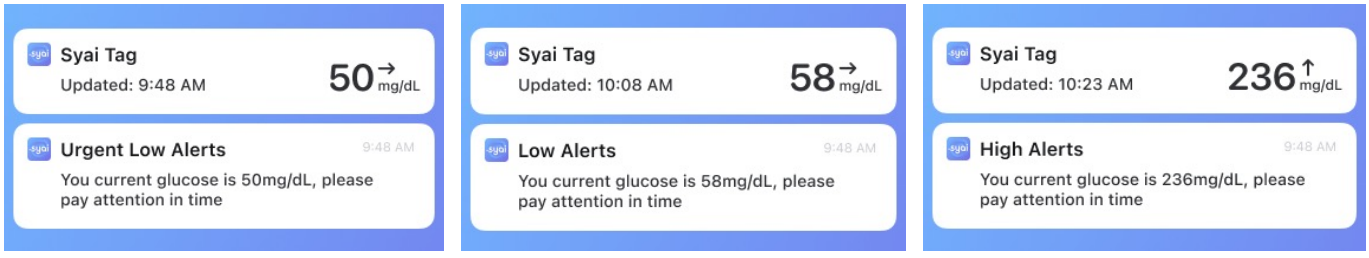


⚠ WARNING: Although the Alert function has been tested in clinical settings, if you have symptoms that do not match well with the Alert information, or Alerts are not triggered when you experience hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, check your glucose by conducting a finger-stick test using a BGM and consult your healthcare provider for professional advice.

7.2 Acknowledge alerts

When you receive an alert, you'll need to acknowledge the alert and make a decision to respond.

Acknowledge that you've received a glucose alert by tapping Alerts.



Alternatively, you can acknowledge the alert from the lock screen by following these instructions:

01. On the lock screen, tap notifications, unlock your phone, and automatically open the App to acknowledge the alert.
02. Pull down the notification and tap the notification to open the App to acknowledge the alert.

⚠ WARNING: Although the Alert function has been tested in clinical settings, if you have symptoms that do not match well with the Alert information, or Alerts are not triggered when you experience hypoglycemia and hyperglycemia symptoms, and you suspect that your readings may be inaccurate, check your glucose by conducting a finger-stick test using a BGM and consult your healthcare provider for professional advice.

7.3 Alert method

7.3.1 Mobile phone ring mode

When the phone is in vibration mode, all alerts will ring, and you can set different notification ringtones for the ring type.

7.3.2 Mobile phone vibration mode

When the phone is in vibration mode, all alerts will vibrate, but they won't make a sound.

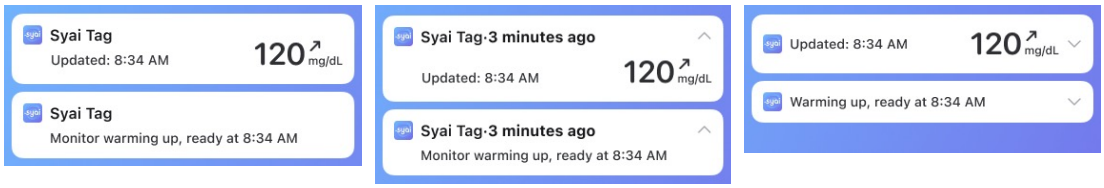
7.3.3 Mobile phone silent mode

When your phone is in silent mode, all alerts won't ring and vibrate, but you'll still see alerts on your phone's lock screen and drop-down page.

7.3.4 Mobile Desktop Widget

7.3.5 System Notifications (for Android)

Swipe down from top of the screen, you can see SyaiTag's resident system notification. Current Glucose Reading, Trend Arrow, and Time of Reading are always included.



7.3.6 Alerts on Smartwatch

You can wear a smartwatch to see alerts and feel their vibrations. Your smartwatch communicates with your phone, and your phone is connected to your monitor.

> ⚠ **Important:**
>
> - Make sure notifications are sent to both your phone and watch in your smart device settings.
> - Don't disable or block notifications from the app.

7.4 Customize general settings

You can set different glucose alerts on different days of the week (a maximum of two alert sets can be set)

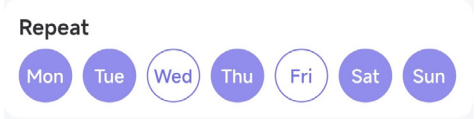
App Settings Path: Profile>Settings>Alerts

The settings are as follows:

7.4.1 Repeat the settings

You can set the day of the week to take effect in Recurrence Settings.

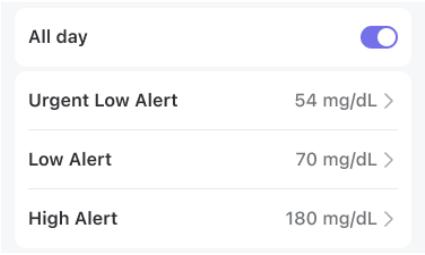
For example, if you don't want to be reminded on Wednesdays and Fridays, you can simply tap the days to remove reminders on Wednesdays and Fridays. It is important to note that if your sensor readings are too high or too low, you will not receive any alerts on Wednesdays and Fridays.



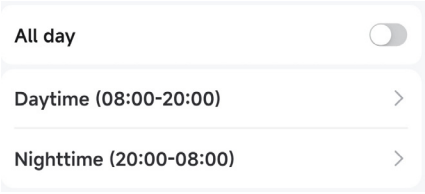
7.4.2 All day

You can set different alert ranges and methods for day and night.

a. All day, which means that your settings will be valid all day long;



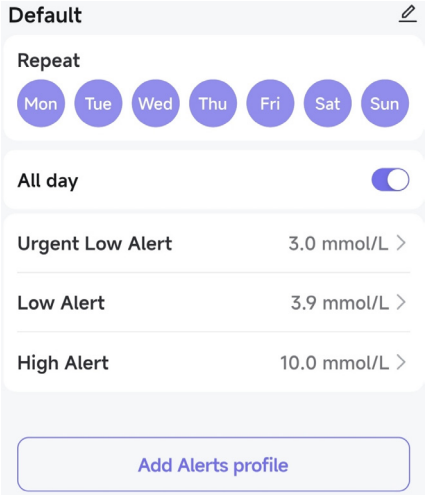
b. If it is off, you can set reminders according to day and night intervals;



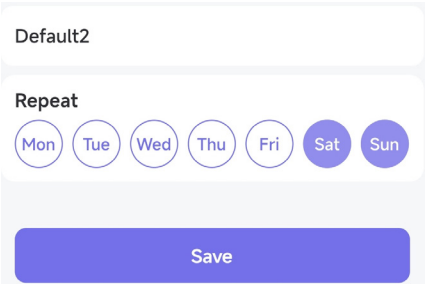
c. Tap to enter the details page to modify the time and alert range of day and night.

7.4.3 Add a second Alert profile

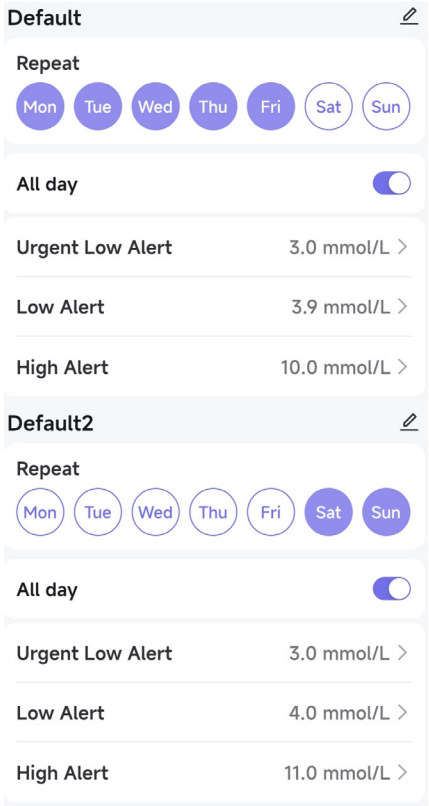
01. Tap "Add Alerts profile" to create a new set of settings that take effect on different dates. Note that if you select the day you set before setting, the previous day's alert settings will be overwritten.



02. You can choose the dates you want to set different glucose reminders.



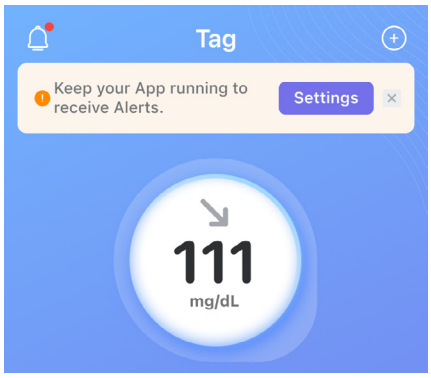
03. After the new operation, you can customize different settings such as whether to apply for all day, glucose range, reminder method, etc.

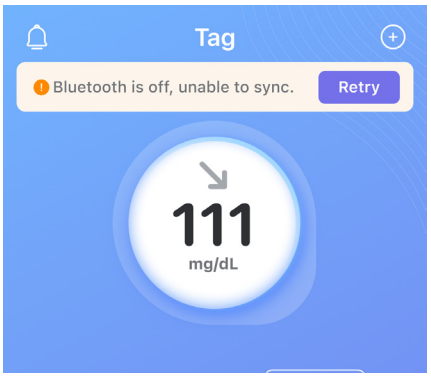


7.5 System Alerts

7.5.1 Signal Loss alerts

When the Bluetooth function of your phone is turned off or unauthorized, or the app is unlocked in the background, the Bluetooth connection between the monitor and your phone is disconnected. In this case, the app generates a system alert and alert users to take action in time.





7.5.2 Monitor expiring soon Alert

7.5.3 Alerts when the monitor is not working properly

Abnormal reading

Monitor reading abnormal, please confirm:
1. if the monitor has fallen off or is not tightly attached;
2. whether blood glucose level is abnormal with a fingerstick test (please seek medical attention if needed);
Please check the readings again after 15 minutes if none of the above applies.

OK

Monitor reading unavailable, please check again after 15 minutes.

Monitor Error

Please change to a new Monitor or contact our Syai Support Team.

Remove device

Monitor Failure

Please remove the device and contact Syai Support Team.

Remove device

7.6 Coming next

7.6.1 Urgent Low Soon

7.6.2 Rising fast and Falling fast alerts

8. Living With Your Syai Tag System

8.1 Bathing, Showering, and Swimming

Syai Tag has a waterproof level of IPX8. It is safe to be worn 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 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.

⚠ 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 unless your glucose goes low.

8.3 Exercising

Intense exercise can cause your Monitor to loosen due to sweat or movement of the Monitor. If this happens, you may receive inaccurate readings that do not reflect how you are feeling. 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 Syai Tag when going through walk-through metal detectors and Advanced Imaging Technology (AIT) body scanners, as the Monitor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI).
- The Monitor should not be exposed to X-ray or millimeter radio waves (sometimes used in full-body scanners). The effect of these scanners has 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 hand-wanding or a full-body pat-down and visual inspection. Ask for a visual inspection of any part of the Syai Tag 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.

⚠ Changing the timezone affects the graphs and statistics.

8.5 Storage and Transportation

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

8.6 Waste Disposal

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

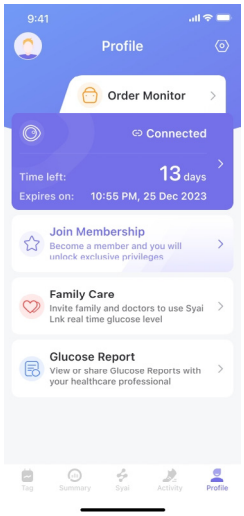
Contact Customer Service for further information on the appropriate disposal of system components.

9. Glucose Reports in Syai Tag APP

9.1 Where to Find

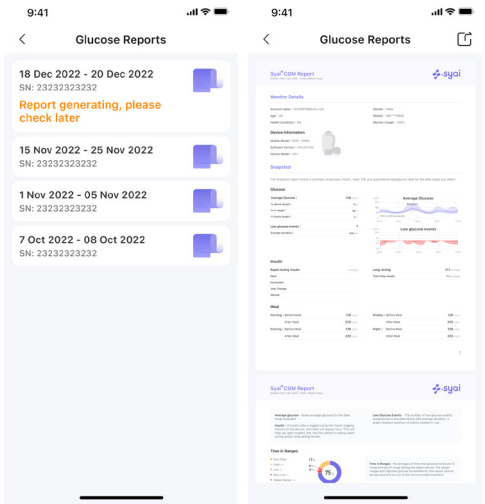
01. Tap Profile on the bottom of the App

02. Tap Glucose Report and you can find all the available glucose reports.

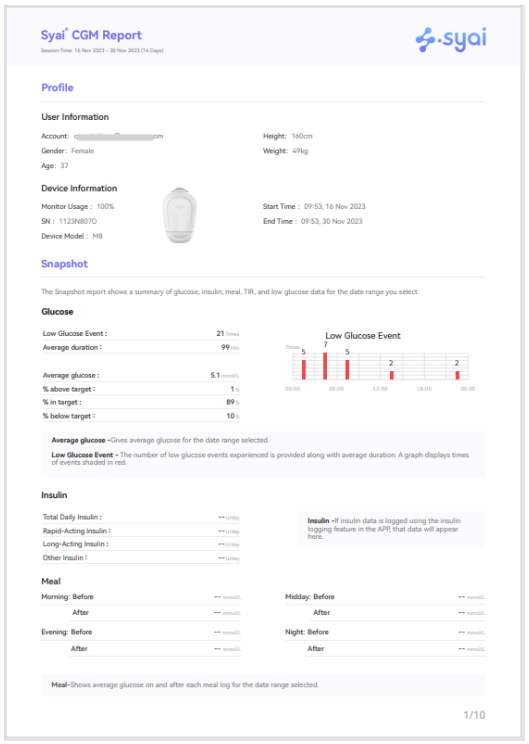


9.2 How to Download

01. Tap the Glucose Report that you wish to download to enter the report page.
02. Tap to download the report.



9.3 Report Overview



Syai® CGM Report

Session Time: 16 Nov 2023 – 30 Nov 2023 (14 Days)

syai

Profile

User Information

Account: [redacted]com
Gender: Female
Age: 37
Height: 160cm
Weight: 49kg

Device Information

Monitor Usage : 100%
SN : 1123N8070
Device Model : M8
Start Time : 09:53, 16 Nov 2023
End Time : 09:53, 30 Nov 2023

Snapshot

The Snapshot report shows a summary of glucose, insulin, meal, TIR, and low glucose data for the date range you select.

Glucose

Low Glucose Event : 21 Times
Average duration : 99 Min
Average glucose : 5.1 mmol/L
% above target : 1 %
% in target : 89 %
% below target : 10 %

Low Glucose Event

Average glucose - Gives average glucose for the date range selected.

Low Glucose Event - The number of low glucose events experienced is provided along with average duration. A graph displays times of events shaded in red.

Insulin

Total Daily Insulin : -- U/day
Rapid-Acting Insulin : -- U/day
Long-Acting Insulin : -- U/day
Other Insulin : -- U/day

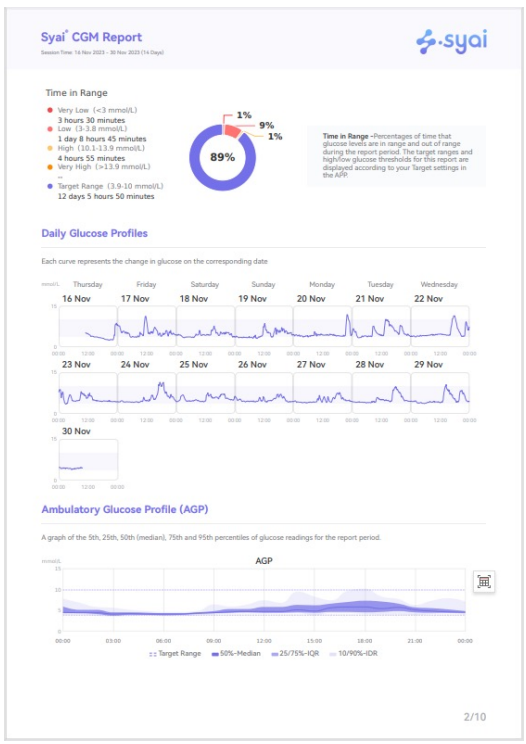
Insulin - If insulin data is logged using the insulin logging feature in the APP, that data will appear here.

Meal

Morning: Before -- mmol/L
After -- mmol/L
Midday: Before -- mmol/L
After -- mmol/L
Evening: Before -- mmol/L
After -- mmol/L
Night: Before -- mmol/L
After -- mmol/L

Meal - Shows average glucose on and after each meal log for the date range selected.

1/10



Syai® CGM Report

Session Time: 16 Nov 2023 – 30 Nov 2023 (14 Days)

syai

Time in Range

- Very Low (<3 mmol/L) 3 hours 30 minutes
- Low (3-3.8 mmol/L) 1 day 8 hours 45 minutes
- High (10.1-13.9 mmol/L) 4 hours 55 minutes
- Very High (>13.9 mmol/L) --
- Target Range (3.9-10 mmol/L) 12 days 5 hours 50 minutes

1% 9% 1% 89%

Time in Range - Percentages of time that glucose levels are in range and out of range during the report period. The target ranges and high/low glucose thresholds for this report are displayed according to your Target settings in the APP.

Daily Glucose Profiles

Each curve represents the change in glucose on the corresponding date

Thursday 16 Nov, Friday 17 Nov, Saturday 18 Nov, Sunday 19 Nov, Monday 20 Nov, Tuesday 21 Nov, Wednesday 22 Nov
Thursday 23 Nov, Friday 24 Nov, Saturday 25 Nov, Sunday 26 Nov, Monday 27 Nov, Tuesday 28 Nov, Wednesday 29 Nov
Thursday 30 Nov

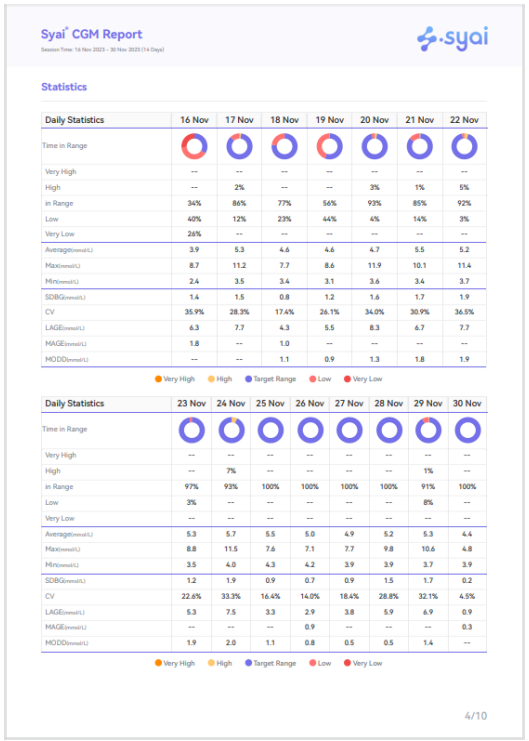
Ambulatory Glucose Profile (AGP)

A graph of the 5th, 25th, 50th (median), 75th and 95th percentiles of glucose readings for the report period.

AGP

Target Range | 50%-Median | 25/75%-IQR | 10/90%-IDR

2/10



Syai® CGM Report

Session Time: 16 Nov 2023 – 30 Nov 2023 (14 Days)

syai

Statistics

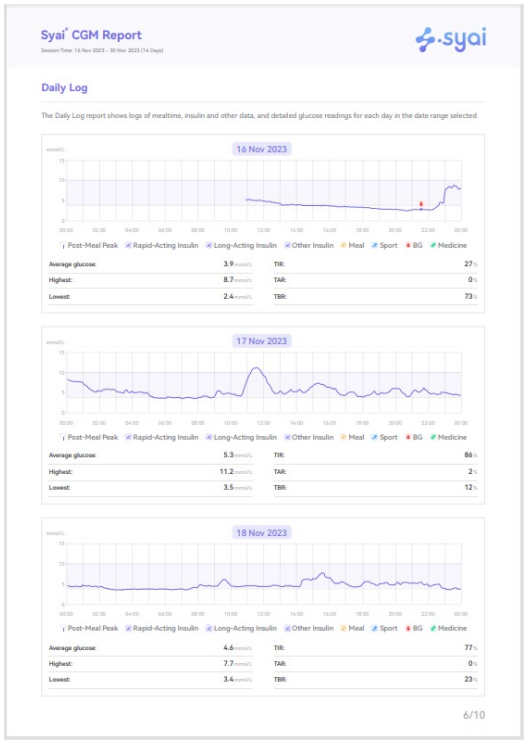
Daily Statistics	16 Nov	17 Nov	18 Nov	19 Nov	20 Nov	21 Nov	22 Nov
Time in Range							
Very High	--	--	--	--	--	--	--
High	--	2%	--	--	3%	1%	5%
in Range	34%	86%	77%	56%	93%	85%	92%
Low	40%	12%	23%	44%	4%	14%	3%
Very Low	26%	--	--	--	--	--	--
Average(mmol/L)	3.9	5.3	4.6	4.6	4.7	5.5	5.2
Max(mmol/L)	8.7	11.2	7.7	8.6	11.9	10.1	11.4
Min(mmol/L)	2.4	3.5	3.4	3.1	3.6	3.4	3.7
SDBG(mmol/L)	1.4	1.5	0.8	1.2	1.6	1.7	1.9
CV	35.9%	28.3%	17.4%	26.1%	34.0%	30.9%	36.5%
LAGE(mmol/L)	6.3	7.7	4.3	5.5	8.3	6.7	7.7
MAGE(mmol/L)	1.8	--	1.0	--	--	--	--
MODD(mmol/L)	--	--	1.1	0.9	1.3	1.8	1.9

Very High | High | Target Range | Low | Very Low

Daily Statistics	23 Nov	24 Nov	25 Nov	26 Nov	27 Nov	28 Nov	29 Nov	30 Nov
Time in Range								
Very High	--	--	--	--	--	--	--	--
High	--	7%	--	--	--	--	1%	--
in Range	97%	93%	100%	100%	100%	100%	91%	100%
Low	3%	--	--	--	--	--	8%	--
Very Low	--	--	--	--	--	--	--	--
Average(mmol/L)	5.3	5.7	5.5	5.0	4.9	5.2	5.3	4.4
Max(mmol/L)	8.8	11.5	7.6	7.1	7.7	9.8	10.6	4.8
Min(mmol/L)	3.5	4.0	4.3	4.2	3.9	3.9	3.7	3.9
SDBG(mmol/L)	1.2	1.9	0.9	0.7	0.9	1.5	1.7	0.2
CV	22.6%	33.3%	16.4%	14.0%	18.4%	28.8%	32.1%	4.5%
LAGE(mmol/L)	5.3	7.5	3.3	2.9	3.8	5.9	6.9	0.9
MAGE(mmol/L)	--	--	--	0.9	--	--	--	0.3
MODD(mmol/L)	1.9	2.0	1.1	0.8	0.5	0.5	1.4	--

Very High | High | Target Range | Low | Very Low

4/10



Syai® CGM Report

Session Time: 16 Nov 2023 – 30 Nov 2023 (14 Days)

syai

Daily Log

The Daily Log report shows logs of mealtime, insulin and other data, and detailed glucose readings for each day in the date range selected.

16 Nov 2023

Post-Meal Peak | Rapid-Acting Insulin | Long-Acting Insulin | Other Insulin | Meal | Sport | BG | Medicine

Average glucose: 3.9 mmol/L
Highest: 8.7 mmol/L
Lowest: 2.4 mmol/L
TIR: 27 %
TAR: 0 %
TBR: 73 %

17 Nov 2023

Post-Meal Peak | Rapid-Acting Insulin | Long-Acting Insulin | Other Insulin | Meal | Sport | BG | Medicine

Average glucose: 5.3 mmol/L
Highest: 11.2 mmol/L
Lowest: 3.5 mmol/L
TIR: 86 %
TAR: 2 %
TBR: 12 %

18 Nov 2023

Post-Meal Peak | Rapid-Acting Insulin | Long-Acting Insulin | Other Insulin | Meal | Sport | BG | Medicine

Average glucose: 4.6 mmol/L
Highest: 7.7 mmol/L
Lowest: 3.4 mmol/L
TIR: 77 %
TAR: 0 %
TBR: 23 %

6/10

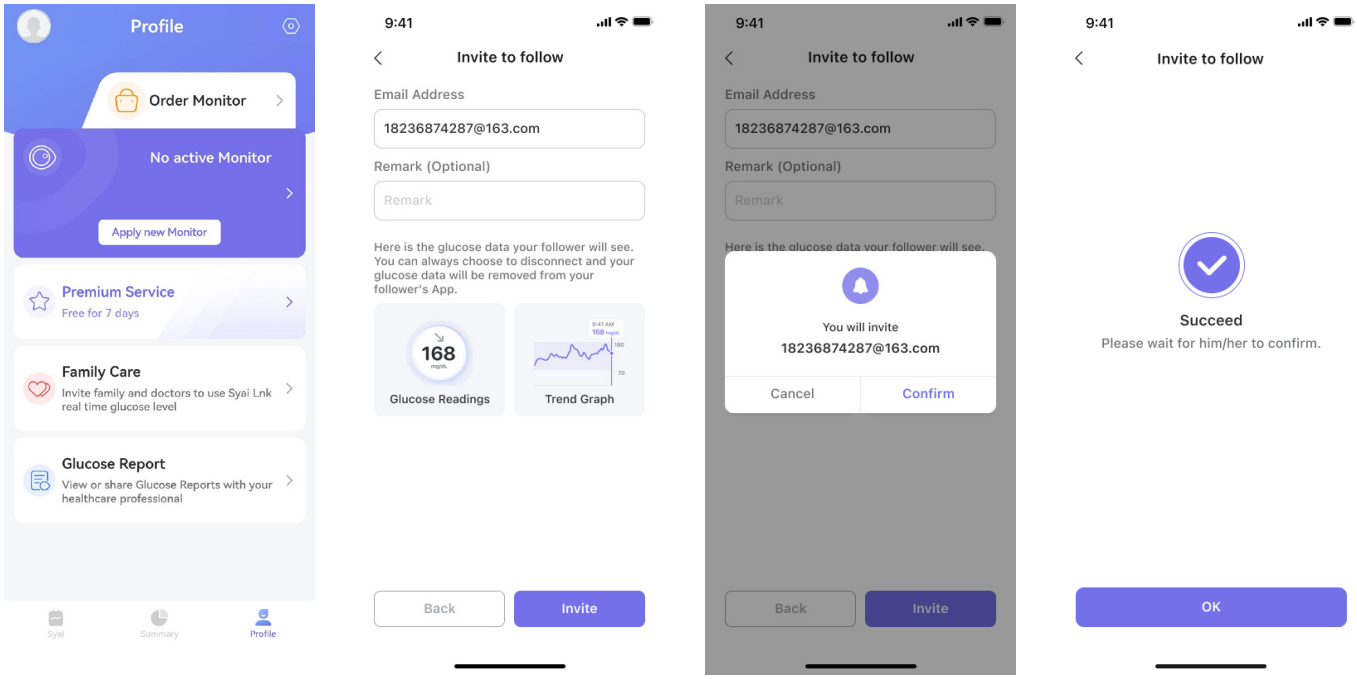
10. App Connections

10.1 Share and Follow

10.1.1 Share your glucose data with family and friends

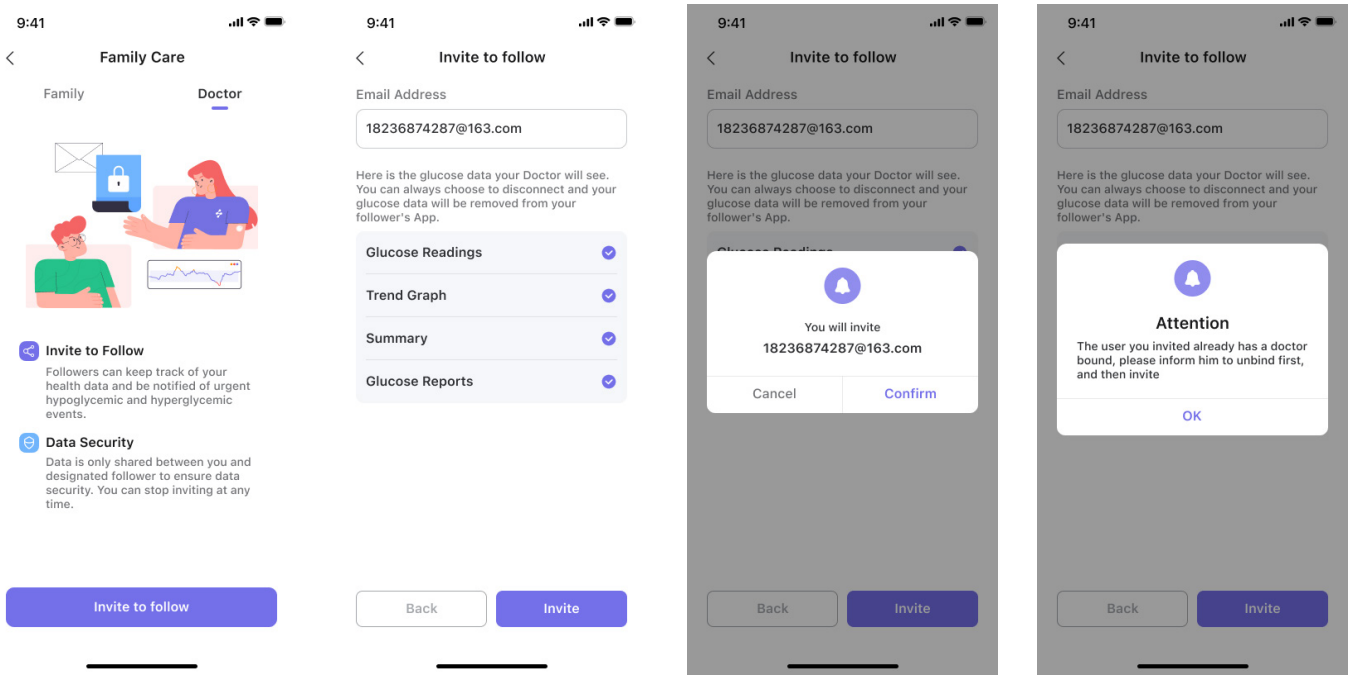
Invite family or friends to follow your glucose data via an email address in the Syai Tag app:

Go to Profile>Family Care>, enter the email address of the one you want to share.



10.1.2 Share Glucose Data with Your Doctor

Invite family or friends to follow your glucose data via an email address in the Syai Tag app:
Go to Profile>Family Care>, enter the email address of the one you want to share.



10.2 Syai Doctor's Platform (APP & Web)

10.2.1 Syai Lnk Professional (App)

A professional app edition tailored for doctors and caregivers to take care of their patients throughout their diabetes management journey.

- Doctors may view patient's current glucose, data summaries, glucose histories, glucose reports, and device information;
- Receive Alerts from patients, and edit Alert profiles for each patient;
- Set special attention for patients with more episodes of hypoglycemia and hyperglycemia events.

For patients already using Syai Tag:

- Doctors can both invite & accept invitations from patients.

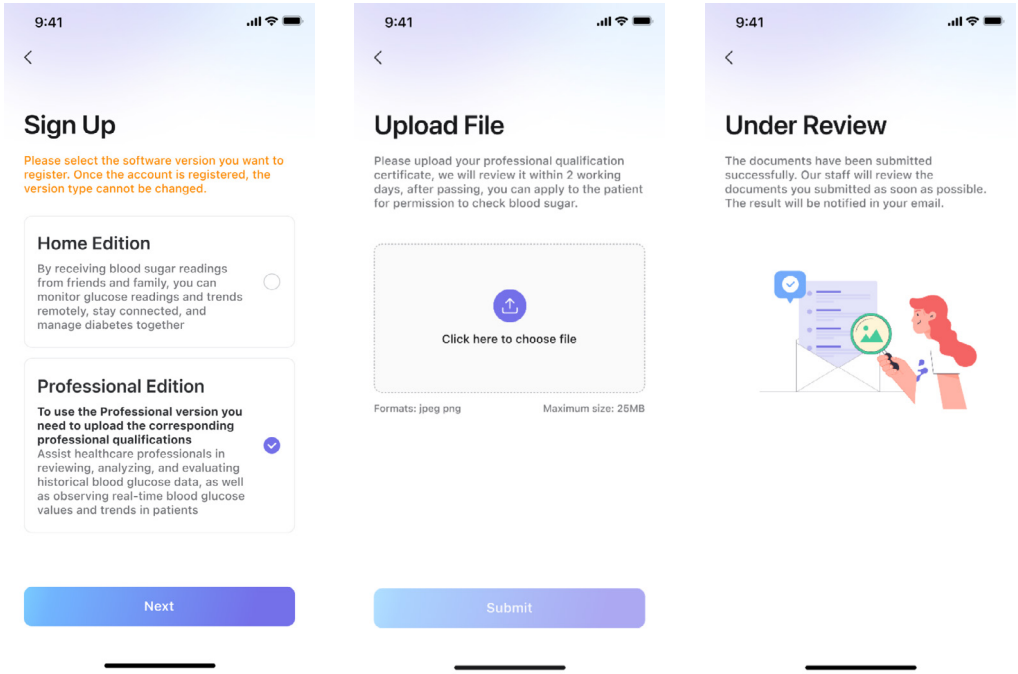
For patients already using Syai Tag:

- Doctors can add patients under his/her watch and help the patient to set up the account.

- **Two ways to obtain a professional account:**

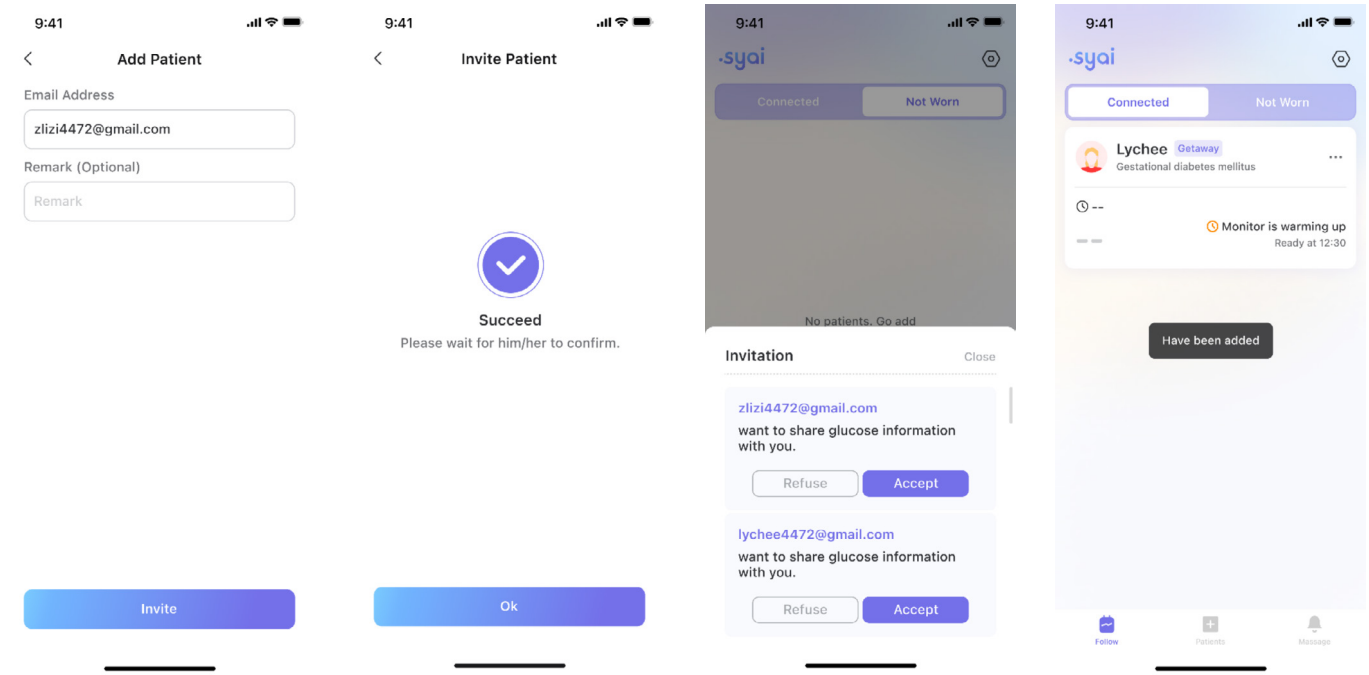
01. The distributor can assign an account to the doctor;

02. The doctor signs up for the professional edition of Syai Lnk app, and uploads their qualifications for review. Once approved, he/she will be able to use the professional account.



- **For patients already using Syai Tag:**

Doctors can both invite & accept invitations from patients to view their glucose information.



- **Three major function tabs at Syai Lnk professional edition:**

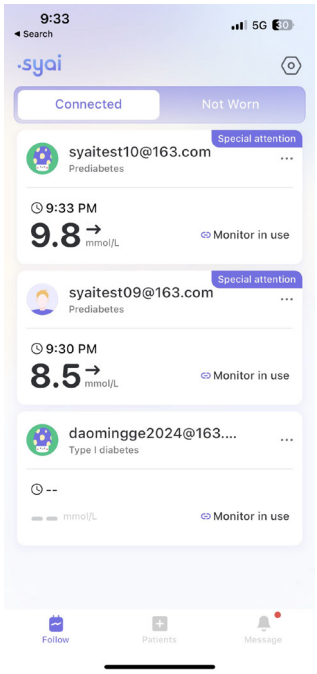
01. **Follow:** All patients managed by the doctor currently wearing a Syai Tag are displayed here.

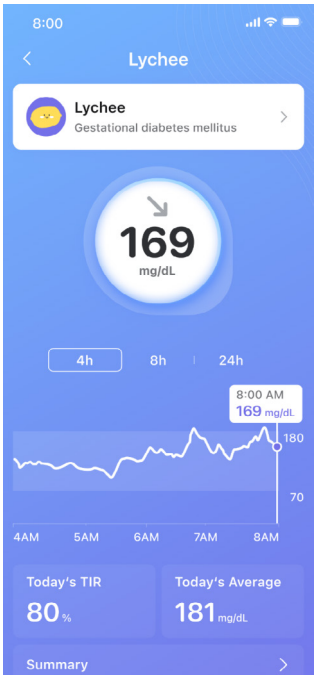
02. **Patients:** All patients can be managed here, including previous users of Syai Tag who are not using the CGM device.

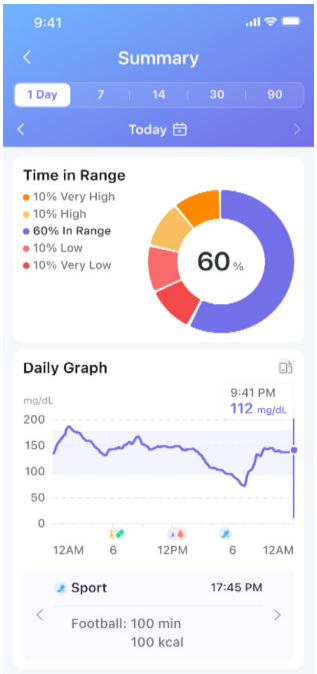
03. **Message:** All alert messages will be displayed here.

Doctors can both invite & accept invitations from patients to view their glucose information.

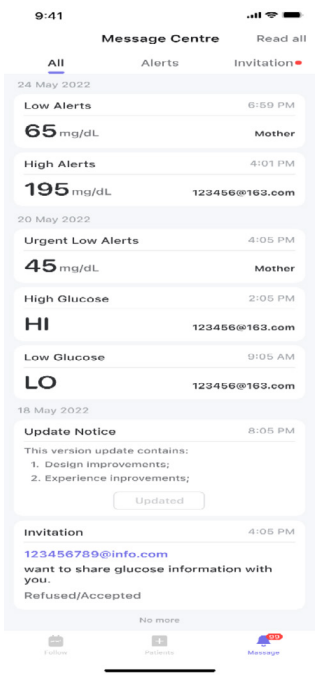
The doctor can also pin on top patients who need special attention.

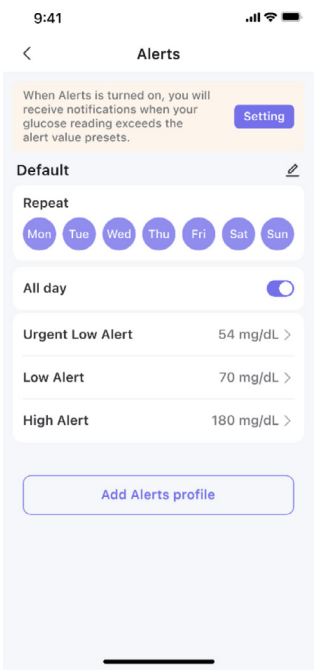


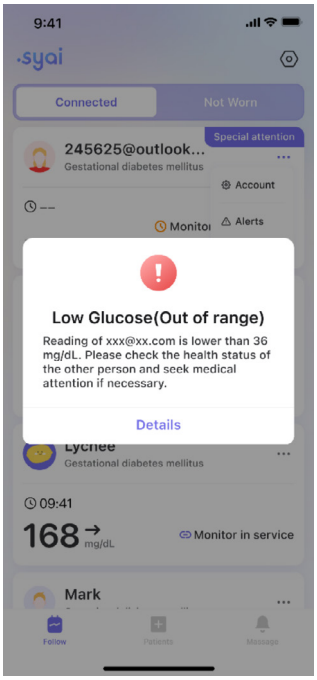




Doctors will receive Alerts from patients, and edit alert profiles for each patient (optional).

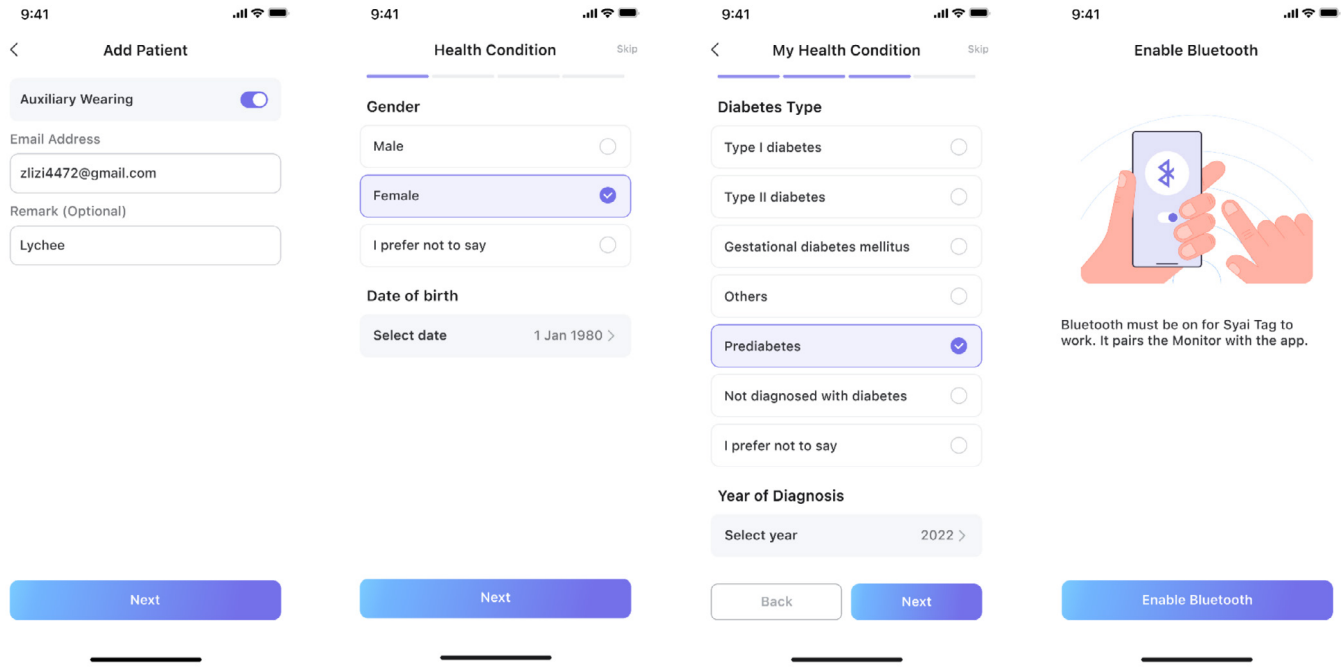






- **For patients not using a Syai Tag app**

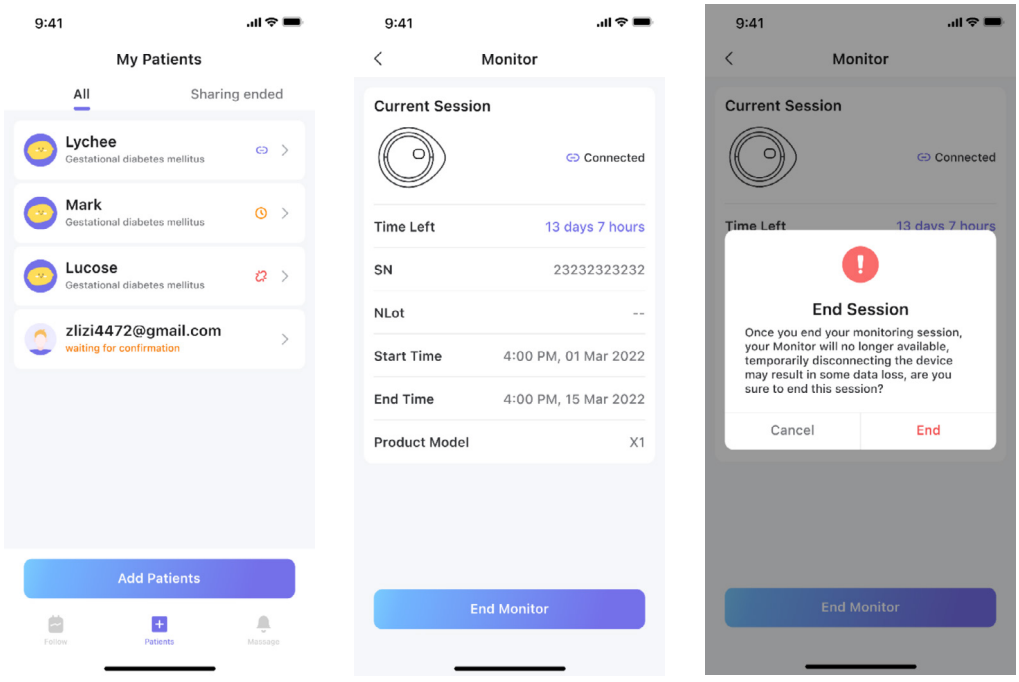
When a doctor is using a Syai Hub, his/her patient is not required to use Syai Tag, the doctor will handle all the registration duties for the patients (similar to a Holter mode).



In-patient treatment: the patient's glucose information will be processed by the Syai Hub and displayed on the Syai doctor's platform.

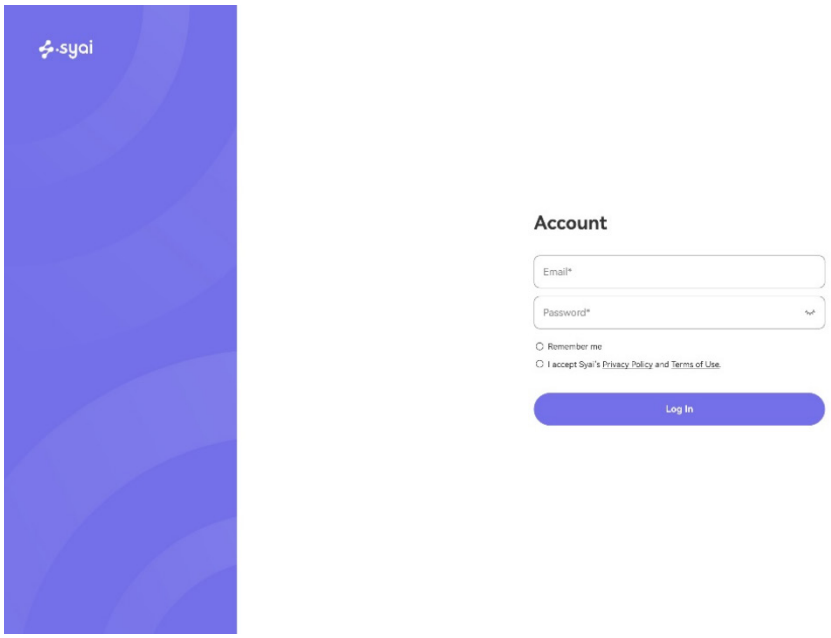
Out-patient treatment: the patient's glucose information will be retrieved by the doctors when he/she revisits.

The doctor can also terminate the use of CGM if needed.

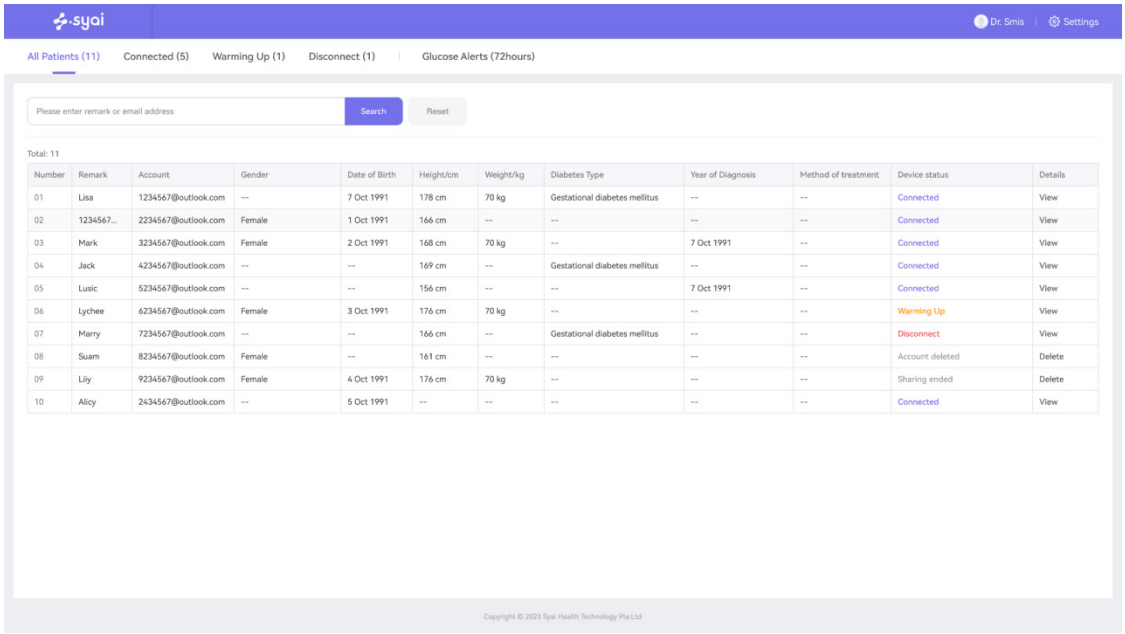


10.2.2 Syai Doctor (Web)

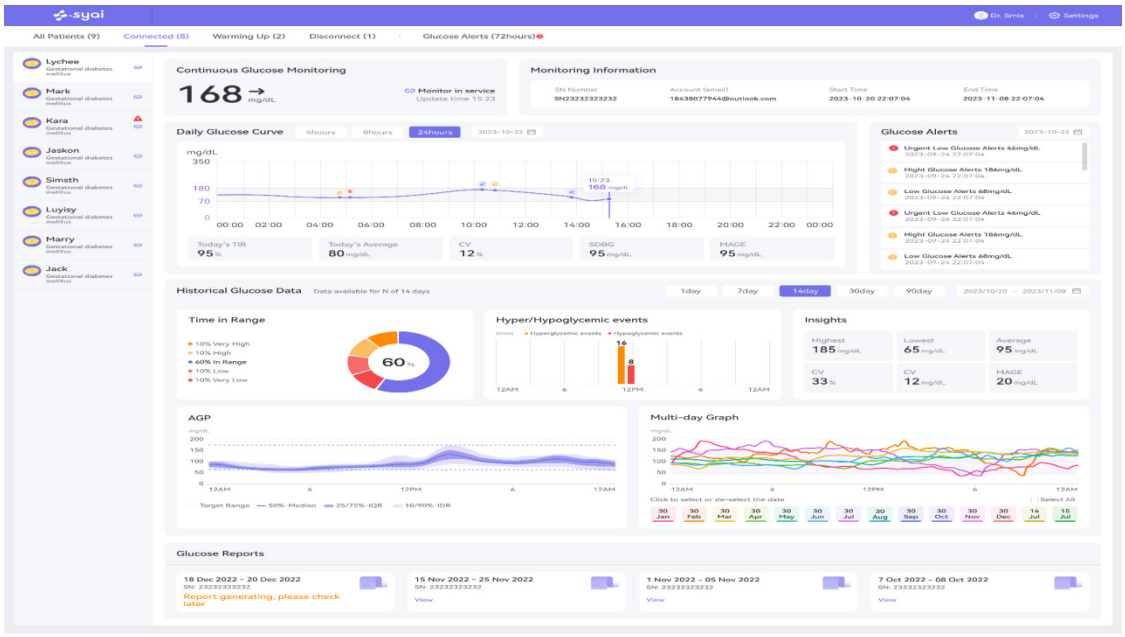
Syai Doctor is a web version to be used in conjunction with Syai Lnk Professional app.



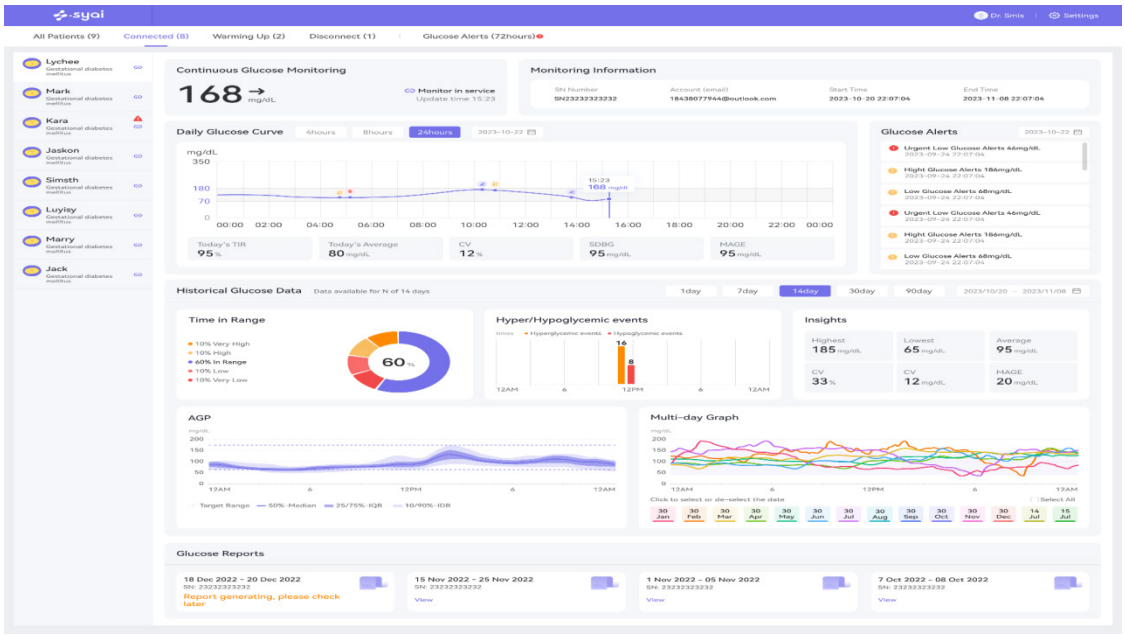
All patient's information can be viewed at a glance.



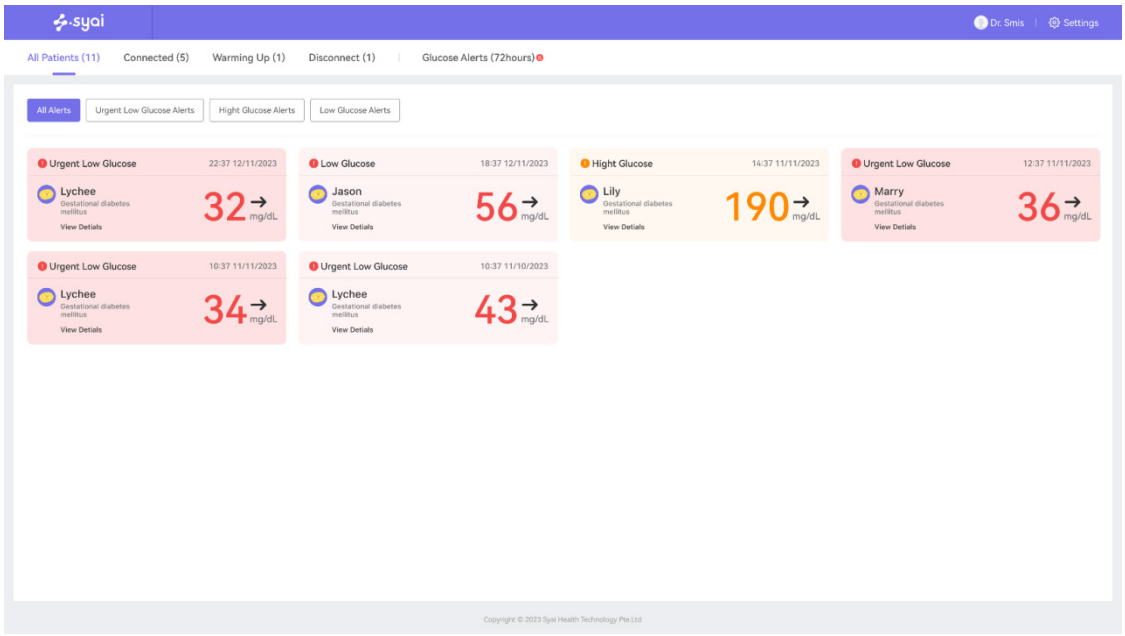
A comprehensive glucose summary page for each patient.



Receive glucose alerts on the clock for every patient. All alerts can be viewed on a dedicated alerts page.



A dedicated Alerts page showing all alerts that have been issued in the past 72 hours.



10.2.3 Specifications

	Syai Lnk Professional (App)	Syai Doctor (Web)
Operation platform	Android & IOS	Windows & Mac, pad
Max. no. of patients	100	100
Add/delete patients	√	×
Edit patient's information	√	×
View patient's glucose information	√	√
Receiving Alerts	√	√
Edit Alert Profile	√	×

10.3 Smartwatch

10.3.1 Check your Syai Tag on Applewatch

To install the app, use the Watch app on your iPhone. See your watch instructions for details about installing apps.

What can you see on your Applewatch

With a Syai Tag Monitor in use, you can see Sensor Reading, Trend Arrow, Trend Graph in past 3 hours, Current sensor reading, Target Range, and Reading Time on the first screen.

Swiping to the second screen, you can see today's TIR, today's Highest Glucose, today's Lowest Glucose, and Monitor's time remaining in use.

Alerts on Applewatch

Glucose Alerts:

Monitor Connection Status Alert:

10.3.2 Check your Syai Tag on MI Smartwath

What can you see on your MI Smartwath

Alerts on MI Smartwath

10.3.3 Be Aware of Your Alerts

Using a smartwatch with your Syai Tag may change how you get alerts.

- Your smartwatch communicates with your phone, not the monitor.
- You won't get alerts or glucose readings on your watch unless it's connected to your phone and your phone is connected to your monitor.
- Make sure you understand how you get notifications when a watch is connected.
- You must wear the watch to see alerts and feel their vibrations.
- In your smart device settings, make sure notifications are sent to both your phone and watch.
- Don't disable or block notifications from the app.
- Waking up your watch updates your Syai Tag data from your phone. There may be a brief delay before your watch app shows current information.

11. Troubleshooting

11.1 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.

⚠ **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 hair between your Monitor and your skin. Consider shaving the application area if necessary.

- Before removing the Applicator, keep holding the Applicator against your arm for a few seconds. This can help the adhesive stick to your skin.
- Enhance the Monitor with the Reinforcement Patch supplied in the package.

⚠ **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 toweling 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 that minimizes 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**

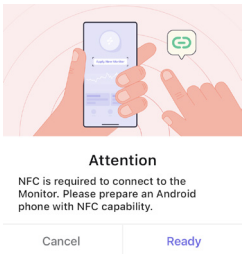
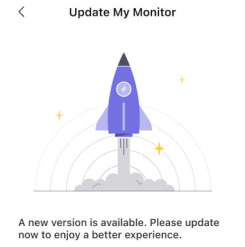
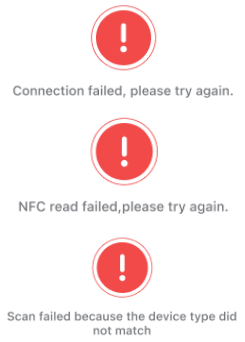
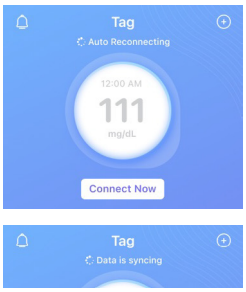
  The adhesive is verified in compliance with bio-testing, so you can use it with confidence. This situation might be caused by sweating or poor ventilation. Please closely monitor the condition of your skin in the affected area. If necessary, we recommend stopping use and seeking medical attention promptly.

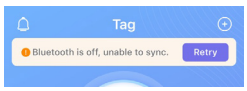
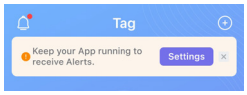
⚠ IMPORTANT

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

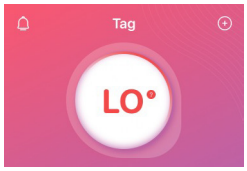
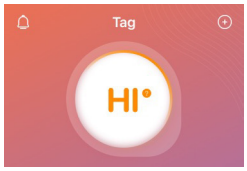
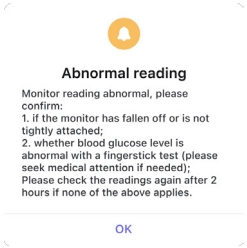
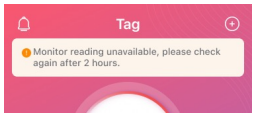
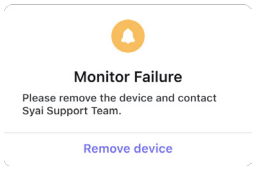
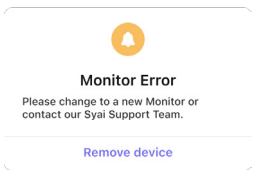
11.2 Problems Starting Your Monitor or Receiving Monitor Readings

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

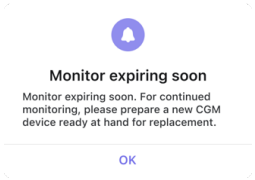
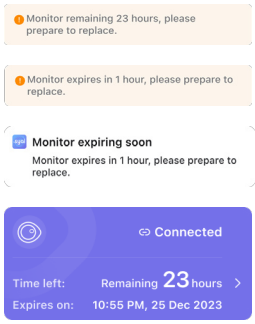
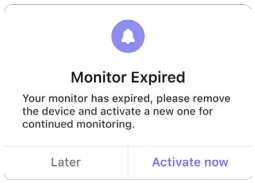
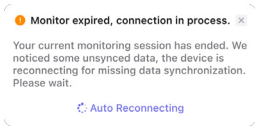
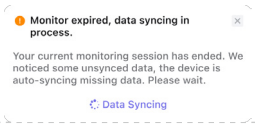
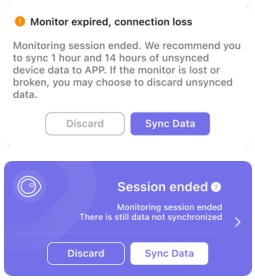
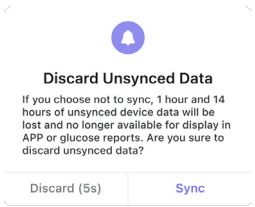
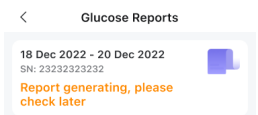
Screen Display Content	What It May Mean	What To Do
	Before you start wearing the monitor, please prepare an NFC-enabled mobile phone, which is required for the monitor activation process. It will prompt when you are using a non-NFC enabled mobile phone	Borrow an NFC-enabled mobile phone for a while and you can return it once the monitor is activated.
	Updates that will offer a better experience are now available. It doesn't happen very often. May appear after NFC scanning, while activating the Monitor.	Once it happens, just 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.
	Monitor is disconnected. When you open the app, it will automatically reconnect and sync the data.	Wait for auto reconnect and sync data. If the connection fails or takes too long, you can tap Connect Now to manually reconnect. To manually reconnect, you need to scan the Monitor with your phone's NFC, similar to what you did during the activation.

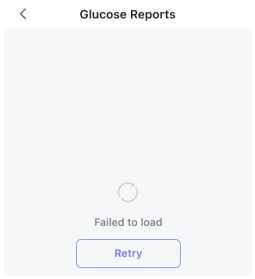
	The Bluetooth function of your phone is turned off and the monitor is disconnected.	Open your phone's Bluetooth, reconnect the monitor and wait for an updated reading.
	The Syai Tag app may be closed in the background of your mobile phone, leaving the monitor disconnected, and data not updating timely, even missing glucose alerts.	Go to Settings. This can keep your App running to receive Alerts.

11.3 Problems Receiving Abnormal Reading

Screen Display Content	What It May 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 Syai Support Team.
	Monitor reading is unavailable in 2 hours as its 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.

11.4 Monitor will expire or has 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 CGM device ready at hand for replacement.
	Your monitor has expired.	Remove the device and activate a new one for continued monitoring.
	Monitor has expired and stopped monitoring. The monitor is auto reconnecting with your phone to synchronise the rest of the data.	Waiting for Monitor to reconnect.
	Monitor connected, synchronising data.	Waiting for data synchronisation complete.
	Monitor has expired and is out of connection. Some data remains in the monitor and a re-connection is needed to synchronise to Syai Tag app.	Tap Sync Data immediately.
	Check if you are giving up unsynchronised data. If the sync is aborted, unsynced data will be lost and no longer available for display in 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.

11.5 Accuracy

Why aren't your BG meter value and Monitor reading the exact same number?

First of all, they're measuring glucose in different fluids. The BG meter measures blood glucose while the Syai Tag measures interstitial fluid. And if your healthcare provider did a lab test at the same time, the lab result may give a third number. The lab test is considered the most accurate number.

Other reasons there could be a difference between your BG meter and your Syai Tag include:

- Hand cleanliness: Wash your hands with soap and water (not hand sanitizer) and dry them. Then test. Many inaccurate BG meter values are from hands not being washed thoroughly before testing.
- Monitor’s first day: With newly inserted monitors, the differences between your BG meter and the monitor reading may be greater. Generally, the numbers get closer over the first 24 hours.
- Pressure on monitor: Sometimes when something is pressing on your monitor, for example, if you’re lying on it, it can affect your readings. Relieve the pressure and the numbers should get closer.
- Glucose changing quickly: When your glucose is rapidly changing, it can be more difficult to compare your BG meter value and monitor reading because blood glucose changes a little before interstitial fluid glucose. The numbers should get closer when your glucose stabilizes.
- Test strips: Make sure your test strips are stored as directed and not expired. Also, make sure to use enough blood on the test strip.

12. Maintenance and Repair

Syai Tag is guaranteed to be free of any defects in materials and workmanship, with a warranty period of 1.5 years starting from the date of manufacture. During the warranty period, Syai will replace the device according to the specific conditions. The warranty period is only applicable for new devices, which cannot be extended due to any replacement of the Monitor.

The warranty shall only be valid for products properly used under related requirements and will not apply if:

01. The device is damaged due to unauthorized disassembly.
02. The damage is caused by force majeure or other events beyond the manufacturer's control.
03. If the damage is caused by negligence or improper use, including but not limited to inappropriate storage or physical abuse, such as drop or other reasons.

This warranty applies only to the original user. Any sale, lease or transfer of the product by the original user will result in immediate invalidation of this warranty.

This product has no serviceable parts, thus requiring no maintenance.

13. Technical Information

13.1 Device performance summary

- Accuracy
- Easy to use
- Comfortable to wear

13.2 System Specifications

Software Operating Environment

	Android	IOS
Operating system	Android 5.0 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)	
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

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 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	2~45 ℃, no freezing
Guide needle size (total length)	10 %~85 % RH, no condensation
Insertion depth of Guide needle	2~30 ℃, no freezing Notice: Even if the Syai(®)CGM device is stored in 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 minimum storage temperature.
Storage and shipping relative humidity	10 %~85 % RH, no condensation
Atmospheric pressure	70~106 KPa
Initiation time	60 min
Wireless transmission distance	10 m
Waterproof level	IPX8
Monitor sterilization method	Sterilized using irradiation

14. Electromagnetic Compatibility

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
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 one-time lithium battery, DC 3V
Input power	N/A
Whether this device has applied parts for protection against 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

14.1 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Syai(®) CGM System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR11	Group 1	The Syai(®) CGM System 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	

14.2 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Syai(®) CGM System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure 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	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	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	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
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table below	Compliance to 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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Syai(®) CGM System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure 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(®) CGM System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2x d=1.2 x 80MHz~800MHz d=2.3 x 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 survey(b), should be less than the compliance level in each frequency ranged (c).

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 broadcast and TV broadcast 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(®) CGM System is used exceeds the applicable RF compliance level above, the Syai(®) CGM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Syai(®) CGM System.
c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

14.3 Radio regulations compliance

Recommended Isolation Distances for Portable and Mobile RF Communication Equipment and the Syai(®) CGM System

The Syai(®) CGM System is intended for use in electromagnetic loop mirrors where radio frequency radiation disturbances are controlled. The purchaser or user of the Syai(®) CGM System can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters) and the Syai(®) CGM System 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	80 MHz–800 MHz d=1.2 x	800MHz–2.5 GHz d=2.3 x
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.

15. Packaging Symbols

CE	CE Mark
	Keep Dry
	Attention! See Instructions for Use.
	Do not use if package is damaged
	Non-Ionizing Radiation
	Single use only. Do not re-use.
	Unsafe Factors
	Temperature Limit
	Humidity Limit
STERILE R	Radiation Sterilization
	Waste Electrical and Electronic Equipment
	Manufacture Date
SN	Serial Number
	Use-by date
	Fragile, handle with care
	Refer to the Instructions for Use
	Type BF Applied Part

Manufacturer

Syai Health Technology Pte. Ltd.

#03-01 112 Robinson SINGAPORE 068902

Factory address

Room 210, floor 2, building 3, yard 58, Jinghai fifth road, Beijing Economic Technological Development Zone, Beijing, PEOPLE'S REPUBLIC OF CHINA.

Manufacture's Contact Information

0086-400-0860-509

After-Service Provider

Syai Health Technology Pte. Ltd.

Lay operators or responsible organizations should contact Syai Health Technology Pte. Ltd. through the before-mentioned contact address or the after-mentioned EU agent contact address:

·For assistance if needed, in setting up or operating the Syai® device.

·To report unexpected operation or events.

European Authorised Representative

Luxus Lebenswelt GmbH

Kochstr.1, 47877, Willich, Germany

0049-1715605732

SRN

DE-AR-000005110

CE 0344