

SIBIONICS

SIBIONICS GS1 CONTINUOUS GLUCOSE MONITORING SYSTEM

APP

User Guide

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ATTENTION:

Before you use the SIBIONICS GS1 App (hereinafter referred to as smartphone app) or the SIBIONICS GSW App (hereinafter referred to as smartwatch app) and the SIBIONICS GS1 Continuous Glucose Monitoring System (hereinafter referred to as GS1 CGM System), review all the product instructions and the insert. The User Guide includes all safety information and instructions for use. Talk to your professional healthcare team about how you should use your Sensor glucose information to help manage your diabetes.

Failure to use the GS1 CGM System according to the instructions for use may result in you missing a severe low glucose or high glucose event and/or making a treatment decision that may result in injury. If your glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

The pictures and images shown in this guide are for illustration purpose only, and may differ in appearance from the actual product.

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1 Important Safety Information

1.1 Overview

The App is used in combination with the GS1 CGM System. It retrieves glucose data from the Sensor to help monitoring the interstitial fluid glucose levels. The App provides 24-hour continuous glucose data, useful for glycemic control.

To get glucose data, you need to prepare and apply a GS1 Sensor when you use the App so that you can get data from the Sensor applied on the back of your upper arm. When you use the App, turn on the Bluetooth of your display device to retrieve the glucose data from the Sensor.

To use the GS1 system safely, you should:

- Be capable of operating smart phones with Android operating system or iOS or smartwatches
- Be capable of reading local language
- Have no visual or hearing impairments

The smartphone app runs on both Android and Apple smart devices. The smartwatch app runs only on Android Watch. For supported smart devices, go to <https://www.sibionicscgm.com/pages/mobile-device-compatibility>.

1.2 Expected Performance

The glucose reading is updated every 5 minutes in real-time monitoring.

1.3 Warnings



WARNING:

The System can replace blood glucose testing except in the following situations. These are the times when you need to do a blood glucose test

before deciding what to do or what treatment decision to make as Sensor readings may not accurately reflect blood glucose levels:

- No number and/or no arrow
- Do a blood glucose test if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose

Using your GS1 CGM System in these situations could result in errors in diabetes management. Go to the [Treatment Decisions](#) to find out more.

For more information on how to make treatment decisions using your GS1 CGM System, go to [System Safety Statements](#), [Treatment Decisions](#), and [Setting Glucose Alarm](#) chapters.

1.4 System Safety Statements

Cautions and Limitations

What to know before using the System:

- Review all product information before use.
- The Sensor Pack and Sensor Applicator are packaged together as a set and share the same serial number. Ensure the serial numbers match before use. Do not use Sensor Packs and Sensor Applicators with different serial numbers, as this will result in incorrect glucose readings.
- Take standard precautions for transmission of blood borne pathogens, for example by wiping the insertion site with an alcohol swab, to avoid contamination.
- In rare cases, insertion of the Sensor may cause insertion site pain, bleeding or Sensor probe breakage. Seek help from your professional healthcare team if the Sensor probe breaks.
- Wearing the adhesive patch may cause inflammation, skin irritation and skin allergy. Some individuals may be sensitive to the adhesive that keeps

the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and contact your professional healthcare team before continuing usage.

- Do not modify the GS1 CGM system without the authorization of the manufacturer.
- Do not use the GS1 CGM system if you are under the age of 3, pregnant, on dialysis, or critically ill. It is not known how health conditions or medications common to these populations may affect performance of the system.
- Performance of the system when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- The system contains small parts that may be dangerous if swallowed.

When not to use the system:

- Do not use the Sensor if its sterile package has been damaged or opened, as it may cause an infection. Contact our Customer Service at support@sibionics.com.
- Do not use expired Sensor Packs or Sensor Applicators.
- The Sensor automatically stops working after the 14-day wearing period and must be replaced.
- The system must be removed prior to Magnetic Resonance Imaging (MRI), X-ray examination, Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, X-ray, CT scans, or diathermy on the performance of the system has not been evaluated.

For proper product storage:

- Transport and store the Sensor Pack and Applicator at temperatures ranging between 4°C (39.2°F) and 25°C (77°F). Do not store in freezer. If transported and stored out of this temperature range, the performance may be affected or devices may become completely ineffective.

- Make sure that your Sensor Pack and Sensor Applicator are kept in a safe place. Prevent anyone from accessing or tampering with the CGM System.

How to interpret the GS1 CGM System results:

- The glucose readings and glucose reports generated by the App are used for glycemic management. Interpretation of the GS1 CGM System results should be based on the glucose trends and several sequential readings.
- Check your glucose levels with blood glucose meter or consult your professional healthcare team for treatment decisions and therapy adjustments when symptoms do not match readings, or readings are suspected to be inaccurate. Seek medical attention when appropriate. Replace the Sensor if needed.

What may affect the GS1 CGM System:

- Interfering Substances

Studies show that taking ascorbic acid (vitamin C) or acetylsalicylic acid containing substances while wearing the Sensor may falsely raise sensor glucose readings. Ascorbic acid or acetylsalicylic acid is oxidized on the surface of the sensing electrode and generate a certain interference current, potentially causing inaccurate sensor readings. The level of inaccuracy depends on the amount of substances present in the body. If symptoms do not match the sensor glucose readings after taking ascorbic acid or acetylsalicylic acid, perform a blood glucose test.

- The CGM System has not been tested in populations using anticoagulant therapy, and potential inaccuracy in Sensor glucose readings may occur. Consult your professional healthcare team for guidance on anticoagulant therapy during Sensor wear.
- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the System and results from a fingerstick test using a blood glucose meter. Differences in

glucose readings between interstitial fluid and capillary blood may also be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.

- Severe dehydration (excessive water loss) may cause false low sensor results. In the presence of symptoms that may lead to suspicion of dehydration, immediately consult a professional healthcare team.

Physical displacement:

- During the course of wearing the device, the Sensor can come loose or the Sensor probe can come out of the skin. This may occur, for example, during intense exercise, or if the Sensor is bumped.

In such cases, the displacement may cause the readings to be unreliable or fail to transmit. If you are experiencing data readings that do not match how you feel, check to make sure the Sensor has not come loose. If it has come loose, remove it, apply a new one. Do not attempt to reinsert the Sensor. If the problem continues contact your professional healthcare team.

- Report these cases by contacting Customer Service at support@sibionics.com.

What to know about Glucose Alarms:

- To prevent missed alarms, make sure your display device has sufficient battery power and that sound and/or vibration are turned on.
- In the event that an App or OS update causes your previously compatible display device to become incompatible, contact Customer Service at support@sibionics.com.
- Your display device must have a Bluetooth connection with your Sensor to receive glucose readings and glucose alarms. In the phone settings, keep Bluetooth ON. For iPhones, in the phone settings for the smartphone app, allow the app to access Bluetooth.

- To turn on Critical Alarms (iPhone) / Do Not Disturb Permission (Android Phone), follow the instructions in the smartphone app.
- If you adjust the ringer volume (iPhone / Apple Watch) or Media volume (Android Phone / Android Watch) to silent or use the Do Not Disturb setting, keep the 'Override Do Not Disturb' setting in the smartphone app ON for glucose alarms and signal loss alarms to ensure you receive audible alarms.
- You should disconnect headphones or speakers from your display device if you are not using them as you may not hear audio for alarms.

To ensure proper App operation:

- Do not let the display device shut down due to low battery, otherwise, no sensor glucose alarms will be obtained from the Sensor. Make sure to have an available charger to charge the display device if needed.
- It takes about 200MB storage for the smartphone app to run on your phone. Insufficient phone storage may cause suboptimal operation. Clear the cache to allow the app to run smoothly.
- For proper smartphone app operation, you should explicitly give permission to smartphone app to access camera and location from your device's privacy settings.
- If you restart your display device, open your App to make sure it's working properly.
- If the display device shuts off when running the App, glucose data may be lost.
- If any error or exception occurs to the App, relaunch the App and no data will be lost.
- Keep the display device secure, for example by using a strong password, installing updates when appropriate, and only using secure Wi-Fi

networks. If you suspect an adverse cybersecurity event related to the GS1 CGM System, contact Customer Service at support@sibionics.com.

- Set the date and time correctly on the display device before using the App. Manual change to these values while the App is running may cause abnormalities to the stored sensor data.
- Regularly logging in and running the App will help minimize the risk of data loss.
- To run the App, the display device should meet the system requirements as specified in [Downloading the App](#) otherwise the App performance may be affected.
- The user account (registered email address) needs to be provided before operating the App. Log in or register using a password (8-20 letters and numbers, or special characters) or a verification code.
- If the smartwatch powers off due to low battery, please recharge it with the designated charger to continue receiving glucose data. Rest assured that no glucose data will be lost if the smartwatch shuts down. Once restarted and the Sensor is reconnected, the data will automatically sync and upload to the smartwatch.
- To download, install, and update the smartwatch app, refer to the smartwatch's Quick Guide.

Reporting of Serious Incidents:

- Report any serious incident that has occurred in relation to this device to the manufacturer and local distributor or service provider. Please contact Customer Service at support@sibionics.com.
- In European Union Member States, serious incidents should also be reported to the competent authority (the government department responsible for medical devices) in your country. Please refer to your

government website for details of how to contact your competent authority.

- Users in the UK can also report suspected side effects electronically via the Yellow Card website (<https://yellowcard.mhra.gov.uk/>).
- A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to:
 - ✧ The death of a patient, user or other person,
 - ✧ The temporary or permanent serious deterioration of a patient's, user's or other persons' state of health.

1.5 How to Use this Guide

The following table describes terms and conventions used in this guide.

Convention	Description
Bold	Bold indicates an item on the screen that you select with your finger or tap to open.
>	> is a shorthand to indicate a series of selections you make on the screen. For example, Alarm Settings > Alarm Target means that you need to tap Alarm Settings , and then on the next screen tap Alarm Target .
Note	A note provides additional helpful information
CAUTION	A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	A warning notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

1.6 System Information

1.6.1 General Description

The CGM System is indicated for the continuous monitoring of interstitial fluid glucose levels in patients with diabetes mellitus. The system provides real-time glucose levels, detects glucose trends, fluctuations and TIR (time in

range). Glucose levels are monitored by an electrochemical Sensor which is factory calibrated, not requiring fingerstick calibration. The Sensor is a single-use device that can be worn for up to 14 days by a single user. The sensor kit comprises a Sensor Applicator and a Sensor Pack. The App is available for both smartphones and compatible smartwatches.

The CGM System is intended for patients 3 years and older with Type 1 or Type 2 Diabetes Mellitus. The indication for children (age 3-12) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the App and Sensor and also for interpreting or assisting the child to interpret Sensor glucose readings.

1.6.2 Intended Use/Purpose

The CGM System is intended for the continuous monitoring of interstitial fluid glucose levels.

1.6.3 Indication for Use

The CGM System is indicated for use in patients with diabetes mellitus type 1 or 2. The GS1 CGM System is a real-time continuous glucose monitoring device for single-use only. The GS1 CGM System is also intended to replace fingerstick testing for diabetes treatment decisions, including dosing of insulin.

The indication for children (age 3-12) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the App and Sensor and also for interpreting or assisting the child to interpret sensor glucose readings.

1.6.4 Intended Users

The CGM System is intended to be used by patients 12 years and older with Type 1 or Type 2 Diabetes Mellitus. The indication for children (age 3-12) is

limited to those who are supervised by a caregiver who is at least 18 years of age.

1.6.5 Target Population

The System is intended for patients with Type 1 or Type 2 Diabetes Mellitus, 3 years and older.

1.6.6 Clinical Benefits

The expected clinical benefits of using the GS1 CGM System include:

- Improved quality of life by increasing hypoglycemic awareness.
- Better glycemic control (through decrease of HbA1c) in children and adolescents.
- The SIBIONICS GS1 CGM System is also intended to replace the fingerstick testing for diabetes treatment decisions, including dosing of insulin. But except in the below situations:
 - ✧ No number and/or no arrow
 - ✧ If you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose

1.6.7 Contraindications

- The system must be removed prior to Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan.
- The system must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.
- The Sensor should not be inserted at a site where severe skin scald, burns, sunburns, wounds, ulcers, or surgical scars are present.

- The system is not intended for patients with severe skin lesions on the whole body, such as extensive eczema, extensive scars, extensive tattoos, herpetic dermatitis, severe edema, and psoriasis.

2 Sensor Kit

The Sensor kit includes:

- Sensor Pack
- Sensor Applicator



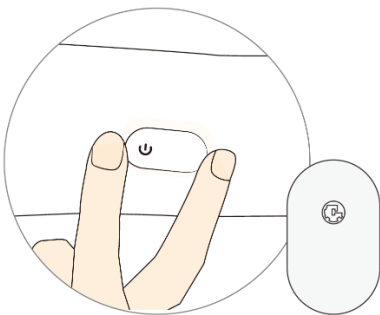
Sensor Pack

Used with the Sensor Applicator to prepare the Sensor for use.



Sensor Applicator

Applies the Sensor to your body.



Sensor (visible after application)

Notes:

- The Sensor kit and the App can be used in the home environment.
- When opening the kit, check that all the contents are present and undamaged. If any parts are missing or damaged, contact the Customer Service at support@sibionics.com.

CAUTION

Read the following information before using the Sensor kit.

- The Sensor includes two main parts; one part, the electrode module, is placed in the Sensor Pack, and the other part, the electronics that transmit the signal to the App, is placed in the Sensor Applicator. Follow the instructions of [Applying Your Sensor](#) to prepare and apply the Sensor on the back of the upper arm.
- The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.
- The Sensor automatically measures the glucose while placed on the body and stores the glucose data. It uses an amperometric electrochemical technique for glucose assay. Your display device configured with the App receives the glucose readings and other information from the Sensor, via Bluetooth communication.

3 Downloading the App

Scan the QR code below or provided elsewhere and follow the on-screen instructions to install the app on your smartphone. When the installation is complete, make sure the app icon appears on the phone screen.

Notes

- To download the smartphone app, your phone must be connected to the internet.
- To download, install, and update the smartwatch app, refer to the smartwatch's Quick Guide.
- See [Recommended System Configurations](#) for system configurations that is recommended to download the App.
- Visit <https://www.sibionicscgm.com/pages/mobile-device-compatibility> to ensure your display devices are compatible with the App.

For iOS and Android



3.1 Recommended System Configurations

Recommended System Configurations for Smartphone

	Harmony OS	iOS	Android OS
Operating system	Harmony 4.2.0	iOS 16.5	Android 10
CPU	Huawei Kirin 9000S	iPhone A15	Huawei Kirin 990
RAM	12 GB	6 GB	8 GB
ROM	512 GB	128 GB	
Bluetooth	5.2	5.0	5.1

	Harmony OS	iOS	Android OS
Network bandwidth	Not less than 5 Mbps		
Display size	(17 centimeters) 6.69 inches	(15.5 centimeters) 6.1 inches	(15.5 centimeters) 6.1 inches
Display resolution	2688*1216	2532*1170	2340*1080
Maximum screen brightness	Greater than 150 cd/m ²		
Ambient light	Ambient light detection, screen brightness correction, automatic and manual adjustment of screen brightness.		
Battery capacity	4650 mAh	3095 mAh	4560 mAh

Recommended System Configurations for Smartwatch

Feature	Specification
Operating system	Android 8.1 and above
CPU	With the dominant frequency of not more than 1.4 GHz
RAM	1 GB
ROM	8 GB
Bluetooth	Supported
WIFI	Supported
Display	368*448 resolution, 1.78 inches (4.52 centimeters)
Touch Screen	Full screen touch
Speaker	Supported
Vibration Motor	Supported
Battery	4.45 V, 570 mAh
Network bandwidth	Not less than 5 Mbps
Maximum screen brightness	Greater than 150 cd/m ²

3.2 Creating an Account

1. Launch the smartphone app by tapping .
2. Tap **Get Started** on the login screen.

Follow the on-screen instructions to create your account.

3. Enter the requested settings on the screens.

Note: You can view or change the settings in **Profile > Edit Profile**.

4. The smartphone app account is now set up and ready for use.

After applying a Sensor, you can pair it with the App. See [Pairing Your Sensor to Receive Glucose Readings](#) for instructions.

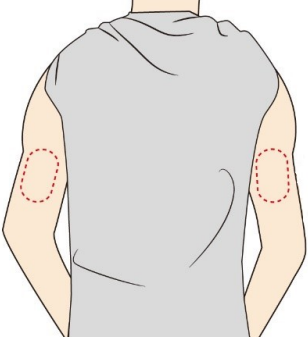
Note: If you have forgotten your password while logging in, tap **Forgot Password?** on the login screen and follow the instructions to reset it.

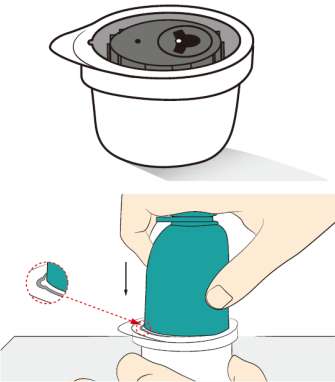
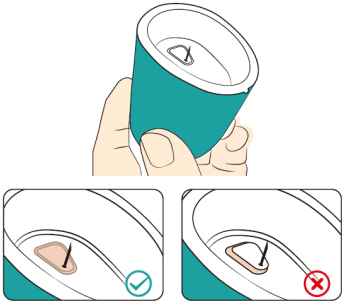
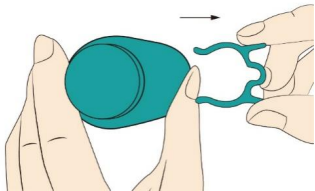
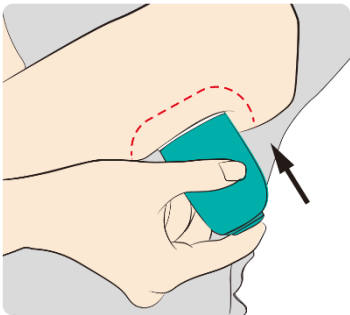
 CAUTION

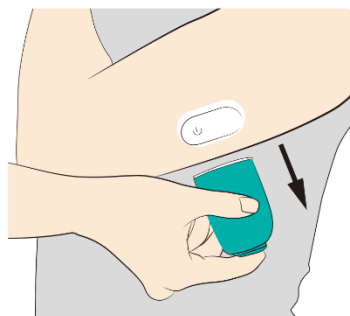
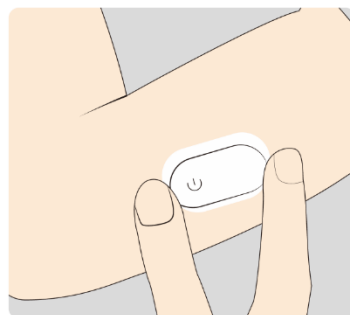
Please keep in mind that uninstalling the smartphone app may cause you to lose historical data. If you have any questions about the app during use, contact Customer Service at support@sibionics.com.

4 Applying Your Sensor

Follow the instructions below to apply your Sensor.

Step	Description
1	 Apply Sensors only on the back of the upper arm. Avoid areas with scars, moles, stretch marks, or lumps. If placed in other areas, the Sensor may not function properly and could give inaccurate readings. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). To prevent discomfort or skin irritation, select a different site other than the one most recently used. CAUTION: Choose a site that is at least 5 centimeters (2 inches) away from an insulin injection site.
2	 Clean the application site, for example with an alcohol wipe, prior to application. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow the site to air dry before proceeding. Note: The area MUST be clean and dry before application, or the Sensor may not stay on for the full 14-day wear period.
3	 Open the Sensor Pack by peeling the lid off completely. Uncover the cap from the Sensor Applicator and set the cap aside. CAUTION: DO NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. DO NOT use if it past the expiration date.

Step	Description
4 	Line up the small white bulge on the Sensor Applicator with the concavity on the edge of Sensor Pack. On a hard surface, press firmly down on the Sensor Applicator until it comes to a stop. CAUTION: DO NOT remove the safety clip (see step 6) from the Sensor Applicator prior to pressing into the Sensor Pack. If the safety clip is removed prior to this assembly, damage may be caused by accidentally pressing the button that inserts the Sensor prematurely.
5 	Lift the Sensor Applicator out of the Sensor Pack. CAUTION: The Sensor Applicator now contains a tip. DO NOT touch the inside of the Sensor Applicator or put it back into the Sensor Pack.
6 	Press the safety clip and pull it out from the Sensor Applicator.
7 	Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body. Precaution: DO NOT push down on the Sensor Applicator until placed over the prepared site to prevent unintended results or injury. Make sure that the small white bulge on the Sensor Applicator is in the upward or downward direction.

Step	Description
8 	Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin. Note: Applying the Sensor may cause bruising or bleeding. In case of persistent bleeding, remove the Sensor and contact your professional healthcare team.
9 	Make sure the Sensor is secure after application. Note: Use your display device to communicate with the Sensor right after application. This will help prevent the built-in lithium battery running out of its power before the end of 14-day Sensor wear.

5 Pairing Your Sensor to Receive Glucose Readings

After applying the Sensor to your arm (see [Applying Your Sensor](#) for instructions), pair it with the App to receive glucose data.

The GS1 CGM system provides two modes to pair your Sensor:

Mode 1: Pair with the smartphone app

Mode 2: Pair with the smartwatch app

You can switch the connection mode between the smartphone app and the smartwatch app as you need.

Note: The Sensor can only pair with one display device at a time.

Mode 1: Pairing with the smartphone app

1. Launch the smartphone app (see [Downloading the App](#) for instructions) and sign in when prompted.
2. Confirm the Sensor is properly applied, then follow the instructions on the home screen.

Note: The app may request access to the camera and Bluetooth. Grant permissions to enable Sensor scanning, otherwise you will not be able to receive any glucose data.

3. Scan the sensor QR code or manually enter the 8-digit code which is printed under the QR code on the packaging box to pair with the Sensor.



Scan this QR code with the App to sync the sensor and receive data

8-digit code for manual entry

Note: Only one Sensor can be paired at a time. Pairing a new Sensor will automatically disconnect the existing one.

 **CAUTION:** Turn on the Bluetooth on the phone so that the phone/App can pair and communicate with the Sensor. Do not force close the App, as this will prevent it from receiving data from the Sensor.

4. Start the Sensor.



Wait. During the warmup period, alarms and glucose readings would not work. Readings become available once the 1-hour warm-up completes. A countdown timer on the screen displays the remaining time.

5. Check the glucose readings.



Sensor warm-up is complete. The app displays the current glucose reading with a trend arrow. Current glucose reading is updated every 5 minutes.

 **CAUTION:** Keep the Sensor and display device within 6 meters (20 feet) with no obstacles (such as walls or metal) between them, otherwise communication may be compromised.

How to switch connection to the smartwatch app

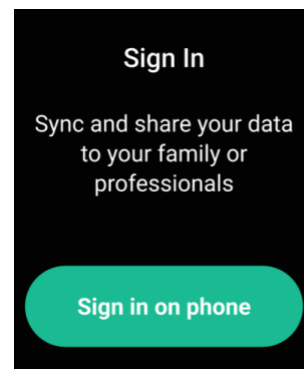
If you initially paired the Sensor with your smartphone app and now want to switch the connection to your smartwatch app:

1. Tap  to launch the smartwatch app.

Note: Ensure that your smartphone and smartwatch are connected to the internet.

 **CAUTION:** Keep the Sensor and smartwatch within 6 meters (20 feet) with no obstacles (such as walls or metal) between them, otherwise communication may be compromised.

2. Tap **Sign in on phone** on the smartwatch app. A login QR code will then appear on the smartwatch face.
3. Open the smartphone app and go to **Profile > Smart Watch**.
4. Scan the QR code displayed on your smartwatch using your smartphone app.
5. Authorize login on your smartphone app to complete the account setup on the smartwatch app.



Your smartwatch app will now pair with the Sensor automatically.

Note: When switching connection modes, check that the device numbers on the screens match to avoid connecting to different devices with your smartphone and smartwatch separately.

Mode 2: Pairing with the smartwatch app

To use the smartwatch app normally, please first register an account on the smartphone app.



CAUTION: Turn on the Bluetooth on the smartwatch so that the smartwatch app can pair and communicate with the Sensor.

1. Refer to steps 1 to 4 in section [How to switch connection to the smartwatch app](#) to log in to your registered account on smartwatch app.
Note: Ensure that both devices are connected to the internet.
2. On the smartwatch app, tap **Apply a new device**.
3. Scan the QR code on the packaging box using your phone. Or you can tap **Enter Sensor Code** and manually enter the 8-digit code printed under the QR code to pair your smartwatch app with the Sensor.
4. Tap **Confirm** on the smartwatch app.
5. Wait for the Sensor to warm up.
6. Check the glucose readings.

Notes:

- Using the smartwatch app may affect how you receive alarms. Ensure you know how to receive notifications on the smartwatch app.
- You should wear the smartwatch to see alarms and feel their vibrations.

How to switch connection to the smartphone app

If you initially paired the Sensor with your smartwatch app and now want to switch the connection to your smartphone app:

1. Open the smartphone app and go to **Profile > Smart Watch**.

Note: Ensure that both devices are connected to the internet.

2. Follow the on-screen instructions to pair your smartphone app with the Sensor.
3. On the smartwatch app, confirm the disconnection.

Your smartphone app will then pair with the Sensor, and the smartwatch app will automatically log out.

When the Sensor completes the warm-up and restores communication, all the recorded glucose data is communicated to your display device. The current glucose level is then updated every 5 minutes and displayed on the screen for the full 14-day period.

What to do if the display device and Sensor are unable to communicate

If the display device and Sensor are not communicating properly, follow the instructions to reconnect:

1. Check if you applied the Sensor properly. If no, refer to [Applying Your Sensor](#) to learn how to apply the Sensor, and re-connect your display device and Sensor. If the problem persists, proceed to the next steps.

2. Check if the Bluetooth is turned on in the display device settings. Follow the prompts on the App to turn on Bluetooth and restore communication with the Sensor.
3. Check if the App has obtained the Nearby Devices permission and the Location permission.
4. Check if the distance is beyond 6 meters (20 feet) between the display device and Sensor. If yes, keep the display device within 6 meters (20 feet) of the Sensor.
5. Check if there is another display device connected to the Sensor (the Sensor cannot be connected to more than one device at the same time). If so, turn off the Bluetooth of the original device before connecting to the new device.
6. Try restarting your display device and connecting to the Sensor again.
7. Check if any event mentioned in section [System Safety Statements](#) occurred.

Note: If the problem still persists, contact our Customer Service at support@sibionics.com.

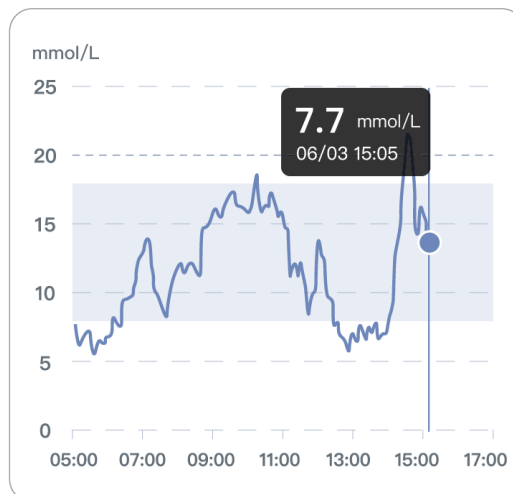
6 Getting Glucose Readings

Viewing glucose data on the smartphone app

The figure shows the glucose trending graph of the smartphone app.

Notes:

- The glucose readings above 25mmol/L are displayed at 25mmol/L.
- The target glucose range is not related to the glucose alarm settings.



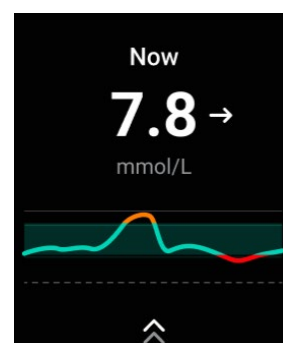
The graphs include:

- Glucose data from the Sensor over the past 3 to 24 hours displayed as a trend line, ending with the most current glucose reading on the far right.
 - ✧ Tap the graph at any glucose data point to highlight the associated value.
 - ✧ Switch between a 3-hour, a 6-hour, a 12-hour and a 24-hour view of the glucose data by tapping on the desired view duration above the graph.
 - ✧ View the graphs in full screen by tapping  below the graph.
- Added events appear as graphic icons at the recorded time. Tap any icon to display detailed information about the event.

Viewing glucose data on the smartwatch app

The figure shows the real-time monitoring page of the smartwatch app.

You can swipe up on this page to view the historical curve for the past 3 hours.



Trend arrows

Trend arrows show the speed and direction of the glucose trends based on recent GS1 readings.

	Rapidly rising (More than 0.11 mmol/L each minute)
	Slowly rising (0.06-0.11 mmol/L each minute)
	Steady (Less than 0.06 mmol/L each minute)
	Falling slowly (0.06-0.11 mmol/L each minute)
	Rapidly falling (More than 0.11 mmol/L each minute)

Logging events

In the smartphone app, you can log daily events to help capture information that may affect your glucose levels.

Event Icon	Description
	The meal time and what you ate or drank.
	The type and duration of the exercise routine.
	The type, amount and time of taking medicine.
	The type, amount and delivery time of insulin.
	Blood glucose meter readings. These can be used to glycemic control.
	The bedtime you spent.
	The mood, for example, happy, angry, or unwell.

Follow the steps to add events:

1. Tap  and select the event icon you want to add.

2. Select or enter the required information.

3. Tap **Done** to save the events.

You can view events by:

- Tapping the event icon on the daily glucose trending graph to display detailed information about the event, or
- Tapping **Profile** > **Logbook** to review all the events that you have added.

7 Setting Glucose Alarm

Glucose alarms are notifications from the App when glucose levels fall out of the set alarm range.

To set or turn on glucose alarms, tap **Profile > Alarm Settings** on the smartphone app. The smartwatch app uses settings from your smartphone app.

CAUTION

- Make sure your display device is always within 6 meters (20 feet) around you and turn on alarms. You might not hear alarms if you are outside of range.
- Avoid forcing the App to close. To receive alarms, the App needs to be operating in the background.
- Turn the Override Do Not Disturb setting in the App ON for Urgent Low Glucose, Low Glucose, High Glucose, and Signal Loss Alarms to make sure you receive audible alarms if do not disturb or silent media volume of your device is ON.
- You must grant permission to the Do Not Disturb feature to use the Override Do Not Disturb feature.
 - ✧ For iOS: You must accept the App's permission request for Critical Alerts to use this feature. You can also enable the Critical Alerts setting directly from the App's notification settings.
 - ✧ For Android: You must accept the App's permission request for Do Not Disturb access permission to use this feature. You can also enable the Do Not Disturb access setting directly from the App's notification settings.
- If you use a Quiet Modes (Silence All or Vibrate), it affects all alarms, including Urgent Low and Technical Alarms.

7.1 Glucose Alarms

Urgent Low Glucose Alarm:

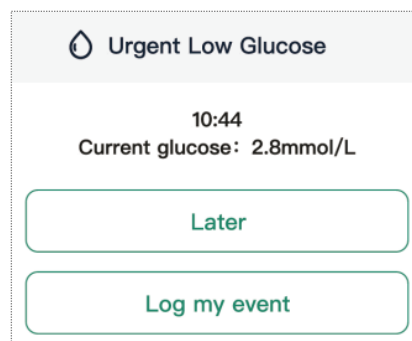
Tells you when your GS1 reading is at 3.1 mmol/L or below. Acknowledge this alarm or log the event that you think might have triggered it.

You can customize this alarm:

1. Set the Snooze (repeat interval) for this alarm as you need.
2. Choose either **Sound**, **Vibration** or both for the alarm style.
3. If you choose **Sound** or both, select the alarm sound. Volume will match your device settings. Skip this step if you choose **Vibration** only.
4. Tap **Save** to save the settings.

Notes:

- Urgent Low Glucose Alarm will always play a sound even if your device is muted or Do Not Disturb is ON.
- The Urgent Low Glucose Alarm level is 3.1mmol/L. You can adjust the Snooze (repeat interval) between 5 and 30 minutes. After you acknowledge your first Urgent Low alarm, it will repeat if your GS1 reading stays below 3.1mmol/L for the selected interval.

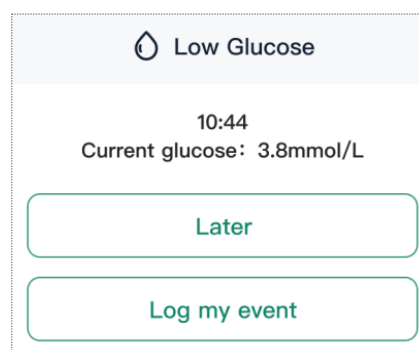


Low Glucose Alarm:

Tells you when the GS1 reading is at or below the level you set. Acknowledge this alarm, or log the event that you think might have triggered it.

You can customize this alarm:

1. Set the Low Glucose Alarm level between 3.3 mmol/L and 5.6 mmol/L.
2. Set the Snooze as you need.
3. Choose from **Sound**, **Vibration**, or both for the alarm style.



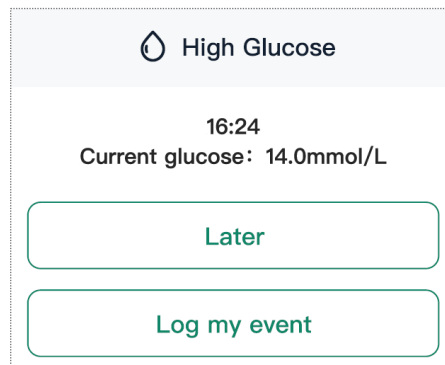
4. If you choose **Sound** or both, select the alarm sound. Volume will match your device settings. Skip this step if you choose **Vibration** only.
5. Tap **Save** to save the settings.

High Glucose Alarm:

Tells you when the GS1 reading is at or above the set level. Acknowledge this alarm, or log the event that you think might have triggered it.

You can customize this alarm:

1. Set the High Glucose Alarm level between 6.7 mmol/L and 22.2 mmol/L.
2. Set the Snooze as you need.
3. Choose from **Sound**, **Vibration**, or both for the alarm style.
4. If you chose **Sound** or both, select the alarm sound. Volume will match your device settings. Skip this step if you chose **Vibration** only.
5. Tap **Save** to save the settings.



Rising Fast Alarm:

Tells you when your glucose is rising faster than 0.11 mmol/L per minute while the current glucose level is above your specified threshold.

Acknowledge this alarm, or log the event that might have triggered it.

Customize this alarm by following the on-screen notifications.

Falling Fast Alarm:

Tells you when your glucose is falling faster than 0.11 mmol/L per minute while the current glucose level is below your specified threshold.

Acknowledge this alarm, or log the event that might have triggered it.

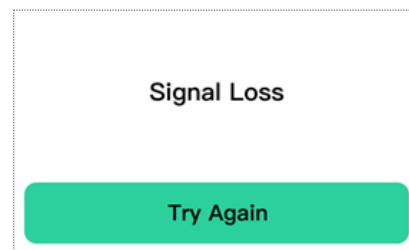
Customize this alarm by following the on-screen notifications.

7.2 System Alarms

Signal Loss Alarm

Tells you when your Sensor has not communicated with the App temporarily and you are not receiving glucose readings or Low or High Glucose Alarms.

Follow the on-screen instructions to try to re-communicate with your Sensor. If the problem continues, contact Customer Service at support@sibionics.com.



You can customize this alarm:

1. Set the Snooze for this alarm to notify you when your Sensor has not communicated with the App for longer than the specified duration.
2. Choose from **Sound**, **Vibration**, or both for the alarm style.
3. If you choose **Sound** or both, select the alarm sound. Volume will match your device settings. Skip this step if you choose **Vibration** only.
4. Tap **Save** to save the settings.

Technical Alarms

Tells you when your Sensor failed. Technical Alarm cannot be turned off. Customize this alarm by following the on-screen instructions.

7.3 Responding to alarms

When you receive an alarm, please acknowledge it on your display device, and make treatment decisions according to your current health condition.

Until you acknowledge the alarm, the notification box will persistently display on your App screen. The sound/vibration will repeat when the system triggers the next alarm. The system analyzes your GS1 readings every 5 minutes.

Note: You can set Snooze (repeat interval) for the urgent low, low and high glucose alarms and for the signal loss alarms. These alarms will repeat at the selected interval if the condition persists.

7.4 Viewing Glucose Alarm Records

You can view the low and high glucose alarms records by tapping  in the upper right corner of the **Monitoring** screen. Reviewing and understanding your glucose history can be an important tool for improving your glucose control. Work with your professional healthcare team to understand your glucose history.

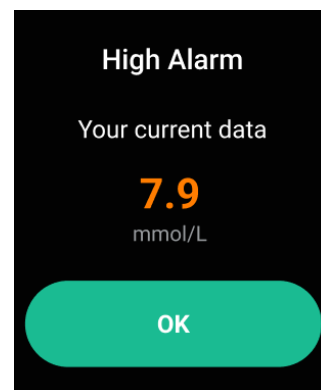
WARNING

- If high/low glucose alarm do not match symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter. Seek medical attention when appropriate.
- The high/low glucose alarm is not applicable in case of pregnancy, dialysis, or critical illness. The high/low alarm levels in this clinical study are the recommended values for type I and type II diabetes patients, excluding the aforementioned populations.

7.5 Using Smartwatch App Alarms

When you pair your Sensor with the smartwatch app, the glucose alarms will be received on the smartwatch app, but not on your smartphone app. To acknowledge an alarm, tap **OK** on the smartwatch face.

You can change glucose alarm settings in your smartphone app. The smartwatch app uses settings from your smartphone app.



Note: Ensure that both devices are connected to the internet to sync alarm settings.

7.6 What to do if you are not getting alarms

Check the following to identify possible causes:

- Battery charge too low: If the display device battery is depleted, no GS1 readings or alarms will be obtained.
- App turned off: Check the smartphone app and/or the smartwatch app settings to ensure it is turned on to receive GS1 readings or alarms.
- Alarms turned off: Keep the alarm function in the smartphone app and/or the smartwatch app turned on to get alarms.
- Volume not working: Keep the volume loud enough to hear the alarms.
- Speaker and vibrations not working: you will not hear or feel your alarms, check if turned off or not functioning.
- Out of range: Keep your display device no more than 6 meters (20 feet) from the sensor, with no obstacles between them, to ensure proper communication. If not in range, no GS1 readings or alarm will be obtained.
- System errors: In the event of a system error indicated in the smartphone app and/or the smartwatch app – such as no readings, sensor error, or signal loss – no GS1 readings or alarms will be obtained.
- During warm-up and after session ends: No alarms or GS1 readings will be obtained during the 1-hour warmup or after a sensor session ends.

8 Getting Glucose Report

View your glucose report for the day or for a specific time range on your smartphone app. If needed, you can also export your AGP report.

8.1 Viewing Daily Report

Viewing daily reports in **Daily Log** which show daily detailed information.

Daily Overall – shows the average of Sensor glucose readings, the percentage of time in which the Sensor glucose readings were within and out of the target glucose range.

Daily Trending – displays daily glucose readings and trend in a graph format. The icons denoting events are shown in the graph.

Events – lists the event information that you logged for the day.

Select Date

- Tap **Previous** and **Next** on the top of the smartphone app screen to see data of the previous and the next day respectively, or
- Tap the icon on the top middle to select the date you want to review.

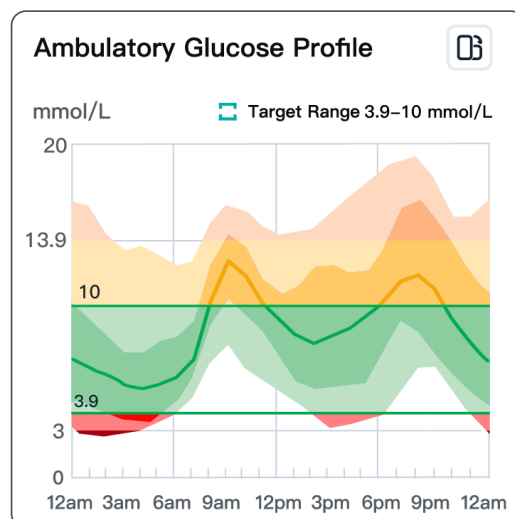
8.2 Viewing AGP Report

Viewing AGP reports in **AGP Report** and glucose trending in **Compare**.

AGP Report

AGP reports show summaries of information over several days.

Ambulatory Glucose Profile (AGP) shows the pattern and variability of the Sensor glucose levels over a typical day. The green part shows the target range of glucose readings.



Note: AGP needs at least 7 days of glucose readings to ensure statistical validity.

Compare

Select a start and end date within a 14-day span to compare the glucose trending.

8.3 Exporting AGP Report

1. Tap **AGP Reports** on the smartphone app.
2. Set the time range.
 - Select from 7/14/30/90 days on the top of the screen, or
 - tap **Others** to adjust start/end dates manually.
3. Tap **Report** to generate the report of the targeted time range.

9 Changing User Profile

Smartphone App Profile

Enter the profile screen to edit the smartphone app settings.

Button Name	Description
Edit Profile	Edit the account information.
Sensor	• Display Sensor information. • View Sensor glucose readings by tapping More Data and export these to an excel file by Export all. • Replace new devices by tapping Connect a new device.
Logbook	Displays a history of events logged in the App.
Alarm Settings	1. Toggle the alarm settings on to set the alarm style and alarm targets. 2. Tap Save to save your settings. 3. Tap Reset Alarm Settings to reset all alarms to default settings.
Target Glucose Range	Set the type of diabetes and target glucose range.
Smart Watch	Share your data with smartwatch device.
Reminders	Add reminders and customize their names, times, and repetition schedules. Swipe left to delete the reminders.
Health Care	In SIBIONICS Proview, you can invite professional medical institutions or clinics to access your data to assist in managing your health status. You can also disconnect from them at any time. In SIBIONICS Companion, you can share your data with whomever you want, and follow others data from here.
Help	Seek for helps in application and connection.

Smartphone App Settings

Tap  in the upper right corner of **Profile** page to configure settings on your smartphone app.

Button Name	Description
Clear All Data	Delete all the Sensor glucose data stored in the phone. - To delete, tap Yes. Note: Data cannot be restored once deleted. - To cancel, tap “x” on the upper right corner of the dialog box.
Set/Reset Password	Set or reset your account password.
Unit	Select the glucose unit of measure used in the App. The smartwatch app uses settings from your smartphone app.
Date Format	Select your preferred date format in the App.
Time Format	Select your preferred time format in the App.
Language	Select the language of the App.
Country/Region	Filter the list or search for a country/region by name.
About Us	View app software version and other information. Upgrade the SIBIONICS App if a new version is available.
Legal Documents	View the Terms of Use and the Privacy Policy.
Remove the Account	Delete the current account and all the data. Note: Data cannot be recovered once deleted.
Shake for Poster	Turn on the button, then gently shake your phone on the Monitoring page to create a poster of your real-time glucose information.
Log Out	Log the current account out.

Smartwatch App Profile

Enter the monitoring page of the smartwatch app, and slide left to enter the **Profile** page.

Button Name		Description
Devices		Display sensor information.
Followers		Display the follower list. Delete the follower if you want. Note: Use the Companion feature on your smartphone app to invite a friend to view your sensor glucose readings and trending graphs on your smartwatch app. Ensure that both the smartphone app and the smartwatch app are logged into the same account. Once the settings are configured on the smartphone app, the invited friend will be shown in the follower list.
Settings	Unit	Display the glucose unit set by the smartphone app. Note: The glucose unit can only be selected through the smartphone app. After selecting the unit on your smartphone, open the smartwatch app, which will automatically sync the changes. Ensure that both the smartphone app and the smartwatch app are logged in with the same account for this synchronization to occur.
	Alarm	Display the alarm threshold set by the smartphone app. Note: You can set the high and low sensor glucose alert targets, and alert style only through your smartphone app. After completing the settings on your smartphone, your smartwatch app will automatically sync the changes, provided that both the smartphone app and the smartwatch app are logged in with the same account.
Log out		Log the current account out.

10 Daily Activities

The GS1 CGM System can be used during a wide variety of activities.

Activity	What You Need to Know
Sleeping	Keep the display device within 6 meters (20 feet) of the Sensor without any obstacles (such as walls or metal) or the communication may be compromised. To receive alarms or reminders while sleeping, make sure that the sound and/or vibration is turned on for your display device.
Bathing, Showering, and Swimming	The Sensor is water-resistant and can be worn while bathing, showering, or swimming. Note: DO NOT immerse the Sensor deeper than 1 meter (3 feet) or for longer than 1 hour.
Other Activities	Intense exercise can cause the Sensor to loose. Protect the Sensor from collision when wearing it during exercise, for example by wearing the patch. Jogging will not affect the Sensor performance.

11 Removing Your Sensor

1. Pull up the edge of the adhesive that keeps the Sensor attached to the skin. Slowly peel away from the skin in one motion. Rubbing alcohol around the adhesive can facilitate the removal of the Sensor.

Note: Any adhesive residue on the skin can be removed with warm, soapy water or a small quantity of isopropyl alcohol. If discomfort occurs after using isopropyl alcohol, rinse thoroughly with water and contact a healthcare provider if symptoms persist.

2. Discard the used Sensor following the directions from your healthcare provider. See [Storage, Maintenance and Disposal of GS1 CGM System](#). When applying a new Sensor, follow the instructions in [Applying Your Sensor](#). If the last Sensor was removed after the 14-day wearing period, you will be prompted to start a new Sensor.

CAUTION

The Sensor can be worn for up to 14 days. At the end of the wear period, the Sensor will stop updating the glucose data and should be removed as instructed.

12 Replacing Your Sensor

The Sensor automatically stops working after the 14-day wear period and must be replaced.

Replace the Sensor in case of any irritation or discomfort at the application site.

CAUTION

If the Sensor becomes loosen or the Sensor tip is coming out of the skin, no readings or unreliable low readings may be obtained. Verify that the Sensor has not come loose. If it has come loose, remove it, and apply a new one.

See [Removing Your Sensor](#) for Sensor removal.

13 Treatment Decisions

Work with your professional healthcare team to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions. You should also talk to your professional healthcare team about the best times to check your glucose.

WARNING:

The System can replace blood glucose testing except in the below situations. These are the times when you need to do a blood glucose test before deciding what to do or what treatment decision to make as Sensor readings may not accurately reflect blood glucose levels:

- No number and/or no arrow
- Symptoms don't match readings:

Do a blood glucose test if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose

If you're the caregiver, pay attention to times when the symptoms of the one you're caring for don't match their Sensor glucose readings. When symptoms don't match readings, do a blood glucose test and treat based on that result.

When how you feel doesn't match your sensor reading, use your BG meter to treat even if you have a number and arrow. For example, you don't feel well, but your sensor readings show you're in range.

Making Treatment Decision

Before you start using the System for treatment decisions, make sure you have a good understanding of how the System works for your body. Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive from your System.

Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even doing nothing and checking again later.

Check your glucose often to see how carbs, medication, exercise, illness, or stress levels impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.

Talk to your professional healthcare team about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.

Getting familiar with the System could take days, weeks, or even months. The more you check readings from the System with a blood glucose meter, the better you will understand how the System works for you. After you check your glucose, use all of the information on the screen when deciding what to do or what treatment decision to make. Remember that you should never make a treatment decision based on the Glucose Trend Arrow alone. Work with your professional healthcare team to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions.

CAUTION:

When there is no Current Glucose number, such as when you receive an error message or a low or high result, you don't have enough information to make a treatment decision. Do a blood glucose test and treat based on that result. Don't trust Sensor glucose readings that you think may be incorrect or that don't match what you would expect based on your recent activity. For example, if you ate dinner but forgot to take insulin before eating, you would expect your glucose to be high. If your glucose reading is low, then it doesn't

match your recent activity, so don't use it to make treatment decisions. Don't make treatment decisions if you think your Sensor glucose readings are incorrect. Do a blood glucose test and treat based on that result.

There may be times when your symptoms don't match your Sensor glucose readings. For example, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose, but your glucose reading is within your target range. When symptoms don't match readings, do a blood glucose test and treat based on that result. Don't ignore symptoms that may be due to low or high blood glucose.

Your professional healthcare team can help you understand when doing nothing and checking again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and check again later. Don't take a correction dose within 2 hours of your meal dose. This may result in “insulin stacking” and low glucose.

Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (fingersticks), particularly during times when your blood glucose is changing quickly. If your glucose readings and alarms from the System do not match your symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions.

Deciding how much rapid-acting insulin to take for different meals and situations can be difficult. Work with your professional healthcare team to discuss different situations and what might work best for you.

14 Troubleshooting

Problem	Possible Cause(s)	Solution
The Sensor is not sticking to the skin.	The site is not free of dirt, oil, hair, or sweat.	1. Remove the Sensor. 2. Clean the site with a plain soap and water and then clean with an alcohol wipe. Wait for the alcohol to dry before applying the Sensor. 3. Apply a new sensor following the instructions in Applying Your Sensor. Consider shaving the site, avoiding the use of lotions prior to insertion, and applying a new Sensor to the non-dominant arm.
Skin irritation at the Sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.	Ensure that nothing rubs on the site.
	You may be sensitive to the adhesive material.	If the irritation is where the adhesive touches the skin, contact your professional healthcare team to identify the best solution.
Glucose reading is not updating.	The display device is not held close enough to the Sensor.	Make sure the display device is within 6 meters (20 feet) of the Sensor and try pairing the Sensor to get a glucose reading.
	The Sensor is too hot or too cold.	Move to a location where the temperature is between 5°C (41°F) and 40°C (104°F) and pair the Sensor again in a few minutes.

15 Storage, Maintenance and Disposal of GS1 CGM System

Storage

Storing the GS1 CGM system correctly helps prevent system failures.

- Keep the Sensor in its sterile packaging until ready to be used.
- Store at temperatures ranging between 4°C (39.2°F) and 25°C (77°F).
- Store Sensors in a cool, dry place. Do not store in a parked car on a hot day or in the freezer.
- Store between 10% and 90% relative humidity.
- Storage outside the recommended range may result in inaccurate GS1 readings.
- You may store Sensor in refrigerator if within the recommended temperature range, but not in a freezer.

Maintenance

The System has no serviceable parts. Software maintenance is provided through software upgrade.

System Disposal

Different regions have different requirements for disposal of electronics (Sensor) and parts that have been in contact with body fluids or blood (Applicator and Sensor).

Sensor must not be disposed of via municipal waste collection. Separate collection of electrical and electronic equipment waste is mandated in the European Union by Directive 2012/19/EU.

Before disposing of the Sensor Applicator, perform the following operations:

- Pull the internal structure of Sensor Applicator backward using the bulge of the cap until it clicks into place. Cover the Sensor Applicator with the cap and put back the safety clip.

- Consult your local waste management authority for instructions on how to dispose of Sensor Applicators at a designated sharps collection site.

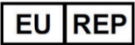
WARNING

- The Sensor used contains a disposable Sensor probe, which is in contact with interstitial fluid during use. Do not reuse Sensors. The Sensor is for single use only. Reuse may result in damage to the Sensor probe, inaccurate glucose readings, and irritation or infection at the application site.
- The Sensor contains a lithium battery that should not be incinerated. Battery may explode upon incineration.
- Sensor Applicator is for single use only and includes a guide needle. DO NOT attempt to remove, clean or sterilize the guide needle, as this may cause unintended results or injury.

Customer Service

Shenzhen SiSensing offers technical support for the GS1 Continuous Glucose Monitoring System. If you have any questions about the GS1 CGM system, please contact our Customer Service team at support@sibionics.com.

16 Labelling Symbols

	Refer to instruction manual/booklet		Consult instructions for use or consult electronic instructions for use
	Manufacturer		Serial number
	Temperature limit		Keep away from rain
	Date of manufacture		Non-ionizing electromagnetic radiation
	MR unsafe		Caution
	Type BF Applied Part		Sterilized using irradiation
	Reference Number		General symbol for recovery/recyclable
	Do not re-use		Humidity limitation
	Do not use if package is damaged and consult instructions for use		Waste Electrical and Electronic Equipment (WEEE)– Follow the Directive 2012/19/EU in the European Union for product disposal.
	Use-by date		Single sterile barrier system
	Medical device		CE mark
	Authorized representative in the European Community		Indicates the degree of protection provided by enclosure according to IEC 60601-1
	Unique device identifier		This way up
	Importer		Keep away from sunlight
	Fragile, handle with care		

17 Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration - electromagnetic emissions

The System is intended for use in the electromagnetic environment as described in the following table. It is the responsibility of the customer or user to ensure that the System is used in this environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The 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 CISPR 11	Class B	The System is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity

The System is intended for use in the electromagnetic environment as described in the following table. It is the responsibility of the customer or user to ensure that the System is used in this environment.

IMMUNITY test	IEC/EN 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV; ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV; ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be of at least 30 %.
Electrical fast transient IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable

IMMUNITY test	IEC/EN 60601 test level	Compliance Level	Electromagnetic environment - guidance
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	Not applicable	Not applicable
Voltage dips and interruptions IEC 61000-4-11	0%, 70%, 0% of U_T	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

Note: U_T is the AC Mains voltage prior to application of the test level.

IMMUNITY test	IEC/EN 60601 test level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3V ISM and amateur radio bands between 150 kHz to 80 MHz 6V	Not applicable	Not applicable
Radiated RF IEC 61000-4-3	80MHz to 2700MHz 10V/m 385MHz 27V/m 450MHz 28V/m 710MHz, 745MHz, 780MHz 9V/m 810MHz, 870MHz, 910MHz 28V/m 1720MHz, 1845MHz, 1970MHz 28V/m 2450MHz 28V/m 5240MHz, 5500MHz, 5785MHz 9V/m	10V/m, 80% Am at 1kHz 27V/m PM at 18Hz 28V/m FM ± 5 kHz deviation at 1kHz sine 9V/m PM at 217Hz 28V/m PM at 18Hz 28V/m PM at 217Hz 28V/m PM at 217Hz 9V/m PM at 217Hz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 80 MHz to 2.5 GHz

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).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

Recommended separation distances between portable and mobile RF communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	Not Applicable	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	Not Applicable	0.12	0.23
0.1	Not Applicable	0.38	0.73
1	Not Applicable	1.2	2.3

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	Not Applicable	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
10	Not Applicable	3.8	7.3
100	Not Applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1

At 80 MHz and 800 MHz, the separation distance for 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.

18 Technical Specification

Classification

As defined by IEC 60601-1, the device is classified as follows:

- Internally powered.
- Type BF applied parts.
- Ordinary equipment.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture.
- Continuous operation.
- IP28

Sensor Specifications

Parameter	Specifications
Sensor Useful Life	14 days
Sensor glucose assay method	Amperometric electrochemical Sensor
Accuracy	≥ 5.55 mmol/L within $\pm 15\%$ at glucose concentrations
	< 5.55 mmol/L ± 0.83 mmol/L
Sensor glucose reading range	2.2 mmol/L to 25.0 mmol/L
Sensor size	33.5 mm $\times$ 20.0 mm $\times$ 5.3 mm
Sensor weight	3.84 g
Sensor power source	One lithium battery DC 3.0V
Sensor memory	Up to 14 days
Operating temperature	5°C (41°F) to 40°C (104°F)
Sensor Pack and Applicator shelf life	18 months
Sensor Pack and Applicator storage, transport temperature	4°C (39.2°F) to 25°C (77°F)
Operating and storage relative humidity	10% to 90%, non-condensing
Operating and storage atmospheric pressure	70 kPa to 106 kPa

Parameter	Specifications
Sensor water resistance and ingress protection	IP28: Protected against insertion of large objects in not less than 12.5 mm diameter and the effects of continuous immersion in water over an hour
Sensor Pack and Applicator transport relative humidity	10% to 90%, non-condensing
Sensor Pack sterilization	Sterile by radiation
Frequency band	2.402 – 2.480 GHz BLE
Bandwidth	1 MHz
Maximum output power	3.7 dBm (2.34 mW)
Modulation	GFSK
Data communication range	6 meters (20 feet)

Quality of service (QoS)

- Sensor wireless communication

The Sensor and App connect via a BLE network. The Sensor sends glucose data and system related alarms to the App. The Sensor and the App verify the integrity of received data after wireless transmission. Quality of the connection is in accordance with the Bluetooth Specification v5.0. The App is designed to only accept radio frequency (RF) communications from recognized and paired Sensors.

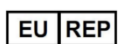
- Security Measures

Unless disabled, the App regularly communicates with cloud server. The App and communication between the App and cloud server are protected by a number of mechanisms designed to safeguard data integrity and data confidentiality.



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