GS1 Continuous Glucose Monitoring System

App User Guide

English

H A0
Revision date: October 2023

WARNING:

Before you use the SIBIONICS App and the GS1 System, review all the product instructions and the insert. The User Guide includes all safety information and instructions for use. Talk to your healthcare professional about how you should use your Sensor glucose information to help manage your diabetes.

Failure to use the System according to the instructions for use may result in you missing a severe low blood glucose or high blood 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.

Contents

Chapter 1 Important Safety Information

1.1 Overview

The SIBIONICS App is used in combination with the GS1 Continuous Glucose Monitoring (CGM) System. It retrieves glucose data from the Sensor to help monitoring the glucose levels. The App provides continuous, comprehensive, and reliable 24-hour 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 phone to retrieve the glucose data from the Sensor.
To use GS1 system safely, users should:

- be capable of operating smart phones with Android operating system or iOS
- be capable of reading English
- have no visual or hearing impairments

1.2 Expected Performance

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

1.3 Cautions and Limitations

- The SIBIONICS App provides interstitial glucose levels via the GS1 CGM Sensor for people aged of 18 years and older. The glucose readings obtained are used for glycemic management but must not be taken as the basis of treatment decision or therapy adjustment.
- Glucose reports generated by the App are intended to help glycemic management but not for immediate treatment decisions.
- For proper App running, you should explicitly give permission to SIBIONICS to access camera and location from your device’s privacy settings.
- If the Sensor glucose readings do not match the symptoms, consult your healthcare provider for advice.

- The user is responsible for protecting privacy against the risk of leakage when using this App.
- It takes about 200M storage for the App to run on your phone. Insufficient phone storage may cause undesired operation. Clear the cache to allow the App to run smoothly. It is recommended to make a backup of the glucose data on a periodic basis.
- The SIBIONICS App is capable of database backup. Regular backup is advised to minimize the risk of data loss.
- Do not let the phone shut down due to low battery, otherwise no Sensor glucose alerts will be obtained from the Sensor. Make sure to have an available charger to charge the phone if needed.
- If the phone shuts off when running the App, glucose data may be lost.
- The user is responsible for keeping the phone secure, for example by using a strong password, installing updates when appropriate, and only using secure WiFi networks.
- Set the date and time correctly on the phone before using the App. Manual change to these values while the App is running may cause abnormality to the stored Sensor data.
- To run the App, the phone should meet the system requirements as specified in *Recommended System Configurations*, otherwise the App performance may be affected.
- If any error or exception occurs to the App, relaunch the App.
- If the App itself closes unexpectedly, relaunch the App. No data will be lost.
- The user account and password need to be provided before operating the App. The user account is the email address you used for registration. And password can be 8 to 20 letters, numbers, special characters, or combination of them.

1.4 System Safety Statements

⚠ Cautions and Limitations

- 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@sibionic.com.
- Transport and store the Sensor pack and Applicator at temperatures ranging between 4°C and 25°C. 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.

- Do not use expired Sensor or Applicator.
- Intense exercise may cause the Sensor to loosen due to sweat or movement of the Sensor. If the Sensor comes loose or the Sensor tip is coming out of the skin, no readings or unreliable low readings may be obtained. Remove and replace the Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. In case of doubt of the accuracy of the Sensor readings as it came loose, verify glucose levels by using a blood glucose meter.
- The system contains small parts that may be dangerous if swallowed. Keep it out of reach of children.
- In the need to check low or close to low Sensor glucose levels, do a blood glucose test.
- The Sensor automatically stops working after the 14-day wear period and must be replaced. If the Sensor is not removed after the wear period, it may be dangerous.
- Inaccurate glucose readings may occur. When symptoms do not match readings, or readings are suspected to be inaccurate, use fingerstick blood glucose values obtained from a blood glucose meter to make diabetes treatment-related decisions. Seek medical attention when appropriate. Replace the Sensor if needed.
- Performance of the system when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- The readings obtained from GS1 CGM system should not be relied on for treatment decision or therapy adjustment.
- 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 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 healthcare professional.
- 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.

- Do not use the system if you are under the age of 18, pregnant, on dialysis, or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system.
- Interfering Substances

  Studies show that taking ascorbic acid (vitamin C) or acetylsalicylic acid supplements while wearing the Sensor may falsely raise Sensor glucose readings. Ascorbic acid or acetylsalicylic acid are 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, do a blood glucose test.
- Magnetic fields could cause the Sensor to power off and stop working. Do not come close to the Sensor Applicator when wearing your Sensor as the Applicator contains a magnet.
- The GS1 CGM System has not been tested in populations following anti-coagulant therapy. The accuracy has not been tested in this population and Sensor glucose readings may be inaccurate. Follow your healthcare provider's advice on the use of anticoagulants when you are wearing the Sensor.
- Seek help from your healthcare provider if the Sensor tip breaks.
- Report any serious incident that has occurred in relation to the device to the manufacturer and local competent authority of the Member State.
- Do not modify the GS1 system without authorization of the manufacturer.

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 >

Convention	Description
	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 About Your Sensor

1.6.1 General Description

The SIBIONICS App is intended for use with the GS1 Continuous Glucose Monitoring (CGM) System which is indicated for the continuous monitoring of interstitial fluid glucose levels in patients suffering from 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.

1.6.2Intended 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 suffering from diabetes mellitus type 1 or 2. The GS1 CGM System is a real-time continuous glucose monitoring device for single-use only.

1.6.4 Intended Users

The CGM System is intended to be used by patients 18 years and older suffering from Type 1 or Type 2 Diabetes Mellitus.

1.6.5 Target Population

The System is intended for patients suffering from Type 1 or Type 2 Diabetes Mellitus, 18 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.

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, or used with software to guide the dosing of insulin.
- 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 suffering from severe skin lesions on the whole body, such as extensive eczema, extensive scars, extensive tattoos, herpetic dermatitis, severe edema, and psoriasis.

1.6.8 Risks

The risks with using the GS1 CGM System are:

- Not getting alerts
- Sensor insertion issues

This section covers each of these risks in detail.

1. Not Getting Alerts

   Absence of alerts may indicate severely low or high glucose levels. Check the display of your device:

   ✧ Battery charged: If the display device battery is dead, no GS1 readings or alerts will be obtained.

   ✧ App on: Keep the App on to receive GS1 readings or alerts.

   ✧ Alerts on: Leave the alert function on to get alerts.

   ✧ Volume up: Keep the volume loud enough to hear the alerts.

- ✧ Speaker and vibrations work: If the speaker or vibrations are not working, you will not hear or feel your alerts.
- ✧ In range: Keep your display device no more than 20 feet from the Sensor, with no obstacles between them, to ensure proper communication. If both devices are not in range, no GS1 readings or alerts will be obtained.
- ✧ No System errors: in the event of a system error – such as no readings, Sensor error, or signal loss – no GS1 readings or alarm/alerts will be obtained.
- ✧ During warm-up and after session ends: no alerts or GS1 readings will be obtained during the 1-hour warmup or after a Sensor session ends.

2. Interfering Substance Risks

   In the GS1 system, ascorbic acid and acetylsalicylic acid may affect the accuracy of glucose readings.

3. Sensor Insertion Risks

   Despite being uncommon, insertion of the Sensor can cause:

   - ✧ Insertion site pain
   - ✧ Bleeding
   - ✧ Sensor probe breakage

   Wearing the adhesive patch can cause:

   - ✧ Inflammation
   - ✧ Skin irritation
   - ✧ Skin allergy

Only a few patients included in the GS1 CGM clinical studies got slight redness and swelling.

Chapter 2 Downloading the App

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

NOTES

- To download the SIBIONICS App, your phone must be connected to the internet.
- See *2.1 Recommended System Configurations* for phone configurations that is recommended to download the App.

For iOS and Android

2.1 Recommended System Configurations

	Harmony OS	iOS	Android OS
Operating system	Harmony 3.0	iOS 16.5	Android 13
CPU	Huawei Kirin990	iPhone A15	Snapdragon 8 Gen2
RAM	8 GB	6 GB	8 GB
ROM	128 GB		256 GB
Bluetooth	5.0		5.3
Network bandwidth	Not less than 5 Mbps		Not less than 5 Mbps
Display size	6.3 inches	6.1 inches	6.78 inches
Display resolution	2400*1176	2532*1170	3200*1440
Maximum screen brightness	Greater than 150 cd/m^2		Greater than 150 cd/m^2

	Harmony OS	iOS	Android OS
Ambient light	Ambient light detection, screen brightness correction, automatic and manual adjustment of screen brightness. Ambient light detection, screen brightness correction, automatic and manual adjustment of screen brightness.		
Battery capacity	4560 mAh	3095 mAh	5000 mAh

2.2 Creating an Account

1. Launch the App on the phone. Tap the icon on the phone.
2. Tap **Register Now** on the login screen.

   Follow the on-screen instructions to create the user account.
3. Enter the requested settings on the My Profile screen, such as diabetes type, unit, and target glucose range.

   Note

   You can view or change the settings in Profile > Edit Profile.
4. Select Alarm Settings.

   Glucose alarms can be turned on by setting the alarm range and the way to receive alarms when glucose levels fall out of the alarm range.

   Note

   You can view or change the alarm settings in Profile > Alarm Settings.
5. The App account is now set up and ready for use.

   After applying a Sensor, you can connect the App with the Sensor. See *3.1 Pairing Your Sensor* for how to pair your Sensor.

Note

If the App password is forgotten when you logging in, tap **Forgot Password?** on the login screen. Follow the App instructions for re-setting the user password.

2.3 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 SIBIONICS 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.

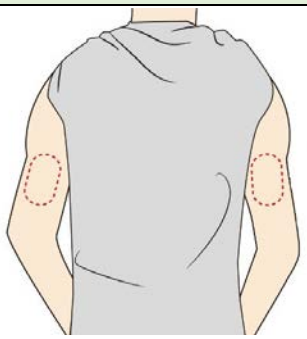
- The Sensor includes two main parts, one is placed in the Sensor Pack, and the other is placed in the Sensor Applicator. Follow the instructions in Applying our Sensor to prepare and apply the Sensor on the back of the upper arm.
- The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.
- The Sensor automatically measures the glucose while placed on the

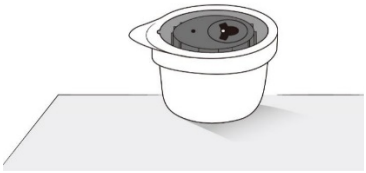
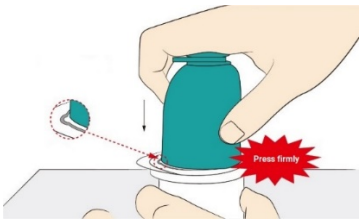
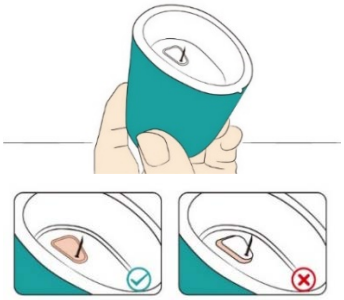
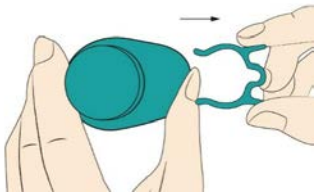
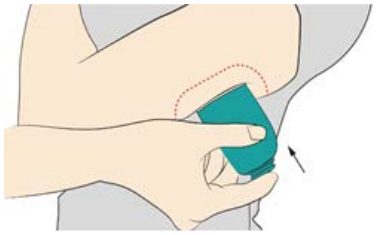
body and stores the glucose data. It uses an amperometric electrochemical technique for glucose assay. Your phone configured with the SIBIONICS App gets the glucose readings and other information from the Sensor, via Bluetooth communication.

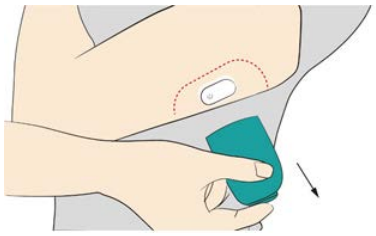
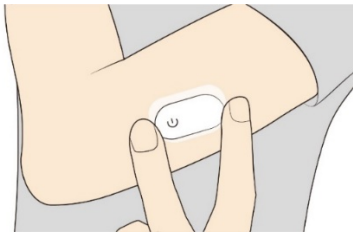
- The Sensor Pack and Sensor Applicator are packaged as a set and have the same serial number. Check that the serial numbers match before using the Sensor Pack and Sensor Applicator. Do not use Sensor Packs and Sensor Applicators with different serial numbers as this will result in incorrect glucose readings.
- Intense exercise may cause the Sensor to loosen due to sweat or movement of the Sensor. If the Sensor becomes loosen or the Sensor tip is coming out of the skin, no readings or unreliable low readings may be obtained. Remove and replace the Sensor if it starts to loosen and follow the instructions to select an appropriate application site.

Chapter 3 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). Note: To prevent discomfort or skin irritation, select a different site other than the one most recently used.
2 	Wash the application site using a plain soap, dry, and then clean with an alcohol wipe. 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 following these instructions, 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 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. If the safety clip is removed first, harm can be accidentally caused by pushing the button that inserts the Sensor before expected.
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 healthcare professional.
9 	Make sure the Sensor is secure after application. Note: Use your phone 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.

Chapter 4 Pairing Your Sensor

After the application of a Sensor, pair the Sensor with the App.

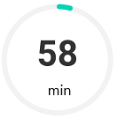
1. Log in to the SIBIONICS App.
2. Tap “Connect a New Device” on the top of the screen.
3. Scan the Sensor QR code (see below) on the packaging box with the pop-up camera to pair with the Sensor. Or you can enter the 8-digit code manually to connect the Sensor.

QR code

NOTE: Only one Sensor can be paired at a time. For example, if a new Sensor is paired, it will automatically unpair the current one.

⚠ **CAUTION:** Turn on the Bluetooth on the phone so that the phone/App can pair and communicate with the Sensor.

4. Start Sensor.



Wait. During the warmup period, the Sensor provides neither alarms nor glucose readings. Readings will start being performed after the 1-hour Sensor warm-up has passed. Screen provides countdown to Sensor warm-up. The ring darkens as the countdown progresses.

5. Check the glucose readings.

Sensor warm-up is complete. The phone displays the current glucose reading along with an arrow indicating the glucose trend. Current glucose reading is updated every 5 minutes.

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

What to do if the phone and Sensor are unable to communicate

If the phone and Sensor are not communicating properly, the following figure will be displayed on the screen.

Follow the instructions:

1. Check if the Bluetooth is turned on in the phone settings. Follow the prompts on the App to turn on Bluetooth and restore communication with the Sensor.
2. Check if the distance is beyond 20 feet between the phone and Sensor. If yes, keep the phone within 20 feet of the Sensor.
3. Check if any event mentioned in section 1.3 *Cautions and Limitations* occurred.

Note

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

When the Sensor has completed the warm-up and restores communication, all the recorded glucose data will be communicated to the phone. After that, the current glucose level continues to be updated every 5 minutes and displayed on the phone until the end of the 14-day wear period.

Chapter 5 Getting Glucose Readings

You can get your glucose readings in the Glucose Trending graph in Monitoring page. See the following figure for reference.

NOTES:

- The graph displays the Sensor glucose readings above 450 mg/dL at 450 mg/dL.
- The target glucose range is not related to the glucose alarm settings.

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

↑	Rapidly rising (2 – 3 mg/dL each minute)
↗	Slowly rising (1 – 2 mg/dL each minute)
→	Steady (Less than 1 mg/dL each minute)
↘	Falling slowly (1 – 2 mg/dL each minute)
↓	Rapidly falling (2 – 3 mg/dL each minute)

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  above the graph.
- Added notes appear as graphic symbols at the recorded time for each event. Tap any symbol to display detailed information about the event.

Event Record

Event record helps capturing information that may affect the glucose levels. The event feature on the app can be used to enter and save certain types of events.

Record Icon	Description
	The meal time and what you ate.
	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 management.
	The time you go to sleep and get up.
	How you feel, for example, happy, anger, or unwell.

Follow the steps below to add event records:

1. Tap the  icon and select the record icon needs to be added.
2. Select or enter the required information.
3. Tap **Done** to save notes.

You can view event records by:

- Tapping the event symbol on the Glucose Trending graph to display detailed information about an event, or
- Tapping Profile > Events to review all the events that you have added.

Chapter 6 Settings Glucose Alarm

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

Resetting Glucose Alarm

You can view or reset glucose alarm by the following steps.

1. Tap Profile > Alarm Settings.
2. Turn on the Alarm button.
3. Turn on/turn off the Override Do Not Disturb button according to actual needs.
   - ✧ When Override Do Not Disturb is turn on, you will still get alarm notifications with sound when your phone is in Do Not Disturb mode.

     Note: You must allow the Do Not Disturb permission to use the Override Do Not Disturb feature.
   - ✧ When Override Do Not Disturb is turned off, you will NOT get alarm notifications with sound when your phone is in Do Not Disturb mode.
4. Set the target value for low alarm and high alarm in Alarm Target.
5. Select the targeted alarm style.
6. Click **Done** to save the settings.

Viewing Glucose Alarm Records

View the low and high glucose alarms history by tapping the icon in the upper right corner of the Monitoring screen.

- Low Alarm

  When the GS1 reading is below the defined level, you get a Low Alarm.
- High Alarm

  When the GS1 reading is above the defined level, you get a High Alarm.

Chapter 7 Getting Glucose Report

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

7.1 Viewing Daily Reports

Viewing daily reports in Daily Reports which show daily detailed information.

Daily Overall

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

Daily trending is a graph of Sensor glucose readings by day. The symbols identifying events are shown in the graph.

Select Date

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

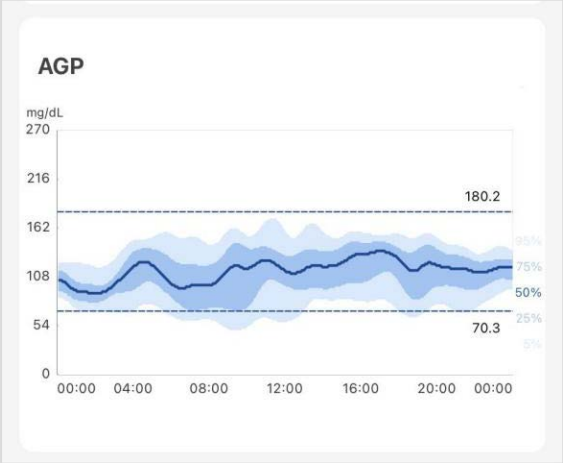
7.2 Viewing AGP Reports over Several Days

Viewing AGP reports in AGP Reports and comparing glucose trend in Trending Comparison.

AGP Reports

AGP reports show summaries of information over several days. AGP shows the pattern and variability of the Sensor glucose levels over a typical day.

- The thick blue line shows the median (midpoint) of glucose readings.
- The blue shading represents a range (5-95 percentiles) of the Sensor readings.



NOTE: AGP needs at least 5 days of glucose data.

Trending Comparison

Select days to compare the glucose trending.

7.3 Exporting AGP Report

1. Tap **AGP Reports**.
2. Select time range on the top of the screen.
3. Tap **Report** to generate the report of the targeted time range.

Chapter 8 Changing User Profile

In Profile screen, you can edit the account information or settings for your App. See the following table for reference.

Button Name	Description
Edit Profile	Edit the account information and set the target glucose range.
Events	Displays a history of events, including time and user added information.
Devices	• Display Sensor information. • View Sensor glucose readings by tapping **More Data** and export these to an excel file by **Export all**. • Replace the Sensor with a new one by tapping **Change**.
Alarm Settings	1. Set the high and low Sensor glucose alarm targets, and alarm style. 2. Toggle the alarm settings on to set the alarm style and alarm targets. 3. Tap **Done** to save your settings.
Remote View	Invite a friend to view your Sensor glucose readings and trending graphs. Follow the on-screen instructions for data sharing.

Settings

Tap the  icon in the upper right corner of **Profile** tab to configure settings.

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.
Reset Password	Reset the login password. Follow the on-screen instructions to reset the password.
Unit	Select the unit displayed on the App.
Language	Select the language of the App.
Country	Select the country in the list or enter country name in the search box to search the target country.
About Us	Display version of SIBIONICS App, update information, contact Email, terms of use and privacy policy. Upgrade the SIBIONICS App if a new version is available.
Remove the Account	Delete the current account and all the data. Note Data cannot be restored once deleted.

Chapter 9 Daily Activities

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

Activity	What You Need to Know
Sleeping	Using the Sensor should not interfere with sleep. Keep the phone and Sensor within 20 feet with no obstacles (like walls or metal) between the devices before going to sleep, as it may affect communication. To receive alarms or reminders while sleeping, place your phone nearby. Make sure that the sound and/or vibration is turned on for your phone.
Bathing, Showering, and Swimming	The Sensor is water-resistant and can be worn while bathing, showering, or swimming. Note Do NOT take the Sensor deeper than 3 feet (1 meter) or immerse it longer than 1 hour in water.
Other Activities	Avoid intense exercise and protect the Sensor from collision with other objects when wearing it. Jogging will not affect its performance.

Chapter 10 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.

   Note: Any remaining adhesive residue on the skin can be removed with warm, soapy water or isopropyl alcohol.
2. Discard the used Sensor following the directions from your healthcare provider. See Chapter 8 - Care, Maintenance and Disposal of GS1 CGM System. When applying a new Sensor, follow the instructions in the *Applying Your Sensor* section in this chapter. 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.

Chapter 11 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, and contact Customer Service at support@sibionics.com.

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.
   Note
   Any remaining adhesive residue on the skin can be removed with warm, soapy water or isopropyl alcohol.
2. Discard the used Sensor following directions from your healthcare provider. See Chapter 8 *Care, Maintenance and Disposal of GS1 System*. When applying a new Sensor, follow the instructions in the *Applying Your Sensor* section in this chapter. If the last Sensor was removed after the 14-day wearing period, you will be prompted to start a new Sensor.

Chapter 12Uninstalling the SIBIONICS App

1. Tap and hold the icon on the desktop of the phone.
2. Select **Remove App** from the pop-up menu.
3. Alternatively, select Settings > App > App Manager, select the SIBIONICS App and uninstall.

Chapter 13 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. 3. Follow the instructions in Applying and Starting Your Sensor sections. Consider shaving the site, avoid using 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 skin, contact your healthcare professional to identify the best solution.
Glucose reading is not updating.	The phone is not held close enough to the Sensor.	1. Make sure the phone is within 20 feet of the Sensor. 2. Try pairing the Sensor to get a glucose reading.
	The Sensor is too hot or too cold.	1. Move to a location where the temperature is between 5°C and 40°C. 2. Pair the Sensor again in a few minutes.

Chapter 14 Care, Maintenance and Disposal of GS1 System

Storage

Storing the GS1 CGM system correctly helps preventing system failures.

Sensor

- Keep in its sterile packaging until ready to be used.
- Store at temperatures ranging between 4°C and 25°C.
- Storing outside the advised range may cause inaccurate GS1 readings.
- May store Sensor in refrigerator if it is within the advised temperature range.
- Store Sensors in a cool, dry place. Do not store in a parked car on a hot day or in the freezer.

Sensor Applicator

• Keep protected until ready to be use.
• Store at temperatures ranging between 4°C and 25°C.
• Store between 10% and 90% relative humidity.

Maintenance

The System has no serviceable parts. Software maintenance is performed by means of software upgrade.

System Disposal

Different regions have different requirements for disposing of electronics (Sensor) and parts that have come in contact with bodily fluids or blood (Applicator and Sensor).
Sensor must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EU in the European Union is required.

Operations Before disposal:

Pull the internal structure of Sensor Applicator backward with 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.

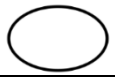
⚠WARNING

- The Sensor used contains a disposable Sensor probe, which is in contact with interstitial fluid during use. The Sensor is for single use only. Reuse of the Sensor may result in damage to the probe, inaccurate glucose readings, and irritation or infection at the application site.
- The Sensor contains a lithium battery which must not be incinerated. Battery may explode upon incineration.
- Sensor Applicator is also for single use only. It contains a guide needle inside after application. Do NOT attempt to remove the guide needle from Applicator or clean or sterilize the guide needle. Otherwise, unintended results or injury may occur.

Customer Service

Shenzhen SiSensing provides users with technical support of the GS1 Continuous Glucose Monitoring System. Customer Service is available to answer any questions regarding the GS1 System. Customer Service is available at support@sibionics.com.

Chapter 15Labelling Symbols

	Refer to instruction manual/booklet		Manufacturer
	Temperature limit		Serial number
	Date of manufacture		Keep dry
	MR unsafe		Non-ionizing electromagnetic radiation
	Type BF Applied Part		Caution
	Environmentally Safe Period		Sterilized using irradiation
	Do not re-use		General symbol for recovery/recyclable
	Use-by date		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.
MD	Medical device		Single sterile barrier system
UDI	Unique device identifier	CE	CE mark
EC REP	Authorized representative in the European Community	IP28	Indicates the degree of protection provided by enclosure according to IEC 60601-1
⎓	Direct current		Importer

Chapter 16 Serial Number/Lot Number, Manufacture Date, Expiration Date

Serial Number/Lot Number

For the serial number, see the label on the Sensor Pack or Sensor Applicator or the container box.
For the lot number, see the label on the container box.

Manufacture Date

For the manufacture date, see the label on the Sensor Pack or on the container box.

Expiration Date

For the expiration date, see the label on the Sensor Pack, Sensor Applicator, or on the container box.
The Sensor Pack is sterilized and expires within 12 months.

Chapter 17Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions

The 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 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 specified below. The customer or the user of the System should assure that it is used in such an 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

IMMUNITY test	IEC/EN 60601 test level	Compliance Level	Electromagnetic environment – guidance
			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
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	$\mathrm{d} = 1.2\ \sqrt{P}$ 80 MHz to 800 MHz $\mathrm{d} = 2.3\ \sqrt{P}$ 80 MHz to 2.5 GHz 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). 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: 

IMMUNITY test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment – guidance
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 Not Applicable	80 MHz to 800 MHz $\mathrm{d} = 1.2\ \sqrt{P}$	800 MHz to 2.7 GHz $\mathrm{d} = 2.3\ \sqrt{P}$
0.01	Not Applicable	0.12	0.23
0.1	Not Applicable	0.38	0.73
1	Not Applicable	1.2	2.3
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.			

Chapter 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	≥ 100 mg/dL	±15 mg/dL
	< 100 mg/dL	within ± 15% at glucose concentrations
Sensor glucose reading range	40 to 450 mg/dL	
Sensor size	33.5 mm × 20.0 mm × 5.3 mm	
Sensor weight	3.84g	
Sensor power source	One lithium battery DC 3.0V	
Sensor memory	Up to 14 days	
Operating temperature	5°C to 40°C	
Sensor pack and Applicator shelf life	12 months	
Sensor pack and Applicator storage, transport temperature	4°C to 25°C	
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	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 SIBIONICS App regularly communicates with cloud server. The SIBIONICS App and communication between the SIBIONICS App and cloud server are protected by a number of mechanisms designed to safeguard data integrity and data confidentiality.

Chapter 19 Low and High Glucose Alert Performance

A clinical study was conducted to evaluate the performance of the GS1 CGM system. The prospective clinical study was carried out at multiple centers across China and single-arm objective performance criteria were adopted. A total of 70 subjects were included, of which 69 subjects completed the clinical study. Subjects wore Sensors on the back of their upper arms. In this study, the low and high glucose alert level were set to 79 and 199.8 mg/dL, respectively.

Low and high glucose alerts are threshold notification when the Sensor glucose level is higher or lower than the alert levels. The alert rate tells how often the Sensor can recognize and notify the user on high/low glucose alerts. The detection rate tells how often the alert is right or wrong.

1) Alert Rate (Sensitivity)

a. True Alert Rate—high glucose
   Tells you: When glucose levels were higher than the threshold, did you get a High Glucose Alert?
   Definition: Percentage of time blood glucose was above the alert level (199.8mg/dL) and the alert issued within 15 minutes before or 30 minutes after the glucose event.

b. False Alert Rate—high glucose
   Tells you: When glucose levels were higher than the threshold, did you miss a High Glucose Alert?
   Definition: Percentage of time blood glucose was above the alert level (199.8mg/dL) and the alert did not issue within 15 minutes before or 30 minutes after the glucose event.

c. True Alert Rate—low glucose
   Tells you: When glucose levels were lower than the threshold, did you get a Low Glucose Alert?
   Definition: Percentage of time blood glucose was below the alert level (79mg/dL) and the alert issued within 15 minutes before or 30 minutes after the glucose event.

d. False Alert Rate—low glucose
   Tells you: When glucose levels were lower than the threshold, did you miss a low glucose alert?
   Definition: Percentage of time blood glucose was below the alert level (79mg/dL) and the alert did not issue within 15 minutes before

or 30 minutes after the glucose event.

2) **Detection Rate (Specificity)**

a) Detection Rate—high glucose
Tells you: When you got a high glucose alert, were glucose levels higher than the threshold?
Definition: Percentage of time the alert issued and blood glucose was above the alert level (199.8mg/dL) within 30 minutes before or after the alert.

b) Missed Detection Rate—high glucose
Tells you: Did you get a high glucose alert when not needed?
Definition: Percentage of time the alert issued, and blood glucose was not above the alert level (199.8mg/dL) within 30 minutes before or after the alert.

c) Detection Rate—low glucose
Tells you: When you got a low glucose alert, were glucose levels lower than the threshold?
Definition: Percentage of time the alert issued and blood glucose was below the alert level (79mg/dL) within 30 minutes before or after the alert.

d) Missed Detection Rate—low glucose
Tells you: Did you get a low glucose alert when not needed?
Definition: Percentage of time the alert issued and blood glucose was not below the alert level (79mg/dL) within 30 minutes before or after the alert. The performance of high and low glucose alerts in the clinical study was as follows:

High Glucose Alert Rate (Sensitivity)		High Glucose Detection Rate (Specificity)		Low Glucose Alert Rate (Sensitivity)		Low Glucose Detection Rate (Specificity)	
True	False	Correct	Missed	True	False	Correct	Missed
95.16%	4.84%	88.52%	11.48%	84.62%	15.38%	90.53%	9.47%

⚠WARNING

- High/low glucose alert is used as a notification of fingerstick test. It is not intended for treatment decision or therapy adjustment. Users should pay attention to their own glucose levels.
- Do not ignore symptoms that may be due to low or high blood glucose. When symptoms do not match readings, or readings are suspected to be inaccurate, use fingerstick blood glucose values obtained from a

blood glucose meter to make diabetes treatment-related decisions. Seek medical attention when appropriate.

- The high/low glucose alert is not applicable in case of pregnancy, dialysis, or when critically ill. The high/low alert levels in this clinical study are the recommended values for type I and type II diabetes patients, excluding the aforementioned populations.

Clinical Investigation Performance

Accuracy of the GS1 system was measured by comparing paired System Glucose Measurement (CGM) and EKF blood glucose values. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the EKF reference. In the clinical study group, the Mean Absolute Relative Difference was 8.8% for the comparison with EKF reference.

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