

SD BIOSENSOR **CGMS**

Personal Continuous Glucose Monitoring System

User Manual

User Manual

Thank you for purchasing this product.

This user manual contains all the information regarding the Continuous Glucose Monitoring System you have purchased.

Please read this manual carefully before use and familiarize yourself with the necessary preparation and measurement procedures.

Using this product to manage blood glucose may provide the following benefits:

- Improved blood glucose control

For further inquiries regarding this product, please contact your local distributor. Once again, thank you for purchasing this product.

Table of Contents

1. General Information	1
• Intended Purpose	1
• Product Information	1
• Principle of Operation	1
2. Safety Information	2
• Safety Instructions	2
• Hazards	3
3. Getting Started	4
• Checking the Components	4
4. Attaching the Sensor	4
• Preparation Before Use	4
• How to Attach the Sensor	5
5. Getting Started with the App	7
• Introduction to the CGMS App	7
• Connection and Setup	7
• Connecting the App to the Sensor	7
• Overview of the App Home Screen	8
• Overview of the Reporting Software	8
6. Viewing Glucose Readings	9
• Checking Glucose Values Using the App	9
7. Calibration	11
7.1 Measuring Calibration Values	12
7.2 Entering Calibration Values	13
8. Notifications	14
• App Notification Guide	14
• User Notification Settings	14
• Types of App Notifications	15

9. Logging Events	17
• Logging Events in the App.....	17
• Viewing Event Log	18
10. Reports.....	19
11. Logging Out.....	25
12. How to Remove the Sensor	25
13. How to Replace the Sensor	26
14. Troubleshooting	26
15. Product Maintenance	26
• Storage	26
• System Disposal	26
16. Warranty	27
17. System Specifications	28
18. Symbols	29
Appendix A. Cybersecurity	30
Appendix B. Electromagnetic Compatibility'	31

1. General Information

- **Intended Purpose**

This product is a continuous glucose monitoring system for self-testing that continuously measures and monitors glucose in the interstitial fluid through a sensor attached to the skin of diabetic patients aged 19 years or older.

- **Product Information**

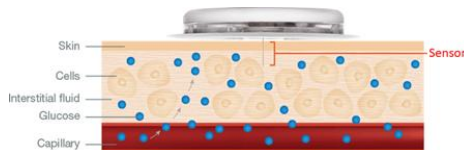
- Item Name: Personal Continuous Glucose Monitoring System
- Product Name: 01CG10
- Model Number: 01CG10
- Authorization Number: To be filled in later

- **Principle of Operation**

This product is a device that helps users easily monitor their blood glucose levels. It continuously measures blood glucose levels in interstitial fluid using a small sensor inserted under the skin and transmits the measured data to a smartphone app via Bluetooth. The system consists of an applicator (insertion tool), a transmitter (data transmission unit) that includes the sensor, and a mobile app.

The applicator serves to attach the transmitter to the skin and contains a small needle used to insert the sensor under the skin. When the applicator is used, the transmitter is secured to the skin with adhesive tape, and the sensor is stably positioned under the skin. The needle is automatically withdrawn at the moment of sensor insertion.

The inserted sensor reaches a depth of approximately 5.5 mm beneath the skin and detects blood glucose levels in the interstitial fluid. The surface of the sensor contains glucose dehydrogenase, which reacts with blood glucose to generate a small electrical current. This electrical signal is transmitted to the transmitter, which sends the data to the smartphone app, allowing the user to view real-time blood glucose readings.



The transmitter converts the blood glucose data received from the sensor into an electrical signal and transmits it to the mobile app for display.

The transmitter is a single-use device that can be used for up to 15 days after being attached to the skin. It automatically stops functioning after 16 days. Therefore, the user must remove the transmitter and replace it with a new one.

The mobile app receives the signal from the transmitter and displays the blood glucose readings on the screen.

- **Supported Mobile Application Device Specifications**

iOS OS: iOS 15 or later, with a resolution of 2340×1080 pixels or higher

Android OS: Android 12.0 (API 31) or later, with a resolution of 2340×1080 pixels or higher

*Some models may have limited compatibility due to device-specific issues.

2. Safety Information

• **Safety Instructions**

- Read the indications, warnings, precautions, and instructions related to this product. Failure to read this information may result in inaccurate sensor readings or missed notifications, increasing the risk of missing critical hypoglycemic or hyperglycemic events.
- Keep the user manual nearby for easy reference at all times.
- This product is intended for blood glucose management. It must not be used for the diagnosis of diabetes without the guidance of a healthcare professional.
- Consult with your healthcare provider to determine your appropriate blood glucose range. Do not alter your treatment plan based on self-interpretation of readings; always consult a healthcare professional.
- If your blood glucose readings do not match your symptoms, do not make any changes to your insulin regimen or other treatments, and seek advice from a healthcare professional.
- Follow all relevant environmental regulations when using, storing, or transporting this product.
- Disinfect the application site with an alcohol swab before attachment, and ensure the area is completely dry.
- If the product becomes detached during attachment, discard it and use a new one.
- Be careful not to press the applicator button before attaching the product.
- Do not apply the sensor to contaminated skin or skin treated with lotion or ointments, as this may cause detachment. Ensure that the product is attached to clean, dry skin.
- After registering the product with the mobile application, allow 30 minutes for sensor stabilization before the first measurement. Measurements should be taken after the 30-minute sensor stabilization period.
- The sensor should be removed prior to exposing it to MRI, CT, or diathermy procedures, as these have not been tested and may pose a risk.
- This product is not intended for use in individuals under the age of 19, critically ill patients, pregnant women, or breastfeeding women.
- Modifications, including the replacement of batteries, are not permitted.
- Do not arbitrarily apply the sensor to areas other than the upper arm for use as the glucose level may vary depending on where it is applied.
- This device can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.
- Do not use if this product is damaged or the seal is broken. It may cause inaccurate reading.
- This device is small and may pose a choking hazard if swallowed by children or pets.
- Do not place the product within reach of infants or toddlers.
- If the application site on the skin is not clean, it may lead to infection or cause the device to become detached during use. Before use, gently clean the area with the enclosed alcohol swab.
- If the device is damaged, stop using it immediately and replace it.
- Do not leave the device in direct sunlight or in hot environments (e.g., inside a car). High temperatures may damage internal components of the device, potentially causing it to malfunction.
- Keep the device away from strong magnetic fields (e.g., speakers, microwave ovens). Otherwise, sensor malfunctions or data errors may occur.
- Be careful to prevent sand or dirt from entering the gaps in the device. This may cause malfunction due to damage or contamination.
- This product must be used only for the specified purposes; use for other purposes is prohibited.
- Keep this product out of reach of children.

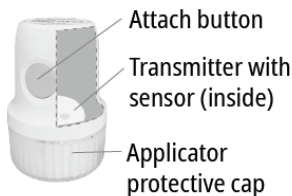
- Device performance may degrade at sub-zero temperatures.
 - Do not use or attach the device in any way other than as instructed in the manual.
 - Do not press or apply excessive pressure to the device.
 - Do not rub or pull the device with excessive force once it is attached.
 - Do not store the device in a freezer. Doing so may damage internal components of the device, potentially causing it to malfunction.
- **Hazards**
The following hazards are associated with the use of the Continuous Glucose Monitoring System:
 - Sensor insertion issues
 - Failure to receive notifications
 - Making treatment decisions using the Continuous Glucose Monitoring System in inappropriate situations
 - Adverse reactions to adhesive
 - Inaccurate sensor readings
 - Sensor wire not removed

3. Getting Started

- **Checking the Components**

Check the components included in the package.

Ensure that you are fully familiar with the instructions before using the product.



Applicator
x 1 ea



Quick Start Guide
x 1 ea

4. Attaching the Sensor

- **Preparation Before Use**



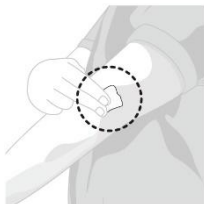
Caution

- The product must be used within the specified expiration date.
- If the application site is not properly cleaned and dried, there is a risk of infection, and the sensor may not adhere properly.
- Ensure that the application site is cleaned with alcohol and completely dried before applying the product.

- 1) Check the product expiration date before use.

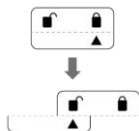


- 2) Clean the upper arm (application site of the sensor) thoroughly with alcohol and allow it to dry.



- **How to Attach the Sensor**

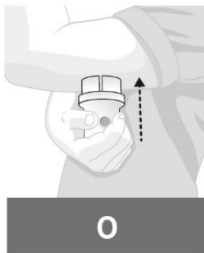
- 1) Twist and remove the applicator protective cap.



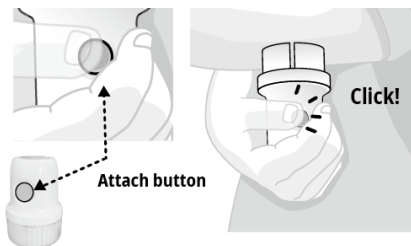
Caution

Do not touch the inside of the applicator once the protective cap has been removed.
Be careful not to press the attach button while removing the protective cap.

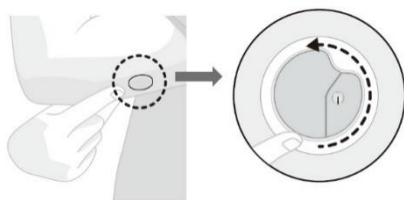
- 2) Hold the applicator stably as shown in the figure and position it perpendicular to the application site on the upper arm.



- 3) Press the applicator firmly onto the skin without any gaps or movement and press the attach button until you hear a “**click**” sound.



- 4) After removing the applicator from the upper arm, check that the sensor is properly attached to the application site.



5. Getting Started with the App

• Introduction to the CGMS App

- After attaching the sensor, connect it to your account via the app to receive glucose-related notifications, monitor glucose levels measured by the sensor, and enter records.
- The CGMS iOS App is available for download from the App Store.
- The CGMS Android App is available for download from Google Play.
- The CGMS App is not compatible with all mobile devices.
- Check the supported specific device requirements under the app menu "Support > Device Compatibility".
- If Bluetooth or storage permission settings are disabled, the app may not function properly, and users will be unable to receive notifications or glucose information.
- To receive critical notifications, Bluetooth and notification permissions must remain enabled at all times. It is also recommended to keep Do Not Disturb mode and Airplane mode turned off.
- Users are responsible for safely managing and protecting their mobile devices.

*In the event of a cybersecurity incident, select "Support > Customer Center" and contact the customer center number on the product site to receive appropriate support from an administrator.

• Connection and Setup

To enable sharing of glucose data between the CGMS App and the sensor, the following connections and settings are required:

- Turn on Bluetooth on the mobile device
- Pair the sensor with your mobile device via bluetooth.
- Allow the app to run continuously in the background
- Make sure your mobile device is connected to Wi-Fi or a mobile network.
- Open the app and log in.
- Connect the App to the Sensor

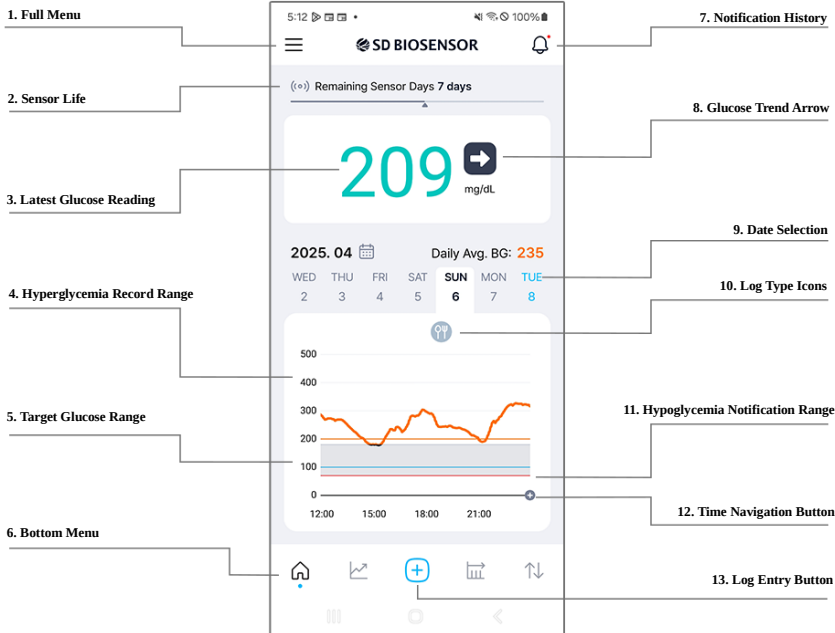
• Connecting the App to the Sensor

- 1) After reviewing the guidance message on the app, tap the "Scan QR Code" button.
- 2) Use the smartphone to scan the QR code located on the top of the applicator.



- ## Overview of the App Home Screen

On the App home screen, the current glucose level and glucose trend are displayed, and users can enter records. The latest glucose reading is updated every 1 minute, and the trend and graph are updated automatically every 5 minutes.



- ## Overview of the Reporting Software

Based on the glucose readings from the CGMS, reports can be viewed through the app and the website. In the app's report menu, you can view sensor data generated or currently connected on your mobile device. To access full data reports, visit the service website and follow the on-screen instructions. You are responsible for keeping your mobile devices and computers secure and up to date, including using antivirus software and installing system updates.

6. Viewing Glucose Readings

- **Checking Glucose Values Using the App**

When the sensor is connected, the user's glucose information is displayed on the home screen. You can view the recent glucose reading, glucose trend arrow, and glucose trend graph.

Latest Glucose Reading

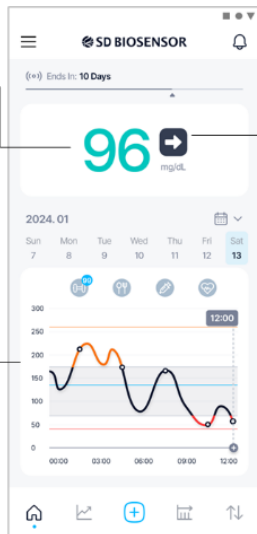
Displays the user's latest glucose value.

Glucose Trend Arrow

Indicates the direction of glucose trend using arrow symbols.

Daily Glucose Graph

Visualizes daily glucose readings in graph format.



Latest Glucose Reading

- The color of the glucose value changes based on the glucose range.
 - **Orange**: Hyperglycemia range (Default: Above 180 mg/dL)
 - **Teal**: Normal glucose range (Default: 70–180 mg/dL)
 - **Red**: Hypoglycemia range (Default: Below 70 mg/dL)

Each glucose range can be customized in the settings menu.

Glucose Trend Arrow

- The glucose trend arrow indicates the increase or decrease in glucose levels.



Rapidly Rising: More than 2 mg/dL per minute



Rising: 1–2 mg/dL per minute



Changing Slowly: Less than 1 mg/dL per minute



Falling: 1–2 mg/dL per minute



Rapidly Falling: More than 2 mg/dL per minute

If the trend cannot be predicted, no arrow will be displayed.

Daily Glucose Graph

- The default maximum value displayed on the glucose graph is 300 mg/dL.
- The graph displays data over a 12-hour period, and you can swipe left or right to view different dates and time ranges.

7. Calibration

The continuous glucose monitoring sensor measures glucose concentration in interstitial fluid and calculates the corresponding blood glucose level, which is then transmitted to the application. However, when blood glucose levels change, glucose concentrations in interstitial fluid typically reflect this change with a delay of approximately 5 to 15 minutes. To minimize potential discrepancies caused by this delay, this product allows users to calibrate the sensor's glucose readings by entering a blood glucose value measured with a personal blood glucose meter using a fingertip blood sample within 5 minutes of measurement. Calibration adjusts the sensor's glucose readings to closely match actual blood glucose levels, ensuring optimal performance of the device.

Calibration Method

Calibration is not mandatory for this product, but users may utilize the calibration function if desired, particularly under the following circumstances:

- When there is a significant discrepancy between the blood glucose value measured by a personal blood glucose meter and the value displayed by this product
- When accuracy may be affected by medications or hormonal changes
- When users want to verify highly accurate glucose values during the use of the product, especially during the initial phase after attaching the product; in such cases, measure your blood glucose using a personal blood glucose meter with a fingertip sample and enter the reading into the CGMS App within 5 minutes. The stored calibration value will be reflected in the application.

 Caution	Perform calibration when your glucose levels are stable. If glucose levels are changing rapidly (more than 2 mg/dL per minute), accuracy may be affected; in such cases, delay calibration until levels stabilize.
 Note	The calibration function may be temporarily disabled under the following conditions: – Poor communication between the sensor and the app – During rapid rise or fall in glucose levels – When the sensor is experiencing excessive signal noise

7.1 Measuring Calibration Values

A fingertip blood glucose measurement is required for calibration. Use a personal blood glucose meter to measure your blood glucose level from a fingertip blood sample.

 Caution	• Do not measure calibration values from alternative sites (e.g., palm, forearm) other than the fingertip. • If the fingertip blood glucose measurement is below 20 mg/dL or above 600 mg/dL, it cannot be entered as the calibration value.
 Note	If the calibration value is inaccurate, this product may not provide accurate blood glucose readings. It is recommended to always use the same personal blood glucose meter. Accuracy may vary between different blood glucose meter models. Replacing your personal blood glucose meter during sensor use may result in inaccurate readings. Before starting calibration, ensure that your blood glucose meter is functioning properly according to the manufacturer's instructions.

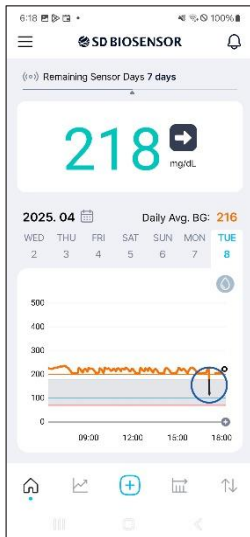
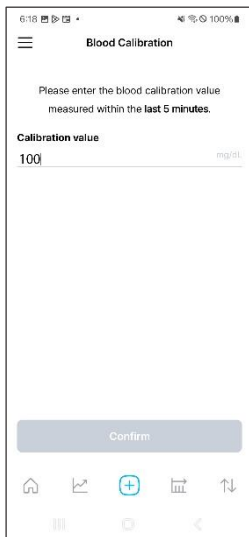
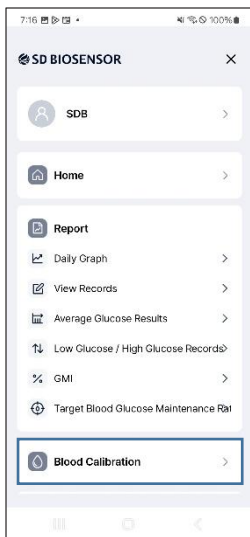
7.2 Entering Calibration Values

To ensure accurate glucose readings, users must measure their blood glucose using a fingertip sample and enter the calibration value within 5 minutes.

Entering a Calibration Value

To perform calibration, enter the calibration value using the following steps:

1) Open the calibration menu.



2) Enter the blood glucose value and tap the confirm button.

3) The calibrated result will appear within 10 minutes.

8. Notifications

- **App Notification Guide**

You can receive various notifications related to glucose levels and the app. All notifications are enabled by default. For critical notifications, sound notifications may be activated regardless of the mobile device's sound settings. Notification options can be configured in the "⚙️ Settings > Notification Settings" menu.

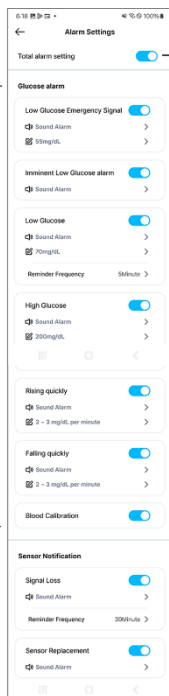
- **User Notification Settings**

In the "Settings > Notification Settings" menu, you can customize notifications according to your needs.

- 1) To access: Launch the app > ≡ Menu > ⚙️ Settings > Notification Settings
- 2) Within the notification settings, you can control all notifications or configure individual items to sound, vibrate, or be silent. You can also customize thresholds for each item to receive notifications that match your specific conditions.

Glucose-related Notifications

Hypoglycemia /
Hyperglycemia
Severe Hypoglycemia /
Severe Hyperglycemia



All Notifications

Tap to control all notifications

Sensor-related Notifications

Sensor Replacement Timing /
Sensor Signal Error

Types of App Notifications

Notification types are listed in the table below. They may vary depending on the OS (operating system) of your smart device.

Notifications	Description
 WARNING 69mg/dL, Low Blood Glucose	Low Glucose Notification (Low) You will receive a notification when your glucose level falls to 70 mg/dL or below the user-defined threshold. Once attached, the notification will occur once initially and then repeat every 5 minutes if glucose remains below the threshold, based on the default notification delay setting (default: 5 minutes).
 WARNING 250mg/dL, High Blood Glucose	High Glucose Notification (High) You will receive a notification when your glucose level exceeds 180 mg/dL or the user-defined threshold. Once attached, the notification will occur once initially and then repeat every 5 minutes if glucose remains above the threshold, based on the default notification delay setting (default: 5 minutes).
 WARNING 260mg/dL, Rapid Increase	Rapid Increase A notification is attached when glucose levels increase rapidly (more than 2 mg/dL per minute). If the value rises rapidly within the target glucose range, the notification repeats every 15 minutes. If the value exceeds the hyperglycemia threshold, the notification repeats every 10 minutes.
 WARNING 65mg/dL, Rapid decrease	Rapid decrease A notification is attached when glucose levels decrease rapidly (more than 2 mg/dL per minute). If the value falls rapidly within the target glucose range, the notification repeats every 15 minutes. If the value falls below the hypoglycemia threshold or enters the urgent low notification range, notifications repeat every 10 minutes. If glucose falls below the urgent low level, notifications repeat every 5 minutes.
 IMPORTANT 55mg/dL, Low Blood Glucose Emergency	Urgent Low Glucose Notification You will receive a notification when glucose drops below 55 mg/dL. If no glucose check is confirmed in the app, notifications will repeat every 5 minutes. If you check your glucose in the app and the value remains below 55 mg/dL after the notification delay time, the notification will repeat every 5 minutes.
 IMPORTANT 58mg/dL, Predicted Urgent Low Glucose	Predicted Urgent Low Glucose Notification You will receive a one-time notification if glucose is predicted to fall below 55 mg/dL within 15 minutes.
 IMPORTANT You can receive more accurate values by entering the blood calibration value.	Calibration Reminder A daily notification is sent as a reminder to calibrate for improved accuracy.

 WARNING Sensor Signal Loss	Sensor Signal Loss You will receive a notification if there is no signal from the sensor. An initial notification is sent immediately, and if the signal is not restored after the user-defined delay time, notifications repeat every 5 minutes.
 INFORMATION The sensor is operating normally.	Sensor Stabilization Complete You will receive a notification when the sensor is ready for use. Glucose readings become available after receiving this notification.
 INFORMATION The sensor will expire in 2 hours.	Sensor Expiration You will receive notifications 3 days, 24 hours, and 2 hours before sensor expiration. Prepare to replace the sensor.
 INFORMATION The sensor has expired.	Sensor Replacement You will receive a notification upon sensor expiration. No glucose readings will be available after sensor expiration. Replace the sensor upon receiving this notification.
 SENSOR FAILURE OCCURRED No readings or alerts are being displayed.	Sensor Issue A notification is attached when a minor issue occurs with the sensor. Do not remove the sensor immediately. Wait and monitor. If the issue persists, contact customer support.
 SENSOR FAILURE OCCURRED No readings or alerts are being displayed.	Sensor Error You will receive a notification when a sensor error occurs that requires replacement. Replace the sensor immediately upon receiving this notification.
 IMPORTANT Due to an unknown issue, there may be disruptions in sensor readings or alarm notifications. Please reinstall the app and reconnect the sensor.	Technical Warning You will receive a notification if an unknown issue requires reinstallation of the app. Please uninstall and reinstall the app.

 IMPORTANT Sensor's results or alarms are not displayed. Please make sure Bluetooth is enabled on your phone.	Bluetooth Disabled A notification is attached immediately when Bluetooth is turned off. Since glucose data cannot be received from the sensor while Bluetooth is off, turn Bluetooth back on immediately.
 IMPORTANT The app has been closed. Please tap to reopen it. If the app is not running in the background, sensor readings and alarms will not be displayed.	App Closed You will receive a notification when the app is closed. Since glucose monitoring and notifications cannot function when the app is closed, restart the app immediately.

9. Logging Events

• Logging Events in the App

In the app, you can log notes related to food, insulin, exercise, health, and other comments alongside your glucose readings.

- 1) To access: Launch the app > Bottom Menu > Tap the  button
Select the appropriate checkboxes for each item to enter detailed information:

 Food: Record meal type (breakfast, lunch, dinner, snack), intake amount (g), and upload an image

 Insulin: Record short-acting/long-acting insulin type and dosage (units)

 Exercise: Record exercise intensity (high, moderate, low) and duration

 Health: Record stress, mood elevation, mood depression, menstruation, medications, illness, alcohol, etc.

 Other: Enter additional comments

- 2) After entering the record, tap the Save button to store the entry.
Saved entries will be displayed as icons on the glucose graph and in the report.
Tap the icon on the glucose graph to view the entry. Tap the More (⋮) button to edit or delete the record.

- Viewing Event Log**

You can view related entries by selecting an event icon on the graph on the home screen. You can also review daily entries by tapping the “View Log” button in the report menu.

Glucose Value

- Glucose value at the time of the entry
- When changing the date and time, the glucose value at the selected time is shown

Log Items

- Select the items to be logged and input corresponding values

Record

6:20 100%

170 mg/dL

2025.04.08

PM 06 : 15

Food

Breakfast 150 g

Rapid-Acting Insulin

Long-Acting Insulin

Workout

Low-Intensity Minute

Health

Medication

Note

Enter Content

Save

Log Time

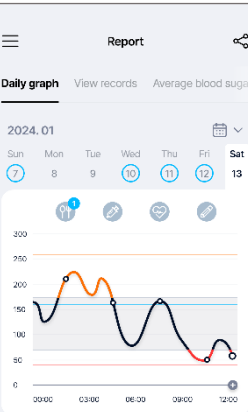
- Select the date and time when the entry was made

Checkbox

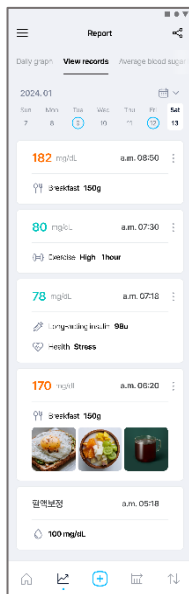
- Select the logged items to be saved
- ※ If a checkbox is not selected, the entry will not be saved even if data is entered.

10. Reports

Tap the Report () button to view your data in report format. The report consists of the following sections: Daily Graph, View Log, Average Blood Glucose Value, Hypoglycemia/Hyperglycemia Records, GMI, and Sensor Usage. Tap each menu to view the corresponding report.

Section	Description
Daily Graph	 This is a daily graph report. It displays a simple graph by date, along with target glucose and fasting glucose threshold lines. Fasting glucose thresholds can be adjusted or toggled On/Off in the "Settings" menu. Hypoglycemia and hyperglycemia thresholds can be adjusted or toggled On/Off in the "Settings > Notification Settings" menu.

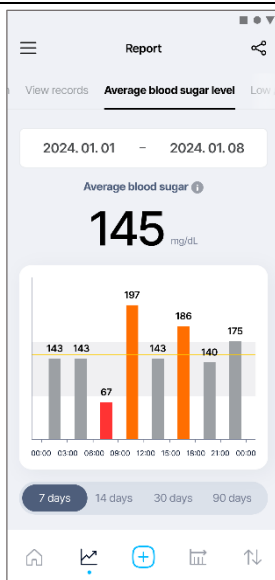
View Log



You can view the glucose value and details of each entry by date.

To edit or delete a record, tap the More () button.

Average
Blood
Glucose
Value



This section displays a graph of time-based average glucose values for the selected period. You can choose to view average blood glucose for the past 7, 14, 30, or 90 days. If the average blood glucose is above the target range, it is shown in **orange**. If it is below the target range, it is shown in **red**.

A line indicating the average blood glucose is displayed on the graph.

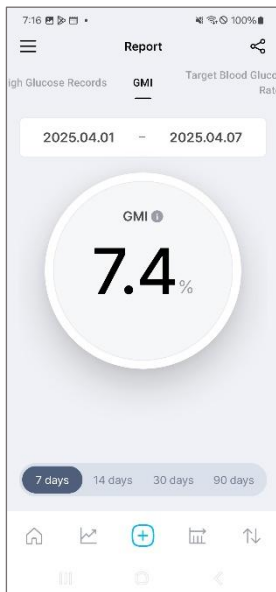
Hypoglycemia/Hyperglycemia Records



This section shows the number of hypoglycemia and hyperglycemia events by time of day over the selected period.

If an event was logged during a hypo/hyperglycemic episode, an icon will be displayed. Tap the icon to view detailed records. Hypoglycemia/Hyperglycemia records can be viewed for the past 7, 14, 30, or 90 days.

GMI



This section provides GMI values by time period.

GMI is based on the sensor's average glucose data and **serves as a reference for evaluating glucose management.**

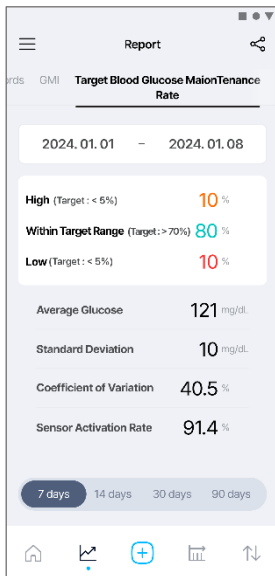
Medical diagnosis should always be conducted through consultation with a healthcare professional.

Recommended glucose targets are based on fasting glucose, postprandial (2-hour) glucose, and hemoglobin A1c (HbA1c) levels. The target ranges include 80–130 mg/dL for fasting glucose, less than 180 mg/dL for postprandial (2-hour) glucose, and less than 6.5% for HbA1c.

GMI is calculated using the following formulas:

- $GMI (\%) = 3.31 + 0.02392 \times (\text{average glucose mg/dL})$
- $GMI (\text{mmol/mol}) = 12.71 + 4.70587 \times (\text{average glucose mmol/L})$

Glucose Readings Within the Target Range



This section displays statistics related to the sensor's glucose readings within the target range over the selected period. You can review statistics, including time in range, high, low, average glucose, standard deviation, coefficient of variation, and sensor activation ratio by time period.



Note

- Tap the Share icon () to share the report via SNS, text message, and other platforms.
- Tap the Help icon () to view guidance related to the report.

11. Logging Out

You can log out from the account management screen by following the steps:

Launch the app >  Menu > Tap “Account” at the top > Account Management > Log Out

12. How to Remove the Sensor

- When the app notifies you that the sensor session has ended, peel off the adhesive tape like a bandage. If you experience difficulty removing the sensor, you may try the following methods to ease removal and reduce skin irritation. Note: These methods are recommended practices. Body oils and adhesive remover wipes are not included with the product.
 - To loosen the edges of the adhesive tape, apply body oil or a skin adhesive remover to the tape (refer to product instructions before use).
 - As you peel off the tape, gently rub the exposed skin with an adhesive remover wipe.
- Alternative method:
- Slowly lift the tape in the direction of hair growth while folding it back on itself.
 - After loosening the edges, insert your fingers under the tape and gently lift it from the skin.
 - Do not pull the tape off abruptly—remove it slowly and carefully.
 - Remove the used sensor before inserting a new one.
 - Dispose of the used sensor in accordance with local regulations.

13. How to Replace the Sensor

The sensor automatically stops functioning after the usage period ends and must be replaced. You should also replace the sensor if you experience irritation or discomfort at the application site, or if the app reports an issue with the current sensor.

If you need to replace a sensor before the end of its usage period due to a malfunction

or other issue, go to:  Menu > "Connection" > Sensor > Current Sensor > End Sensor. After ending the current sensor, you can register a new one.



Caution

- If the sensor becomes partially detached or is used in an unsuitable environment, it may not provide readings or may display unreliable results. If you suspect a sensor malfunction, please contact customer support.

14. Troubleshooting

For detailed troubleshooting information, please refer to the Frequently Asked Questions section on the product website or contact SD Biosensor Customer Support or your local distributor. Any serious incident related to this device must be reported to the manufacturer and the competent health authority in your country.

15. Product Maintenance

- **Storage**
 - Keep the product in its packaging until you are ready to use it.
 - Do not open the applicator protective cap until the sensor is ready for use.
 - The product can be stored at room temperature or in a refrigerator, but not in a freezer. (Storage temperature: 2°C (36°F) - 30°C (86°F))
- **System Disposal**
 - After use, dispose of the applicator, sensor, and protective cap in accordance with medical waste disposal regulations.



Caution

- The sensor can be used for up to 15 days after opening and attachment. It is not reusable.
- After use or if the sensor becomes detached during use, it must be discarded. Attach a new sensor to a different site (e.g., upper arm on either side or an area near the original site where tape was not previously applied).
- The disposal regulations for medical devices that have come into contact with body fluids may differ by country.
- Follow the regulations of the respective country for the classification and disposal of medical waste. In South Korea, dispose of the sensor as general waste.

16. Warranty

※ The following cases are not eligible for after-sales service (A/S), even within the warranty period:

- Malfunction caused by user negligence or mishandling
- Disassembly or modification of the product
- Damage caused by natural disasters such as fire, earthquake, or flood
- Damage or malfunction due to impact
- Malfunction caused by water immersion or foreign substances

We hope this product supports you in maintaining healthy glucose management.

For any additional inquiries after using the product, please contact SD Biosensor, Inc.

Phone: 080-970-9700

FAX: 031-300-0499

Adverse Event Reporting Contact (Korea National Institute of Medical Device Safety Information Center): 080-080-4183

*Consumables and Accessories: The following consumables and accessories can be purchased from SD Biosensor, Inc. or an authorized distributor.

17. System Specifications

Analysis Method	Electrochemical biosensor (enzyme electrode using redox reaction of electron mediator)
Enzyme Type	GDH-FAD
Measurement Range	40–500 mg/dL
Classification	Internally powered device / Type BF applied part (transmitter/sensor)
Wear Duration	15 days
Communication Method	Bluetooth LE
Communication Range	10meters
Data Update Interval	1 minute
Data Storage Period	Daily storage, up to 15 days
Battery Life	15 days of operation
Water and Dust Resistance	IP27rating
Operating Conditions	Temperature: 8°C to 45°C, Relative Humidity: 10% to 90%, non-condensing Pressure: 700 to 1060hPa / Altitude: -382 to 3011m
Storage Conditions	Temperature: 2°C to 30°C, Relative Humidity: 10% to 90%, non-condensing
Audible Notifications	None (Notifications provided via mobile application)
Sterilization	E-beam
Usage	Single-use
Rated Voltage	1.55 V (silver oxide battery)
TX/RX frequency	2.4GHz
Max. RF Power	0 dBm
Power Consumption	80 µWh to 16 mWh

18. Symbols

	Reference number		Batch code
	Consult Instructions for Use		Manufacturer
	Caution		Indicate that you should keep the product dry
	Humidity Limitation		Keep away from sunlight
	WEEE Directive – Waste Electrical and Electronic Equipment		Do not use if packaging is damaged
	To indicate the temperature limitations in which the transport package has to be kept and handled		Serial number
	Use by		IP Rating – Dust and Water Resistance
	Type BF Applied Part		For research use only
	Sterilized Using Radiation		Single Sterile Barrier System with Protective Packaging
			Do not re-use

Appendix A. Cybersecurity

Cybersecurity Precautions

- Install antivirus or security software on your smart device to prevent malicious programs from accessing your personal information.
- If you are logged out due to login from another device, and it was not initiated by you, change your password immediately.
- If the password is entered incorrectly more than 5 times, access will be temporarily restricted.
- Accounts that remain inactive for one year will be converted to dormant status. Re-authentication is required to reactivate a dormant account.
- In the event of a cybersecurity incident, please contact the SD Biosensor Customer Center at 080-970-9700 for appropriate assistance from an administrator.

Appendix B. Electromagnetic Compatibility'

- **FCC ID** : RPJ-01CG10

- **IC** : 33860-01CG10

• This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

• This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

• Changes or modifications not expressly approved by the manufacturer (or party responsible) for compliance could void the user's authority to operate the equipment

• This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

• This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1) This device may not cause interference.

2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1) L'appareil ne doit pas produire de brouillage;

2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

- This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the IC radio frequency (RF) Exposure rules.

L'appareil a été testé et jugé conforme aux limites d'exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d'exposition aux fréquences radioélectriques (RF) CNR-102 de l'ISDE.

Appendix B. Electromagnetic Compatibility*

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
01CG10 is intended for use in the electromagnetic environment specified below. The customer or the user of 01CG10 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emission CISPR 11	Group 1	01CG10 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 Emission CISPR 11	Class B	
Harmonic Emission IEC 61000-3-2	Not applicable	
Voltage fluctuation and flicker IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile communication equipment and 01CG10		
01CG10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of 01CG10 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Inc-CGM-ST-101 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]	
	IEC 60601-1-2: 2014	
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0

10	3.8	6.3
100	12	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Guidance and manufacturer's declaration - electromagnetic immunity			
01CG10 is intended for use in the electromagnetic environment specified below.			
The customer or the user of 01CG10 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 Vrms	$d = 2.0 \sqrt{P}$ 80 MHz to 2.7 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, ^a should be less than the compliance level in each frequency range. ^b 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.			

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 01CG10 is used exceeds the applicable RF compliance level above, 01CG10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating 01CG10

b Over the frequency range 150kHz to 80MHz, field strengths should be less than the compliance level 3V/m.

c The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipments should be used no closer than 30 cm (12 inches) to any parts of the product. Otherwise, the performance of this equipment could be degraded.

Guidance and manufacturer's declaration - electromagnetic immunity					
01CG10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30cm (12 inches) to any part of 01CG10. Otherwise, degradation of the performance of this equipment could result.					
Immunity test	Band ^a	Service ^a	Modulation	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25	Pulse modulation 217 Hz	28 V/m	28V/m

		UMTS			
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28V/m	28V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

NOTE : If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting

antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is

permitted by IEC 61000-4-3.

a For some services, only the uplink frequencies are included.

b The carrier shall be modulated using a 50% duty cycle square wave signal.

c As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it

does not represent actual modulation, it would be worst case.



Manufacturer

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L21CG1ENR1

Issue date: 2025.11