BUZUD

Continuous Glucose Monitoring System

Instruction for Use



Roffe International Holdings Pte Ltd

For use with BUZUD
REimagined Healthcare App

AVAILABLE ON Google Play

AVAILABLE ON App Store

Language

English 2
Bahasa Melayu 43

System Description

Thank you for choosing the BUZUD Continuous Glucose Monitoring (hereafter referred as CGM). The BUZUD Continuous Glucose Monitoring consists of two devices: a Continuous Glucose Monitoring System Sensor and a Continuous Glucose Monitoring App.

The BUZUD CGM Sensor provides real-time glucose levels and allows you to continuously view your sensor glucose values on your selected mobile device. The system tracks your glucose every minutes by measuring the amount of glucose in the interstitial fluid.

A sensor, inserted in your skin, sends glucose results to the BUZUD CGM App.

The app then displays your glucose levels and long-term glucose trends. The app also provides alerts if your glucose is in or projected to be in an unsafe zone.

The BUZUD CGM App also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the system results should be based on the glucose trends and several sequential results over time.

Note: Please read all the instructions provided in this Instruction for Use before using the system.

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1. Important information

1.1 Indications for use

The Continuous Glucose Monitoring System sensor is a real time, continuous glucose monitoring device. When the system is used together with compatible devices, it is indicated for the management of diabetes in persons age 2 and older. It is designed to replace finger stick blood glucose testing for diabetes treatment decisions. Interpretation of the system results should be based on the glucose trends and several sequential readings over time. The system also detects trends and tracks patterns, and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustment.

1.1.1 Intended Purpose

Continuous Glucose Monitoring System Sensor: When the Continuous Glucose Monitoring System Sensor is used together with compatible software application, it is intended to continuously measure the glucose in the interstitial fluid and is designed to replace fingerstick blood glucose (BG) testing for treatment decisions.

Continuous Glucose Monitoring App (iOS/Android): When the Continuous Glucose Monitoring App is used together with compatible sensors, it is intended to continuously measure the glucose in the interstitial fluid and is designed to replace fingerstick blood glucose (BG) testing for treatment decisions.

1.1.2 Indications

1. Type 1&2 Diabetes Mellitus
2. Special types of diabetes (excluding monogenic diabetes syndromes , diseases of the exocrine pancreas, and drug or chemical induced diabetes)
3. Abnormal blood glucose levels
4. Patients requiring improved glycemic control
5. People requiring frequent or continuous monitoring of blood glucose, including pregnant women

1.2 Patients

Patients with diabetes (>2 years old).

1.3 Intended user

The target users of this medical device are individuals aged 18 and above, who possess basic cognitive, literacy, and independent mobility skills. It is intended for both medical

professionals and non-professional adults who need to continuously or periodically monitor their own or others' glucose levels.

1.4 Contraindications



The Continuous Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

Don't wear your CGM sensor for computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

Taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the CGMS readings and make them look higher than they really are.

The CGM System was not evaluated for the following persons:

- Peritoneal dialysis patients
- Patients with implanted pacemakers
- Patients with coagulation disorders or those taking anticoagulant drugs

1.5 Warning

- Don't wear your CGM sensor for computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.
- Don't wear your CGM while use electrocautery, elec- trosurgical units and diatherny equipment.
- The CGM System was not evaluated for the Peritoneal dialysis patients, Patients with implanted pacemakers and Patients with coagulation disorders or those taking anticoagulant drugs. Before you use the BUZUD System, review all the product instructions.
- The CGMS should not be used by Patients who have diffuse subcutaneous nodules.
- Before you use the BUZUD System, review all the product instructions.
- The User's Manual includes all safety information and instructions for use.
- Talk to your health care 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.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [GX-01S] including cables specified by the Product Owner. Otherwise, degradation of the performance of this equipment could result.
- After restarting your phone, please check again if Bluetooth is turned on. If it's turned off, please enable Bluetooth again to ensure real-time data transmission and notifications.
- • Avoid areas:

  1. With loose skin or without enough fat to avoid mucles and bones.
  2. Th at get bumped, pushed, or you lie on while sleeping.
  3. Within 3 inches of infusion or injection site.
  4. Near waistband or with irritations, scarring, tattoos, or lots of hair.
  5. With moles or scars.
- Android users, after enabling airplane mode, please double-check if Bluetooth is turned on. If it's turned off, please enable Bluetooth again to ensure real-time data transmission and notifications. iOS users don't need to consider this for the time being.

1.6 Precautions

- No modifications to the Continuous Glucose Monitoring System Sensor are allowed. Unauthorized modification of the CGMS may cause the product to malfunction and become unusable.
- Before using this product, you need to read the Instruct ion Manual or be trained by a professional. No doctor's prescription is required for use at home.

- The CGMS contains many small parts that can be dangerous if swallowed.
- During rapid changes in blood glucose (more than 0.1 mmol/L per minute), glucose levels measured in interstitial fluid by the CGMS may not be the same as blood glucose levels. When blood glucose levels drop rapidly, the sensor may produce a higher reading than the blood glucose level; Conversely, when blood glucose levels rise rapidly, the sensor may produce a lower reading than the blood glucose level. In these cases, the sensor's reading is checked by a fingertip blood test using a glucose meter.
- Severe dehydration or excessive loss of water may result in inaccurate results. When you suspect you are dehydrated, consult a health care professional immediately.
- If you think the CGMS sensor reading is inaccurate or inconsistent with the symptoms, use a blood glucose meter to test your blood glucose level or calibrate the glucose sensor. If the problem persists, remove and replace the sensor.
- The performance of the CGMS has not been evaluated when used with another implantable medical device, such as a pacemaker.
- Details of what interferences may affect the accuracy of the detection are given in "Potential Interference information".
- The sensor loosens or takes off may cause the APP to have no readings.
- If a sensor tip breaks, do not handle it yourself. Please seek professional medical help.
- This product is waterproof and can be worn during showers and swimming, but do not bring sensors into water more than 2 meters deep for longer than 1 hour.
- If the product is not working properly or has been damaged, stop using the product.
- When children and adolescents use the CGM system, their legal guardians, care givers or healthcare professionals shall operate the CGM system on their behalf.
- Once the cap of the applicator has been unsealed and opened, do not attempt to put the cap back onto the applicator without having applied the sensor.

1.7 Potential clinical side-effects

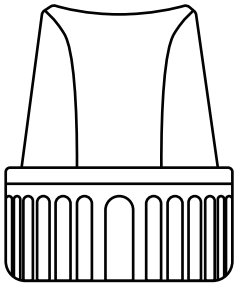
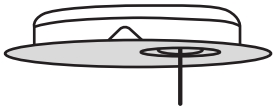
Like any medical device, the BUZUD CGMS has potential side effects. The most common side effects include Skin redness and Skin ulceration at the sensor insertion site.

1.8 Additional security information

- Physiological differences between interstitial fluid and interstitial fluid capillary blood may cause different glucose readings. Differences between sensor glucose readings from interstitial fluid and capillary blood can be observed during periods of rapid changes in blood glucose levels, such as after eating, insulin doses, or exercise.
- If you are going to have a physical examination, there is strong magnetic or electromagnetic radiation (for example, MRI or CT), remove your sensor, and install a new sensor after the inspection date. The impact of these procedures on sensor performance has not been evaluated.
- The sensor applicator is sterile in unopened and undamaged packages.
- Don't freeze the sensor. Do not use it after it expires.
- You are responsible for properly securing and managing your phone. If you suspect an adverse cyber security event related to the BUZUD CGM App, contact Customer Service.
- Make sure that your phone and Sensor kit are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.
- The BUZUD CGM app is not intended for use on a phone that has been altered or customized to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that otherwise violates the manufacturer's warranty.

2. Product list

Product list: The continuous glucose monitoring system sensor is intended to be used together with CGM App as a system. The compatibility list is as flows:

What you see	What it's called	Model Number	What it does
 Glucose Sensor before insertion (Sensor applicator)	Continuous glucose mon-itoring system	GX-01S (For 15 Days)	• The Sensor-Applicator helps you insert the Sensor under your skin. It contains a needle which is used to puncture the skin to introduce the flexible sensor tip into skin but will be retracted into the canister once the sensor is placed. • The Sensor is an applied part which is only visible after applied, the sensor measures and stores glucose readings when worn on your body.
 Glucose Sensor after insertion			

What you see	What it's called	What it does
	Continuous Glucose Ivlonitoring App	It is a healthcare app available on your phone with the feature to be able to receive and display the glucose concentration value and remind when the blood glucose value exceeds the upper or lower limit of the preset blood glucose value. It also has other settings and functions to help users analyze and evaluate the glucose reading of the continuous glucose monitoring system and form a report.

3. Apps and Software

3.1 Software Download

You can download the BUZUD Continuous Glucose Monitoring App from Apple APP Store or Google Play. Please check the Operating System (OS) on your mobile device to make sure you get the correct App version.

3.2 Minimum Requirements for Software Installation

iOS

Model No.: RC2107 (mg/dL), RC2108 (mmol/L)

Operating System (OS): iOS 14 and above

Memory: 2GB RAM

Storage: Minimum 200 MB

Network: WLAN (Wireless Local Area Network) or cellular network, as well as Bluetooth function

Screen Resolution: 1334 x 750 pixels

Android

Model No.: RC2109 (mg/dL), RC2110 (mmol/L)

Operating System (OS): Android 10.0 and above.

Memory: 8GB RAM

Storage: Minimum 200 MB

Network: WLAN (Wireless Local Area Network) or cellular network, as well as Bluetooth function

Screen Resolution: 1080*2400 pixels and above

Note

- To receive alerts, make sure:
  - Turning on Alert function.
  - Keeping your mobile phone and CGMs equipment within 2 meters (6,56ft) maximum. If you want to receive alerts from the app, make sure your device is connect.
  - Do not force-quit BUZUD that must be running in the background to receive alerts. Otherwise, alerts can not be received. If alerts are unavailable, restarting the application may help you.
  - Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not receive alerts.
- When you are not using headphones or speakers, you should take them off your smartphone, otherwise, you may not hear the alert. When you use headphones, put them in your ears.
- If you use a peripheral connected to your smartphone, such as a wireless headset or smart watch, you may receive alerts on only one device or peripheral, rather than all devices.
- Your smartphone should always be charged and turned
- Open the application after the operating system is update.

3.3 IT Environment

Do not use the APP when the Bluetooth function is turned off, in a complex Bluetooth environment or a high electrostatic discharge environment, otherwise it will cause the data reading failure of the continuous glucose detection system. Because Bluetooth will have communication barriers in complex Bluetooth environments or high electrostatic discharge environments, users need to ensure that they stay away from complex Bluetooth environments or high electrostatic discharge environments, and ensure that the Bluetooth function is turned on. No other external software or applications have been found to cause critical defects. Using in an environment with poor communication may cause signal loss, connection interruption, incomplete data, and other issues.

4. BUZUD App Overview

4.1 CGMS Service Life

The app will cease maintenance five years after the final batch of CGMS devices is discontinued from the market. During the maintenance period, it is necessary to ensure the normal operation of the servers, and the interactive functions related to CGMS devices should not be affected.

4.2 APP Setup

4.2.1 Software Registration

If you do not have an account, click "Register" button to enter the registration screen. Please input your email address and password. Read the Terms of Use and Privacy Policy before ticking the box. By ticking

the box, you agree to comply with the Terms of Use and the Privacy Policy. Click "Send verification code" to receive a six-digit code. After keying

in the verification code, click "Continue" to complete your registration. The rules for setting a username and password are:

Username:

✔ Use your email address as your username.

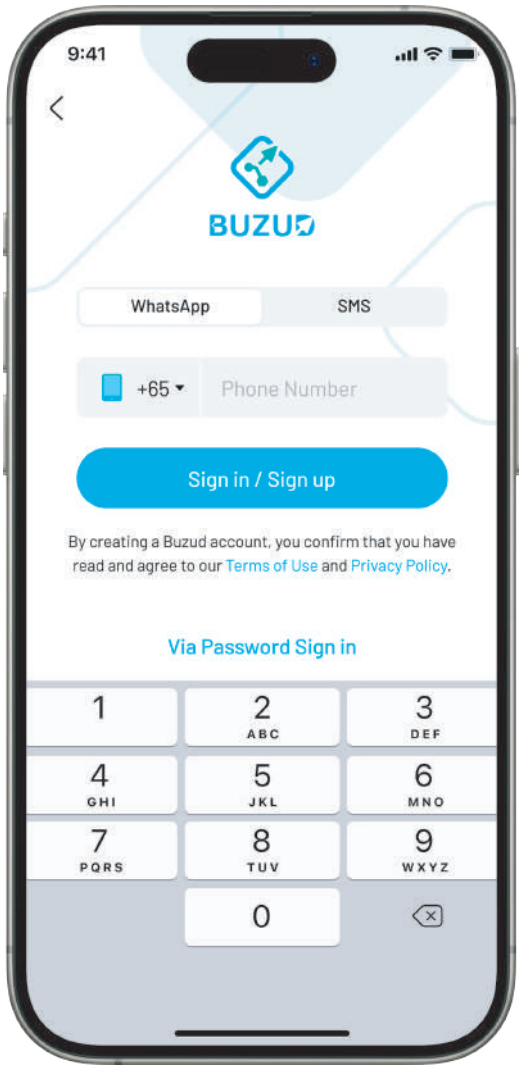
Password:

✔ Password must contain at least 8 characters.

✔ Password must contain 1 capital letter, 1 small letter and 1 numerical number.

4.2.2 Software Login

Use your registered account email address and Password to log in to the App.



4.2.2 Software Login

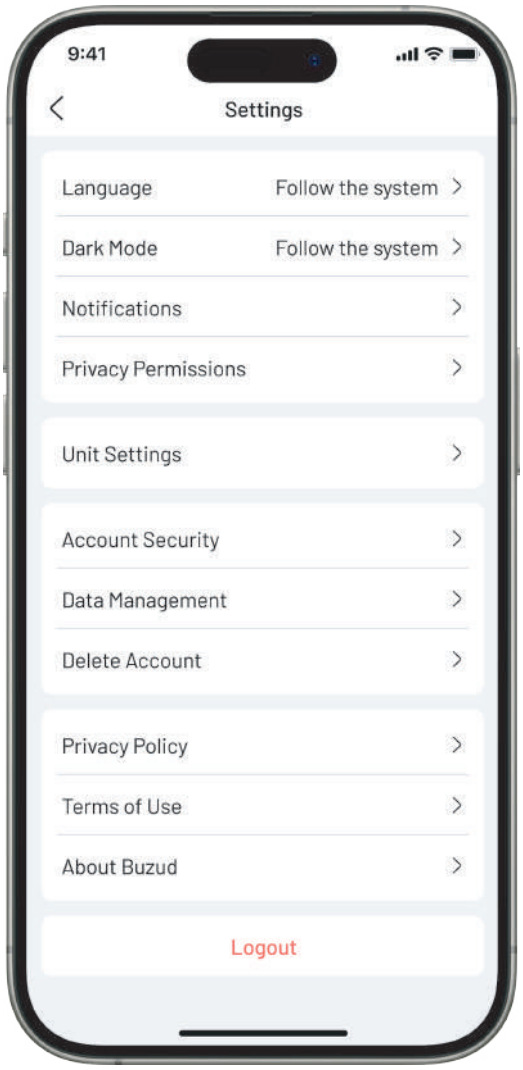
Use your registered account email address and Password to log in to the App.

Note

- You may only log in your account on one mobile device at a time.
- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the BUZUD app, contact a local distributor. Make sure that your phone is kept in a safe place, under your control. Do not disclose your password to others. This is important to help prevent anyone from accessing or tampering with the System.
- It is recommended to use the protection system of your mobile phone, such as lock screen password, biometrics, to strengthen the data protection of the APR

4.2.3 Software Logout

To log out of the current account, click "Logout" under "Settings" from the Profile page.

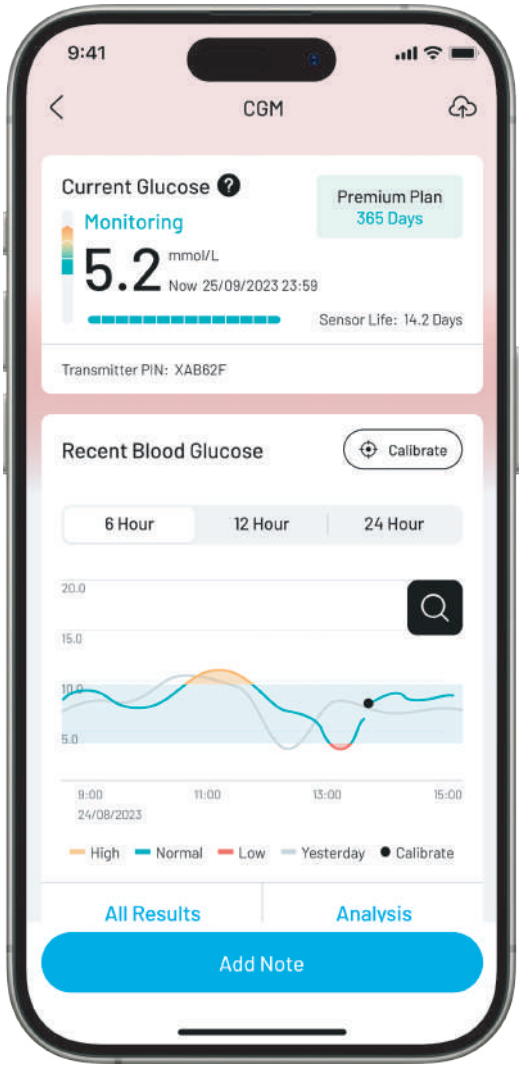


4.2.4 Software Update

Please ensure that your application software is the latest version. Keep the network environment stable during the upgrade process, if the upgrade fails, please uninstall the application and reinstall it.

4.3 Functions

4.3.1 Home Dashboard



Home dashboard displays the overview of your blood glucose levels.

In the upper section of the dashboard, the real-time blood glucose level is displayed (updated every minute).

In the lower section of the dashboard, the blood glucose against time graph is displayed. You can select the time interval to see the glucose level history and trend in the past 6 hours, 12 hours or 24 hours.

Scroll the plot to view blood glucose levels over different periods. The data point gives you the blood glucose value and the time of measurement (updated every minute).

When your sensor expires, the sensor status on the BUZUD App will also change to "expired". Please replace the used sensor.

Note

When "Sensor is stabilizing" or "Sensor Error Please wait ..." appears on the Home Dashboard, the user needs to wait patiently.

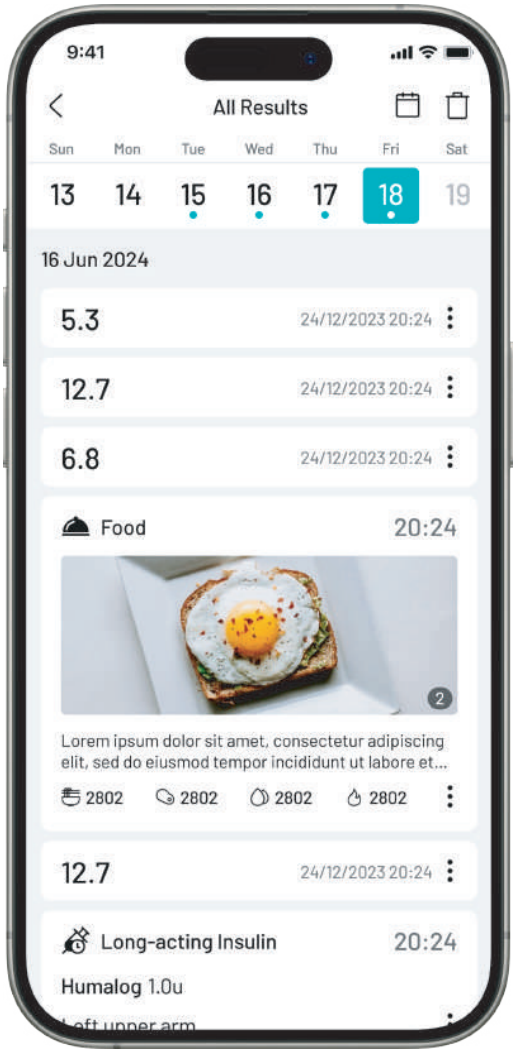
When "Replace sensor" appears on the Home Dashboard, the user needs to replace the sensor with a new one.

There is no need to unpair the sensor when replacing the sensor.

4.3.2 All Results Dashboard

All Results Dashboard displays glucose alert records, events, as well as glucose data each day.

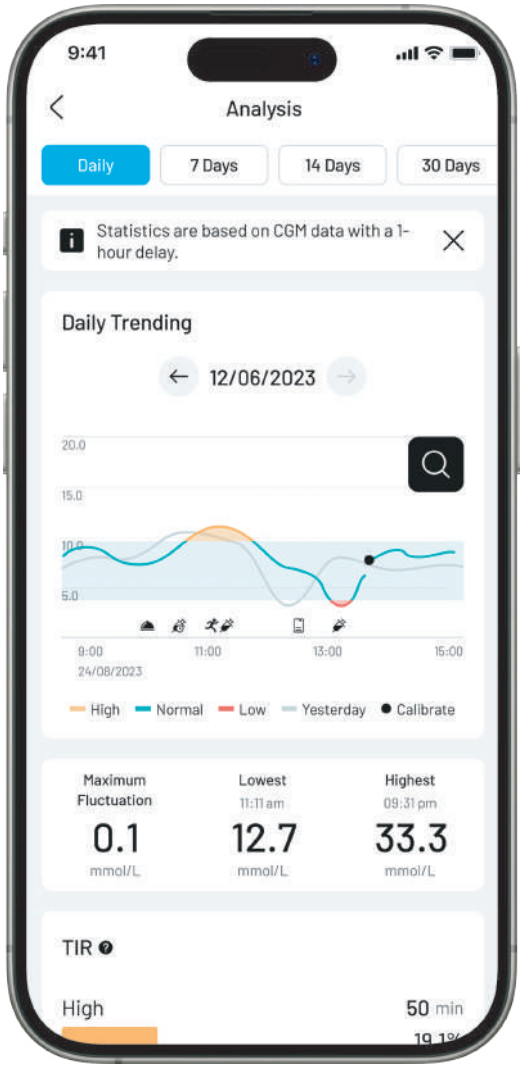
1. When the sensor blood glucose level is lower/higher than the pre-set alert value, the App will alert you every 30 minutes about your glucose levels. The alert and the time it took place are displayed in the All Results Dashboard.
2. The notes you added will be displayed in the All Results Dashboard.
3. The glucose levels recorded in the "Home" screen will be displayed in the History dashboard.



4.3.3 Trends Dashboard

The Trends dashboard displays the blood glucose analysis results, which displays the various analysis results over a certain period (Last 7 days, Last 14 Days, Last 30 Days, or your customized interval).Different periods can be switched to display.

1. Display Estimated HbA1c, Average Glucose Value, Time in Range, AGP profile, Multi-day Bg curves and Low BG Index over a period of time.
2. Multi-day Bg curves: Users can freely select different dates to compare the daily blood glucose curve.
3. Generate and share AGP reports.



Note

Please consult your healthcare professionals for the interpretation of the above parameters.

4.3.4 CGM Dashboard - Calibration

In the CGM dashboard, you can calibrate the CGMS and record the reference blood glucose level for sensor calibration.

You can take regular or irregular finger blood glucose measurements while wearing this product. However, it is recommended taking a finger blood test to confirm your BG level in the following situations:

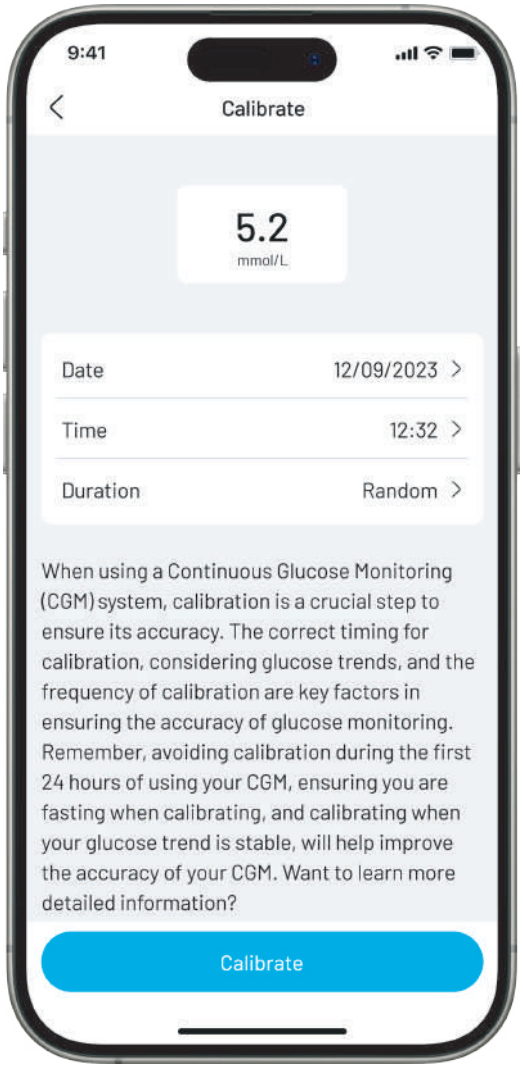
1. When you perceive symptoms of hypoglycemia such as palpitations, hand tremors, tremors, sweating, but the BG reading of your device is still normal.
2. When the reading indicates hypoglycemia (low blood glucose) or close to hypoglycemia (high blood glucose).
3. When you expect a large gap between your blood glucose and CGM readings based on past experience. If the current reading of this product is more than 20% higher or lower than the finger blood measurement, please take the finger blood measurement again after 2 hours, and if the second measurement is still more than 20% higher or lower, you can calibrate the current sensor.

If you choose to calibrate, please make sure that you have not taken carbohydrates or insulin injections in the 15 minutes prior to calibration, and that your current blood

glucose trend is not rising or falling rapidly (you can check the current blood glucose trend by looking at the trend arrow shown on the homepage of BUZUD APP). The blood glucose value entered for calibration should be the finger blood glucose value measured within 5 minutes. If your current blood sugar trend is rising or falling rapidly, please wait for the blood sugar change to stabilize before taking a finger blood measurement and calibrating the product.

In the CGM dashboard, there is the "Calibration" function.

1. Click "Calibrate" to enter the glucose value measured (from blood glucose meters or by your healthcare professionals). The record will be displayed on the Home and All Results dashboard.
2. When the glucose value measured from other channels is different from the sensor glucose level displayed in the Home dashboard, user can manually input the calibration glucose level to calibrate the sensor.



Note

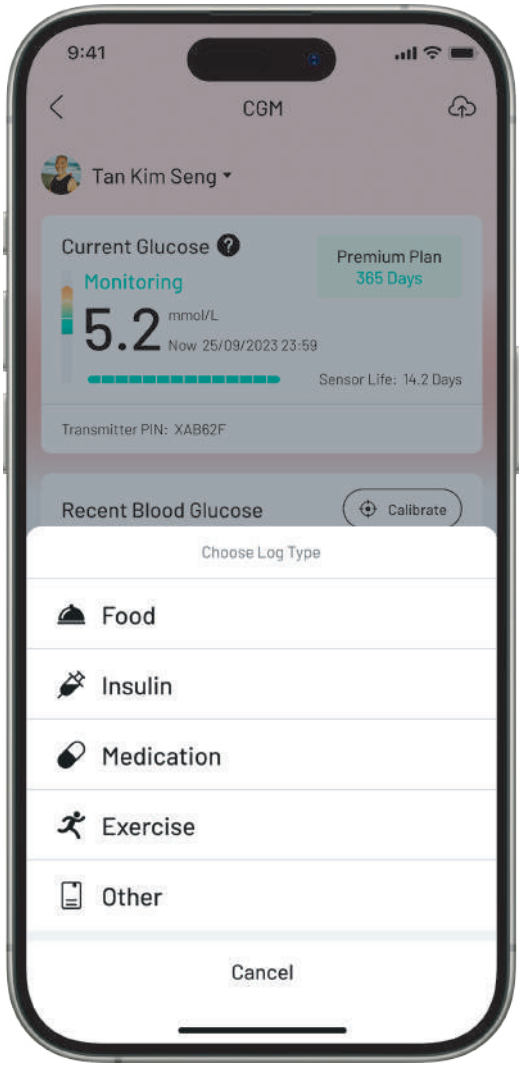
Do not calibrate the system frequently afterward. Do not calibrate while your blood glucose is rising or falling rapidly. The glucose value used for calibration should be the value measured no earlier than 1 minute before the blood glucose test.

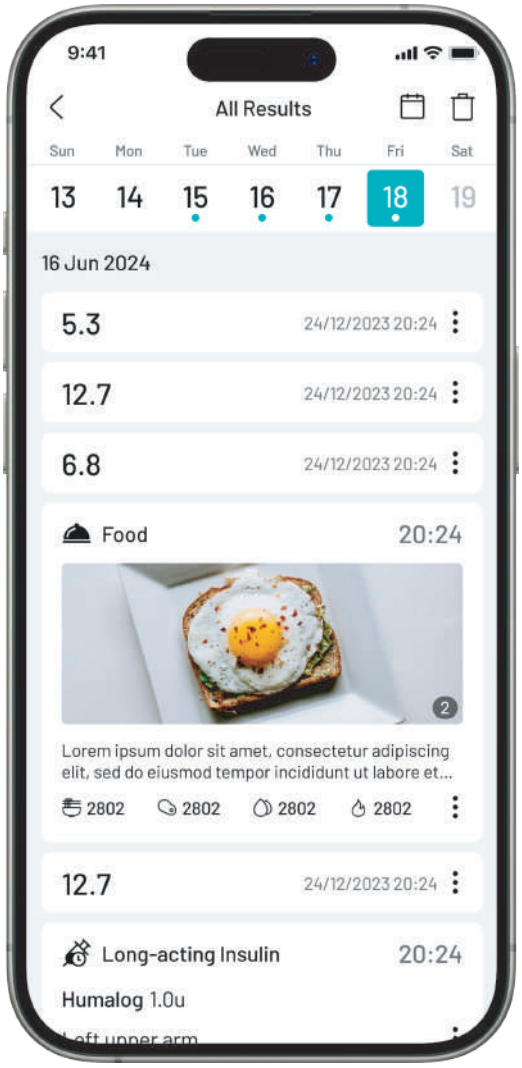
Scroll the slider to input your blood glucose test value. Once you have selected the right value, click "Calibrate" to complete the calibration.

4.3.5 Notes Dashboard

The BUZUD CGMS system allows you to log and track events that can affect your blood glucose level.

1. You can note down different types of events including “Food”, “Exercise”, “Medicine”, “Insulin” and "Other” on the top of the Notes dashboard.
2. You can record the time that the event occurred.
3. The added events will also be displayed in the All Results dashboard.
4. The recorded events are uploaded to the Cloud Services. You can access the event history on the Cloud by using your BUZUD REimagined Healthcare App account.





5. Using a New Glucose Sensor

5.1 Applying Your Sensor

Caution

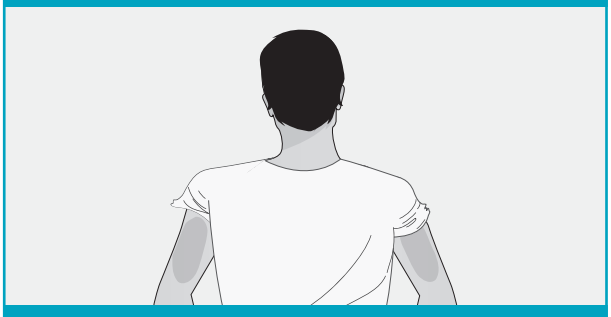
During intense exercise, your sensors may fall off due to sweat or sensor movement. If your sensors come off your skin, you may not get any readings, or only unreliable readings that are inconsistent with your health. Select the appropriate application site according to the instructions.

Note

Click Help in the main menu to enter the tutorial in the application that explains how to install the sensor.

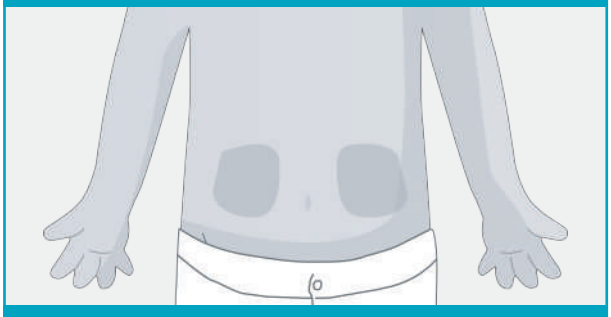
1. Recommended areas for sensor application include the abdomen (age 2-17 years), the back of the upper arm(age > 18). For best performance, avoid excessive motion which may weaken the sensor and its adhesive tape. Avoid accidental knocking off the sensor. Choose a skin area that is normally not affected by your usual daily activities (stretching or pressing). Choose a site at least 2.5 cm (1 inch) away from the insulin injection site. To avoid discomfort or skin irritation, you should choose a site different from the site you used last time.

Ages 18 years and older



Back of the upper arm

Ages 2-17 years



Abdomen

2. Wash the smeared part with simple soap, dry it, and then clean it with alcohol pads. Remove any oily residue that may affect the adhesion of the sensor.

Note

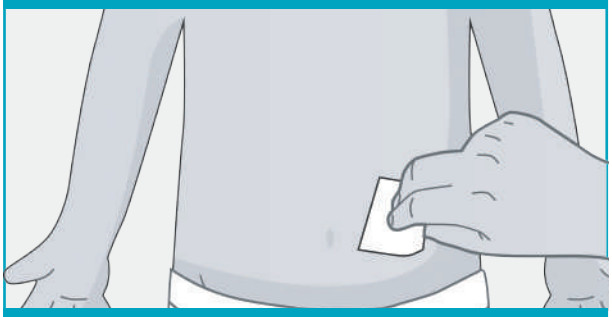
The skin area must be clean and dry. Otherwise, the sensor will not stick to the skin.

Ages 18 years and older



Back of the upper arm

Ages 2-17 years



Abdomen

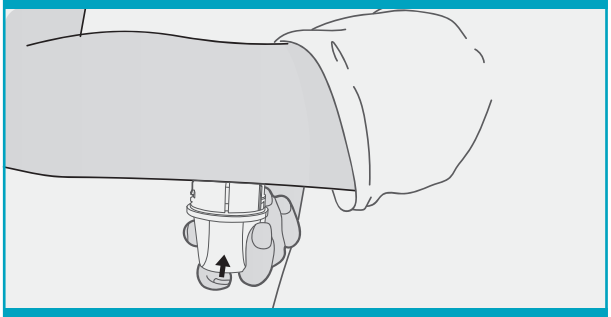
3. Remove cover from sensor applicator and set it aside.

Caution

- Do not use the sensor applicator if it is damaged or if the safety seal indicates that the sensor applicator is open.
- Do not reattach the sensor applicator, as this will damage the sensor.
- Do not grasp the inside of the sensor applicator, because there are needles here.
- Do not use it after it expires.

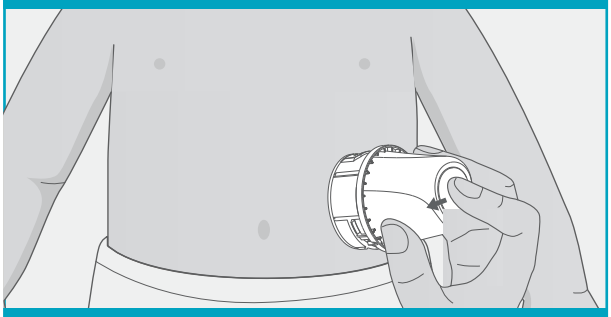
4. Align the opening of the applicator with the skin where you want to apply it and press it tightly on the skin. Then press the implantation button of the applicator, wait for a few seconds after hearing the sound of the spring retreating to make the sensor stick on the skin, and the puncture needle in the applicator will automatically retreat.

Ages 18 years and older



Back of the upper arm

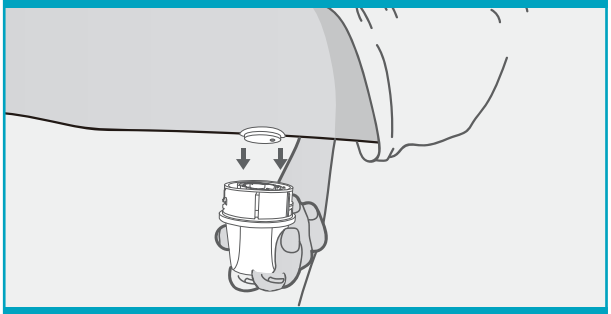
Ages 2-17 years



Abdomen

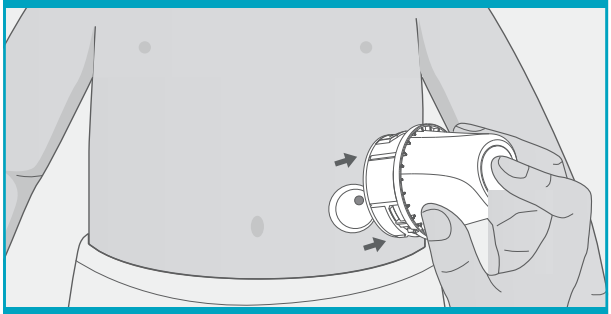
5. Gently pull the sensor applicator away from the body, and the sensor should now be attached to the skin.

Ages 18 years and older



Back of the upper arm

Ages 2-17 years



Abdomen

Note

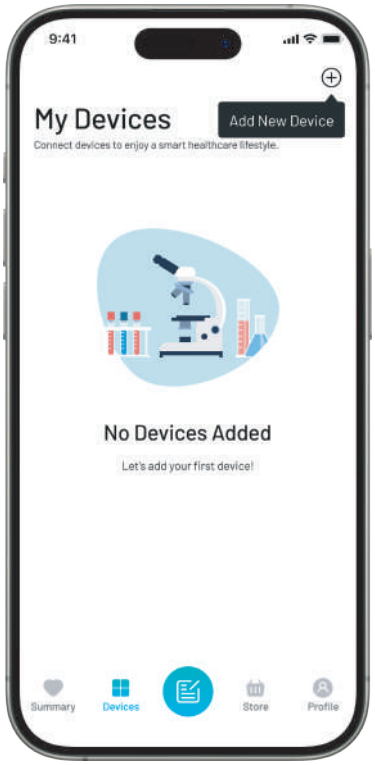
There may be bruises or bleeding when installing the sensor. If bleeding persists, remove the sensor and install a new sensor elsewhere.

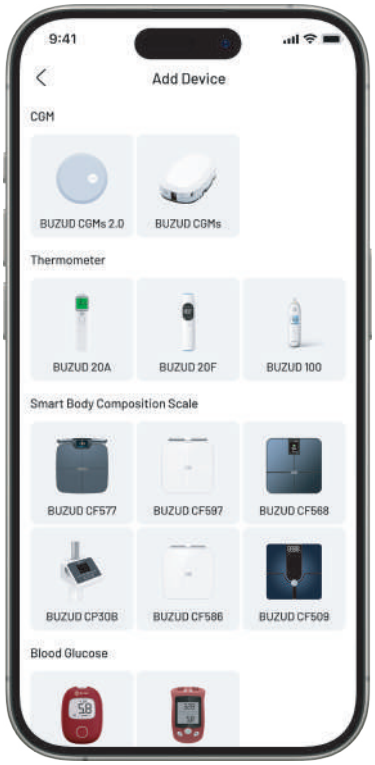
6. After installing the sensor, make sure that the sensor is firmly in place. Put the cover back on the sensor applicator.

5.2 Starting the sensor

Pairing a sensor

Click "**Add a new device**" in My Devices and select your sensor by searching for devices.





Note

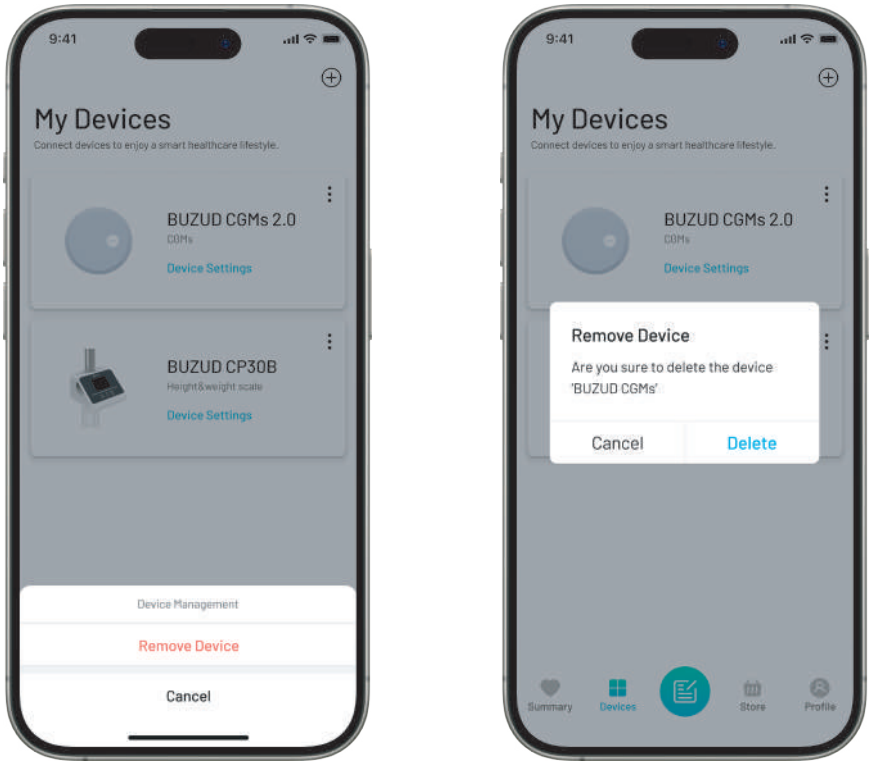
Please enable the Bluetooth function on your mobile device. The communication radius between your mobile device and sensor should be no more than 2 meters without obstacles. If pairing fails, a notification box will appear. Users can choose to retry or input the serial number again.

Sensor Warm-up

When you have successfully paired the sensor, you need to wait for one hour for your sensor to warm up. You will see the real-time glucose readings (updated every 1 minute) on the "Home" screen after the sensor warm-up has finished.

5.3 Unpairing a sensor

Enter "**My Devices**", click the "**Unpair**" button. If unpairing fails, you can choose to delete the sensor permanently.



Note

Please make sure the BUZUD App is paired with the sensor before unpairing. If the sensor is not connected to the App, you may delete the sensor record permanently by clicking "Delete".

5.4 Removing a sensor

1. The sensor needs to be removed from the skin when the phone application prompts the sensor to expire or when the user feels any irritation or discomfort with the application area during use.
2. Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.

Note

1. Any remaining adhesive residue on the skin can be removed with warm soapy water or alcohol.
2. The sensor and sensor applicator are designed for single use. Reuse may result in no glucose readings and infection. Please dispose of the used sensor and sensor applicator in accordance with local regulations.

When you are ready to apply a new Sensor, follow the instructions in "Chapter 5.1 Applying Your Sensor" and "Chapter 5.2 Starting Your Sensor".

5.5 Replacing the sensor

After 10 or 15 days of use, your sensor will automatically stop working and need to be replaced. In addition, if you notice irritation or discomfort at the application site, or if the application fails, you should replace your sensor.

Note

If the glucose reading on the sensor does not appear to be consistent with your health, check the sensor for looseness. If the sensor tip is no longer in the skin, or if the sensor is loose from the skin, remove the sensor and install a new one.

6. Personal Settings

6.1 Reminder Settings

This section describes how to set up and use alerts. Read all the information in this section to make sure you receive glucose alerts when they are activated.

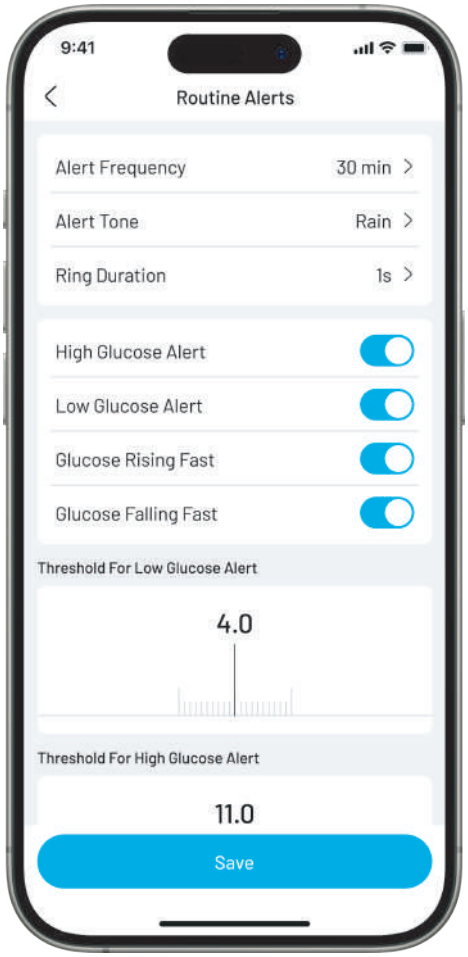
Note

To receive alerts, make sure:

- The alert is on, and your smartphone is always at the maximum distance of 2 meters (6.56 ft) away from you. The transmission range is 2 meters (6.56 ft) free environment. If you are outside the range, you may not receive the alerts. If you want to receive alerts from the app, make sure your device is connect.
- The application must be running in the background all the time to receive alerts.
- The App will ask for phone permissions which are needed to receive alerts.

Setting Alerts

In the Alerts dashboard, you can set up alerts. You can set the values for high glucose alerts, low glucose alerts and urgent low alerts. High glucose alerts, low glucose alerts, rapid increase alerts, rapid decrease alerts, urgent Low Glucose alerts and sensor signal lost alerts will appear as pop-up notifications. The records of high glucose alerts and low glucose alerts will also be displayed in History dashboard.



You will be alerted by notification when:

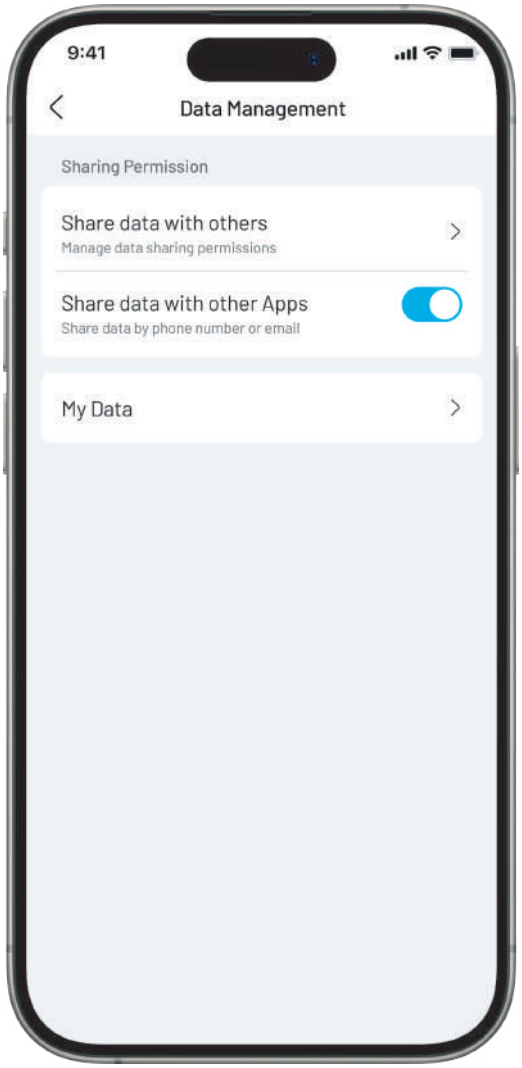
- Your glucose is too low.
- Your glucose is too high.
- Your glucose is decreasing rapidly.
- Your glucose is increasing rapidly.
- Sensor signal is lost.
- Urgent Low Glucose happens.

6.2 Share/Follow

In the Profile page, click "**Settings**" and then "**Data Management**" to adjust the Sharing Permission for your health data.

Note

Blood glucose data is for your private use only. Please think carefully before sharing your data with other accounts. Please also keep the blood glucose data shared with others confidential.



7. Maintenance

The sensor has no components that need maintenance.

The company uniformly collates and evaluates whether software functionality needs to be improved. If a new version of the Software is available and can be upgraded directly online for users who have installed the Software, please NOTE:

- Sensor is a precision device. If failure is not serviceable, third-party individuals or institutions are not allowed to disassemble and repair, and circuit diagrams and component lists are not provided in the instructions.
- Mobile phone applications continue to improve to meet new requirements or problem resolution. Customer service, sales staff feedback user usage, and feedback to follow the prompts to complete the up grade when the Software prompts for an update.
- If the app update fails, you can uninstall the original app and install the latest one.

7.1 Cleaning

Sensors are disposable sterile products and do not require cleaning, disinfection, maintenance or maintenance.

7.2 Disposal

Sensor:

Please do not discard old products or accessories at will. The disposition of sensors and sensor applicators should comply with the requirements of relevant local regulations for electronic devices, batteries and materials that may be exposed to body fluids. As Sensors may have been exposed to bodily fluids, you may wipe prior to disposing. Please consult your local waste management authority for instructions on how to dispose Sensor Applicators at a designated place. Ensure the cap is on the Sensor Applicator as it contains a needle.

Note

Sensors contain non-removable batteries and must not be incinerated. Batteries may explode upon incineration.

7.3 Transportation

Sensor sterile packaging should prevent heavy pressure, direct sunlight and wet rain when transporting. It shall be transported in accordance with the storage and transportation conditions specified in the product. Avoid placing heavy weight on top of the sensor. Avoid direct sunlight and rain.

7.4 Storage

If you are temporarily not using the sensor system, store it in a cool, dry, clean, well ventilated, non-corrosive gas environment.

8. Troubleshooting

Data Lost

When the App is disconnected from the CGMS, please first check if the Bluetooth function in your mobile device has been turned on. If so, the pairing will be restored automatically. If the problem still persists, restart the App.

The App can recover data after restarting. After restarting, the saved App data will be restored automatically. All the saved but not displayed data can be displayed again. If the App fails to display blood glucose data, please restart the Bluetooth and re-pair the App and the corresponding sensor or contact Roffe International.

Sensor Signal Lost

When BSensor Signal Lost" notification pops up, please check if you have turned off your Bluetooth. After turning on your Bluetooth function, the signal connection between the App and the sensor will be restored automatically. If "Error" notification pops up, please restart the App or Bluetooth. The blood glucose data is temporarily stored in the sensor during signal lost. When the connection between the App and the sensor is restored, all relevant data will be transmitted to the App.

Fail to Read Data

Data reading failure can be caused by signal interference. Users are required to stay away from environments with strong electromagnetic interference or contact Roffe International.

9. Performance Characteristic

Note

Please consult your healthcare team on how to use the information in this section.

Two prospective clinical studies were conducted at seven centers.

Adult Trial

The study included a total of 91 subjects (18 years and older). Each subject wore up to two sensors for up to 15 days on the back of the upper arm. During the study, subjects had their venous blood glucose analyzed over up to three separate visits to the clinical center using the Glucose and lactate measuring Instruments manufactured by EKF-diagnostic GmbH.

Clinical performance

Accuracy

Indicator	Result
Mean Absolute Relative Difference (MARD%)	8.66%
When glucose concentration ≥ 3.90mmol/L and < 10.00mmol/L	
Results within a deviation range of ±15% from the reference value.	87.2%
Results within a deviation range of ±40% from the reference value.	99.8%
When the glucose concentration ≥ 10.00mmol/L	
Results within a deviation range of ±15% from the reference value.	90.2%
Results within a deviation range of ±40% from the reference value.	100.0%
When the glucose concentration < 3.90mmol/L	
Results within a deviation range of ±0.83mmol/L from the reference	94.6%
Results within a deviation range of ±2.22 mmol/L from the reference	100.0%
The percentage of data points that fell within Clarke error grid zones A+B	99.7%
The percentage of data points that fell within Consensus error grid zones A+B	100.0%

Alert Rate

Success rate of hyperglycemic alert: 89.4% (hyperglycemic alert threshold set at 11.1mmol/L);

Success rate of hypoglycemic alert: 89.3% (hypoglycemic alert threshold set at 4.4mmol/L).

Adverse Event

In the clinical trial, a total of 174 sensors were worn, and only three adverse events were possibly related to the product. The adverse events were characterized by local abnormalities in the area where the sensor was worn, but they resolved on their own without treatment.

Pediatric Trial

The clinical trial was conducted at four clinical trial institutions, with 82 subjects (2-17 years) screened and 82 subjects enrolled. Three subjects withdrew after the first intensive blood sampling due to complete detachment of both the left and right abdominal test devices, resulting in 79 subjects completing the trial. According to the statistical analysis plan, the trial results for the 6-17 years and 2-5 years age groups were analyzed statistically. Participants wore two sensors for up to 15 days in the abdomen. Clinic session(s) took place on Day 1-2, Day 7-9 and Day 15-16. Depending on the participant's age, they participated in one clinic session of varying duration.

The right abdomen clinical data is selected to state in the following accuracy results table since the main effectiveness evaluation was conducted on the test device worn on the right abdomen of the subject.

Accuracy results obtained from the pediatric study (6-17 years)

Indicator	Result
Mean Absolute Relative Difference (MARD%)	8.16%
When glucose concentration ≥ 3.90mmol/L and < 10.00mmol/L	
Results within a deviation range of ±15% from the reference value.	83.4%
Results within a deviation range of ±40% from the reference value.	99.2%
When the glucose concentration ≥ 10.00mmol/L	
Results within a deviation range of ±15% from the reference value.	94.9%
Results within a deviation range of ±40% from the reference value.	99.8%
When the glucose concentration < 3.90mmol/L	
Results within a deviation range of ±0.83mmol/L from the reference	90.2%
Results within a deviation range of ±2.22 mmol/L from the reference	100.0%
The percentage of data points that fell within Clarke error grid zones A+B	99.8%
The percentage of data points that fell within Consensus error grid zones A+B	99.9%

Pediatric Trial

The success rate of hyperglycemic alert: 97.9%
(hyperglycemic alert threshold set at 11.1 mmol/L);

The success rate of hypoglycemic alert: 97.4%
(hypoglycemic alert threshold set at 4.4mmol/L).

Accuracy results obtained from the pediatric study (2-5 years)

Indicator	Result
Mean Absolute Relative Difference (MARD%)	8.45%
When glucose concentration ≥ 3.90mmol/L and < 10.00mmol/L	
Results within a deviation range of ±15% from the reference value.	80.3%
Results within a deviation range of ±40% from the reference value.	100.0%
When the glucose concentration ≥ 10.00mmol/L	
Results within a deviation range of ±15% from the reference value.	95.3%
Results within a deviation range of ±40% from the reference value.	100.0%
When the glucose concentration < 3.90mmol/L	
Results within a deviation range of ±0.83mmol/L from the reference	90.9%
Results within a deviation range of ±2.22 mmol/L from the reference	100.0%
The percentage of data points that fell within Clarke error grid zones A+B	99.7%
The percentage of data points that fell within Consensus error grid zones A+B	100.0%

Pediatric Trial

The success rate of hyperglycemic alert: 100.0%
(hyperglycemic alert threshold set at 11.1 mmol/L);

The success rate of hypoglycemic alert: 100.0%
(hypoglycemic alert threshold set at 4.4mmol/L).

Safety Results

3 device related adverse events (Only 2 cases of skin ulceration and 1 case of skin redness related to the device were reported in the adult trial & no device related adverse events were reported in the pediatric trial) were recorded.

Pregnancy Trial

The clinical trial was conducted at two clinical trial institutions, A total of 61 subjects were screened for this clinical trial, with 60 enrolled. There are no dropouts, and all 60 subjects completed the trial. Ultimately, all 60 subjects were included in the FAS set, PPS set, and SS set. All 60 subjects completed one intensive blood sampling session, with venous blood glucose levels measured using the control device. A total of 1,500 venous blood glucose values were obtained, including 208 low-concentration glucose values (less than 4.4 mmol/L) and 6 high-concentration glucose values (greater than or equal to 11.1 mmol/L).

The clinical data referenced in this user guide is based exclusively on measurements taken from the right arm of the subjects in the clinical trial.

Accuracy results obtained from the pregnant study

Indicator	Result
Mean Absolute Relative Difference (MARD%)	7.62%
When glucose concentration ≥ 3.90 mmol/L and < 10.0mmol/L	
Results within a deviation range of ± 15% from the reference value	88.78%
Results within a deviation range of ± 40% from the reference value	100%
When the glucose concentration ≥ 10.00 mmol/L	
Results within a deviation range of ±15% from the reference value	100%
Results within a deviation range of ±40% from the reference value	100%
When the glucose concentration < 3.9 mmol/L	
Results within a deviation range of ±0.83mmol/L from the reference value.	88.71%
Results within a deviation range of 2.22 mmol/L from the reference value.	100%
The percentage of data points that fall within Clarke error grind zones A+B	99.3%
The percentage of data points that fall within Consensus error grid zones A+B	100%

Alarm performance rate

The success rate of hyperglycemic alert: 90.5%
The success rate of hyperglycemia alarm: 100%

10. Specifications

Continuous glucose monitoring system sensor	
Item	**Specification**
Model number	GX-01S
Operating temperature	5-40°C (41-104°F)
Operating humidity	10-93% (non-condensing)
Storage and transportation temperature	2°C-25°C
Storage and transportation humidity	10-90% (non-condensing)
Storage and transportation pressure	700hPa~1060hPa
Ingress protection level	IP68
Use life	GX-01S: 15 days
Shelf life	16 months
Detection range	2.0 mmol/L- 25.0 mmol/L
Wreless frequency and bandwidth	Frequency: 2.402GHz ~ 2.48 GHz Bandwidth: 1Mbps
Wireless modulation	GFSK
Radiated power	-2dBm

Continuous glucose monitoring App	
Item	**Specification**
Platform	iOS 14 and above. Android 10.0 and above
Memory	2GB RAM for iOS 8GB RAM for Android
Resolution	1080*2400 pixels and above
Network	WLAN (Wireless Local Area Network) or cel-lular network, as well as Bluetooth function
Display	Real-time glucose value: glucose level history and trend in the past 6.12 and 24 hours
Calibration	User can use the BG value for calibration
Alerts	Low blood glucose alert; High blood glucose alert; Rapid blood glucose rise alert; Rapid blood glucose drop alert; Urgent low blood glucose alert; Signal lost alert
Glucose Reading Update Interval	Every 1 minute
Data loading time	Within seconds
Server response time	Within seconds
Mobile phone storage Space	Minimum 200 MB
Data download time in 15-day monitoring session	Within seconds
Data transmission bandwidth	8 M or above

11. Electromagnetic Compatibility

These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that the device is used in such an environment.

Portable and mobile RF communication interference may have an impact on the device.

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic interference can still occur in the home healthcare environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in CGMS readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

If your symptoms don't match your CGMS readings, use your BG meter when making treatment decisions. If your CGMS readings don't consistently match your symptoms or BG meter values, then talk to your healthcare professional about how you should be using the CGMS to help manage your diabetes. Your healthcare professional can help you decide how you should best use this device.

The essential performance for this product is that within the measurement range, the glucose concentration measurement should meet the technical requirements for linearity and repeatability.

Guidance and product owner's declaration electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal Rindion. 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply.
Harmonic emissions IEC 61000-3- 2	Not Applicable	Move to a place within the normal operating temperature range and repeat the test.
Voltage fluctuations/Flicker emissions IEC 61000-3- 3	Not Applicable	Repeat test. If you see the same result, contact your healthcare professional immediately.

Manufacturer's Declaration - Electromagnetic Immunity		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance Level**	**Electromagnetic environment - guidance**
Electromagnetic discharge (ESD) (IEC61000-4-2)	± 8 kV Contact ± 2 kV ± 4 kV, ± 8 kV,±15kVAir	The device uses RF energy only for its internal Rindion. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Power frequency (50/60 Hz) magnetic field (IEC 6100-4-8)	30A/m	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply.
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz, PM, 2.1 kHz, 65A/m 13.56 MHz, PM, 50 kHz, 7.5 A/m	The sources of proximity magnetic fields should be used no closer than 0.15 m to any part of the product.
Radiated RF (IEC 61000-4-3)	80 MHz ~2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the sensor. Recommended separation distance. $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=1.2\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the sensor in watts (W) according to the sensor manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF sensor, as detetmlned by an electromagnetic site sun/eyja). 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.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
3. To estaolished the proximity threshold 0.15 m for Proximity magnetic fields, the I EC Subcommittae (SC) 62A considered the types of praxjrriity magnetic field disturbance sources expected:
   - induction cooking appliances and ovens operating at frequencies up to 30 kHz;
   - RFID readers operating at both 134.2 kHz and 13.56 MHz;
   - electronic article surveillance (EAS) systems;
   - sponge detection systems;
   - equipment used for position detection (e.g. in catheter labs);
   - wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 I<Hz.

These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of the collateral standard IEC 60601-1-2:2014+A1:2020.

a. Field strengths from fixed sensor, 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 sensor, an electromagnetic site survey should be considered. Ifihe measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the equipment.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note

a. The continuous glucose monitoring system are tested according to the recommendation of IEC TS 60601-4-2:2024, medical electrical equipment - Part 4-2: Guidance and interpretation -Electromagnetic immunity: Performance of medical electrical equipment and medical electrical systems.
b. The performance in relation with the intended use of continuous glucose monitoring systems is Within the measurement range, the repeatability of glucose concentration measurements should meet the specified requirements.

Recommended minimum separation distances:

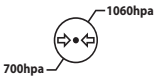
Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This Systems has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this Systems as recommended below:

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ± kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

12. Appendix

12.1 Symbols

The app will cease maintenance five years after the final batch of CGMS devices is discontinued from the market. During the maintenance period, it is necessary to ensure the normal operation of the servers, and the interactive functions related to CGMS devices should not be affected.

Refer to Instruction manual	
Do not re-use	
Type BF applied part	
Temperature limit	
Atmospheric pressure limitation	
Humidity limitation	
Single sterile barrier system with protective packaging outside using irradiation	
The level of protection against ingress of solid foreign objects is 6 (Protected against access to hazardous parts with a wire). The level of protection against ingress of water with harmful effects is 8 (Protected against the effects of continuous immersion in water).	
Consult the Instructions for Use.	
Manufacturer	
Importer	
MR unsafe	
Do not use if package is broken	
Date of manufacture	

Use-by date	
Batch code	
Serial number	
Waste Electrical and Electronic Equipment (WEEE)	
Caution	
Unique device identifier	
Medical device	

12.2 Potential Interference Information

It has been studied that when users take normal doses of ascorbic acid or acetaminophen (ascorbic acid blood concentration < 6mg/dL, acetaminophen blood concentration < 20mg/dL), the drug will not interfere with the sensor glucose measurement. When the user's blood uric acid is significantly higher than the normal range (blood uric acid concentration > 10mg/dL or 600umol/L), the uric acid in the body may produce interference current on the surface of the sensor electrode, which reduces the accuracy of the final glucose measurement. However, hydroxyurea has a significant impact on CGM measurement values. The error size depends on the actual concentration of the blood uric acid value. If the user feels that the current physical condition does not match the glucose readings obtained by the Continuous Glucose Monitoring System or suspects that the measurements may be inaccurate, the blood glucose test can be performed using a finger blood glucose meter and corresponding management actions can be taken based on the test values. When use finger blood glucose meter, record your blood glucose values promptly after measurement to avoid forgetting or inaccuracies in the readings.

Any serious injury or death that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

12.3 Potential Risks

- **Inaccurate glucose values**
  Exposure to heat for longtime may cause inaccurate results.
- **Mild to severe to sensor related -wear reactions**
  E.g. allergic reaction, moderate to severe itching, rash, erythema, bleeding, minor

infection at the insertion site, discomfort during insertion.

- **Hyperglycemia or hypoglycaemia**
  Hypo and Hyperglycemia events stemming from missed alerts or sensor inaccuracies.

12.4 Potential Clinical Benefit

Some potential benefits of using your BUZUD Continuous Glucose Monitoring are improved management of glycemic control:

- Improved management of HbA1c/A1c value (denoting improvement of glycemic control)
- Reduced events of severe hypoglycemia in hypoglycemia unawareness
- Reduced events and duration of hyperglycemia
- Potential for increased self-management
- Increased patient insight regarding food, portions, physical activity, stress, diabetes medication choices
- Increased proactive and retroactive decision-making by patients as a result of easy and timely access to more data, including postprandial and overnight data
- Increased ability and speed to self-assess validity of management changes which can increase sense of empowerment and self-efficacy.
- Increased types of glycemic metrics available (% time in range, etc)

Potential for improved quality of life:

- Decreased fingerstick testing, Increased ease of glucose monitoring
- Decreased manual record keeping
- Increased ability to identify and treat hypoglycemia
- Increased reassurance for those fearful of hypoglycemia during sleep, sports, driving etc
- Reduced limitations of fingerstick blood glucose tests
- CGM overcomes some limitations of fingerstick blood glucose monitoring include: inconvenience; physical intrusiveness of "poking" multiple times daily; limited single "point-in-time" glucose measurement; missed data (between meals, overnight, with sports or with asymptomatic hypo/hyperglycemia)
- CGM provides real-time blood glucose readings throughout the day, using the device as close to daily as possible could provide real-time, dynamic glucose information, increase tighter glycemic control and result in fast, proactive response, therefore enable maximal clinical benefft to the user.

13. Glossary

Blood glucose meter

A device used to measure the levels of glucose in the blood. Blood glucose result The concentration of glucose in the blood, measured as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L).

Continuous glucose monitor (CGM)

A CGM uses a small sensor inserted below your skin to measure the amount of glucose in the ffuid in your skin, called interstitial ffuid. Those glucose results are then sent to an App, where they are displayed as glucose levels and long-term glucose trends.

Hyperglycemia (high blood glucose)

High levels of glucose in the blood, also known as high blood glucose. When left untreated, hyperglycemia can lead to serious complications. Talk to your healthcare professional to determine your high glucose level.

Hypoglycemia (low blood glucose)

Low levels of glucose in the blood, also known as low blood glucose. When left untreated, hypoglycemia can lead to serious complications. Talk to your healthcare professional to determine your low glucose level.

Interstitial fluid

The fluid that surrounds all the cells of the body.

Insulin

A hormone produced by the pancreas that regulates the metabolism of glucose and other nutrients. Insulin injections may be prescribed by a healthcare professional to help people with diabetes process glucose (sugar), if their pancreas is damaged and does not produce insulin.

Limitations

A safety statement outlining specifFc situations in which the CGM should not be used because it may be harmful to you or damage the system.

mg/dL

Milligrams per deciliter; one of two standard units of measure for the concentration of blood glucose (sugar).

mmol/L

Millimoles per liter; one of two standard units of measure for the concentration of blood glucose (sugar).

Complies with
IMDA Standards
DB107824

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